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Vol. 94

Summer 2026

No. 4

## ARTICLES

Regulating Wellness: Reimagining Legal Frameworks in the Age of Preventative and Aspirational Health .....	<i>Barbara J. Zabawa</i>	777
Changing the Definition of Medical Expenses to Include Preventative Health: The PHIT Act .....	<i>Amy Bantham, Tom Richards, and Mike Goscinski</i>	785
Wellness Disputes .....	<i>Maria Cudowska</i>	809
Wellness, Transhumanism, and the Death of Health Law .....	<i>Leah R. Fowler</i>	827
Sacred Wellness .....	<i>Haley Palfreyman Jankowski</i>	847
Should All Entry Points to Wellness be Regulated Equally? What Mapping Existing and Emerging Entry Points Reveals .....	<i>Tanya E. Karwaki</i>	857
Illness/Wellness, Ableism & Perfectibility in the Tax Code .....	<i>Diane Klein Kemker</i>	877
The Wellness Data Conundrum: Privacy, Power, and Regulation Beyond HIPAA .....	<i>Gary Hsuanyu Liu</i>	901
Wellness Influencer Scienceploitation: An American Medicine Show Revival .....	<i>Jennifer D. Oliva</i>	931

## COMMENTS

Breaking the Lease, Breaking the Cycle: Restructuring Missouri's Lease Termination Law for Survivors of Domestic Violence .....	<i>Ries Freeman</i>	985
Visual Arts are the Only Arts with Morals: Generative AI and Aural Arts .....	<i>Megan Pilege</i>	1015

# REGULATING WELLNESS: REIMAGINING LEGAL FRAMEWORKS IN THE AGE OF PREVENTIVE AND ASPIRATIONAL HEALTH

Barbara J. Zabawa, JD, MPH\*

## I. INTRODUCTION

The United States is facing a watershed moment in health. Propelled in part by the new Make America Healthy Again (“MAHA”) movement,<sup>1</sup> the defunding of traditional health care institutions,<sup>2</sup> the failures of conventional health care to meet patient needs and to provide high value, low cost care,<sup>3</sup> and billionaire backing of high tech wellness and longevity innovation,<sup>4</sup> some health care stakeholders view the wellness industry eclipsing conventional health care as the primary source of disease prevention and health optimization. Groups like Your Freedom Hub,<sup>5</sup> the Free Market Medical Association,<sup>6</sup> and Self-Fund Health<sup>7</sup> are blazing new, privatized trails for the delivery of health and wellness services. As one presenter from the National Health Foundation proclaimed recently, conventional health care is beyond repair.<sup>8</sup> This is especially the case for patients

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\* Associate Professor of Law, University of Missouri–Kansas City School of Law. Professor Zabawa teaches and writes extensively about wellness law topics, including the juxtaposition of medical care and wellness, state licensure laws, government oversight of wellness products, and workplace wellness incentive law. Professor Zabawa would like to thank the Dean, Faculty, and Staff at UMKC School of Law for helping host the first-ever Wellness Law Symposium. She would also like to thank the symposium attendees and presenters for offering valuable insight into this emerging area of law, and the *UMKC Law Review*, especially Professor Nancy Levit, for dedicating this issue to Wellness Law.

<sup>1</sup> Maria Cudowska, *Wellness Disputes*, 94 UMKC L. REV. 809, 810 (2026); Tanya E. Karwaki, *Should All Entry Points to Wellness Be Regulated Equally? What Mapping Existing and Emerging Entry Points Reveals*, 94 UMKC L. REV. 857, 859 (2026); Jennifer D. Oliva, *Wellness Influencer Scienceploitation: An American Medicine Show Revival*, 94 UMKC L. REV. 931, 969 (2026) (noting that the confirmation of Robert F. Kennedy as HHS Secretary, the executive order to establish a Make America Healthy Again (MAHA) Commission illustrates the mainstreaming of wellness-based conspiracy theories and the erosion of scientific authority in policymaking).

<sup>2</sup> Cudowska, *supra* note 1, at 810-811.

<sup>3</sup> *Id.* at 811-12 (noting that patients experience frustration with the decentralized and fragmented health care system); Barbara J. Zabawa, *Health Care Corporatization as a Catalyst for Wellness Legal Partnerships*, AM. J. L. & MED. (forthcoming), manuscript at 12 (noting the corporatization trend in health care is causing higher costs, lower quality, and shrinking the availability of health care options for purchasers of health care).

<sup>4</sup> Leah R. Fowler, *Wellness, Transhumanism, and the Death of Health Law*, 94 UMKC L. REV. 827, 827 (2026).

<sup>5</sup> See generally YOUR FREEDOM HUB, <https://joinmpb.com/cfrohmanfreedomhub/> (last visited Mar. 2, 2026) (offering a medical sharing plan where members share medical expenses with one another and view it as an alternative to Affordable Care Act marketplace plans).

<sup>6</sup> See generally FREE MKT. MED. ASS’N, <https://fmma.org/> (last visited Mar. 2, 2026) (stating that health care’s problems will not be solved with more regulation or watchdogs but allowing consumers and purchasers to trust the free market).

<sup>7</sup> See generally SELF-FUND HEALTH, <https://selffundhealth.com/> (last visited Mar. 2, 2026) (offering a direct primary care plan without insurance billing to employers).

<sup>8</sup> Matt Ohrt, *CEO’s Needed to Build Parallel Health System*, BITCHUTE, at 08:40 (Aug. 6, 2025)

and employers who bear the most cost and receive the least benefit from the current health care payment and delivery structure.<sup>9</sup> As a result, patients and purchasers are looking for new ways to help people feel better by seeking more holistic and preventive services that often incorporate wellness products and services into the delivery mechanism. This is not to say that acute care is no longer of any importance to the wellness movement. Rather, the stakeholders pushing for more wellness are doing so because conventional medicine has not met the market need and desire for disease prevention and wellness.

Unfortunately, law has not kept up with the wellness market. The legal category of “wellness” sits awkwardly between healthcare, consumerism, and self-optimization. Once a vague descriptor for general well-being, wellness now denotes a sprawling industry of supplements, devices, diagnostics, therapies, and platforms, often marketed to healthy individuals in pursuit of better sleep, longer lifespans, or heightened productivity. But not entirely. Another segment of the wellness industry targets individuals suffering from disease, illness, or injury, offering an alternative to traditional healthcare. These alternative health providers often describe their wellness products and services as a “more natural” or “more holistic” approach to health, sympathizing with individuals who may feel gaslit by conventional medical providers.<sup>10</sup> Regardless of whether wellness serves healthy or sick individuals, the law remains mostly absent and murky. The legal community’s historical lack of care or concern about the wellness industry may stem in part from the stigma attached to wellness by the scientific medical community.<sup>11</sup> Yet, as the wellness economy matures into a multibillion-dollar force, its entanglement with legal systems grows more consequential and more fraught. In short, law can no longer remain agnostic to wellness’s slippery semantics and market reach.

This symposium edition of the University of Missouri – Kansas City Law Review gathers scholars confronting the mismatch between how law defines, classifies, and regulates wellness (if at all) and what wellness means in practice. The scholarly work uniformly recognizes the growing popularity and staying power of wellness. It also reveals a deeply fractured legal landscape shaped by outdated binaries between health care and wellness, implicit normative ideals about what it means to be well, and a pervasive privatization of regulation that has been described as the “wild west” of wellness.<sup>12</sup> The scholars contributing to this law review edition also recognize that despite the lack of legal guardrails, wellness is replacing traditional health care for many people and for a variety of reasons that are not going away any time soon. From tax deductions and arbitration clauses to

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(quoting Charles Frohman of the National Health Foundation), <https://api.bitchute.com/video/Jgq473CKwsPU/>.

<sup>9</sup> Zabawa, *supra* note 3, at 13 (“Higher prices and more spending leads to higher costs for patients and group health plan purchasers.”).

<sup>10</sup> Karwaki, *supra* note 1, at 866 (discussing medical gaslighting).

<sup>11</sup> Fowler, *supra* note 4, at 839 (noting the assumption that wellness is less serious and therefore less worthy of regulation than medicine).

<sup>12</sup> Oliva, *supra* note 1, at 972 (citing Barbara Zabawa, *No More Wild West: The Need for Wellness Professional Standards*, 50 AM. J. L. & MED. 74, 75 (2024)).

psychedelic therapy and biohacking apps, the contributions from these scholars collectively illustrate how wellness exposes and exacerbates law's doctrinal and normative fault lines. They wrestle with the tension between the legal values of consumer autonomy and patient protection, as well as between real and perceived scopes of wellness services and products. Together, these scholarly works begin to sketch the contours of what may become a coherent legal field: Wellness Law.

## II. CONCEPTUAL AND DOCTRINAL FRACTURES

One theme that arises from the authors is whether it is helpful to legally distinguish between wellness and health. For some legal scholars, a distinction offers a helpful analytical framework. Unlike health, which from a legal lens is measured by an individual's ability to be productive in society, the measure of wellness is arguably much more personal.<sup>13</sup> Separating health from wellness explains why the law treats the concepts so differently, with health operating as a status quo necessary for proper functioning in society and wellness operating as an aspirational goal that may never be fully reached. Professor Tanya Karwaki recognizes this distinction between health and wellness by examining the different entry points at which individuals approach wellness, with some individuals accessing wellness because of a desire to self-actualize, others in response to medical gaslighting, and a third category finding wellness through organizational wellness programs.<sup>14</sup> Professor Karwaki suggests regulating wellness at those entry points where the individuals are most vulnerable. In her view, the law should only lightly touch people who access wellness from an entry point that is self-driven, cultural, and social. This is in contrast to entry points that are the result of dismissive care by conventional medicine or employer wellness programs, where individuals exercise less autonomy in deciding to pursue wellness. At those entry points, law may have a bigger role to play.

Diane Kemker traces one of the most striking examples of doctrinal misfit: the medical expense deduction under Section 213 of the Internal Revenue Code. She demonstrates that tax law presumes a normative life trajectory where one is healthy, productive, and punctuated only occasionally by deductible illness. Such a model marginalizes disabled people and ignores the preventive goals that wellness often targets.<sup>15</sup> Kemker and Karwaki together highlight that law does not

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<sup>13</sup> See generally Barbara Zabawa, *Defining the Field of Wellness Law*, 53 HOFSTRA L. REV. 491, 502-03 (2025) (noting that the Internal Revenue Code permits taxpayers to deduct from their income expenses address illness so that the person can be restored to their full earning potential, as opposed to wellness expenses that are incurred merely because of an individual's own desire to optimize their wellbeing).

<sup>14</sup> Karwaki, *supra* note 1, at 874-75 (stating that "self-driven, cultural, and social prescription entry points may be among those entry points fostered or at least not suppressed" whereas "dismissive care and employer wellness programs may be among those entry points requiring closer consideration and possible discouraging").

<sup>15</sup> Diane Klein Kemker, *Illness/Wellness, Ableism & Perfectibility in the Tax Code*, 94 UMKC L. REV. 877, 895 (2026) (stating that the medical expense deduction is justified only insofar as these expenditures "restore" a state of health that may not be available to the disabled or chronically ill person").

merely fail to classify wellness accurately; it misapprehends wellness's social and economic functions.

The examination of the PHIT Act by authors Amy Bantham, Tom Richards, and Mike Goscinski, expose the disconnect between how the tax code defines “medical care” under IRC § 213(d), which includes “prevention” of disease,<sup>16</sup> and the types of medical care expenses that are actually deductible from an individual's income tax. The PHIT Act is legislation proposing tax-deductible status for fitness expenses and rests on the empirical claim that physical activity reduces healthcare costs by preventing a multitude of chronic conditions, most of which are tied to lifestyle factors. The authors point out that exercise can help alleviate the most pressing health challenges in the United States, such as obesity, heart disease, diabetes, cancer, and depression,<sup>17</sup> so allowing individuals to deduct fitness expenses from their taxes could increase exercise prevalence and thereby reduce health care costs.<sup>18</sup> Unfortunately, the current tax code does not consider exercise expenses as “medical care expenses” despite their likelihood in preventing disease.<sup>19</sup>

### III. THE JURISPRUDENCE OF THE NORMATIVE BODY

Across these contributions, a shared critique emerges: law's treatment of wellness is governed less by objective need than by normative ideals about bodies, labor, and productivity. Using critical disability theory, Diane Kemker's essay highlights the bias that wellness generally, and the tax code more specifically, exhibits when it comes to defining health. As Kemker aptly points out, critical disability theory forces governing authorities to reckon with disability as not something to be fixed or improved upon but as a social construct that is subject to disadvantage only because of how society views the life status.<sup>20</sup> Kemker's analysis challenges wellness to be more inclusive and shed ableist beliefs and principles that currently plague wellness culture.<sup>21</sup> This can start with tax law, which “encodes an ableist norm” in the standard medical deduction by presuming “large medical expenses are . . . unusual, short-lived, and transitory[.]”<sup>22</sup> This assumption fails to account for the lived experience of those with health conditions that incur regular, expensive medical care. The current structure of the standard

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<sup>16</sup> I.R.C. § 213(d)(1) (defining “medical care expenses” as “amounts paid for the diagnosis, cure, mitigation, treatment, or *prevention of disease*”) (emphasis added).

<sup>17</sup> Amy Bantham, Tom Richards & Mike Goscinski, *Changing the Definition of Medical Expenses to Include Preventive Health: The PHIT Act*, 94 UMKC L. REV. 785, 803 (2026).

<sup>18</sup> *Id.* at 804-05.

<sup>19</sup> *Id.* at 805 (noting that “a specific disease is what prompts treatment as a medical expense; thus, prevention is not recognized as medical care”).

<sup>20</sup> Kemker, *supra* note 15, at 880 (stating that “critical disability theory emphasizes those aspects of disability that are not the necessary consequences of bodily or mental conditions and are instead susceptible to social intervention—and it further demands, in the name of disability justice, that those interventions take place.”).

<sup>21</sup> *Id.* at 892 (citing as an example employer wellness programs that disproportionately exclude disabled and chronically ill people due to the employment discrimination and underemployment they experience).

<sup>22</sup> *Id.* at 888.

medical deduction, paired with the new standard income tax deduction, penalizes individuals who have long-term medical expenses that are not covered by insurance.<sup>23</sup>

#### IV. LEGAL INVISIBILITY AND PRIVATIZATION

While law may poorly define or support wellness, it often delegates governance to private actors. Maria Cudowska exposes the dangers wellness products and services present when they cross the line into conventional medicine uses with no medical oversight. Growing numbers of wellness products and services put consumers in the driver's seat to take charge of their own health, a role encouraged by the MAHA movement.<sup>24</sup> But when these products and services cause consumer harm, the private legal dispute system that pervades the wellness market often offers little relief. She documents how companies like Function Health resolve disputes over misdiagnoses or emotional distress via mandatory arbitration, shielding emerging harms from public scrutiny.<sup>25</sup> In a sector where new technologies increasingly mediate wellness decisions, such privatization insulates legal standards from evolving in tandem with commercial practice and denies access to data about the wellness products and services that could improve their performance and access.<sup>26</sup>

Hsuan Yu Liu underscores the problem of legal invisibility in the domain of wellness data privacy. Wellness apps and devices collect sensitive health-adjacent data with adhesive privacy contracts and without the protections of HIPAA or consistent state laws.<sup>27</sup> This creates gaps in user knowledge, consent, and recourse. Liu argues persuasively for a fiduciary duty by wellness data collectors, recognizing the sensitive nature of the data, but collected in a regulatory desert. Similar to Professor Jennifer Oliva's article regarding wellness influencers, Professor Liu's article laments the ineffective piecemeal enforcement actions by federal and state agencies and advocates for a more proactive, standardized approach to wellness regulation in the context of wellness data collection.<sup>28</sup> Professor Liu argues persuasively for the construction of "Wellness Law" as an integrative discipline, one that harmonizes FTC regulation, state privacy statutes,

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<sup>23</sup> *Id.* at 887-88 (applying the new increased standard income tax deduction of \$15,570 for a single filer to a "taxpayer with regular medical expenses of \$15,000 a year *still* will not deduct them or obtain any tax benefit, because the amount falls short of the standard deduction, and itemizing will therefore not reduce their tax bill").

<sup>24</sup> Maria Cudowska, *supra* note 1, at 810-11 (noting that as federal funding for traditional health care regulation decreases, the MAHA movement encourages to become "bosses of their own biology" and encourages use of Direct-to-Consumer testing services).

<sup>25</sup> *Id.* at 822 (claiming that wellness disputes matter because in wellness, being the "boss of your own biology" and informed consent are central, and "arbitration provisions may shield companies from meaningful public accountability and limit consumers' access to legal remedies.").

<sup>26</sup> *Id.* (stating that arbitration clauses in private platforms avoid meaningful public oversight and frames dispute resolution as individually tailored for each consumer).

<sup>27</sup> Gary Hsuanyu Liu, *The Wellness Data Conundrum: Privacy, Power, and Regulation Beyond HIPAA*, 94 UMKC L. REV. 901, 904 (2026).

<sup>28</sup> *Id.* at 907. See Oliva, *supra* note 1, at 976-84.

and FDA oversight.<sup>29</sup> Professor Liu's proposal marks a significant step toward reclaiming regulatory legitimacy in a space too often left to market discretion.

## V. EMERGING ARCHITECTURES AND FUTURE DIRECTIONS

What emerges from these interventions is a call not merely to reform discrete doctrines, but to recognize wellness as a legal domain in its own right. Professor Jennifer Oliva's work on the evolution of wellness exploitation demands coordinated, proactive regulatory efforts by legal actors at the federal and state levels.<sup>30</sup> Professor Oliva notes that technology has empowered wellness influencers to prey on vulnerable health consumers and those same technological platforms make it difficult for those consumers to critically analyze the veracity of the information being communicated.<sup>31</sup> Yet, Professor Oliva does not advocate for the eradication of wellness products and services entirely. She acknowledges that the success of modern wellness reflects individualistic values, control, and distrust of conventional health care institutions.<sup>32</sup> As a result, the law cannot dismiss wellness as inconsequential but must do more to protect consumers from harm without stifling innovation.

Leah Fowler observes a blurring between the health and wellness binary by exploring wellness expansion into transhumanism, treating wellness not as a fringe aspiration but as a logical extension of wellness consumerism.<sup>33</sup> Professor Fowler observes the billionaire interest in transhumanism, a concept that aims to prolong human life through a variety of biological and technological mechanisms, the lines between medical patient and tech user begin to blur.<sup>34</sup> She warns that as wellness merges with enhancement, law's reliance on private contracts rather than health law frameworks accelerates, raising profound concerns about equity, accountability, and access.<sup>35</sup>

Finally, Haley Jankowski emphasizes a need to expand the concept of wellness, particularly in the worksite, to include spiritual wellness. Through sharing her personal story about how her spiritual life contributes to her overall wellbeing, Professor Jankowski advocates for improved employer structures that

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<sup>29</sup> Liu, *supra* note 27, at 930 (“The time has arrived for comprehensive federal action establishing ‘Wellness Law’ as a coherent discipline.”).

<sup>30</sup> Oliva, *supra* note 1, at 982 (noting that the “[t]he current patchwork of federal agencies—FDA, FTC, state attorneys general, and platform-specific policies—creates opportunities for regulatory arbitrage while imposing compliance costs on legitimate businesses . . .”).

<sup>31</sup> *Id.* at 975 (noting that the “pace of scientific discovery and technical complexity of modern research make it difficult for consumers to evaluate health claims critically” and that wellness entrepreneurs exploit this confusing information by tapping into consumer’s psychological needs through the echo chamber of social media platforms).

<sup>32</sup> *Id.* at 959 (noting skepticism in mainstream institutions like “Big Pharma” and wellness culture’s emphasis on “individual intuition”).

<sup>33</sup> Fowler, *supra* note 4, at 828 (noting that “[i]f you have ever worn a Fitbit or an Apple Watch, you have already participated in the logic of transhumanism by treating your body as a system to be technologically monitored, improved, and optimized”).

<sup>34</sup> *Id.* at 838.

<sup>35</sup> *Id.* at 845-46.

can foster wellness on its most personal level.<sup>36</sup> She highlights the importance of creating environments that encourage individuals to flourish in one of the many dimensions of wellness, which include not only physical and spiritual, but also social, intellectual, vocational, emotional, and financial.<sup>37</sup> Jankowski contends that free exercise of religion is not only a constitutional matter, but a matter of wellness and therefore aligns with the Founders' intent in creating a free society.<sup>38</sup> In the worksite wellness context, employers must do more to incorporate religious freedom into workplace wellness programming.<sup>39</sup> Her perspective is unique and valuable to the discussion of empowering individuals to find their own meaning of wellness.

## VI. CONCLUSION: LAW'S WELLNESS RECKONING

The contributions to this symposium issue suggest that wellness is not merely an unregulated terrain but also a revealing one. It exposes how law encodes assumptions about health, merit, and access. It reveals how private law has attempted to fill the void left by public regulation and traditional health care delivery systems. And it invites a rethinking of the legal architectures that govern our bodily, mental, and spiritual futures.

If the 20th century was shaped by the rise of health law as a coherent field, the 21st may require its expansion or reconfiguration to include the normative, economic, and technological dimensions of wellness. Doing so will not only clarify law's role in shaping who can access what kind of care but will also help secure legal footing for those navigating the borderlands between treatment and optimization, survival and enhancement.

This is the moment to ask: What and who is wellness for? And what kind of law do we need to answer those questions well?

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<sup>36</sup> Haley Palfreyman Jankowski, *Sacred Wellness*, 94 UMKC L. REV. 847, 852-56 (2026).

<sup>37</sup> *Id.* at 847.

<sup>38</sup> *Id.* at 854 (stating “a person’s free exercise of religion embodies a critical part of her overall wellness for the *very same reasons* our Founders enshrined the Free Exercise Clause in the First Amendment to the Constitution”).

<sup>39</sup> *Id.* at 852-56.



# CHANGING THE DEFINITION OF MEDICAL EXPENSES TO INCLUDE PREVENTIVE HEALTH: THE PHIT ACT

Amy Bantham, DrPH, Tom Richards, and Mike Goscinski\*

## I. INTRODUCTION

This Article examines the distinction in U.S. tax law between medical expenses and personal expenses related to general health and wellness, with a particular focus on the treatment of fitness-related costs. Under Section 213 of the Internal Revenue Code and clarified in IRS Publication 502, medical expenses are defined narrowly as those directly incurred for the diagnosis, cure, mitigation, treatment, or prevention of a specific disease.<sup>1</sup> In contrast, expenses that merely promote general health and wellness—such as gym memberships, swimming lessons, or dance lessons—are usually classified as personal and nondeductible.<sup>2</sup> Drawing on statutory language, IRS guidance, and case law, the Article analyzes legal precedents to demonstrate how courts consistently require clear medical necessity, direct connection to a diagnosed condition, and lack of alternatives to allow fitness expenses as deductions. Within this context, the Article reviews the legislative history and rationale for the Personal Health Investment Today (PHIT) Act, which proposes expanding the definition of medical care to include qualified sport and fitness expenses.<sup>3</sup> By allowing the use of pre-tax dollars for structured physical activity, the PHIT Act would lower cost barriers, prevent disease, and

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<sup>1</sup> I.R.C. § 213; I.R.S. Pub. No. 502, Medical and Dental Expenses (2024) at 2, <https://www.irs.gov/pub/irs-pdf/p502.pdf> [hereinafter I.R.S. Pub. 502].

<sup>2</sup> See I.R.S. Pub. 502, *supra* note 1, at 15-17.

<sup>3</sup> See Personal Health Investment Today (PHIT) Act of 2025, S. 1144, 119th Cong. (2025); Personal Health Investment Today (PHIT) Act of 2024, S. 1144, 119th Cong. (2024).

generate long-term healthcare savings—offering a fiscally responsible, bipartisan strategy to address chronic disease and rising healthcare costs.<sup>4</sup>

## II. DEFINITION OF MEDICAL EXPENSES AND PERSONAL EXPENSES FOR GENERAL HEALTH AND WELLNESS

The Internal Revenue Service (IRS) makes a clear distinction between medical expenses and personal expenses for general health and wellness.<sup>5</sup> Section 213 of the Internal Revenue Code of 1986 defines medical expenses as amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease.<sup>6</sup> Also included are amounts paid for the purpose of affecting any structure or function of the body.<sup>7</sup> In contrast, personal expenses that merely benefit or improve general health and wellness are excluded.<sup>8</sup>

Publication 502 provides detailed information about medical expenses as a guide for taxpayers preparing their federal income tax returns.<sup>9</sup> Medical expenses primarily alleviate or prevent a physical or mental disability or illness.<sup>10</sup> Examples include: payments for legal medical services rendered by physicians, surgeons, dentists, and other medical practitioners; costs of equipment, supplies, and diagnostic devices needed for these purposes; premiums paid for insurance that covers the expenses of medical care; and transportation to obtain medical care.<sup>11</sup> In comparison, examples of personal expenses that are merely beneficial to general health and wellness are vitamins and vacations.<sup>12</sup>

## III. DEDUCTIBILITY OF MEDICAL EXPENSES

Taxpayers can deduct medical expenses for themselves, their spouse, and dependents.<sup>13</sup> They can only deduct amounts that exceed 7.5% of their adjusted gross income.<sup>14</sup> Medical expenses must be paid during the taxable year, paid for out-of-pocket, and not covered by insurance.<sup>15</sup>

Taxpayers cannot double-count. In other words, if any amount is paid or reimbursed under a Health Savings Account (HSA), Flexible Spending Account

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<sup>4</sup> Josh Liberatore, *Congress Reintroduces PHIT Act, Which Could Have New Life Under Trump*, ATHLETECH NEWS (Mar. 26, 2025), <https://athletechnews.com/congress-reintroduces-phit-act-trump-administration/> (“According to HFA research, the PHIT Act could inspire up to 17 million more Americans to become physically active and save an estimated \$12.2 billion in healthcare costs. The organization also says the bill could generate up to \$12.3 billion in additional consumer spending and create 230,000 new jobs.”).

<sup>5</sup> See I.R.S. Pub. 502, *supra* note 1, at 15-17.

<sup>6</sup> I.R.C. § 213.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*; I.R.S. Pub. 502, *supra* note 1, at 15-17.

<sup>9</sup> I.R.S. Pub. 502, *supra* note 1, at 1-3.

<sup>10</sup> *Id.* at 2.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 3.

<sup>14</sup> *Id.*

<sup>15</sup> I.R.S. Pub. 502, *supra* note 1, at 17.

(FSA), Archer Medical Savings Account (Archer MSA), or Health Reimbursement Arrangement (HRA), a taxpayer cannot also deduct the amount as a medical expense.<sup>16</sup>

#### IV. DISTINCTION AMONG TAX-FAVORED ACCOUNTS

HSAs and FSAs are both tax-favored accounts designed to give individuals tax advantages to offset healthcare costs, but there are key differences in terms of ownership, rollover rules, eligibility, and contribution limits as laid out by the IRS in Publication 969:<sup>17</sup>

1. *Ownership*: HSAs are owned by individuals and set up with a qualified HSA trustee (e.g., bank, insurance company); FSAs are employer-established benefit plans funded through voluntary salary reduction agreements.<sup>18</sup>
2. *Rollover Rules*: HSAs are portable and stay with individuals even if they change employers or leave the workforce; FSAs are not portable, and employers can allow up to a \$660 rollover or a 2.5-month grace period to use unused funds.<sup>19</sup>
3. *Eligibility*: To contribute to an HSA, an individual must be covered by a qualified high-deductible health plan with no other major medical coverage; self-employed individuals are not eligible for FSAs.<sup>20</sup>
4. *Contribution Limits*: The annual HSA contribution limit for 2025 is \$4,300 for individuals and \$8,550 for families; employees determine the annual contribution amounts for FSAs but cannot go over the IRS 2025 limit of \$3,300.<sup>21</sup>

#### V. TREATMENT OF FITNESS EXPENSES

Historically, the IRS has treated fitness expenses as personal expenses for general health and wellness, rather than as medical expenses.<sup>22</sup> Personal expenses for general health and wellness are not tax-deductible or reimbursable using tax-favored accounts (e.g., HSAs, FSAs, Archer MSAs, HRAs).<sup>23</sup>

Publication 502 devotes a section to health club dues.<sup>24</sup> Specifically, taxpayers can not include in medical expenses “health club dues or amounts paid to improve one’s general health or to relieve physical or mental discomfort not

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<sup>16</sup> See *id.* at 8, 15–16.

<sup>17</sup> See I.R.S. Pub. No. 969, Health Savings Accounts and Other Tax-Favored Health Plans (2024), [https://www.irs.gov/publications/p969#en\\_US\\_2024\\_publink1000204023](https://www.irs.gov/publications/p969#en_US_2024_publink1000204023) [hereinafter I.R.S. Pub. No. 969].

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*; see also I.R.S. News Release IR-2024-287 (Nov. 7, 2024), <https://www.irs.gov/newsroom/irs-healthcare-fsa-reminder-employees-can-contribute-up-to-3300-in-2025-must-elect-every-year> [hereinafter I.R.S. IR-2024-287].

<sup>20</sup> I.R.S. Pub. No. 969, *supra* note 17.

<sup>21</sup> *Id.*; I.R.S. IR-2024-287, *supra* note 19.

<sup>22</sup> I.R.S. Pub. No. 502, *supra* note 1, at 15-17.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 15.

related to a particular medical condition.”<sup>25</sup> Similarly, they cannot include in medical expenses “the cost of membership in any club organized for business, pleasure, recreation, or other social purpose.”<sup>26</sup> Health club dues are also mentioned in the section on weight-loss programs, where taxpayers are directed not to include amounts paid to lose weight unless the weight loss is a treatment for a specific disease diagnosed by a physician (such as obesity, hypertension, or heart disease), and reminded that they cannot include membership dues in a gym, health club, or spa.<sup>27</sup>

The other fitness expenses that are explicitly mentioned in Publication 502 are dancing and swimming lessons.<sup>28</sup> Taxpayers cannot include in medical expenses the costs of “dancing or swimming lessons, even if they are recommended by a doctor, if they are only for the improvement of general health.”<sup>29</sup>

## VI. CASE LAW

There are a number of relevant court cases that clarify the distinction between medical expenses and personal expenses for general health and wellness and, in some cases, specifically address whether fitness expenses are medical expenses.

In one case, *L. Keever Stringham v. Commissioner of Internal Revenue*, L. Keever Stringham (petitioner) sent his five-year-old daughter from Cleveland, Ohio, to Tucson, Arizona, to enroll her in a private boarding school after a diagnosis of deep bronchitis bordering on pneumonia and a discussion with her physician about finding a better climate for the winter.<sup>30</sup> On his 1944 tax return, the petitioner claimed a deduction for total medical expenses of \$1,996.05, including tuition, meals, and lodging paid to the private boarding school, and transportation of his daughter from Ohio to Arizona.<sup>31</sup> The Commissioner of Internal Revenue (respondent) found a deficiency of \$731.23 in income tax for the year 1944 and held that \$1,519.82 of the total medical expenses incurred by the petitioner in connection with sending his daughter to school in Arizona did not meet the requirements of section 23(x) of the Internal Revenue Code.<sup>32</sup> The Court allowed the meals, travel, and lodging portion (\$988.82) of the expenses to be deducted as medical expenses, but disallowed the tuition portion as nondeductible.<sup>33</sup> The Court ruled:

The conduct of the parents and the clear showing of the relation of their course of action to the illness from which the child was suffering,

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<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *See id.* at 14.

<sup>28</sup> I.R.S. Pub. No. 502, *supra* note 1, at 15-16.

<sup>29</sup> *Id.* at 15.

<sup>30</sup> *Stringham v. Comm’r*, 12 T.C. 580, 581-82 (1949).

<sup>31</sup> *Id.* at 582.

<sup>32</sup> *Id.* at 580, 588.

<sup>33</sup> *Id.* at 582.

together with all the other evidence herein, leads us to the conclusion that the travel expense and the cost of maintaining the child while in Arizona were expenses that were clearly incurred primarily for and essential to the cure and mitigation of the daughter's illness.<sup>34</sup>

The Court reasoned that:

The real difficulty arises in connection with determining the deductibility of expenses which, depending upon the peculiar facts of each case, may be classified as either "medical" or "personal" in nature. There would seem to be little doubt that the expense connected with items which are wholly medical in nature and which serve no other legitimate function in everyday life is incurred primarily for the prevention or mitigation of disease. On the other hand, it is obvious that many expenses are so personal in nature that they may only in rare situations lose their identity as ordinary personal expenses and acquire deductibility as amounts claimed primarily for the prevention or alleviation of disease. Therefore, it appears that in cases such as the one now before us, where the expenses sought to be deducted may be either medical or personal in nature, the ultimate determination must be primarily one of fact.<sup>35</sup>

In another case, *Havey v. Commissioner of Internal Revenue*, the wife of Edward A. Havey (Petitioner), Jane Reed Havey, suffered a coronary occlusion and lung infarction in October of 1943.<sup>36</sup> Her cardiologist advised the petitioner to take his wife to the seashore in the summer and Arizona in the winter, which he did three times in 1945.<sup>37</sup> The petitioner claimed a deduction of \$3,179.18 in travel and accommodation expenses as medical expenses on his 1945 income tax return, and the Commissioner of Internal Revenue (respondent) disallowed a deduction for medical expenses of \$2,175.83 and determined a deficiency of \$1,067.60 in income tax for the year 1945.<sup>38</sup>

The Court ruled that the trips were for general health improvement and, thus, were considered nondeductible personal expenses, not medical expenses: "On the entire record, we are not convinced that the travel in connection with which petitioner sustained the expense he seeks to deduct was incurred primarily for the cure, prevention, or alleviation of a disease or physical condition within the meaning of section 23(x) of the code as amended."<sup>39</sup> In its ruling, the Court specifically mentions categorizing the cost of fitness expenses, such as health club dues, as personal expenses, not tax-deductible medical expenses: "[M]any expenses, such as the cost of vacations, though undoubtedly highly and directly beneficial to the general health, or athletic club expenses by means of which an

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<sup>34</sup> *Id.* at 586.

<sup>35</sup> *Id.* at 584-85.

<sup>36</sup> *Havey v. Comm'r*, 12 T.C. 409, 409-410 (1949).

<sup>37</sup> *Id.* at 410.

<sup>38</sup> *Id.* at 409, 411.

<sup>39</sup> *Id.* at 413.

individual keeps physically fit, are not deductible because they fall within the category of personal or living expenses.”<sup>40</sup>

In *Thoene v. Commissioner of Internal Revenue*, John J. Thoene (Petitioner) experienced post-operative weakness of his abdominal and leg muscles and had difficulty in walking and in standing erect.<sup>41</sup> His physician advised him to pursue mild exercise (e.g., dancing, table tennis) as beneficial to strengthen his abdominal muscles.<sup>42</sup> Petitioner claimed, and the Commissioner of Internal Revenue (respondent) disallowed, the following amounts expended for dance lessons: \$370 in 1953, \$1,270 in 1954, and \$2,428 in 1955.<sup>43</sup> The Court ruled for the respondent, noting the personal nature of the dance lessons:

It is not at all unusual for doctors to recommend to a patient a course of personal conduct and personal activity which, if pursued, will result in health benefits to the patient, but the expenses therefore are generally to be considered ordinary personal expenses. There may be rare situations when such expenses would lose their identity as ordinary personal expenses and become properly classified as medical care expenses, but this record does not present such a case.<sup>44</sup>

The Court likened the dance lessons to golf, categorizing both as ordinary personal expenses:

The instructresses in the dance studio had no training in physical or psychiatric therapy. The fact that the dance lessons were beneficial to petitioner is not determinative of the issue. Conceivably the same benefits might have been derived from petitioner's taking up golf and participating in the social activity of a country club but it could hardly be argued the expenditures therefore would be deductible as medical care.<sup>45</sup>

In *Daniels v. Commissioner of Internal Revenue*, Fred H. Daniels and Eleanor G. Daniels (petitioners) claimed \$9,355.75, incurred in the construction of a fallout shelter, as medical expenses on their 1960 federal income tax return.<sup>46</sup> Petitioners were advised by their physician to build a fallout shelter because it would reduce anxiety affecting the petitioner's heart and hypertensive condition in the event of a nuclear fallout disaster.<sup>47</sup> The Commissioner of Internal Revenue (respondent) determined a deficiency in federal income tax for the calendar year

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<sup>40</sup> *Id.* at 411–12.

<sup>41</sup> *Thoene v. Comm'r*, 33 T.C. 62, 63 (1959).

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 65.

<sup>45</sup> *Id.*

<sup>46</sup> *Daniels v. Comm'r*, 41 T.C. 324, 324–25 (1963).

<sup>47</sup> *Id.* at 325.

1960 in the amount of \$6,377.48.<sup>48</sup> The Court ruled for the respondent on the grounds that:

Deductions are matters of legislative grace and petitioners have failed to show that there is more than a remote possibility, if any, that a disease threatening them in the Worcester area would be prevented by the shelter, nor that its cost was different from other nondeductible personal expenses “related to factors and equations of personal life and situation that leave them without the persuading certainty and undubious objectivity necessary to a tax deduction.”<sup>49</sup>

The Court stated:

It seems clear that the construction of petitioners’ fallout shelter was not for the “diagnosis, cure, mitigation,” or “treatment” of an existing disease. Any justification for the deduction of its cost as a medical expense must arise from its characterization as “prevention.” But we have been referred to no authority extending the concept of prevention to so remote a hazard to health as would be required here to sustain petitioners. On the contrary, the Congressional intent is sufficiently evident to require the showing of the present existence or the imminent probability of a disease, physical or mental defect, or illness as the initial step in qualifying an expenditure as a medical expense.<sup>50</sup>

In *Altman v. Commissioner of Internal Revenue*, Leon S. Altman (petitioner) suffered from pulmonary emphysema.<sup>51</sup> On his 1965 federal tax return, he claimed automobile expenses incurred in transportation to a golf course so he could play golf, a therapeutic measure prescribed by his physician for his pulmonary emphysema condition.<sup>52</sup> The Commissioner of Internal Revenue (respondent) determined a deficiency in petitioners’ 1965 income tax in the amount of \$693.94, disallowing most of the claimed medical expenses totaling \$3,737.44.<sup>53</sup> The Court ruled for the respondent, characterizing golfing as a personal rather than a medical expense: “We cannot conclude on the record presented that the golf activity constituted ‘medical care.’ We hold petitioner’s transportation expenses to and from the golf course were personal expenses within the provisions of sec. 262 and not ‘primarily for and essential to medical care’ within the provisions of sec. 213(e).”<sup>54</sup> In this ruling, the Court confirmed its

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<sup>48</sup> *Id.* at 324.

<sup>49</sup> *Id.* at 329.

<sup>50</sup> *Id.* at 327–28.

<sup>51</sup> *Altman v. Comm’r*, 53 T.C. 487, 488 (1969).

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 487–88.

<sup>54</sup> *Id.* at 490.

previous rulings on fitness expenses, categorizing both golfing and dancing as personal expenses:

There we had occasion to consider whether doctor-recommended dancing lessons for postoperative treatment would constitute medical care under section 213. We held the dancing could not be characterized as medical care within the definition of medical care in section 213(e) even though such activity gave needed mild exercise activity and that the activity could not be characterized as anything but personal. In fact, in our consideration of the issue we referred to “taking up golf” as illustrating a classic example of a personal rather than a medical activity.<sup>55</sup>

In *Haines v. Commissioner of Internal Revenue*, Petitioner fractured his right femur while skiing, and his physician recommended whirlpool treatment, massage, and exercise.<sup>56</sup> The physician stated he “ought to build him a swimming pool at home.”<sup>57</sup> On his 1972 income tax return, the petitioner deducted \$13,149.28 of the pool’s total cost as a medical expense.<sup>58</sup> The Commissioner determined a deficiency of \$4,025.01 in the petitioners’ federal income tax for 1972 on the basis that it was not an allowable medical expense deduction.<sup>59</sup> The Court ruled for the respondent, holding that:

[T]he expenses the petitioner incurred in building a swimming pool were not for the primary purpose of, and were not related directly to, his medical care. Undoubtedly, swimming was beneficial to his condition, but such evidence is insufficient to establish that the primary purpose of the building of his own pool was related directly to his medical care.<sup>60</sup>

The Court noted there were less expensive alternatives for the petitioner to access exercise therapy for his leg, namely: “The petitioner could have secured the necessary therapy at the hospital or he could have arranged to swim at a health club which was not far from his residence.”<sup>61</sup>

In *Cherry v. Commissioner of Internal Revenue*, Herbert Cherry was diagnosed with severe emphysema and bronchitis and advised by his physician to quit smoking and to develop an exercise regime, with swimming as the best recommended exercise for his condition.<sup>62</sup> Petitioner investigated pools in his community at local Ys and health spas, and found they did not open early enough, or stay open long enough, to allow him to swim on a regular basis.<sup>63</sup> Therefore, in

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<sup>55</sup> *Id.*

<sup>56</sup> *Haines v. Comm’r*, 71 T.C. 644, 644-45 (1979).

<sup>57</sup> *Id.* at 645.

<sup>58</sup> *Id.* at 646.

<sup>59</sup> *Id.* at 644, 646.

<sup>60</sup> *Id.* at 647.

<sup>61</sup> *Id.* at 648.

<sup>62</sup> *Cherry v. Comm’r*, No. 20779-80, 1983 Tax Ct. Memo LEXIS 317, at \*2-3 (T.C. Aug. 11, 1983).

<sup>63</sup> *Id.* at \*3.

1974, he constructed a new house which contained an indoor swimming pool.<sup>64</sup> He swam in the pool at least twice a day, and his wife, Adele Cherry, also used the pool occasionally as prescribed by her doctor to relieve arthritis pain.<sup>65</sup> The respondent disallowed the petitioners' deductions on their 1976 and 1977 federal income tax returns and determined deficiencies of \$4,186 and \$5,759, respectively.<sup>66</sup> The Court held that:

Herbert's doctor recommended swimming to help his emphysema and bronchitis. Herbert mitigated the effect of the lung disease through diligent use of the pool. The disease symptoms returned after 5 days when he could not swim regularly. Further, maintaining a pool at his own house was the only way Herbert could swim on a regular basis. These facts convince us that the expenditures for operating and maintaining the pool were directly related to Herbert's medical care because they mitigated the effects of severe emphysema and bronchitis.<sup>67</sup>

The Court did not find merit in the respondent's argument that the expenses were personal, ruling: "Respondent argues that the recreational nature of the swimming pool, the lack of specialized medical equipment associated with the pool and the recreational use by other members of the family support his conclusion that the pool expenditures were essentially personal rather than medical. We disagree."<sup>68</sup>

## VII. SUMMARY OF CASE LAW

Three main themes emerge from the case law regarding the distinction between medical expenses and personal expenses for general health and wellness:

1. The Courts distinguish between deductible medical expenses and nondeductible personal expenses by assessing whether their primary purpose is for diagnosis, cure, mitigation, treatment, or prevention of a specific medical condition. If the expense is dual purpose, it is generally disallowed unless medical necessity is clearly established.<sup>69</sup>

2. Fitness expenses are generally classified as expenses for general health improvement, personal in nature, and nondeductible—even when recommended by a physician—unless uniquely tailored and essential to medical treatment.<sup>70</sup>

3. Deductibility is contingent on factual determinations, such as medical necessity, the unavailability of alternatives, or the direct relationship between the expense and alleviation of the specific medical condition.<sup>71</sup>

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<sup>64</sup> *Id.* at \*3-4.

<sup>65</sup> *Id.* at \*4-5.

<sup>66</sup> *Id.* at \*1.

<sup>67</sup> *Id.* at \*2.

<sup>68</sup> *Cherry*, No. 20779-80, 1983 Tax Ct. Memo LEXIS 317, at \*10-11.

<sup>69</sup> See discussion *supra* Section VI.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

### VIII. CLARIFICATION OF GUIDANCE ON EXPENSES FOR GENERAL HEALTH AND WELLNESS

On March 17, 2023, the IRS issued frequently asked questions (FAQs) to clarify whether certain costs related to general health and wellness are medical expenses under section 213 of the Internal Revenue Code.<sup>72</sup>

Questions 9-11 pertained to treatment of weight-loss programs, gym memberships, and swimming and dancing lessons:<sup>73</sup>

Q9: Is the cost of a weight-loss program a medical expense that can be paid or reimbursed by an HSA, FSA, Archer MSA or HRA? (added March 17, 2023)

A9: Yes, but only if the program treats a specific disease diagnosed by a physician (such as obesity, diabetes, hypertension, or heart disease). Otherwise, the cost of a weight-loss program is not a medical expense.

Q10: Is the cost of a gym membership a medical expense that can be paid or reimbursed by an HSA, FSA, Archer MSA or HRA? (added March 17, 2023)

A10: Yes, but only if the membership was purchased for the sole purpose of affecting a structure or function of the body (such as a prescribed plan for physical therapy to treat an injury) or the sole purpose of treating a specific disease diagnosed by a physician (such as obesity, hypertension, or heart disease). Otherwise, the cost of a gym membership is for the general health of the individual and is not a medical expense.

Q11: Is the cost of exercise for the improvement of general health, such as swimming or dancing lessons, a medical expense that can be paid or reimbursed by an HSA, FSA, Archer MSA or HRA? (added March 17, 2023)

A11: No, because the exercise, even if recommended by a doctor, is only for the improvement of general health.<sup>74</sup>

### IX. WARNINGS ABOUT MISREPRESENTATION OF EXPENSES FOR GENERAL HEALTH AND WELLNESS

On March 6, 2024, the IRS issued an alert reminding taxpayers and health plan administrators that personal expenses for general health and wellness are not

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<sup>72</sup> See I.R.S., *Frequently Asked Questions About Medical Expenses Related to Nutrition, Wellness and General Health* (Mar. 17, 2023), <https://www.irs.gov/individuals/frequently-asked-questions-about-medical-expenses-related-to-nutrition-wellness-and-general-health> [hereinafter I.R.S. Medical Expenses FAQ].

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

considered medical expenses under tax law.<sup>75</sup> The IRS warned that companies misrepresenting that Letters of Medical Necessity based on self-reported health information convert personal food, wellness, or exercise expenses into medical expenses.<sup>76</sup> The IRS confirmed that these types of personal expenses do not qualify as medical expenses, even with a doctor's note.<sup>77</sup>

## X. CONDITIONS WHEN FITNESS EXPENSES ARE DEDUCTIBLE OR REIMBURSABLE

IRS guidance and case law indicate that there are certain, very specific, very narrowly defined conditions where a fitness expense is tax-deductible or reimbursable using tax-favored accounts (e.g., HSA, FSA, Archer MSA, HRA).<sup>78</sup>

These conditions are:

1. An individual has been diagnosed with a specific disease by a healthcare provider.<sup>79</sup>
2. The healthcare provider has prescribed physical activity and provided a statement (Letter of Medical Necessity) indicating that physical activity is necessary to treat or prevent the progression of the specific disease.<sup>80</sup>
3. The individual would not incur the physical activity expense “but for” the specific disease.<sup>81</sup>

## XI. THE PHIT ACT OVERVIEW

The Personal Health Investment Today (PHIT) Act amends the Internal Revenue Code of 1986 to treat certain amounts paid for physical activity, fitness,

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<sup>75</sup> I.R.S. News Release IR-2024-65 (Mar. 6, 2024), <https://www.irs.gov/newsroom/irs-alert-beware-of-companies-misrepresenting-nutrition-wellness-and-general-health-expenses-as-medical-care-for-fsas-hsas-hras-and-msas>.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> See I.R.S. Medical Expenses FAQ, *supra* note 72; Physical Activity Alliance, *Can I Use My FSA/HSA to Pay for Physical Activity Expenses*, YOUTUBE (Dec. 14, 2023), <https://www.youtube.com/watch?v=8cvaTA8rrNM>.

<sup>79</sup> See I.R.S. Medical Expenses FAQ, *supra* note 72, at Q8-Q10, Q14.

<sup>80</sup> See EMP. BENEFIT CORP., *From Gym Memberships to Saunas: IRS Criteria for Reimbursing Wellness Expenses* (July 8, 2024), <https://www.ebcflex.com/wellnessexpenses/> (“A letter of medical necessity from the individual’s diagnosing and treating physician or health provider typically is required to show that a general health/well-being expense is ‘medical.’ The letter of medical necessity should show that the requirements described below are satisfied with respect to the prescribed treatment.”).

<sup>81</sup> *Id.* (“The expense is not medical if the individual would have purchased it regardless of their medical condition. This is called the ‘but for’ test, and asks if someone would have purchased the service or product ‘but for’ their medical condition. The letter of medical necessity should indicate that to the provider’s knowledge, the patient would not have purchased the service or product but for their medical condition.”).

and exercise as amounts paid for medical care.<sup>82</sup> It does this by inserting the words “for qualified sport and fitness expenses” into paragraph (1) of section 213(d).<sup>83</sup>

The purpose of the bill is to “promote health and prevent disease, particularly diseases related to being overweight or obese by: encouraging healthier lifestyles; providing financial incentives to ease the financial burden of engaging in healthy behavior; and increasing the ability of individuals and families to participate in physical fitness activities.”<sup>84</sup>

Qualified sport and fitness expenses are defined as “amounts paid exclusively for the sole purpose of participating in a physical activity, including: for membership at a fitness facility; for participation or instruction in physical exercise or physical activity; or for equipment used in a program (including a self-directed program) of physical exercise or physical activity.”<sup>85</sup>

Fitness facilities are defined as those “providing instruction in a program of physical exercise, offering facilities for the preservation, maintenance, encouragement, or development of physical fitness, or serving as the site of such a program of a State or local government.”<sup>86</sup> It is a facility where health and fitness is core (not incidental) to its overall function and purpose.<sup>87</sup>

It is not a private club owned and operated by its members; it does not offer golf, hunting, sailing, or riding facilities.<sup>88</sup>

Videos, books, and similar materials are included if they constitute instruction in a program of physical exercise or physical activity.<sup>89</sup> Sport and fitness equipment is included if: it is utilized exclusively for participation in fitness, exercise, sport, or other physical activity, or it is apparel or footwear that is necessary for a specific physical activity; amounts for single items may not exceed \$250.<sup>90</sup>

The medical tax deduction for qualified sport and fitness expenses for any taxpayer for any year is limited to \$1,000 (\$2,000 for families).<sup>91</sup>

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<sup>82</sup> Personal Health Investment Today (PHIT) Act of 2025, S. 1144, 119th Cong. (2025); Personal Health Investment Today (PHIT) Act of 2024, S. 1144, 119th Cong. (2024).

<sup>83</sup> H.R. 2369, § 3(a); S. 1144, §3(a).

<sup>84</sup> H.R. 2369, § 2(1)-(3); S. 1144, § 2(1)-(3).

<sup>85</sup> H.R. 2369, § 3(b)(12)(A); S. 1144, § 3(b)(12)(A).

<sup>86</sup> H.R. 2369, § 3(b)(12)(C)(i); S. 1144, § 3(b)(12)(C)(i).

<sup>87</sup> H.R. 2369, § 3(b)(12)(C)(iv); S. 1144, § 3(b)(12)(C)(iv).

<sup>88</sup> H.R. 2369, § 3(b)(12)(C)(ii)-(iii); S. 1144, § 3(b)(12)(C)(ii)-(iii).

<sup>89</sup> H.R. 2369, § 3(b)(12)(D); S. 1144, § 3(b)(12)(D).

<sup>90</sup> H.R. 2369, § 3(b)(12)(E); S. 1144, § 3(b)(12)(E).

<sup>91</sup> H.R. 2369, § 3(b)(12)(B); S. 1144, § 3(b)(12)(B).

## XII. THE PHIT ACT HISTORY

The PHIT Act was introduced in every Congress from the 109th to the 119th Congress.<sup>92</sup>

### A. 109th Congress

It was first introduced on May 25, 2006 as H.R. 5479. Primary sponsor Rep. Weller and original cosponsors Rep. Ramstad, Rep. Bishop, Rep. Shuster, Rep. Smith, and Rep. Shuster introduced the bill.<sup>93</sup> H.R. 5479 reached a total of 10 cosponsors—7 Republicans and 3 Democrats.<sup>94</sup> The PHIT Act of 2006 amended section 213 (d) of the Internal Revenue Code of 1986 by adding language that the term medical care shall include amounts paid to purchase or use equipment used in a program (including a self-directed program) of physical exercise, and to participate, or receive instruction, in a program of physical exercise.<sup>95</sup> It limited amounts treated as medical care to under \$1,000 for any individual for any taxable year.<sup>96</sup>

### B. 110th Congress

The Personal Health Investment Today Act of 2007 was introduced on January 5, 2007 as H.R. 245.<sup>97</sup> It had the same primary sponsor, same original cosponsors, and same bill text as the previous year.<sup>98</sup> It reached a total of 25 cosponsors—17 Republicans and 8 Democrats.<sup>99</sup>

### C. 111th Congress

On April 27, 2009, the Personal Health Investment Today Act of 2009 was introduced as H.R. 2105 by primary sponsor Rep. Kind and original cosponsors Rep. Blumenauer, Rep. Brady, and Rep. Wamp.<sup>100</sup> It reached a total of 23 cosponsors—12 Republicans and 11 Democrats.<sup>101</sup> The bill text was significantly changed, taking the form of what is seen in the most recent versions, with two exceptions: it made no mention of books or videos, and it excluded footwear and apparel from sport and fitness equipment.<sup>102</sup>

In addition, findings were added, including: that almost 20% of American children between the ages of 2 and 19 are overweight or suffer from obesity; that

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<sup>92</sup> See discussion *infra* Section XII.

<sup>93</sup> PHIT Act of 2006, H.R. 5479, 109th Cong. § 2(a) (2006).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> PHIT Act of 2007, H.R. 245, 110th Cong. (2007).

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> See PHIT Act of 2009, H.R. 2105, 111th Cong. (2009).

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

8 of the 9 most expensive illnesses in the United States are more common among overweight and obese individuals; that according to the Centers for Disease Control and Prevention, the increase in the number of overweight and obese Americans between 1987 and 2001 resulted in a 27% increase in per capita healthcare costs; that the World Health Organization determined that in the United States a \$1 investment in physical activity alone (in time and equipment) would reduce medical expenses by \$3.20; research indicates that 2 in 5 Americans would become more physically active if offered a financial incentive; that the United States ranks last in the world in reducing the number of preventable deaths resulting from obesity-related chronic illnesses; and that engaging in physical activities at young ages when children are learning lifelong behaviors can have a significant impact on their long-term health.<sup>103</sup>

Finally, a purpose was added: to promote health and prevent disease, particularly diseases related to being overweight and obese, by encouraging healthier lifestyles, providing financial incentives to ease the financial burden of engaging in healthy behaviors, and increasing the ability of individuals and families to participate in physical fitness activities.<sup>104</sup>

#### D. 112th Congress

H.R. 2649, the Personal Health Investment Today Act of 2011, was introduced on July 26, 2011, by primary sponsor Rep. Brady and original cosponsors Reps. Barton, Blumenauer, Clay, Gerlach, Kind, McIntyre, Paul, Ruppertsberger, and Shuster.<sup>105</sup> It reached a total of 27 cosponsors—12 Republicans and 15 Democrats.<sup>106</sup> The bill text was identical to the preceding version (H.R. 2105).<sup>107</sup>

#### E. 113th Congress

On March 5, 2013, the Personal Health Investment Today Act of 2013 (H.R. 956) was introduced by Rep. Kind.<sup>108</sup> It reached a total of 50 cosponsors—24 Republicans and 26 Democrats.<sup>109</sup> The bill text was identical to the prior version (H.R. 2649), with one notable exception: treatment of books and videos was added

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<sup>103</sup> *Id.* § 2(a).

<sup>104</sup> *Id.* § 2(b).

<sup>105</sup> PHIT Act of 2011, H.R. 2649, 112th Cong. (2011).

<sup>106</sup> *Id.*

<sup>107</sup> Compare H.R. 2649, with H.R. 2105.

<sup>108</sup> PHIT Act of 2013, H.R. 956, 113th Cong. (2013).

<sup>109</sup> *Id.*

for the first time, including them if the content constitutes instruction in a program of physical exercise or physical activity.<sup>110</sup>

### F. 114th Congress

H.R. 1218, the Personal Health Investment Today Act of 2015, was introduced on March 3, 2015, by primary sponsors Reps. Kind and Boustany.<sup>111</sup> It reached a total of 89 cosponsors—38 Republicans and 51 Democrats.<sup>112</sup> The bill text was identical to the preceding version (H.R. 956).<sup>113</sup>

Its companion bill was introduced in the Senate for the very first time.<sup>114</sup> S. 228, the Personal Health Investment Today Act of 2015, was introduced on October 29, 2015, by primary sponsor Senator Thune.<sup>115</sup> It reached a total of 12 cosponsors—5 Democrats and 7 Republicans.<sup>116</sup> The bill text was identical to H.R. 1218 with two key exceptions—the findings section was not included, and the language on apparel and footwear was changed from “amounts paid for equipment shall be treated as qualified sports and fitness expenses only if such equipment is not apparel or footwear” to “amounts paid for equipment shall be treated as qualified sports and fitness expenses only if such apparel or footwear is of a type that is necessary for, and is not used for any purpose other than, a specific physical activity.”<sup>117</sup>

### G. 115th Congress

The PHIT Act reached several key milestones during the 115th Congress: It had its peak number of cosponsors, with 135 cosponsors (64 Republicans, 71 Democrats) for H.R. 1267 (introduced on March 1, 2017 by primary sponsor Rep. Smith and original cosponsors Reps. DelBene, Fitzpatrick, Kelly and Sewell) and 16 cosponsors (9 Republicans, 6 Democrats) for S. 482 (introduced on March 1, 2017 by primary sponsor Senator Thune and original cosponsors Senators Capito, Donnelly, and Murphy).<sup>118</sup>

In addition, on July 25, 2018, the PHIT Act passed the U.S. House of Representatives as part of a larger HSA bill package (H.R. 6199, Restoring Access

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<sup>110</sup> Compare H.R. 956, § 3(b)(D) (2013) (“Videos, books, and similar materials shall be treated as described in *subparagraph (A)(ii)* if the content of such materials constitute instruction in a program of physical exercise or physical activity.”), with H.R. 2649 § 3(b)(D).

<sup>111</sup> PHIT Act of 2015, H. 1218, 114th Cong. (2014).

<sup>112</sup> *Id.*

<sup>113</sup> Compare H.R. 1218, with H.R. 956.

<sup>114</sup> PHIT Act of 2015 S. 2218, 114th Cong. (2015).

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> Compare H.R. 1218 (“[A]mounts paid for equipment shall be treated as qualified sports and fitness expenses only if such equipment is not apparel or footwear”), with S. 2218 (“[A]mounts paid for equipment shall be treated as qualified sports and fitness expenses only if such apparel or footwear is of a type that is necessary for, and is not used for any purpose other than, a specified physical activity.”).

<sup>118</sup> PHIT Act of 2017, H.R. 1267, 115th Cong. (2017); PHIT Act of 2017, S. 482, 115th Cong. (2017).

to Medication and Modernizing Health Savings Accounts Act of 2018).<sup>119</sup> In this version of the bill, the following language changes were made:

1. Overall Dollar Limitation—The aggregate amount treated as qualified sports and fitness expenses with respect to any taxpayer for any taxable year shall not exceed \$500 (twice such amount in the case of a joint return or a head of household).<sup>120</sup>

2. Exclusion of Exercise Videos—Qualified sports and fitness expenses shall not include videos, books, or similar materials.<sup>121</sup>

3. Exclusions—The Secretary, after consultation with the Secretary of Health and Human Services, shall issue guidance to determine for purposes of this paragraph what does not constitute a qualified physical activity, including golf, hunting, sailing, horseback riding, and other similar activities.<sup>122</sup>

4. Inflation Adjustment—In the case of any taxable year beginning in a calendar year after 2019, the \$500 amount (overall dollar limitation) and the \$250 amount (equipment dollar limitation) shall be increased by a cost-of-living adjustment.<sup>123</sup>

#### H. 116th Congress

Rep. Kind was the primary sponsor of H.R. 1679, the Personal Health Investment Today Act of 2019, joined by original cosponsor Rep. Kelly.<sup>124</sup> Introduced on March 12, 2019, it reached a total of 95 cosponsors—46 Republicans and 49 Democrats.<sup>125</sup> The Senate version (S. 680) was introduced on March 6, 2019, by Senator Thune with Senators Barrasso, Capito, Isakson, King, Murphy, Peters, Rounds, and Wicker.<sup>126</sup> It reached a total of 14 cosponsors—9 Republicans, 3 Democrats, and 2 Independents.<sup>127</sup> The major changes between the preceding House version (H.R. 1267) and this House version (H.R. 1679) was deletion of the findings section and changing the footwear and apparel language to match the Senate version of the bill, namely: “amounts paid for equipment shall be treated as qualified sports and fitness expenses only if such apparel or footwear is of a type that is necessary for, and is not used for any purpose other than, a specific physical activity.”<sup>128</sup>

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<sup>119</sup> Restoring Access to Medication and Modernizing Health Savings Accounts Act of 2018, H.R. 6199, 115th Cong. (2018).

<sup>120</sup> *Id.* § 8(b)(12)(B)(i).

<sup>121</sup> *Id.* § 8(b)(12)(B)(iii).

<sup>122</sup> *Id.* § 8(b)(12)(C)(ii).

<sup>123</sup> *Id.* § 8(b)(12)(F).

<sup>124</sup> PHIT Act of 2019, H.R. 1679, 116th Cong. (2019).

<sup>125</sup> *Id.*

<sup>126</sup> PHIT Act of 2019, S. 680, 116th Cong. (2019).

<sup>127</sup> *Id.*

<sup>128</sup> Compare H.R. 1679, with H.R. 1267.

### I. 117th Congress

H.R. 3109, the Personal Health Investment Today Act of 2021, was introduced on May 11, 2021, by Rep. Kind and 3 original cosponsors (Reps. Kelly, LaHood, and Sewell) and reached 78 total cosponsors (41 Republicans, 47 Democrats).<sup>129</sup> Senator Thune was again the primary sponsor of S. 844, the Personal Health Investment Today Act of 2021, with 8 original cosponsors (Senators Barrasso, Capito, Cramer, King, Murphy, Murkowski, Rounds, Wicker).<sup>130</sup> Introduced on March 18, 2021, it reached a total of 17 cosponsors (12 Republicans, 4 Democrats, 1 Independent).<sup>131</sup> The text of the bills did not change from their prior versions.<sup>132</sup>

### J. 118th Congress

Introduced as H.R. 1582 in the U.S. House of Representatives and S. 786 in the Senate, both on March 14, 2023, the Personal Health Investment Today Act of 2023 reached a significant milestone in the 118th Congress.<sup>133</sup> It remained a standalone bill with 18 Senate cosponsors (10 original, 10 Republicans, 6 Democrats, 2 Independents) and 95 House cosponsors (6 original, 50 Republicans, 45 Democrats).<sup>134</sup> For the first time in the legislation's history, in the 118th congress the PHIT Act garnered the support of a bipartisan majority of House Ways and Means Committee members.<sup>135</sup>

### K. 119th Congress

Introduced as H.R. 2369 in the U.S. House of Representatives and S. 1144 in the Senate, both on March 26, 2025, the PHIT Act made notable strides in the 119th Congress.<sup>136</sup> In a key moment of progress, a scaled-back provision rooted in the PHIT Act was incorporated into the House-passed version of the One Big Beautiful Bill (OB BB) Act, a comprehensive reconciliation package.<sup>137</sup> However, in order to address longstanding concerns from the Joint Committee on Taxation (JCT) regarding the "score" or projected cost of the policy, lawmakers significantly narrowed the provision.<sup>138</sup>

Specifically, the House version:

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<sup>129</sup> PHIT Act of 2021, H.R. 3109, 117th Cong. (2021).

<sup>130</sup> PHIT Act of 2021, S. 844, 117th Cong. (2021).

<sup>131</sup> *Id.*

<sup>132</sup> Compare H.R. 3109, and S. 844, with H.R. 1679, and S. 680.

<sup>133</sup> See PHIT Act of 2023, H.R. 1582, 118th Cong. (2023); PHIT Act of 2023, S. 786, 118th Cong. (2023).

<sup>134</sup> See H.R. 1582; S. 786.

<sup>135</sup> See H.R. 1582.

<sup>136</sup> PHIT Act of 2025, H.R. 2369, 119th Cong. (2025); PHIT Act of 2025, S. 1144, 119th Cong. (2025).

<sup>137</sup> One Big Beautiful Bill Act, H.R. 1, 119th Cong. § 110208 (as reported in the house, May 20, 2025).

<sup>138</sup> *Id.*

1. Restricted eligibility solely to HSA holders, removing FSA applicability.<sup>139</sup>

2. Cut the allowable deduction limit in half—from PHIT’s original \$1,000 per individual and \$2,000 per household to just \$500 and \$1,000, respectively.<sup>140</sup>

3. Excluded non-activity-related expenses such as fitness equipment and instructional materials, limiting eligibility strictly to direct participation costs.<sup>141</sup>

These compromises were made in an effort to reduce the fiscal impact of the policy and improve the chances of Congressional passage, but despite these efforts, the provision was ultimately stripped from the final Senate version of the OBBB Act during negotiations—again due to cost concerns—without full consideration of the long-term healthcare savings that expanded access to physical activity can generate, as outlined in our economic impact analysis.<sup>142</sup>

Although it did not make it into the final legislation, this inclusion marked the furthest a PHIT-aligned policy has advanced through the legislative process to date.<sup>143</sup> It demonstrated growing bipartisan recognition that tax policy can and should be used to incentivize healthier lifestyles.<sup>144</sup>

The PHIT Act remains active as standalone legislation, with strong bipartisan and bicameral support: 23 cosponsors in the House (14 Republicans, 9 Democrats) and 5 in the Senate (2 Republicans, 3 Democrats).<sup>145</sup> Work continues to lead advocacy efforts to secure passage of the full PHIT Act—or its core provisions—as part of future tax, healthcare, or wellness legislative vehicles.<sup>146</sup>

### **XIII. A PUBLIC HEALTH AND FISCAL IMPERATIVE: THE CASE FOR PHIT IN COMBATING CHRONIC DISEASE AND INACTIVITY**

While the Internal Revenue Code and case law have historically restricted the definition of medical care to expenses incurred for the treatment of specific diseases or conditions, emerging public health and economic data demonstrate that this narrow interpretation is increasingly out of step with today’s healthcare realities.<sup>147</sup> The United States is facing a chronic disease and physical inactivity crisis that not only undermines public health but also places an unsustainable burden on the healthcare system.<sup>148</sup> Expanding the definition of medical care to

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<sup>139</sup> *Id.* § 110208(a).

<sup>140</sup> *Id.* § 110208(b)(E)(ii)(I).

<sup>141</sup> *Id.* § 110208(b)(E)(i)-(vii).

<sup>142</sup> *See* One Big Beautiful Bill Act, Pub. L. No. 119-21, 139 Stat. 72.

<sup>143</sup> *See* discussion *supra* Section XII.

<sup>144</sup> *Id.*

<sup>145</sup> *See* H.R. 2369; S. 1144.

<sup>146</sup> *See* Josh Liberatore, *As Senate Tosses PHIT Act, HFA Calls for Fitness Industry Action*, ATHLETECH NEWS (June 20, 2025), <https://athletechnews.com/as-senate-tosses-phit-act-hfa-calls-for-fitness-industry-action/>.

<sup>147</sup> *See* Jennifer L. Matjasko et al., *Inadequate Aerobic Physical Activity and Healthcare Expenditures in the United States: An Updated Cost Estimate*, 39 AM. J. HEALTH PROMOTION 1085, 1085-87 (2025).

<sup>148</sup> *See* Sheryl Gay Stollberg & Dani Blum, *Kennedy and Trump Paint Bleak Picture of Chronic Disease in U.S. Children*, N.Y. TIMES (May 22, 2025), <https://www.nytimes.com/2025/05/22/us/politics/kennedy-trump-maha-report.html>.

include structured physical activity, as proposed in the PHIT Act, is not only a reasonable policy evolution—it is a necessary one.

#### XIV. THE INACTIVITY EPIDEMIC AND ITS COSTS

Physical inactivity has become a defining public health challenge of the 21st century.<sup>149</sup> According to the Physical Activity Alliance’s 2025 “Fast Facts,” only 25.3% of adults meet the recommended guidelines for both aerobic and muscle-strengthening activity, while more than 26% report doing no physical activity whatsoever in their free time.<sup>150</sup> These trends are especially alarming given the strong association between inactivity and the most costly and deadly chronic conditions in the United States, including heart disease, type 2 diabetes, obesity, depression, and multiple types of cancer.<sup>151</sup>

The healthcare costs tied to inactivity are staggering. A 2025 study published in the *American Journal of Health Promotion* estimates that 12.6% of all healthcare expenditures—equivalent to over \$192 billion annually—are directly attributable to inadequate levels of aerobic physical activity.<sup>152</sup> Inactive individuals incur an average of \$2,025 more in healthcare costs per year compared to those who meet the recommended physical activity guidelines—translating not only into higher personal health risks and diminished quality of life, but also into substantial and preventable strain on public and private healthcare payers alike.<sup>153</sup>

This situation is exacerbated by shifting demographic and economic trends. As reported by Keehan et al. in *Health Affairs* (2025), national health expenditures are projected to rise from \$5.3 trillion in 2024 to \$8.6 trillion by 2033.<sup>154</sup> Over this period, healthcare spending is expected to grow at an average annual rate of 5.8%, outpacing GDP growth and ultimately consuming more than 20% of the U.S. economy by 2033.<sup>155</sup> Chronic conditions and an aging population are key drivers of this growth.<sup>156</sup> The evidence is clear: unless we make strategic investments in prevention, rising healthcare costs will jeopardize economic stability and erode the sustainability of public health programs.

#### XV. FITNESS AFFORDABILITY AS A STRATEGIC POLICY LEVER

Despite overwhelming evidence of the benefits of physical activity, cost remains a leading barrier to participation in structured exercise programs. According to the 2024 Health & Fitness Association and Portas Consulting *Fitness Affordability as Strategic Policy* study, 72% of non-members cite affordability as

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<sup>149</sup> See Matjasko et al., *supra* note 147, at 1086.

<sup>150</sup> *Physical Activity Fast Facts 2025*, PHYSICAL ACTIVITY ALL. (2025), <https://paamovewithus.org/wp-content/uploads/2025/02/Physical-Activity-Fast-Facts-2025.pdf>.

<sup>151</sup> *Id.*; Matjasko et al., *supra* note 147, at 1086.

<sup>152</sup> Matjasko et al., *supra* note 147, at 1086.

<sup>153</sup> *Id.*

<sup>154</sup> Sean P. Keehan et al., *National Health Expenditure Projections, 2024–33: Despite Insurance Coverage Declines, Health to Grow as Share Of GDP*, 44 HEALTH AFFS. 776, 777 (2025).

<sup>155</sup> *Id.* at 776.

<sup>156</sup> *See id.*

the primary reason for not joining a health or fitness facility.<sup>157</sup> This finding is particularly concerning given that structured, professionally guided exercise is one of the most effective tools available to help individuals meet the recommended levels of physical activity.<sup>158</sup>

The same study shows that a modest 10% reduction in membership costs—if supported by policy incentives like the PHIT Act—could significantly expand access to structured exercise in the United States.<sup>159</sup> The U.S. fitness industry already plays a significant role in facilitating physical and mental health benefits: according to the 2025 *U.S. Health & Fitness Consumer Report*, nearly 96 million Americans used a fitness facility in 2024, and more than 77 million currently hold memberships.<sup>160</sup> The industry consists of thousands of fitness facilities, ranging from full-service health clubs to boutique studios and community centers.<sup>161</sup> A large proportion of facility users participate in instructor-led activities such as group fitness classes, small-group training, or personal training, highlighting the importance of structured environments in supporting physical activity adherence.<sup>162</sup> Importantly, most facility users say that gym access is one of the top contributors to their overall well-being.<sup>163</sup>

The fitness industry has the infrastructure, professional expertise, and geographic reach to deliver preventive health benefits at scale—if access barriers, such as cost, can be reduced.

## XVI. PHIT: ALIGNING TAX POLICY WITH MODERN PUBLIC HEALTH REALITIES

Current tax law, rooted in decades-old definitions, fails to treat preventive physical activity as a qualified medical expense. As detailed earlier in this Article, the IRS has repeatedly denied deductions or reimbursements for fitness-related expenses unless tied to the treatment of a specific diagnosed disease.<sup>164</sup> This outdated distinction overlooks the extensive and growing body of evidence that supports physical activity as both a preventive and therapeutic tool.<sup>165</sup>

The PHIT Act's importance lies in the fact that it changes the way that medical expenses are defined, to specifically include sport and fitness expenses.<sup>166</sup> Historically, the IRS and case law have made a clear distinction between medical expenses and personal expenses for general health and wellness; sport and fitness expenses have generally been considered the latter, unless narrow, specific

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<sup>157</sup> HEALTH & FITNESS ASS'N & PORTAS CONSULTING, REVERSING THE PHYSICAL INACTIVITY CRISIS: FITNESS AFFORDABILITY AS STRATEGIC POLICY 7 (2024).

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 3.

<sup>160</sup> HEALTH & FITNESS ASS'N, 2025 U.S. HEALTH & FITNESS CONSUMER REPORT 7 (2025).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> See discussion *supra* Sections I-V.

<sup>165</sup> See Matjasko et al., *supra* note 147, at 1085.

<sup>166</sup> See discussion *supra* Sections XI-XVIII.

conditions were met.<sup>167</sup> Those conditions included diagnosis of a specific disease by a healthcare provider or prevention of the progression of a specific disease.<sup>168</sup> A specific disease is what prompts treatment as a medical expense; thus, prevention is not recognized as medical care.<sup>169</sup> The PHIT Act not only recognizes prevention as medical care, but it recognizes physical activity as prevention as medical care.<sup>170</sup>

The PHIT Act corrects this disconnect by allowing Americans to use pre-tax dollars from HSAs and FSAs to cover qualified expenses related to physical activity.<sup>171</sup> These include fitness facility memberships, youth sports fees, personal training, group fitness classes, and other structured programs.<sup>172</sup> Importantly, the Act maintains appropriate guardrails—only evidence-based, activity-focused expenses would qualify, and the benefit would be capped annually to preserve fiscal responsibility.<sup>173</sup>

PHIT is not a mandate. It does not require insurers to cover fitness services, nor does it establish new federal spending programs. Rather, it empowers individuals to make health-promoting choices using the money they already set aside for medical expenses. In doing so, it advances three key public policy goals: improving population health, reducing long-term healthcare expenditures, and promoting health equity by increasing access to preventive resources for more Americans.<sup>174</sup>

## XVII. ADDRESSING EQUITY AND EXPANDING IMPACT

By making physical activity more affordable, the PHIT Act can help expand opportunities and promote healthier lifestyles—especially for those who currently face the greatest barriers to being active. Low-income communities, rural residents, and historically marginalized groups often have limited access to safe, affordable exercise opportunities.<sup>175</sup> PHIT would allow these individuals to use tax-advantaged savings to offset costs, making it easier to engage in preventive behaviors that improve health and well-being.<sup>176</sup>

For non-customers of fitness facilities, 72% cite affordability and cost as the main reason for not joining a facility.<sup>177</sup> The PHIT Act would reduce the cost barrier, with a 20–30% savings on fitness expenses with pre-tax dollars from

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<sup>167</sup> See discussion *supra* Sections II-VII.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> See discussion *supra* Sections XI-XVIII.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> Bantham et al., *Overcoming Barriers to Physical Activity in Underserved Populations*, 64 *PROGRESS CARDIOVASCULAR DISEASES* 64, 64-71 (2021).

<sup>176</sup> See discussion *supra* Sections XI-XVIII.

<sup>177</sup> HEALTH & FITNESS ASS'N & PORTAS CONSULTING, *supra* note 157, at 1.

HSA/FSA accounts.<sup>178</sup> By removing the cost barrier by just 10%, an estimated 17 million more Americans would become physically active.<sup>179</sup>

Additionally, expanding access to physical activity aligns with broader efforts to address social determinants of health. Structured exercise is associated not only with lower rates of chronic disease but also with improved mental health, stronger social connections, and greater workplace productivity.<sup>180</sup> These broader societal benefits support a more resilient economy and a healthier, more inclusive society.

### XVIII. THE TIME TO ACT IS NOW

As healthcare costs continue to rise and chronic disease becomes the norm rather than the exception, the need for preventive solutions is more urgent than ever.<sup>181</sup> The evidence from the HFA-Portas study, the National Health Expenditure projections, the Consumer Report, and peer-reviewed health economics research leaves no doubt: increasing access to structured physical activity is a high-impact, fiscally responsible strategy for improving public health and reducing long-term medical spending.<sup>182</sup>

Fitness facility users are 50% more likely to meet global physical activity guidelines.<sup>183</sup> Incentivizing more Americans to be physically active, at fitness facilities or generally, would prevent nearly 500,000 disease cases annually, save 95,000 disability-adjusted life years (DALYs), and avoid 3,500 deaths each year.<sup>184</sup> The projected benefits go beyond physical health: 3.6 million people would report higher life satisfaction, and 2.6 million would experience greater trust in their communities.<sup>185</sup> These improved overall outcomes could translate into \$12.2 billion in annual health savings—representing a 3.3 times return on a hypothetical \$3.7 billion investment.<sup>186</sup>

Americans overwhelmingly support the PHIT Act, according to a recent study.<sup>187</sup> Over 86% of U.S. adults support expanding pre-tax accounts for fitness expenses.<sup>188</sup> This crosses party lines, with 88% of Democrats, 84% of Republicans, and 86% of Independents in favor.<sup>189</sup> These figures reflect the broad-based

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<sup>178</sup> *Id.*

<sup>179</sup> *See id.*

<sup>180</sup> *See id.*

<sup>181</sup> *See* Matjasko et al., *supra* note 147, at 1085-87.

<sup>182</sup> HEALTH & FITNESS ASS'N & PORTAS CONSULTING, *supra* note 157.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> HEALTH & FITNESS ASS'N & PORTAS CONSULTING, *supra* note 157.

<sup>187</sup> *See Congress Reintroduces Game-Changing Bill to Lower Healthcare Costs Through Fitness*, HEALTH & FITNESS ASS'N (Mar. 26, 2025), <https://www.healthandfitness.org/about/media-center/press-releases/congress-reintroduces-game-changing-bill-to-lower-healthcare-costs-through-fitness/>.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

understanding that prevention is the smartest path forward—for our health and our economy.<sup>190</sup>

### **XIX. CONCLUSION: A NEW CHAPTER IN PREVENTIVE HEALTH POLICY**

Just as tax policy has evolved to support smoking cessation, mental health treatment, and preventive screenings, it must now adapt to include structured exercise. The legal precedent around medical deductions should not remain fixed in a time when the greatest threats to public health were infectious diseases and acute conditions. Today, the nation's most pressing health challenges—obesity, heart disease, diabetes, and depression—are deeply rooted in lifestyle and behavior. Recognizing this, the PHIT Act would mark a meaningful shift toward preventive, equitable, and evidence-based public health policy.

The PHIT Act has another chance at passage in the 119th Congress, as part of a healthcare package taken up in the fall of 2025.<sup>191</sup> Policymakers, healthcare leaders, and taxpayers alike need to recognize that the benefits of the PHIT Act extend well beyond fitness. They include a more sustainable healthcare system, a healthier workforce, and stronger communities. Enacting the PHIT Act is not only legally and economically justified—it is morally imperative. We have the data. We have the policy mechanism. Now we need the political will to act.

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<sup>190</sup> *Id.*

<sup>191</sup> See H.R. 2369; S. 1144 (both introduced with the potential for later passage and enactment as of February 2026).



# WELLNESS DISPUTES

Maria Cudowska\*

## I. INTRODUCTION

On October 25, 2024, days before the presidential election, Robert F. Kennedy Jr. posted on X that the FDA’s war on public health was about to end,<sup>1</sup> sparking a public debate.<sup>2</sup> Months later, shortly after his inauguration, President Trump issued an executive order establishing “The Make America Healthy Again Commission,” highlighting the Trump administration’s endorsement of a focus on disease prevention rather than treatment.<sup>3</sup> The healthcare views espoused by Kennedy and the Trump administration have come to be known as “Make America Healthy Again,” or “MAHA.”<sup>4</sup>

A commitment to disease and injury prevention is not a new government policy goal.<sup>5</sup> Yet, what makes MAHA novel is its emphasis on prevention at the expense of scientifically proven forms of treatment, like vaccines. The executive order embodies this focus, providing:

To fully address the growing health crisis in America we must re-direct our national focus towards understanding and drastically lowering chronic disease rates. . . . This includes fresh thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. We must restore the integrity of the scientific process by protecting expert recommendations from inappropriate influence and increasing transparency regarding

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<sup>1</sup> See Robert F. Kennedy Jr. (@RobertKennedyJr), X (Oct. 25, 2024, at 05:25 PM ET), <https://x.com/RobertKennedyJr/status/1849925311586238737> (Kennedy criticized the FDA’s purported “suppression” of “psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine, vitamins, clean foods, sunshine, exercise, [and] nutraceuticals,” interventions he characterized as anything that “advances human health and can’t be patented by Pharma.”).

<sup>2</sup> See generally Christina Jewett, *Kennedy’s F.D.A. Wish List: Raw Milk, Stem Cells, Heavy Metals*, N.Y. TIMES (Nov. 12, 2024), <https://www.nytimes.com/2024/11/12/health/robert-kennedy-jr-fda.html> (describing the contradictions between Robert F. Kennedy’s suggestions about raw milk, hydroxychloroquine, chelation, and stems cells and the administrations put in place to regulate these topics).

<sup>3</sup> Exec. Order No. 14212, 90 Fed. Reg. 9833 (Feb. 13, 2025).

<sup>4</sup> *Id.*

<sup>5</sup> See, e.g., Richard A. Epstein, *In Defense of the “Old” Public Health: The Legal Framework for the Regulation of Public Health*, 69 BROOK. L. REV. 1421, 1423 (2004).

existing data. We must ensure our healthcare system promotes health rather than just managing disease.<sup>6</sup>

Despite its potential to be read as a good faith attempt to combat and prevent chronic disease, the MAHA rhetoric fuels existing antagonisms about healthcare—about good versus bad science, for example—and adds to consumer distress.<sup>7</sup> That distress is also exacerbated by the administration’s emphasis on conditioning access to healthcare on individual adherence to government-imposed behavioral norms.<sup>8</sup>

Of course, government has always played a role in U.S. healthcare. Historically, the federal government has been a major investor and active participant in the healthcare market.<sup>9</sup> It has imposed rules and provided funding, creating symbiotic relationships in the free market economy between public and private entities.<sup>10</sup> MAHA represents a stark departure from those traditions, it is consistent with another notable change. Federal funding for health-promoting behavior, and regulation of healthcare and adjacent industries, is decreasing.<sup>11</sup> As a result, consumers are increasingly becoming “bosses of their own biology”<sup>12</sup>—

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<sup>6</sup> Exec. Order No. 14212, *supra* note 3, at 9834.

<sup>7</sup> The Supreme Court addressed the issue of misinformation and health in the context of First Amendment rights in *Murthy v. Missouri*, 603 U.S. 43 (2024). Research suggests that infodemics and misinformation negatively affect health behaviors. Israel Junior Borges de Nascimento et al., *Infodemics and Health Misinformation: A Systematic Review of Reviews*, BULL. WORLD HEALTH ORG. (2022).

<sup>8</sup> See Lauren Weber, *RFK Jr.: If You Eat Doughnuts or Smoke, Should Society Pay for Your Health Care?*, WASH. POST (Apr. 10, 2025), <https://www.washingtonpost.com/health/2025/04/10/rfk-jr-personal-responsibility-health-care-donuts-smoking/>; see also Jerel Ezel, *The One Area Where Trump’s N.I.H Cuts Might Actually Make Sense*, N.Y. TIMES (June 13, 2025, at 05:00 AM ET), <https://www.nytimes.com/2025/06/13/opinion/health-disparities-nih.html?searchResultPosition=22> (explaining how health disparities in healthcare are not solved simply by adjusting individual behavior—rather, eliminating discrimination and bias will eliminate the racial inequity gap in healthcare).

<sup>9</sup> See, e.g., Robert I. Field, *Government as the Crucible for Free Market Health Care: Regulation, Reimbursement, and Reform*, 159 U. PA. L. REV. 1671, 1676 (2011) (explaining how achieving universal access to healthcare has been an elusive goal, and how the healthcare system has progressively become one based on private market mechanisms); see generally Yaniv Heled, Liza Vertinsky & Cass Brewer, *Why Healthcare Companies Should Be(come) Benefit Corporations*, 60 B.C. L. REV. 73, 121 (2019) (explaining how for-profit corporations produce ill-fitting social welfare outcomes, and that “encouraging (or requiring) healthcare companies to operate under new hybrid legal forms that mandate consideration of stakeholder (not just shareholder) interests will narrow the divergence between private incentives and public health needs in ways that benefit public health, provided that there is robust regulatory enforcement of the hybrid rules”).

<sup>10</sup> See Field, *supra* note 9, at 1674.

<sup>11</sup> Congress has limited the scope of agency oversight over key health science-related agencies—the National Institutes of Health (NIH) and the Federal Drug Administration, for example—by eliminating funding and terminating key employees. See Richard G. Frank & Sherry Glied, *The Trump Administration’s NIH and FDA Cuts Will Negatively Impact Patients*, BROOKINGS (May 14, 2025), <https://www.brookings.edu/articles/the-trump-administrations-nih-and-fda-cuts-will-negatively-impact-patients/>.

<sup>12</sup> While the phrases “the boss of your own biology” and the “CEO of your health” cannot be attributed to one source, they have become popular in the wellness and functional medicine

facilitating the growth of a new industry of direct-to-consumer testing services (“DTCs”) and wellness diagnostic platforms focused on personalized health and wellness and disease prevention,<sup>13</sup> a development that MAHA at least implicitly endorses.<sup>14</sup> As more users turn to wellness platforms for answers about their health,<sup>15</sup> and federally-funded health insurance continues to shrink, reliance on personalized wellness trends will only grow, demanding immediate attention from lawyers and policymakers. The wellness platforms are filling a market gap, but in the most dangerous and unregulated way possible.

Although research suggests that wellness platforms may offer some benefits for affluent, well-educated consumers,<sup>16</sup> personalized health alone will not fix a decentralized and fragmented healthcare system,<sup>17</sup> in which patients

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community. See, e.g., TRANSFORM: *Biology and How to Be The CEO of Your Own Health with Dr. Mark Hyman*, at 04:14 (Spotify, Oct. 9, 2024); The Dr. Hyman Show, *How to Hack Your Biology for a Longer, Healthier Life with Gary Brecka*, MARK HYMAN, MD (Mar. 12, 2025), <https://drhyman.com/blogs/content/podcast-ep1015>; see also Rob Rossitier, *How to Become the CEO of Your Health*, FORBES (Jan. 24, 2023, at 09:55 AM ET), <https://www.forbes.com/consent/ketch/?toURL=https://www.forbes.com/councils/forbesbusinesscouncil/2023/01/19/how-to-become-ceo-of-your-health/>.

<sup>13</sup> Personalized health is a subset of personalized medicine and uses advanced diagnostic tools for individual patients and includes, but is not limited to, genetic, molecular, and environmental screening and analysis, used to provide tailored approaches for preventing disease, diagnosing and managing risk factors, or managing and treating conditions. Shaun Callaghan et al., *The Trends Defining the \$1.8 Trillion Global Wellness Market in 2024*, MCKINSEY & CO. (Jan. 16, 2024), <https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/the-trends-defining-the-1-point-8-trillion-dollar-global-wellness-market-in-2024> (explaining how the development of generative AI tools will contribute to personalized wellness recommendations).

<sup>14</sup> See, e.g., Press Release, Centers for Medicare & Medicaid Services, White House, Tech Leaders Commit to Create Patient-Centric Healthcare Ecosystem (July 30, 2025), <https://www.cms.gov/newsroom/press-releases/white-house-tech-leaders-commit-create-patient-centric-healthcare-ecosystem>.

<sup>15</sup> See, e.g., PURSUIT OF WELLNESS: *How Lab Testing Will Change Your Health: What Dr. Hyman Found in My Results*, at 04:57 (Spotify, Nov. 18, 2024) (Dr. Mark Hyman, a co-founder of Function Health, stating that “[w]e’ve now had over 80,000 members join, we have over 300,000 people on the waitlist, [and] we’ve had over 10 million biomarkers tested.”). One year later, Function announced that it had surpassed 50 million lab tests. *With a \$2.5B Valuation, Function Becomes the New Standard for Health and Launches Medical Intelligence Lab*, FUNCTION: THE FUNCTION J. (Nov. 19, 2025), <https://www.functionhealth.com/article/function-announcement#:~:text=Now%20they're%20accessible%2C%20too,and%20proactive%20as%20lab%20testing>.

<sup>16</sup> See Laurel Thomas, *Consumers of Commercial Genetic Tests Understand More Than Many Believe*, UNIV. MICH. NEWS (June 22, 2015), <https://news.umich.edu/consumers-of-commercial-genetic-tests-understand-more-than-many-believe>.

<sup>17</sup> Andrew Twinamatsiko & Katie Keith, *Slouching Towards Deregulation: The Health Threat to Health Policy*, GEO L.: O’NEILL INST. NAT’L & GLOB. HEALTH L. (Apr. 2022), [https://oneill.law.georgetown.edu/wp-content/uploads/2022/04/ONL\\_Derugulation\\_Report\\_P4.pdf](https://oneill.law.georgetown.edu/wp-content/uploads/2022/04/ONL_Derugulation_Report_P4.pdf). The system is comprised of a network of insurers, providers, and programs that must follow both state and federal requirements. See *id.*

experience “frustration,”<sup>18</sup> and/or “hit[] a wall with traditional healthcare.”<sup>19</sup> Yet the idea of controlling one’s health, or the ability to hack one’s health problems, is powerful, potentially capable of luring in the medically illiterate or those who have lost hope in traditional medicine.<sup>20</sup> For instance, users of the wellness diagnostic platform Function Health<sup>21</sup> report that the platform helped identify the root cause of their illness,<sup>22</sup> discover cancer early,<sup>23</sup> and allowed individuals to take control of their health.<sup>24</sup> User comments about Viome, a direct-to-consumer testing platform, make similar points:

Nothing has worked. However, by mostly following the Viome diet + supplements + probiotics I feel the best I have in my entire life. . . . Here we are 2 months in, and the results speak for themselves. Eating what my body needs. Not what someone is telling me to eat or what I think I need.<sup>25</sup>

The traditional healthcare system is notoriously paternalistic.<sup>26</sup> Wellness platforms provide a seemingly less condescending alternative that addresses

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<sup>18</sup> See *About*, JOI + BLOKES, <https://joiandblokes.com/about/> (last visited July 8, 2025) (quoting Blokes founder Josh Whalen as stating “[he] created Blokes after going through [his] own health journey—and hitting wall after wall with the traditional healthcare system”) (also quoting Joi founder Kathy Whalen as stating “[she] started Joi because [she] lived the frustration so many women face—[she] was exhausted, foggy, emotional, and just didn’t feel like [her]self”).

<sup>19</sup> See *id.*

<sup>20</sup> See *Testimonials*, FUNCTION HEALTH, <https://www.functionhealth.com/testimonials> (last visited July 8, 2025) (“I think being proactive is empowering. I feel like I’m in control of my health.”) [hereinafter *Testimonials*].

<sup>21</sup> See generally FUNCTION HEALTH, <https://www.functionhealth.com/> (last visited July 13, 2025) (presenting the Function Health homepage).

<sup>22</sup> See *Testimonials*, *supra* note 20 (“I have been searching for many years for the root cause of my health problems. I have seen many doctors and specialists . . . but finally found the true root cause of my issue SLE Lupus due to extensive testing that Function provided.”).

<sup>23</sup> See *id.* (“I learned through my participation with Function that I have CLL. I am now under the care of MD Anderson Cancer Center for my form of Leukemia.”).

<sup>24</sup> See *Testimonials*, *supra* note 20 (stating that a wellness app “gives you access to blood work results a Primary Care Physician refuse[s] to test,” allowing individuals to take control of their health without “fighting with insurance companies”).

<sup>25</sup> VIOME, <https://www.viome.com/> (last visited July 13, 2025). The concept of personalized health differs significantly from the offerings of consumer-facing wellness applications and services. See *Terms of Service*, VIOME, <https://www.viome.com/terms> (last visited July 8, 2025) (describing its services as “an AI-driven, personalized therapeutics company” that uses data from microbial, mitochondrial, and human gene expression to offer tools for early disease detection and prevention); *Terms of Service*, FUNCTION HEALTH (Mar. 4, 2025), <https://www.functionhealth.com/terms-of-service> (describing its services as including laboratory testing, AI-driven informational chatbots, and health-related content, while disclaiming that it provides medical advice or creates a doctor-patient relationship).

<sup>26</sup> See Wendy E. Parmet, *Beyond Paternalism: Rethinking the Limits of Public Health Law Response*, 46 U. CONN. L. REV. 1771, 1781 (2002) (“Policymakers may have one goal and perspective, while those who are regulated may have others. One challenge for those thinking about paternalism and public health law is that many laws that seem paternalistic to those being regulated may not appear as such to public health advocates and regulators who share a population perspective.”). For a discussion on “paternalism v. parentalism” in law, see generally Stephen J. Ware, *Paternalism or*

individuals' desire to understand their bodies by providing them with an appearance of, if not actual, control, all the while taking advantage of the fact that the efficacy of wellness and related services are difficult to disprove.<sup>27</sup>

Wellness diagnostic platforms' marketing also creates a sense of urgency to determine what plagues us faster, because wellness cannot wait.<sup>28</sup> While lab test results provided by wellness diagnostic platforms can give some useful information to patients, the risks are still high.<sup>29</sup> Moreover, the turn to personalized health and "democratization of health" through access to information<sup>30</sup> introduces legal risk through the platforms' insistence on out-of-court dispute resolution.<sup>31</sup>

Most wellness diagnostic platforms and DTC testing terms of service contain dispute resolution provisions, and a significant number incorporate mandatory arbitration clauses.<sup>32</sup> Although arbitration can be an efficient and

*Gender-Neutrality?*, 52 CONN. L. REV. 537 (2020) (focusing on the distinction between the terms "paternalism" and "parentalism" within legal scholarship and advocating for the general use of "parentalism" as a gender-neutral term to describe laws or policies that aim to protect individuals by restricting their choices, as "[p]aternalism" should be reserved for instances in which male dominance or attitudes predominantly characteristic of men are present).

<sup>27</sup> Wellness and alternative therapies are difficult to test through clinical trials as treatments vary from patient to patient, which further explains the growth and expansion of personalized wellness and health services. See Casey Ross et al., *Medicine with a Side of Mysticism: Top Hospitals Promote Unproven Therapies*, STAT (Mar. 7, 2017), <https://www.statnews.com/2017/03/07/alternative-medicine-hospitals-promote/>; Jessica Wapner, *Medicine's Wellness Conundrum*, NEW YORKER (Nov. 6, 2021), <https://www.newyorker.com/science/annals-of-medicine/medicines-wellness-conundrum>.

<sup>28</sup> See, e.g., JOI + BLOKES, *supra* note 18 ("Health isn't a luxury, it's a non-negotiable. Life is already challenging and full of friction. Still, it's even more complicated when your physical and mental health aren't at their best.").

<sup>29</sup> See generally Diane E. Hoffmann et al., *The DTC Microbiome Testing Industry Needs More Regulation*, 383 SCI. 1176, 1176 (Mar. 14, 2024) ("Yet companies' claims of having the ability to detect "abnormal" microbiomes are not substantiated by research; the testing processes are analytical validity and results have no demonstrated clinical validity. As a result, consumers may be financially exploited or harmed by inappropriate use of test result that neither they nor their doctors understand.").

<sup>30</sup> See generally *About*, FUNCTION HEALTH, <https://www.functionhealth.com/about> (last visited July 13, 2025) (quoting Dr. Mark Hyman as stating that "I wish I could see millions of patients. We are building Function to democratize so much of what I do and give you the keys to own your health. It is the most powerful approach to health I've seen in my career as a doctor.").

<sup>31</sup> See discussion *infra* Part IV. The data democratization approach also alienates some physicians and turns them into skeptics; the tests run by Function are also typically ordered by primary care practitioners, contradicting the novelty narrative pushed by the company. See Angela Haupt, *What Getting 105 Blood Tests from a Health Startup Taught Me*, TIME (Dec. 4, 2024), <https://time.com/7176591/function-health-startup-blood-tests-preventive-medicine/>.

<sup>32</sup> Instead of arbitration, some platforms also rely on "good faith informal efforts" which may include a personal meeting, a teleconference, or a videoconference, intended to demonstrate a good faith effort to resolve the dispute. Parties initiating an Informal Dispute Resolution Conference ("IDRC") have the option to be accompanied by counsel, however, the parties' presence is mandatory. While the IDRC is not mediation per se, if an injured party is not represented by counsel, a pro se representation may have detrimental consequences to the injured party. The terms and conditions state that "[i]f you are represented by counsel, your counsel may participate in the conference, but you will also participate in the conference." *Terms and Conditions*, MAREK HEALTH (May 28, 2025), <https://marekhealth.com/terms-and-conditions>. The intent to initiate an IDRC is subject to notice to

private mechanism for resolving healthcare-related disputes, its implications for both consumers and wellness diagnostic services providers are complex.<sup>33</sup>

This Article situates novel wellness disputes within the larger context of U.S. healthcare. The accuracy of test results, the potential for misinterpretation, and the psychological burden of uncertain or misleading health data create a new category of legal and ethical conflicts, or “wellness disputes.” Part II describes how the wellness diagnostic platforms and direct-to-consumer testing services have changed the wellness industry. Part III applies the wellness dispute paradigm to arbitration, summarizing recent and key decisions related to misdiagnoses and failure to obtain informed consent. The Article focuses specifically on how such disputes are shaped by the prevalence of arbitration clauses in terms of service agreements. Part IV applies these framings to study the wellness app Function Health and its terms of service. The Article then concludes, noting that consumers’ increased use of unregulated and not-yet-court-tested diagnostic platforms will result in the suppression of relevant health data, potentially stalling public-private partnerships and making Americans not healthier, but sicker, again.

## II. THE WELLNESS ENTERPRISE

Everyone is different—but we all share a common desire for good health. The prediction is that by 2030, the healthcare industry will marry personalized

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the other party, and shall occur within forty-five days of the other party receiving notice, “unless an extension is mutually agreed upon by the parties.” *See id.* Further, the AAA created a monopoly for administering arbitrations of DTCs and diagnostic platforms. *See Terms and Conditions*, KALE HEALTH, <https://kalediagnosics.com/termsandconditions/> (last visited June 8, 2025). There also seems to be a growing interest in AAA’s administration of healthcare disputes, as case numbers rose from 618 in 2021 to 1,027 in 2024. *Healthcare Dispute Resolution*, AM. ARB. ASS’N, [https://go.adr.org/rs/294-SFS-516/images/2024\\_Healthcare\\_Dispute\\_Resolution\\_Infographic.pdf](https://go.adr.org/rs/294-SFS-516/images/2024_Healthcare_Dispute_Resolution_Infographic.pdf) (last visited July 9, 2025) (providing graphics of healthcare cases filed from 2021-2024).

<sup>33</sup> On one hand, arbitration may reduce litigation costs and expedite resolutions; on the other, it may limit patients’ access to judicial remedies, reduce transparency, and raise concerns about procedural fairness. *See* David Larson & David Dahl, *Medical Malpractice Arbitration: Not Business as Usual*, 8 Y.B. ARB. & MEDIATION 69 (2016) (arguing that as litigation outcomes are generally favorable for physicians, they may be less inclined to accept a different venue of dispute resolution; also accounting for litigation costs and the “politics” of arbitration making arbitration unattractive for physicians); Katherine Benesch, *The Increasing Use of Arbitration and Mediation in Adjudicating Healthcare Cases*, 2007 N.J. L. 28, 30 (2007) (explaining which healthcare cases that may be successfully resolved through arbitration, for instance manager care contract disputes between providers, payors, consumers and management companies involving contract interpretation and/or reimbursement issues, employment contract disputes, medical staff, credentialing and peer review disputes, shareholder disputes within physician practices).

care, technology and biology,<sup>34</sup> making the consumer the center of the ecosystem,<sup>35</sup> driving innovation in the global economy.<sup>36</sup> The private sector's focus on holistic health<sup>37</sup> aligns with the federal government's interest in advancing research on "Whole Person Health."<sup>38</sup>

Our desire for good health is reflected in the post-pandemic shifts in the wellness economy. The industry switched gears and investment focused on reversing disease through individualized supplement protocols and dietary interventions,<sup>39</sup> drawing in both health-conscious consumers and individuals managing chronic conditions.<sup>40</sup> These developments are accompanied by increased demand for personalized health strategies, through which individuals assume greater responsibility for proactively managing their wellbeing; however, consumers may be disappointed with the results of personalized health protocols,

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<sup>34</sup> See Hanno Ronte & Elizabeth Hampson, *Interdependent Innovations in Science and Technology Are Reshaping Treatment Paradigms*, DELOITTE (Sept. 30, 2024), <https://www.deloitte.com/uk/en/Industries/life-sciences-health-care/research/interdependent-innovations-in-science-and-technology-are-reshaping-treatment-paradigms.html>. A focus on the biological factors that influence wellness throughout human lifespan can improve health, prevent disease, and enhance quality of life for individuals. For instance, the interactions between diet, the microbiome, metabolites and the human host lead to the development of community-scale metabolic models ("MCMMs") which attempt to predict the "effects of various interventions on microbiome composition, microbial metabolite production, and human health." See generally *Understanding Our Unique Response to Foods*, INST. SYS. BIOLOGY, <https://isbscience.org/research/health/understanding-our-unique-response-to-foods/> (last visited July 3, 2025). As a result, an MCMMs "CyberGut" model has been developed, providing "highly personalized information on diet, microbiome composition, and, if available colonic tissue gene expression." *Id.*

<sup>35</sup> Deloitte Center for Health Solutions, *The Future of Health: Are Consumers Already Living the Future of Health?*, DELOITTE INSIGHTS (2020), [https://www2.deloitte.com/content/dam/insights/us/articles/6851\\_Consumer-survey-and-FOH/DI\\_Consumer-survey-and-FOH.pdf](https://www2.deloitte.com/content/dam/insights/us/articles/6851_Consumer-survey-and-FOH/DI_Consumer-survey-and-FOH.pdf).

<sup>36</sup> The wellness economy is a major force in the global economy, larger in size than the green economy, IT, and sports, and peaked at \$6.3 trillion in 2023 (representing 6.03% of global GDP). Katherine Johnston et al., *Global Wellness: Economy Monitor 2024*, GLOB. WELLNESS INST. at iv (Nov. 2024).

<sup>37</sup> In the future, consumers will expect a combination of products and solutions to deliver best health outcomes. See, e.g., Pamela Spence, *Five Trends Redefining the Health Sciences and Wellness Operating Model*, EY INSIGHTS (May 19, 2021), [https://www.ey.com/en\\_gl/insights/life-sciences/five-trends-health-sciences-wellness-operating-model](https://www.ey.com/en_gl/insights/life-sciences/five-trends-health-sciences-wellness-operating-model).

<sup>38</sup> In its (FY) 2021-2025 Strategic Plan, the National Center for Complementary and Integrative Health has advanced research to "define and map a path to whole person health" focusing on the effectiveness of complimentary health treatments, how treatments combining conventional medicine and alternative healing practices affect patients' health. *NCCIH Strategic Plan FY 2021-2025*, NAT'L CTR. COMPLEMENTARY & INTEGRATIVE HEALTH, <https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025> (last visited July 8, 2025).

<sup>39</sup> The public health, prevention, and personalized medicine sector has demonstrated "strong[] resilience, recovery and growth since the pandemic." Johnston et al., *supra* note 36, at 8. Public health, prevention, and personal medicine has been "(+15.2% annual growth 2019-2023; now at 176% of its 2019 level) [growing] by 42.8% in 2020[] due to governments and healthcare systems accelerating their public health and prevention expenditures in response to the pandemic. Worldwide, public and private spending on public health/prevention has increased as a share of overall health expenditures (from 4.0% in 2019 to 6.1% in 2021-2023) and remains far above pre-pandemic levels." *Id.*

<sup>40</sup> See generally Hoffmann et al., *supra* note 29.

ultimately giving up on costly interventions, which render temporary results.<sup>41</sup> Now, this emerging responsibility is often exercised through personalized testing of biological markers offered by wellness diagnostic platforms such as Function Health and DTC services like Viome.<sup>42</sup> Neither Viome<sup>43</sup> nor Function Health received the FDA's approval,<sup>44</sup> and both have been criticized for lacking clinical validity.<sup>45</sup> The FDA recognizes such risks of inaccurate test administration, which can lead to misdiagnosis, patients skipping treatment, or receiving unnecessary medication or surgery.<sup>46</sup> The FDA also acknowledges the risk of consumers misinterpreting positive and false-positive test results.<sup>47</sup> As a result, consumers run the risk of financial exploitation or can otherwise be harmed by inappropriate use of tests that are not understood by them or their doctors.<sup>48</sup>

Since wellness platforms involve clinical professionals or present AI-generated content as individualized medical advice, they risk regulatory scrutiny and liability—especially in the absence of clear disclosure and FDA approval. Function Health offers an asynchronous “store-and-forward” model, delivering “clinician’s notes” based on stored patient data. While marketed as providing “doctor-level” insights, in the absence of FDA oversight, these notes lack actual clinical validation and create potential risks if consumers treat them as medical advice: “[A clinician note] is not a substitute for your primary care provider or care team. If you have any questions or concerns, please review these results with your

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<sup>41</sup> See, e.g., Lindsay Gellman, *An Expensive Alzheimer's Lifestyle Plan Offers False Hope, Experts Say*, N.Y. TIMES (May 31, 2025), <https://www.nytimes.com/2025/05/21/well/alzheimer-symptoms-reversal-dale-bredesen.html>.

<sup>42</sup> See, e.g., *Testimonials*, *supra* note 20; VIOME, *supra* note 25.

<sup>43</sup> *FDA Grants Breakthrough Device Designation for a Viome Device for the Proposed Intended Use*, VIOME: VIOME BLOG, <https://www.viome.com/blog/fda-grants-breakthrough-device-designation-for-a-viome-device-for-the> (last visited July 14, 2025) (Viome has not received full FDA approval or clearance for its diagnostic tests but has been granted the FDA Breakthrough Device Designation for a specific technology platform); Daniel Imperiale, *Viome Reviews: Should You Try a Viome Gut Microbiome Test?*, INNERBODY (Dec. 31, 2024), <https://www.innerbody.com/viome-review> (on file with author) (“Viome’s broader AI-powered microbiome and molecular health analysis platform, including at-home tests and personalized supplements, does not have FDA approval. Dietary supplements and probiotics offered by Viome are also not FDA-approved, as the FDA does not approve supplements in the same way as drugs.”).

<sup>44</sup> Matthew Perrone, *Top RFK Jr. Aide Attacks US Health System While Running Company That Promotes Wellness Alternatives*, ASSOCIATED PRESS (June 10, 2025, at 08:54 AM CT), <https://apnews.com/article/calley-means-rfk-maha-wellness-ethics-f2702b2e26c2883f15dc281f02fe3008>.

<sup>45</sup> *Id.*; Rina Raphael, *A Gut Check for a Wellness Startup*, BLOOMBERG: BUSINESSWEEK DAILY (Oct. 30, 2023, at 11:24 AM CT), <https://www.bloomberg.com/news/newsletters/2023-10-30/viome-s-tests-raise-questions-about-microbiome-science>.

<sup>46</sup> Matthew Perrone, *FDA Wants to Regulate Thousands of Lab Tests That Have Long Skirted Oversight*, ASSOCIATED PRESS (Sept. 29, 2023, at 11:38 AM CT), <https://www.apnews.com/article/laboratory-tests-medical-fda-theranos-ef8794541b5237f8d2b54fe070d596ce>.

<sup>47</sup> *Direct-to-Consumer Tests*, FDA (Dec. 20, 2019), <https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests> (“A positive direct-to-consumer genetic health risk does not indicate that an individual will develop a given disease or a condition.”).

<sup>48</sup> Hoffmann et al., *supra* note 29.

doctor.”<sup>49</sup> Similarly, other platforms like Levels use AI to offer personalized nutrition guidance and goals,<sup>50</sup> potentially triggering medical decision making.

Decision making—whether it be the consumer, a clinician, or AI—is based on an assessment of biomarkers. A biological marker (“biomarker”) is a “defined characteristic that is measured as an indicator of normal biological process, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions.”<sup>51</sup> Various biomarkers change over different timeframes,<sup>52</sup> and depending on the consumer/patient’s goals, monitoring can be either short-term, mid-term, or long-term focused.<sup>53</sup>

Biomarkers have a wide range of use in a variety of fields such as medicine and mental health and improve understanding of diseases, help make good clinical decisions, as well as guide policies impacting public health.<sup>54</sup> Biomarkers, however, do not measure how an individual feels, functions, or survives.<sup>55</sup>

Thus, the responsibility to manage one’s health proactively and effectively may be impacted by the U.S. regulatory environment for wellness diagnostic

<sup>49</sup> This information comes from the author’s Function Health Portal. *Clinician Notes*, FUNCTION HEALTH, <https://my.functionhealth.com/clinician-notes> (last visited July 9, 2025).

<sup>50</sup> See *Why Food Logging Matters to Metabolic Health and How Levels Can Help*, LEVELS HEALTH (Oct. 13, 2024), <https://www.levels.com/blog/why-food-logging-matters-to-metabolic-health-and-how-levels-can-help>.

<sup>51</sup> *BEST (Biomarkers, EndpointS, and other Tools) Resource: Glossary*, FDA-NIH BIOMARKER WORKING GRP. 47 (Jan. 16, 2025), [https://www.ncbi.nlm.nih.gov/books/NBK326791/pdf/Bookshelf\\_NBK326791.pdf](https://www.ncbi.nlm.nih.gov/books/NBK326791/pdf/Bookshelf_NBK326791.pdf). Categories of biomarkers include susceptibility/risk, diagnostic, monitoring, prognostic, predictive, multicomponent, response, and safety. *Id.* at 47-48.

<sup>52</sup> Ramachandran S. Vassan, *Biomarkers of Cardiovascular Disease: Molecular Basis and Practical Considerations*, 113 *CIRCULATION* 2335, 2340 (2006), <https://www.ahajournals.org/doi/10.1161/circulationaha.104.482570?#core-R61-175195-1> (“For a biomarker to be accepted as a routine screening test it is important to demonstrate that a strategy of measuring the biomarker improves patient outcomes relative to a conventional strategy that does not include the biomarker measurement, usually in the context of a randomized controlled clinical trial.”) (citing Jes S Lindholt et al., *Screening for Abdominal Aortic Aneurysms: Single Centre Randomized Controlled Trial*, 330 *BMJ* 750 (2005)).

<sup>53</sup> For example, a routine monitoring of serum cholesterol, blood glucose, and urine creatinine may potentially determine a risk for medical conditions like hypercholesterolemia, diabetes, and impaired kidney function in healthy adults. FDA-NIH BIOMARKER WORKING GRP., *supra* note 51, at 10.

<sup>54</sup> INST. MED. NAT’L ACADS., *EVALUATION OF BIOMARKERS AND SURROGATE ENDPOINTS IN CHRONIC DISEASE* 34 (Christine M. Micheel & John R. Ball eds., 2010), [https://www.ncbi.nlm.nih.gov/books/NBK220297/pdf/Bookshelf\\_NBK220297.pdf](https://www.ncbi.nlm.nih.gov/books/NBK220297/pdf/Bookshelf_NBK220297.pdf). For instance, the National Health and Nutrition Examination Survey is a survey that measures the health and nutrition of adults through interviews, dental exams, body measurement, and laboratory testing by trained medical professionals. *About NHANES*, NAT’L CTR. HEALTH STATS. (Dec. 18, 2024), <https://www.cdc.gov/nchs/nhanes/about/index.html>. Public policies are shaped based on data, and data related to supplement intake is critical with respect to the growth of the consumer healthcare market. Supplements are part of recommended treatments offered by telehealth companies. In the future, if consumers decide to go with the telehealth industry as their primary healthcare advisory, in consequence even if supplement intake is expected to raise as a result, that data may go largely unreported for purposes of national surveys, and skew health recommendations for the United States. For instance, the National Health Statistics Reports indicate that dietary supplement intake in the United States increases with age, income, and education. It varies by race and Hispanic origin. Suruchi Mishra et al., *Dietary Supplement Use in the U.S.: National Health and Nutrition Examination Survey*, NAT’L CTR. HEALTH STAT. (Apr. 18, 2023), <https://www.cdc.gov/nchs/data/nhsr/nhsr183.pdf>.

<sup>55</sup> FDA-NIH BIOMARKER WORKING GRP., *supra* note 51.

platforms. Specifically, Function’s business model implicates several intersecting federal regulatory regimes, potentially compounding more legal risks for consumers. Regulatory obligations are based on how platforms classify and market their tests,<sup>56</sup> use consumer data,<sup>57</sup> and comply with state health and clinical testing mandates.<sup>58</sup> The following section provides a brief overview of key laws potentially impacting wellness diagnostic platforms.

The FDA has regulatory authority over medical devices. Function Health is not a medical device under FDA regulatory definitions. The company explicitly positions itself as a wellness platform that facilitates access to laboratory testing services rather than a medical device that provides diagnosis, treatment, or medical advice.<sup>59</sup> The design and functionality of a wellness diagnostic platform may trigger classification as a regulated device. The regulated medical devices are products that make diagnostic claims, including software that screens, detects, and diagnoses disease, platforms processing medical images or physiological signals, as well as AI tools providing specific medical information.<sup>60</sup>

Companies that own wellness platforms also need to be mindful when advertising to consumers to ensure compliance with the Federal Trade Commission’s rules and policies. The marketing of wellness and diagnostic products need be truthful, not misleading, and scientifically substantiated.<sup>61</sup> Therefore, DTC and other wellness platforms must exercise caution not to overstate their test’s medical or health benefits—especially when scientific claims are not fully substantiated.<sup>62</sup>

Wellness diagnostic platforms will be subject to regulations mandated by the Clinical Laboratory Improvement Amendments (“CLIA”).<sup>63</sup> Since wellness

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<sup>56</sup> See *General Wellness: Policy for Low Risk Devices*, FDA (Sept. 27, 2019), <https://www.fda.gov/media/90652/download>; see generally Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h).

<sup>57</sup> See, e.g., Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 42 U.S.C.); California Consumer Privacy Act of 2018, CAL. CIV. CODE §§ 1798.100–1798.199.100 (West 2025).

<sup>58</sup> See, e.g., Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a; N.Y. PUB. HEALTH L. § 576 (McKinney 2025).

<sup>59</sup> *Terms of Service*, FUNCTION HEALTH, *supra* note 25.

<sup>60</sup> See Medical Devices; Laboratory Developed Tests, 21 C.F.R. pt. 809 (2024), <https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-08935.pdf>; 21 U.S.C.A. § 360j(o)(1)(B) (excluding certain software functions from the definition of “device,” including software intended “for maintaining or encouraging a healthy lifestyle and [that is] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition . . .”).

<sup>61</sup> See 15 U.S.C. § 45(a)(1) (“Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful”); see also *Section 5: Unfair or Deceptive Acts and Practices*, CONSUMER COMPLIANCE HANDBOOK 40 (2008), <https://www.federalreserve.gov/boarddocs/supmanual/cch/200806/ftca.pdf>; Kyle Diamantas et al., *The FTC Overhauls and Expands 25-Year-Old Health Products Advertising Compliance Guide*, MONDAQ (Jan. 6, 2023), <https://www.mondaq.com/unitedstates/healthcare/1268388/the-ftc-overhauls-and-expands-25-year-old-health-products-advertising-compliance-guide>.

<sup>62</sup> See Hoffmann et al., *supra* note 29, at 1176.

<sup>63</sup> 42 U.S.C. § 263a(a) (defining “laboratory” or “clinical laboratory” as “a facility for the . . . examination of materials derived from the human body for the purpose of providing information for

platforms partner with laboratories and healthcare entities, maintaining CLIA-compliant laboratory affiliations is impervious for complying with relevant state-level licensure and consumer protection laws. CLIA regulations apply to all U.S. facilities or sites that test human specimens for health or disease assessment.<sup>64</sup> According to Function, laboratory services provided through its partnership with Quest Diagnostics are performed in CLIA- and CAP-certified labs, widely trusted by the medical community.<sup>65</sup>

However, New York law makes it illegal for any provider or a lab testing facility, directly or indirectly, to bill or get paid by anyone other than the person who actually receives the test—that is the patient.<sup>66</sup> While the law’s purpose is to shield patients from doctors who may be profiting off of lab referrals, in order to secure fair and transparent lab services,<sup>67</sup> the protections granted to patients also “stifl[e] public health partnerships.”<sup>68</sup> These limitations stifling public health partnerships are the driver of the amendments currently pending before the Assembly Committee.<sup>69</sup> While the legislation in support of collection of small samples of biological material to further health equity and accessibility of clinical laboratory testing is meant to strengthen New York’s public health surveillance microcosm, it also increases the costs of usage for Function’s consumers who live in the state of N.Y. Despite paying an annual fee of \$499 a year, information regarding the necessity to incur additional charges may not be immediately apparent to consumers until scheduling the lab visit.<sup>70</sup>

By focusing on consumer empowerment, preventive care, and health monitoring—rather than diagnosis or treatment—Function Health is likely to remain outside of FDA jurisdiction. This distinction gained importance after a

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the diagnosis, prevention, or treatment of any disease or impairment . . . .”); *Clinical Laboratory Improvement Amendments (CLIA)*, CDC (Sept. 11, 2024), <https://www.cdc.gov/clia/php/about/index.html> (“CLIA regulations establish quality standards . . . [regarding examination of materials derived from the human body] for the purpose of diagnosis, prevention, or treatment . . . .”).

<sup>64</sup> CDC, *supra* note 63.

<sup>65</sup> *FAQs: Exploring the Tests*, FUNCTION HEALTH, <https://www.functionhealth.com/faq> (last visited July 20, 2025) (“Your range of tests available blood and urine samples are collected by a licensed medical technician on-site and processed with state-of-the art [sic] equipment. This is the safest and most accurate way to be tested, given the advanced processing needs for the wide range of biomarkers.”).

<sup>66</sup> N.Y. PUB. HEALTH L. § 586 (McKinney 2024).

<sup>67</sup> *Id.* § 587.

<sup>68</sup> N.Y. Senate Bill No. 9344, 247th Sess., Legislative Memorandum of Sen. Rivera (2024), <https://www.nysenate.gov/legislation/bills/2023/S9344>. The public health partnerships between clinical laboratories and healthcare nonprofit organizations as well as pharmacies and other entities who offer self-collected testing kits. *Id.*

<sup>69</sup> See S. 9344, 2024-2025 Leg., Reg. Sess. (N.Y. 2024), [legislation.nysenate.gov/pdf/bills/2023/S9344](https://www.nysenate.gov/pdf/bills/2023/S9344) (demonstrating that section (j) of the Amendment intends to make section 2 of the Lab Services Accessibility Act inapplicable to nonprofit clinics, healthcare providers, and health services purveyors that are supporting a public health program).

<sup>70</sup> See *List of Tests*, FUNCTION HEALTH, <https://www.functionhealth.com/our-tests> (last visited July 20, 2025) (explaining that while Function informs the customer of potential charges that may be incurred as part of the testing regimen, the prepaid access to testing is subject to bars in New York and New Jersey because New York State and New Jersey have different rules around lab test billing and administration, & accordingly, in New York and New Jersey, Quest Diagnostics will charge additional fees at the time of the laboratory visits.).

March 2025 federal court vacated the FDA's attempt to regulate laboratory developed tests ("LDTs"), reaffirming CLIA's primary oversight.<sup>71</sup> Thereby, it seems that if all wellness diagnostic platforms provide informational content relating to health, wellness, fitness, diet, and lifestyle, they will remain on FDA regulatory periphery. There is still hope though, in consumer protection laws, to safeguards wellness-seeking consumers.

### III. ARBITRATION

"Skin mirrors the liver. Posture reflects fascia. Fat distribution follows hormonal state. Jaw structure reflects airway health. Fluid retention reflects lymphatics. Tongue coating mirrors microbiome. Muscle tone marks longevity. Appearance matters because the body is honest."<sup>72</sup> A blend of truth and metaphor lacking scientific accuracy is an oversimplified statement and may be misleading.<sup>73</sup> After all, human existence—and the human body—do not always outwardly reveal what is happening internally.<sup>74</sup>

The truth is our bodies are not always honest and the self-monitoring makes us paranoid—and perhaps sicker.<sup>75</sup> Consider users who get stressed out over knowing how stressed they are, or others who admit being in a state of chokehold because they did not get enough steps in.<sup>76</sup> Next, consider a consumer who got a false positive cancer marker test result—does the law assume a different type of liability of the testing company, especially if it is all under the guise of personal care, wellness, and preventative care? Finally, consider the user of a blood sugar

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<sup>71</sup> See *Am. Clinical Lab'y Ass'n v. FDA*, 776 F. Supp. 3d 554 (E.D. Tex. 2025).

<sup>72</sup> Melanie, (@vittallymelanie), Instagram (June 19, 2025), <https://www.instagram.com/p/DLF55CwySVB/>.

<sup>73</sup> Leah R. Fowler, Max Helveston & Zoë Robinson, *Influencer Speech-Torts*, 114 *GEO. L.J.* (forthcoming 2025), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4933788](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4933788) (describing how, thanks to the rise of social media influencers, health has become "an individual project of self-improvement, and social media [a] legitimate authority"; also noting that while some content may be beneficial, it may also be "extreme, false and dangerous").

<sup>74</sup> See, e.g., Katherine Macfarlane, *Disability Without Documentation*, 90 *FORDHAM L. REV.* 59, 61 (2021) (describing how the validation of existence of disability by physicians contributes to the harms in the ADA accommodation process and explaining that "the medical documentation requirement is likely influenced by the widespread belief that people who claim disability are faking it," a societal fear that leads to "second-guessing of a person's disability" (quoting Doron Dorfman, *Fear of the Disability Con: Perceptions of Fraud and Special Rights Discourse*, 53 *L. & SOC'Y REV.* 1051, 1078 (2019))).

<sup>75</sup> See, e.g., Madison Malone Kircher, *Is All of This Self-Monitoring Making Us Paranoid?*, *N.Y. TIMES* (May 22, 2025), <https://www.nytimes.com/2025/05/21/style/oura-ring-anxiety.html>.

<sup>76</sup> See, e.g., Nicole Wetsman et al., *Fitness Trackers Can Help Monitor Health for Some People, but Can Exacerbate Disordered Eating for Others*, *ABC NEWS* (Feb. 8, 2024, at 11:32 AM), <https://abcnews.go.com/Technology/fitness-trackers-monitor-health-people-exacerbate-disordered-eating/story?id=107024066>.

monitor,<sup>77</sup> or a metabolic coaching device,<sup>78</sup> or the direct-to-consumer self-testing kits<sup>79</sup>—how may consumers seek meaningful legal redress through arbitration?

Under the Federal Arbitration Act (“FAA”), a “written provision . . . to settle by arbitration . . . shall be valid, irrevocable, and enforceable.”<sup>80</sup> A longstanding constitutional issue of enforcement of arbitration clauses resulted in a system where dispute resolution is outsourced and outcomes are often opaque.<sup>81</sup> The Supreme Court has consistently upheld most consumer arbitration agreements, including those that suppress class action waivers.<sup>82</sup> Unless a party opposing arbitration can demonstrate a clear congressional command to the contrary, courts will generally enforce such agreements.<sup>83</sup> Few if any arbitration awards against direct to consumer testing firms have been made public through court enforcement actions. This suggests that most consumer arbitrations in this sector are either settled or resolved without contentious award challenges.<sup>84</sup> The result is arbitration compliance, allowing companies to evade settling court precedent.

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<sup>77</sup> See, e.g., *Keto Mojo*, DR. MINDY PELZ, <https://drmindypelz.com/product/keto-mojo/> [<https://web.archive.org/web/20250327071911/https://drmindypelz.com/product/keto-mojo/>] (last visited June 19, 2025) (demonstrating such devices are endorsed by chiropractors with extensive knowledge in women’s health, who also shield their online activity with arbitration clauses; “[i]t’s an essential tool for anyone following a keto or low-carb diet for weight loss, diabetes, general health benefits, or therapeutic purposes[;]” purporting that this device also helps track and monitor results including biomarkers such as GKI which is important for tracking metabolic health and the level of ketosis); see also *Disclaimers*, DR. MINDY PELZ, <https://www.drmindypelz.com/disclaimers> (last visited Oct. 31, 2025).

<sup>78</sup> Lumen helps users lose weight by helping them switch from burning carbohydrates to fat. See *How It Works*, LUMEN, <https://www.lumen.me/how-lumen-works/weight-loss> (last visited July 20, 2025). Jurisdiction for U.S. users is New York, while European users are subject to the laws of England and Wales and to the exclusive jurisdiction of the city of London courts. *Terms of Use*, LUMEN (Feb. 5, 2026), <https://www.lumen.me/terms-of-use>.

<sup>79</sup> See, e.g., VIOME, *supra* note 25 (explaining that Viome tests help identify gut microbiome through key biometrics).

<sup>80</sup> 9 U.S.C. § 2; see generally STEPHEN J. WARE & ARIANA R. LEVINSON, *PRINCIPLES OF ARBITRATION LAW* (2d ed. 2023) (summarizing arbitration law and policy).

<sup>81</sup> Judith Resnik, *Diffusing Disputes: The Public in the Private Arbitration, the Private in Courts, and the Erasure of Right*, 124 *YALE L.J.* 2804, 2809, 2815 (2015).

<sup>82</sup> *The Market Participant Doctrine and Forced Arbitration*, 137 *HARV. L. REV.* 1359, 1359 (2024). The current framework strongly favors enforcement of arbitration agreements, individual arbitration over class proceedings, and federal preemption over state laws. *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 341 (2011) (the FAA preempts state laws that prohibit class action waivers in arbitration agreements); *Am. Express Co. v. Italian Colors Rest.*, 570 U.S. 228, 228 (2013) (“The FAA does not permit courts to invalidate a contractual waiver of class arbitration on the ground that the plaintiff’s cost of individually arbitrating a federal statutory claim exceeds the potential recovery.”).

<sup>83</sup> *Shearson/Am. Express, Inc. v. McMahon*, 482 U.S. 220, 226-27 (1987) (“The [Arbitration] Act’s mandate may be overridden by a contrary congressional command, but the burden is on the party opposing arbitration to show that Congress intended to preclude a waiver of judicial remedies for the statutory rights at issue.”).

<sup>84</sup> Further, empirical studies suggest that after major Supreme Court decisions such as *Rent-A-Center*, *Concepcion*, and *Italian Colors*, “extreme repeat players”—large corporations that frequently engage in arbitration—tend to win more and pay less in damages. See David Horton & Andrea Cann Chandrasekher, *After the Revolution: An Empirical Study of Consumer Arbitration*, 104 *GEO. L.J.* 57 (2015) (observing that the Supreme Court’s “arbitration revolution” not only shields businesses from

So why do wellness disputes matter in the greater context of dispute resolution and health? It matters because in wellness disputes—where being the “boss of your own biology” and informed consent are central—arbitration provisions may shield companies from meaningful public accountability and limit consumers’ access to legal remedies. While the wellness and personalized health industry creates an illusion that it serves a public health mandate, though unlikely, continued deregulation raises the prospect that public entities may eventually contract with private service providers like Function Health. In such cases, consumers agree in advance that any disputes concerning products, services, and transactions will be resolved through private arbitration<sup>85</sup>—a mechanism typical to adhesive contracts.<sup>86</sup>

Although highly unlikely, if such public-private partnerships materialize, states and local governments may impose conditions on their commercial dealings, such as refusing to contract with companies that require arbitration without triggering federal preemption—so long as they act as buyers or service providers, not regulators.<sup>87</sup> These choices reflect proprietary interests in delivering safe and lawful public services.<sup>88</sup> Nevertheless, because diagnostic platforms often fall outside the scope of formal public health mandates,<sup>89</sup> state influence may remain limited.<sup>90</sup> As a result, arbitration clauses in these private platforms may continue to avoid meaningful public oversight.<sup>91</sup> The status quo reinforces arbitration’s stature in wellness disputes, mirroring the personalized health philosophy in the realm of dispute resolution—that frames dispute resolution as individually tailored for each consumer.

That said, at increasing rates wellness platforms have faced legal challenges concerning consumer rights and regulatory compliance. What follows is a summary of the key arbitral decisions with a focus on cases related to consumer protection, false advertising, data privacy, and compliance with health regulations. Common issues include alleged misrepresentation about test accuracy, violations of FDA or state health regulations, breaches of genetic privacy, and challenges to the validity of scope of arbitration clauses. As will be described below, *Tompkins*

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class-action liability but also enhances their advantage in individual arbitration cases, suggesting important policy implications for access to justice and fairness); *see also* Charlotte Alexander & Nicole G. Iannarone, *Winning, Defined? Text-Mining Arbitration Decisions*, 42 *CARDOZO L. REV.* 1695 (2021) (noting that most consumer arbitration proceedings are private and awards rarely are made public, revealing that settlement is the most frequent outcome, followed by claimant losses); Nicole G. Iannarone, *A Model for Post-Pandemic Remote Arbitration?*, 52 *STETSON L. REV.* 393, 394 (2023) (observing how investors, despite their level of sophistication, do not understand that they are bound by pre-dispute arbitration agreements).

<sup>85</sup> *See, e.g., Terms of Service*, FUNCTION HEALTH, *supra* note 25.

<sup>86</sup> The centrist position advocates for the enforcement of adhesive arbitration agreements, asserting that they are consensual contracts, not “forced” or “mandatory” arbitration, provided they are not formed under duress or other traditional contract defenses. Stephen J. Ware, *The Centrist Case for Enforcing Adhesive Arbitration Agreements*, 23 *HARV. NEGOT. L. REV.* 29, 38 (2017).

<sup>87</sup> *See The Market Participant Doctrine and Forced Arbitration*, *supra* note 82, at 1377.

<sup>88</sup> *Id.* at 1359.

<sup>89</sup> *See discussion supra* Part II.

<sup>90</sup> *See The Market Participant Doctrine and Forced Arbitration*, *supra* note 82.

<sup>91</sup> *See generally id.* at 1362.

*v. 23andMe, Inc.* and *Toth v. Everywell* demonstrate judicial deference to arbitration in clickwrap agreements, with the exception when consumers are minors, as explained in *Coatney v. Ancestry.com DNA, LLC*. Finally, *Herzog v. Superior Court* demonstrates that to enforce an arbitration clause, unambiguous consent must be present. Based on known arbitration outcomes and settlements, the likelihood of future wellness disputes being resolved through arbitration is very high.

In *Tompkins v. 23andMe*,<sup>92</sup> the Ninth Circuit addressed the enforceability of an arbitration clause in 23and Me’s Terms of Service.<sup>93</sup> Plaintiffs challenged the clause as unconscionable under California law, citing provisions related to fee-shifting,<sup>94</sup> forum selection,<sup>95</sup> intellectual property exemptions,<sup>96</sup> statutory limitations,<sup>97</sup> and unilateral modification.<sup>98</sup> The court upheld the clause, finding it enforceable under California precedent and the FAA.<sup>99</sup> Significantly, 23andMe “claimed that its service could be used to help customers manage health risks, as well as prevent or mitigate diseases such as diabetes, heart disease, and breast cancer,”<sup>100</sup> claims which are similar to health claims of Function<sup>101</sup> and Viome, and continuing glucose monitors, which advance a particular diet and lifestyle optimization philosophies.<sup>102</sup> Finally, *Tompkins* has been criticized as overly

<sup>92</sup> *Tompkins v. 23andMe, Inc.*, 840 F.3d 1016 (9th Cir. 2016).

<sup>93</sup> See generally *id.* at 1020 (“When purchasing the kit, the customer can click on a link to the company’s Terms of Service that was available at the bottom of the webpage. However, the customer is not required to read or click through the terms before making a purchase.”).

<sup>94</sup> See *id.* at 1031 (citing *Sanchez v. Valencia Holding Co.*, 353 P.3d 741 (Cal. 2015) and the general rule that parties may validly agree to a bilateral prevailing party clause, *Santisas v. Goodin*, 951 P.2d 399, 405 (Cal. 1998)); see also CAL. CIV. CODE § 1717 (concluding that the bilateral attorneys’ fee shifting clause in the Terms of Service is not unconscionable under California law).

<sup>95</sup> *Tompkins*, 840 F.3d at 1029 (quoting *Smith, Valentino & Smith, Inc. v. Superior Court*, 551 P.2d 1206, 1208 (Cal. 1976)) (“Here, plaintiffs have not met their burden of proving that the forum selection clause in the Terms of Service is unreasonable. San Francisco is not ‘unavailable or unable to accomplish substantial justice.’”).

<sup>96</sup> *Id.* at 1031 (“[P]laintiffs have not carried their burden of demonstrating that the intellectual property exemption is unconscionable under current California law.”).

<sup>97</sup> *Moreno v. Sanchez*, 131 Cal. Rptr. 2d 684, 696 (Cal. Ct. App. 2003), cited with approval in *Sanchez*, 353 P.3d at 749 (exemplifying the application of California’s unconscionability doctrine to statute of limitations clauses). “*Moreno* explained that California courts ‘have afforded contracting parties considerable freedom to modify the length of a statute of limitations.’” *Tompkins*, 840 F.3d at 1032 (quoting *Moreno*, 131 Cal. Rptr. 2d at 695).

<sup>98</sup> *Tompkins*, 840 F.3d at 1033 (“[T]hat plaintiffs have not carried their burden of demonstrating that the unilateral modification provision renders the arbitration clause, set forth in a separate provision, unconscionable.”).

<sup>99</sup> *Id.* (quoting 9 U.S.C. § 2) (“We conclude that under principles established by recent California Supreme Court decisions, California’s common law rule of unconscionability does not provide a basis to revoke the arbitration agreement in the Terms of Service here. Accordingly, the arbitration agreement is ‘valid, irrevocable, and enforceable.’”).

<sup>100</sup> *Tompkins*, 840 F.3d at 1021.

<sup>101</sup> See *How It Works*, *supra* note 78 (“Doctors across specialties carefully selected each test to help give you the broadest and deepest understanding of your ever-changing health.”); see also *Terms of Service*, FUNCTION HEALTH, *supra* note 25.

<sup>102</sup> See *Kickstart Guide: Keto for Beginners*, KETO-MOJO 3 (Oct. 2024), <https://keto-mojo.com/wp-content/uploads/2024/10/Keto-Mojo-Kickstart-Guide.pdf> (“[T]he keto diet is being touted as a

broad—particularly in its treatment of attorneys’ fees borne by the losing party in arbitration—which may deter consumers from pursuing their claims altogether.<sup>103</sup> The case serves as an early precedent and signpost of arbitration deference in wellness disputes. Other wellness disputes follow suit.

Similar to *Tompkins, Toth v. Everywell, Inc.*<sup>104</sup> represents a landmark dispute in the wellness sector. In *Toth*, the court specifically considered whether a clickwrap agreement validly created a binding obligation to arbitrate. The case originated from Joyce Toth’s purchase of an at-home Food Sensitivity Test from Everlywell.<sup>105</sup> Toth received tests results which she believed to be inaccurate and deceptive.<sup>106</sup> As a result, she filed a putative class action and alleged Everlywell deceptively marketed its tests and misled consumers into providing personal medical information for commercial use.<sup>107</sup> The court found that Toth had reasonable notice of the terms and had manifested assent by clicking “accept,” thus compelling arbitration.<sup>108</sup> The decision also confirmed that incorporating AAA rules in an agreement delegates questions of arbitrability—including scope and enforceability—to the arbitrator, not the court.<sup>109</sup>

Conversely, *Herzog v. Superior Court*<sup>110</sup> demonstrates the importance of clear notice when seeking to compel arbitration. While *Herzog* concerned enforcement of a clickwrap arbitration clause, the malfunctioning Dexcom G6 glucose monitoring devices resulted in actual plaintiffs’ injuries such as diabetic injuries requiring hospitalization and death.<sup>111</sup> The court found that Dexcom failed to unambiguously inform users of the arbitration clause’s effect, thereby invalidating the agreement.<sup>112</sup> In *Herzog*, even though the mobile app contained a clickwrap with a checkbox, the court observed that despite the terms of service being present, plaintiffs did not assent to be bound by arbitration. “[T]he prospective G6 App user’s act of clicking the box next to ‘I agree to Terms of Use’ on the ‘Legal’ screen cannot be taken as an unambiguous manifestation of assent to be bound by all the terms in the hyperlinked Terms of Use webpage, including the arbitration provision.”<sup>113</sup>

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means to improve heart health, general metabolic health, and acne; protect brain functioning and act as a therapy for several brain disorders (including seizures and migraines); reduce risks of cancer; and improve the health of women with polycystic ovary syndrome (PCOS).”).

<sup>103</sup> Melissa Daniels, *9th Circ. Affirms Arbitration for 23andMe in Marketing Case*, LAW360 (Aug. 23, 2016, at 6:32 PM ET), <https://www.law360.com/articles/831824/9th-circ-affirms-arbitration-for-23andme-in-marketing-case>.

<sup>104</sup> See generally *Toth v. Everly Well, Inc.*, 118 F.4th 403 (1st Cir. 2024).

<sup>105</sup> *Id.* at 408.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 406-07.

<sup>109</sup> *Id.* at 414.

<sup>110</sup> See generally *Herzog v. Superior Court*, 321 Cal. Rptr. 3d 93 (Cal. Ct. App. 2024), *cert. denied*, 2024 Cal. LEXIS 4841 (Cal. 2024) (granting petition to vacate arbitration orders for lack of sufficient, unambiguous notice to arbitrate).

<sup>111</sup> *Id.* at 100.

<sup>112</sup> *Id.* at 106–16.

<sup>113</sup> *Id.* at 114.

Finally, *Coatney v. Ancestry.com DNA, LLC*<sup>114</sup> illustrates a key limit on arbitration enforcement. In *Coatney*, the court addressed whether minor children could be bound by Ancestry.com’s arbitration agreement, which their guardians had assented to when activating DNA test kits. The court ultimately affirmed that the children were not bound to arbitrate their claims.<sup>115</sup>

Judicial deference to arbitration clauses—as seen in *Tompkins, Toth*—suggests that similarly structured general wellness platforms like Function Health, or DTC test kits such as Viome, are well-positioned to compel arbitration, assuming they implement robust, unambiguous user agreements. These cases demonstrate that hyperlinking terms of service can provide consumers with adequate notice to create a binding agreement to arbitrate.

A final point of consideration is how the Terms of Service of Function Health tie the wellness dispute discussion together. Function’s Terms of Service offer a useful case study for anticipating the types of disputes likely to arise in the wellness diagnostics sector.

#### IV. FUNCTION HEALTH’S TERMS OF SERVICE

First, Function signals its intention to preclude nearly all forms of litigation, a common but controversial feature in the wellness sector where disputes often involve health-related harms or sensitive personal data.<sup>116</sup> Next, any errors or misrepresentations in the interpretation of a consumer’s biomarker data—arguably among the most legally and ethically sensitive areas in wellness services—must be resolved privately.<sup>117</sup> Moreover, the clause wraps in not just contractual disputes but also “[c]laims relating to any aspect of the relationship between consumers and Function, whether based in contract, tort, negligence, fraud, misrepresentation, trespass, or any other statutory or common-law legal theory.”<sup>118</sup> It explicitly covers claims “arising out of or relating in any way to . . .

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<sup>114</sup> See generally *Coatney v. Ancestry.com DNA, LLC*, 93 F.4th 1014 (7th Cir. 2024) (holding the arbitration clause did not apply where children brought an action against DNA testing company when their guardians submitted their DNA unbeknownst to them).

<sup>115</sup> *Id.* at 1029.

<sup>116</sup> The arbitration clause in Section 17 of its Terms of Service imposes an expansive and mandatory framework for binding arbitration, reflecting a strategic effort to funnel all wellness-related disputes into a private resolution forum. *Terms of Service*, FUNCTION HEALTH, *supra* note 25. The provision mandates that “any and all disagreements, controversies, disputes, or claims that have arisen or may arise between you and Function . . . shall be resolved exclusively through final and binding arbitration . . . .” *Id.* This includes disputes “arising out of or relating in any way to these Terms (including any alleged breach thereof), the Service, the Site, the Mobile App, any advertising or communications you receive, or any aspect of the relationship or transactions between us (each a ‘Dispute’) . . . .” *Id.* On September 1, 2025, Function Health overhauled its dispute resolution policies, making them more consumer-oriented. For instance, an “Informal Dispute Resolution” provision suggests the company’s interest in resolving disputes “amicably and efficiently.”

<sup>117</sup> By requiring consumers to arbitrate all disputes arising out of “the Service,” Function binds users in any claims relating to “access to Lab Results in conjunction with [your] Samples[,] report[s] relating thereto, . . . informational content relating to health, wellness, fitness, diet, and lifestyle, including but not limited to in connection with a set of parameters in Lab Results,” and Function’s “generative-AI powered informational chatbot.” *Id.*

<sup>118</sup> *Id.*

any advertising or communications you receive,” allowing Function to arbitrate away liability related to potentially deceptive advertising practices. Even claims “that arose or that involve facts occurring before the existence of this or any prior versions of the Terms,” as well as those “that may arise after the termination of these Terms,” are swept into arbitration. Finally, “regarding the interpretation or application of the Arbitration Agreement, including the enforceability, revocability, scope, or validity of the Arbitration Agreement or any portion of the Arbitration Agreement . . . .”<sup>119</sup>

## V. CONCLUSION

This Article has highlighted how wellness diagnostic platforms may create a shadow healthcare system, keeping wellness disputes private. For wellness platforms that straddle the line between consumer technology and health service delivery, arbitration offers a mechanism to resolve disputes efficiently, but obscures them from public view. For consumers, “clickwrap” arbitration provisions may drastically narrow access to legal recourse, particularly where harms involve novel interpretations of biomarker, biomarker misinterpretation, privacy breaches, or deceptive marketing. Wellness-driven consumers may unknowingly be jeopardizing their legal rights, or, on the contrary, preserving their privacy in a fit-for-purpose arbitration proceeding. These developments reinforce the legal complexity of wellness disputes. While case law presents some evidence that tips the scale in favor of arbitration, there is still not enough data to support a definitive conclusion. Ultimately, the resolution of wellness disputes must strike a careful balance—one that allows consumers to be the bosses of their own biology while safeguarding the rights and well-being of those who rely on these technologies for their health and peace of mind.

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<sup>119</sup> *Id.*

# WELLNESS, TRANSHUMANISM, AND THE DEATH OF HEALTH LAW

Leah R. Fowler\*

## I. INTRODUCTION

Bryan Johnson, a technology entrepreneur and venture capitalist, publicly tracks his nighttime erections to prove that his Blueprint Protocol can slow aging.<sup>1</sup> Peter Thiel, a venture capitalist and republican mega-donor, reportedly receives blood transfusions from young people to prolong his life through a process called parabiosis.<sup>2</sup> Ray Kurzweil, scientist, futurist, and angel investor, takes about 80 pills per day (down from over 200 in the early 2000s) to reach the human singularity when human and artificial intelligence merge.<sup>3</sup> Jeff Bezos, Elon Musk, and Mark Zuckerberg embrace transhumanist and singularitarian ideals.<sup>4</sup> Meanwhile, Google's Calico is just one of many biotechnology companies pouring vast resources into solving the humble problem of death.<sup>5</sup>

The pursuit of radically—perhaps infinitely—longer lives, while extraordinary, reflects more than just the whims of a few eccentric billionaires (though their interest in the subject matters, too). It is the endpoint of an already

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<sup>1</sup> See Bryan Johnson, *How I'm De-Aging My Penis*, BLUEPRINT (Dec. 9, 2024), <https://blueprint.bryanjohnson.com/blogs/news/how-i-m-de-aging-my-penis>.

<sup>2</sup> Maya Kosoff, *Peter Thiel Wants to Inject Himself with Young People's Blood*, VANITY FAIR (Aug. 1, 2016), <https://www.vanityfair.com/news/2016/08/peter-thiel-wants-to-inject-himself-with-young-peoples-blood>.

<sup>3</sup> Steven Levy, *If Ray Kurzweil Is Right (Again), You'll Meet His Immortal Soul in the Cloud*, WIRED (June 13, 2024), <https://www.wired.com/story/big-interview-ray-kurzweil/>; RAY KURZWEIL, *THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY* 65, 318 (2005) (The singularity is also defined as the point at which computer intelligence will surpass that of human intelligence); Brooke Becher, *What Is the Technological Singularity*, BUILT IN (Sept. 4, 2024), <https://builtin.com/artificial-intelligence/technological-singularity>.

<sup>4</sup> See Alexander Thomas, *Transhumanism: Billionaires Want to Use Tech to Enhance Our Abilities – the Outcomes Could Change What It Means to Be Human*, CONVERSATION (Jan. 16, 2024), <https://theconversation.com/transhumanism-billionaires-want-to-use-tech-to-enhance-our-abilities-the-outcomes-could-change-what-it-means-to-be-human-220549>; Roberto Paura, *Singularity Believers and the New Utopia of Transhumanism*, IM@GO. J. SOC. IMAGINARY, July 2016, at 23-25; Irina Ivanova, *Jeff Bezos Reportedly Invests in Altos Labs, the Latest Startup Trying to Extend Human Life*, CBS News (Sept. 7, 2021), <https://www.cbsnews.com/news/jeff-bezos-altos-labs-startup-trying-to-extend-human-life-reprogramming-stem-cells/>; Emile P. Torres, *The Endgame of Edgelord Eschatology*, TRUTHDIG (Apr. 25, 2025), <https://www.truthdig.com/articles/the-endgame-of-edgelord-eschatology/>.

<sup>5</sup> See CALICO LABS, <https://www.calicolabs.com/> (last visited Oct. 25, 2025); see also Brandon Milholland & Jan Vijg, *Why Gilgamesh Failed: The Mechanistic Basis of the Limits to Human Lifespan*, 2 NATURE AGING 878, 881 (2022) (identifying multiple billionaire-funded organizations like the SENS Institute, the Methuselah Foundation, Altos Labs, and Craig Venter's Human Longevity, a "concierge longevity service" all looking into longevity extension and rejuvenation research).

booming wellness economy that frames health as a personal responsibility and self-optimization as a moral imperative.<sup>6</sup> If “wellness” describes voluntary efforts to optimize the human body,<sup>7</sup> transhumanism extends this logic to its extreme, treating any possible human limitation, including aging, as a solvable problem.<sup>8</sup> This Essay thus uses transhumanism as a lens through which to consider how, as consumer wellness continues to proliferate and evolve, it accelerates the increasing privatization of healthcare. And, as health becomes privatized, existing public oversight erodes,<sup>9</sup> leaving regulatory gaps that we must either address or decide we are willing to embrace.

The logic of wellness as bodily maintenance and optimization unfolds across a wide spectrum, revealing how transhumanism is not a radical departure from, but an extension of, current practices.<sup>10</sup> At the far end of that spectrum are invasive interventions, including experimental gene therapies designed to preserve telomeres—the protective caps at the ends of chromosomes that help keep our DNA stable but naturally shrink each time a cell divides.<sup>11</sup> The other end is what we would recognize as already ubiquitous wellness products. It includes apps and wearables that track and improve sleep, which has been shown to improve health and longevity.<sup>12</sup> In this way, transhumanist ideals, often associated with the fringes, are more ingrained in everyday life than they might seem. If you have ever worn a Fitbit or an Apple Watch, you have already participated in the logic of transhumanism by treating your body as a system to be technologically monitored, improved, and optimized.<sup>13</sup>

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<sup>6</sup> See Deborah Lupton, *Quantified Sex: A Critical Analysis of Sexual and Reproductive Self-Tracking Using Apps*, 17 CULTURE, HEALTH & SEXUALITY 393, 395 (2015) [hereinafter Lupton, *Quantified Sex*]; see also Deborah Lupton, *The Digitally Engaged Patient: Self-Monitoring and Self-Care in the Digital Health Era*, 11 SOC. THEORY & HEALTH 3, 256, 260 (2013) [hereinafter Lupton, *Digitally Engaged*]; Deborah Lupton, *Quantifying the Body: Monitoring and Measuring Health in the Age of mHealth Technologies*, 23 CRITICAL PUB. HEALTH 393, 397 (2013) [hereinafter Lupton, *Quantifying the Body*].

<sup>7</sup> See Barbara J. Zabawa, *Defining the Field of Wellness Law*, 53 HOFSTRA L. REV. 681, 682 (2025).

<sup>8</sup> See Julian Huxley, *Transhumanism*, 8 J. HUMANISTIC PSYCH. 1, 73-76 (Jan. 1968); see also P.D. HOPKINS, ENCYCLOPEDIA OF APPLIED ETHICS 414 (2nd ed. 2012) (Transhumanism grew as a movement and philosophy in the late eighties and nineties, alongside the distinct but similar concept of “posthumanism”); Francesca Ferrando, *Posthumanism, Transhumanism, Antihumanism, Metahumanism, and New Materialisms: Differences and Relations*, 8 EXISTENZ 26, 29 (2013) (explaining that “Posthumanism is often defined as a post-humanism and a post-anthropocentrism: it is ‘post’ to the concept of the human and to the historical occurrence of humanism, both based, as we have previously seen, on hierarchical social constructs and human-centric assumptions.”).

<sup>9</sup> See William M. Sage, *Public Funds, Public Functions, Private Actors: The Cognitive Dissonance of US Health Law*, in 3 HEALTH L. AS PRIVATE L. 3, 6–7 (I. Glenn Cohen et al. ed., 2025).

<sup>10</sup> See discussion *infra* Section II.A; see also I. Glenn Cohen, *What (if anything) Is Wrong with Human Enhancement? What (if anything) Is Right with It?*, 49 TULSA L. REV. 645, 646-51 (2014).

<sup>11</sup> JinWoo Hong & Chae-Ok Yun, *Telomere Gene Therapy: Polarizing Therapeutic Goals for Treatment of Various Diseases*, 8 CELLS 392, 393 (2019).

<sup>12</sup> See Lasse Folkersen, *Bryan Johnson’s Sleep Routine Explained: Decoding His Top 10 Sleep Habits*, NUCLEUS (Oct. 29, 2024), <https://mynucleus.com/blog/bryan-johnson-sleep-routine>.

<sup>13</sup> See Joseph Vokov, *Never die? The Dangers of Transhumanism in the 21st Century*, AM. MAG. (Dec. 4, 2024), <https://www.americamagazine.org/faith/2024/12/04/transhumanism-influencers-death-dignity-laws-249220>.

Transhumanism is also an increasingly inevitable outcome of demographic shifts, deregulation, and the growing power of billionaire technocrats to shape the future of science and healthcare. As the U.S. population ages and birth rates decline,<sup>14</sup> the rising cost of healthcare creates economic incentives to pursue lifespan and healthspan extension.<sup>15</sup> Simultaneously, the weakening of publicly funded research and regulatory oversight shifts the locus of innovation to private funders.<sup>16</sup> Techno-oligarchs with vast wealth and increasing political influence (including those mentioned above) fill this vacuum,<sup>17</sup> reshaping scientific agendas to align with their own visions of progress, often prioritizing longevity.<sup>18</sup> Meanwhile, the rollback of public health insurance programs and protections<sup>19</sup> portends a system in which private investment dictates priorities rather than public need. In this environment, consumer wellness and, by extension, transhumanist technologies may simply become the future of health.

Prior work has examined transhumanism through personhood debates<sup>20</sup> and racial inequalities.<sup>21</sup> While scholars have explored the ethical and regulatory implications of human enhancement more generally,<sup>22</sup> they have largely focused

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<sup>14</sup> See *The Demographic Outlook: 2024 to 2054*, CONG. BUDGET OFF. (Jan. 2024), <https://www.cbo.gov/publication/59899>.

<sup>15</sup> See Cassandra Willyard, *Is Aging Without Illness Possible?*, SCI. NEWS (Jan. 16, 2024), <https://www.sciencenews.org/article/aging-geroscience-health-span-drugs>.

<sup>16</sup> See, e.g., *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates*, Notice No. NOT-OD-25-068, NAT'L INSTS. HEALTH (Feb. 7, 2025), [https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-068.html#\\_ftnref2](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-068.html#_ftnref2); William J. Broad, *Billionaires with Big Ideas Are Privatizing American Science*, N.Y. TIMES (Mar. 15, 2014), [https://www.nytimes.com/2014/03/16/science/billionaires-with-big-ideas-are-privatizing-american-science.html?hp&\\_r=0](https://www.nytimes.com/2014/03/16/science/billionaires-with-big-ideas-are-privatizing-american-science.html?hp&_r=0).

<sup>17</sup> See Andrew Ross Sorkin et al., *The Billionaires' Row at the Inauguration*, N.Y. TIMES (Jan. 21, 2025), <https://www.nytimes.com/2025/01/21/business/dealbook/billionaires-trump-zuckerberg-bezos-musk.html>.

<sup>18</sup> See Jurica Dujmovic, *Opinion: Billionaires Are Spending Big on Anti-Aging Drugs so They—and Maybe You—Can Live Forever*, MARKETWATCH (Aug. 24, 2024), <https://www.marketwatch.com/story/billionaires-are-spending-big-so-they-and-maybe-you-can-live-forever-82041ed7>; CALICO LABS, *supra* note 5; Elke Schwarz, *Conjuring the End: Techno-eschatology and the Power of Prophecy*, OPINIOJURIS (Jan. 1, 2025), <https://opiniojuris.org/2025/01/30/conjuring-the-end-techno-eschatology-and-the-power-of-prophecy/>.

<sup>19</sup> See Madeline Morcelle, *President Trump's Day One Actions Threaten Medicaid and the ACA*, NAT'L HEALTH L. PROGRAM (Jan. 27, 2025), <https://healthlaw.org/president-trumps-day-one-actions-threaten-medicare-and-the-aca/>; Apoorva Mandavilli, Margot Sanger-Katz & Jan Hoffman, *Trump Administration Abruptly Cuts Billions from State Health Services*, N.Y. TIMES (Mar. 26, 2025), <https://www.nytimes.com/2025/03/26/health/trump-state-health-grants-cuts.html>.

<sup>20</sup> See Chad D. Cummings, Comment, *Transhumanism: Morality and Law at the Frontier of the Human Condition*, 20 AVE MARIA L. REV. 216, 240 (2022); Alexandra M. Franco, *Transhuman Babies and Human Pariahs: Genetic Engineering, Transhumanism, Society, and the Law*, 37 CHILD. LEGAL RTS. J. 185, 186 (2017).

<sup>21</sup> See Lisa C. Ikemoto, *Race to Health: Racialized Discourses in a Transhuman World*, 9 DEPAUL J. HEALTHCARE L. 1101, 1103 (2005).

<sup>22</sup> See Cohen, *supra* note 10, at 646-51.

on ethics and philosophy,<sup>23</sup> FDA oversight,<sup>24</sup> intellectual property,<sup>25</sup> and insurance-based access models.<sup>26</sup> This Essay builds on that scholarship by reframing transhumanism not as a fringe techno-utopian project, but as an extension of entrenched wellness ideologies and health consumerism. It argues that the rise of wellness reveals an ongoing shift in health governance from public to private ordering, from collective care to individual optimization, and from regulation to contract. By tracing how its underlying logic seeps into and reshapes medical care and scientific research, this Essay builds on a growing literature exploring the regulatory gaps and power imbalances pervasive in the wellness economy.<sup>27</sup>

This Essay proceeds in three parts. Part II traces the cultural and ideological foundations of transhumanism, showing how everyday practices of self-tracking and bodily optimization—currently framed as personal wellness—create societal expectations and moral imperatives that legitimize more extreme forms of health privatization. Part III explores the legal tensions that arise as consumer health technologies blur foundational regulatory categories, such as treatment versus enhancement, patient versus consumer, and healthcare versus wellness, and argues that these breakdowns expose critical gaps in oversight and accountability. It then examines how, for better or worse, in the absence of effective public regulation, private law emerges as the dominant governance structure for everything from everyday wellness to the most radical transhumanist interventions. Finally, Part IV uses the example of Próspera, Honduras, a semiautonomous “charter city,” to examine what a transhumanist future might look like if these trends continue unchecked.

## II. SELLING AMERICAN IMMORTALITY

From medicine shows and patent medicine to the moment the first human entered cryogenic suspension in 1967,<sup>28</sup> to today’s ever-present wearable wellness devices, transhumanism has been a long time in the making. This Part traces the cultural and technological evolution of health as a personal project of self-improvement and optimization, focusing on the quantified-self movement that frames health as a matter of data, discipline, and consumer choice rather than the result of structural, genetic, or environmental factors. It then connects this wellness

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<sup>23</sup> See Miriam Piven Cotler, *Wondergenes: Genetic Enhancement and the Future of Society*, 24 WHITTIER L. REV. 417, 417 (2002); see also Daniel L. Tobey, *What’s Really Wrong with Genetic Enhancement: A Second Look at Our Posthuman Future*, 6 YALE J. L. TECH. 54, 120 (2004).

<sup>24</sup> See Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 699-703 (1999).

<sup>25</sup> See Andrew W. Torrance, *Open Source Human Evolution*, 30 WASH. U. J. L. & POL’Y 93, 122-33 (2009).

<sup>26</sup> See Mehlman, *supra* note 24, at 685-86.

<sup>27</sup> See Zabawa, *supra* note 7, at 682-83; see also Leah R. Fowler, *Buyer Be Well*, 67 BOS. C. L. REV. (forthcoming July 2026) (manuscript at 19-23) (on file with author).

<sup>28</sup> Mike Perry, *The First Suspension*, CRYONICS ARCHIVE (July 1991), <https://www.cryonicsarchive.org/library/bedford-suspension> (the first cryogenically suspended person was Dr. James Bedford).

logic to transhumanism, arguing that the leap from step-counting to gene editing is smaller than it seems. Together, this Part shows how modern wellness normalizes extreme health privatization and commodification, laying the groundwork for society to see the pursuit of immortality as a natural extension of self-care. And, ultimately, how transhumanism reveals the risks inherent in even the most commonplace consumer health technologies.

### A. The Quantified Self

If you have ever worn a smartwatch, you might be closer to being a transhumanist than you think.<sup>29</sup> Self-tracking technologies are part of the broader quantified-self movement, in which digital monitors offer high-tech yet “natural” ways to optimize and control the human body.<sup>30</sup> Unlike traditional health monitoring conducted by medical professionals, the quantified-self movement embraces a do-it-yourself, experimental, and often non-clinical ethos, empowering individuals to become both subject and scientist.<sup>31</sup> This movement fits seamlessly within an American political and economic landscape that champions personal responsibility, market-driven health solutions, and the belief that transforming one’s body and mind is both possible and expected.<sup>32</sup> It is part of a rich tradition of health libertarianism that has existed since the country’s founding,<sup>33</sup> as well as ongoing trends toward consumerization in health that have taken place over the last several decades.<sup>34</sup>

Modern wellness gained popularity in the 1970s<sup>35</sup> and has arguably yet to reach its zenith.<sup>36</sup> Today, mainstream technologies like fitness trackers and smartphone health applications (apps) are integrated into our lives and have shifted human behavior toward the seemingly innocuous or even beneficial goal of personal optimization.<sup>37</sup> Health apps and wearables can help achieve this by providing the data and predictions that define a body’s limits and capabilities, serving as actionable information, and alleviating the psychological fear of bodily

<sup>29</sup> See Vokov, *supra* note 13.

<sup>30</sup> See Lupton, *Quantified Sex*, *supra* note 6, at 395; see also Lupton, *Digitally Engaged*, *supra* note 6, at 260; Lupton, *Quantifying the Body*, *supra* note 6, at 397.

<sup>31</sup> See DEBORAH LUPTON, *THE QUANTIFIED SELF: A SOCIOLOGY OF SELF-TRACKING* 69 (2016) [hereinafter LUPTON, *THE QUANTIFIED SELF*]; MARK O’CONNELL, *TO BE A MACHINE: ADVENTURES AMONG CYBORGS, UTOPIANS, HACKERS, AND THE FUTURISTS SOLVING THE MODEST PROBLEM OF DEATH* 134-159 (2017).

<sup>32</sup> See Lupton, *Quantifying the Body*, *supra* note 6, at 397.

<sup>33</sup> Lewis Grossman, *The Origins of American Healthcare Libertarianism*, 13 *YALE J. HEALTH POL’Y, L. & ETHICS* 79, 88 (2013).

<sup>34</sup> See TIMOTHY STOLTZFUS JOST, *HEALTHCARE AT RISK* 18–20, 42–43 (2007); Clark C. Havinghurst, *Starr on the Corporatization and Commodification of Healthcare: The Sequel*, 49 *J. HEALTH POL., POL’Y, & L.* 947, 949 (2004).

<sup>35</sup> STEPHANIE ALICE BAKER, *WELLNESS CULTURE: HOW THE WELLNESS MOVEMENT HAS BEEN USED TO EMPOWER, PROFIT AND MISINFORM* XI (2023).

<sup>36</sup> See *What Is the Future of Wellness?*, MCKINSEY & Co. (Nov. 20, 2024), <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-the-future-of-wellness> (noting that “in the United States, the wellness market is growing as much as 10 percent per year and is now worth \$480 billion”).

<sup>37</sup> See Leah R. Fowler, *Health App Lemons*, 74 *ALA. L. REV.* 65, 71 (2022).

degeneration.<sup>38</sup> These digital technologies reinforce this imperative by enabling individuals to monitor their biological functions, identify patterns, and make data-driven decisions to enhance their lives, turning optimization into an accessible, everyday practice.<sup>39</sup> This process aligns with a broader societal expectation of self-reinvention, where transformation—whether physical, mental, or emotional—is not only possible but necessary to alleviate anxieties about health, productivity, and longevity and to avoid disease and illness.<sup>40</sup> The body is like a machine to tinker with.<sup>41</sup>

Apps and wearables reflect one piece of a broader wellness framework in which individuals are expected to take full responsibility for their health and well-being.<sup>42</sup> Rooted in neoliberal ideals, this movement frames self-tracking as an ethical project that requires self-awareness, critical reflection, and continuous self-improvement.<sup>43</sup> In Western societies, achieving self-knowledge is seen as essential to being a “good citizen,” someone who is responsible, disciplined, and actively engaged in optimizing their body and mind.<sup>44</sup> Those who do so are celebrated as responsible and engaged, while those who do not—or cannot—are cast as morally deficient or irresponsible.<sup>45</sup> This moralization of wellness deepens inequality while reinforcing the belief that health is simply a matter of individual virtue.<sup>46</sup>

We also see this moralization echoed in contemporary health policy debates. Robert F. Kennedy Jr., Secretary of Health and Human Services, has suggested in interviews that access to publicly funded healthcare should be limited or potentially even eliminated for individuals who engage in unhealthy behaviors.<sup>47</sup> He has expressed interest in encouraging universal adoption of

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<sup>38</sup> See Lupton, *Quantifying the Body*, *supra* note 6, at 396-397.

<sup>39</sup> *See id.*

<sup>40</sup> See LUPTON, THE QUANTIFIED SELF, *supra* note 31, at 47 (“An expectation of instant transformation is part of the self-reinvention ideal, as is the notion that transforming the self will alleviate anxieties and fears about one’s destiny.”).

<sup>41</sup> *See id.* at 69.

<sup>42</sup> *Id.* at 68 (“Self-tracking may be theorized as a practice of selfhood that conforms to cultural expectations concerning self-awareness, reflection, and taking responsibility for managing, governing oneself, and improving one’s life chances.”).

<sup>43</sup> *Id.* at 47 (“This is taking place in a political context of the developed world—that of neoliberalism—that champions self-responsibility, the market economy and competition and where the state is increasingly withdrawing from offering economic support to citizens.”).

<sup>44</sup> *Id.* at 46 (“In contemporary western societies, the care of the self is viewed as an ethical project, which requires a self-awareness based on critical and considered reflection and the acquisition of self-knowledge as part of achieving the ideal of the ‘good citizen’—that is, a citizen who is responsible, capable, and self-regulated in the pursuit of happiness, health, productivity, and wellbeing.”).

<sup>45</sup> *See id.* at 68–69.

<sup>46</sup> See Lupton, *Quantifying the Body*, *supra* note 6, at 397 (“This discourse tends to gloss over the social and economic determinants of health states for a focus on ‘empowerment’ and ‘taking charge’ of one’s own health.”).

<sup>47</sup> See Lauren Weber, *RFK Jr.: If You Eat Doughnuts or Smoke, Should Society Pay for Your Healthcare?*, WASH. POST (Apr. 10, 2025), <https://www.washingtonpost.com/health/2025/04/10/rfk-jr-personal-responsibility-health-care-donuts-smoking/>.

wearable wellness devices.<sup>48</sup> Here, we see a glimpse of the systemic stakes of what initially feels purely like a personal choice with nothing but upsides. As the state increasingly withdraws from offering economic and health support, the wellness economy reinforces the ideas that individuals bear primary responsibility for their own well-being and that any governmental attempts to intervene are paternalistic infringements on individual liberty.<sup>49</sup> Similarly, the logic of self-tracking and personal responsibility erodes the justification for collective risk-sharing systems like health insurance, shifting the burden of well-being entirely onto individuals.<sup>50</sup>

The push for bodily optimization has already crept into everyday life through wellness, normalizing a mindset that views improving the body beyond its natural state as both possible and desirable. This shift blurs the line between wellness, health, and enhancement, creating a continuum in which extraordinary becomes ordinary and ordinary becomes expected. What counts as optional optimization today—daily step goals, cold plunges, or sleep trackers—may be tomorrow’s baseline for moral or medical responsibility.

## B. Beyond Wellness

Wellness culture primes individuals to accept the promise of transhumanism and its accompanying paradigm shifts.<sup>51</sup> If wellness encourages individuals to optimize their bodies through tracking, discipline, and consumer choice, transhumanism simply continues that logic by embracing technologies that push the body even further beyond its natural limits. It is an escalation of wellness—different in degree, not in kind—rooted in the same moral and market-based imperatives to optimize, upgrade, and perfect the self. As consumer expectations around health shift from maintenance to optimization, the adoption of gene therapies, neural implants, nootropics, and other enhancement tools stands to become normalized. Wellness, rooted in personal responsibility and productivity, thus paves the way for transhumanist interventions to enter the

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<sup>48</sup> Puya Singh, *US Health Secretary Kennedy Says HHS to Launch Campaign to Encourage Wearable Devices*, REUTERS (June 24, 2025), <https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-secretary-kennedy-says-hhs-launch-campaign-encourage-wearable-devices-2025-06-24/>.

<sup>49</sup> See LUPTON, *THE QUANTIFIED SELF*, *supra* note 31, at 47; *see also* Ikemoto, *supra* note 21, at 1105 (“The resulting biomedical individualism filters out root causes of health risk that would justify regulation or other government intervention.”).

<sup>50</sup> See Joseph Choi, *Trump Swears in Mehmet Oz as CMS Administrator*, HILL (Apr. 18, 2025), <https://thehill.com/homenews/5255977-trump-swears-in-mehmet-oz-as-cms-administrator/>; Deborah Stone, *The Struggle for the Soul of Health Insurance*, 18 J. HEALTH POL. POL’Y & L. 288, 290 (1993) (stating that burden-shifting of well-being entirely onto the individual has been an ongoing debate for decades).

<sup>51</sup> See Ben Popper, *Cyborg America: Inside the Strange New World of Basement Body Hackers*, VERGE (Aug. 8, 2012), <https://www.theverge.com/2012/8/8/3177438/cyborg-america-biohackers-grinders-body-hackers> (“I asked what they thought the potential was for biohacking to become part of the mainstream. ‘That’s the thing, it’s not that much of a leap.’”).

mainstream, reframing health as a private, market-driven pursuit and the human body as a site for perfectibility.

The search for the fountain of youth is ancient,<sup>52</sup> but the concept of “transhumanism” formally emerged in the mid-20th century with figures like Julian Huxley, who coined the term and envisioned using science and technology to transcend human biological limitations.<sup>53</sup> It grew as a movement and philosophy in the late eighties and nineties, alongside the distinct but similar concept of “posthumanism.”<sup>54</sup> Embedded in transhumanist thought are concepts like the “longevity escape velocity,”<sup>55</sup> which is the idea that medical advancements will eventually extend lifespans faster than aging occurs, effectively allowing people to outrun death indefinitely when science enables a biological year to be less than a chronological year.<sup>56</sup> Overlapping with these ideas are views on the technological singularity, which, at least as Ray Kurzweil envisions, is the point at which humans and machines will merge.<sup>57</sup>

Though the movement has evolved,<sup>58</sup> the general idea of transhumanism will sound familiar: human bodies are like machines, and our brains are like wet computers.<sup>59</sup> Like any other machine, if you maintain your body and replace parts as needed, it can theoretically remain in good working order indefinitely.<sup>60</sup> This metaphor aligns closely with the logic of wellness optimization, where proactive maintenance and enhancement are framed as rational self-care.<sup>61</sup> The optimization imperative thus extends seamlessly from modern wellness to more extreme enhancement, supported by the same metaphors and moral reasoning. In this evolving landscape, the right to remain “unenhanced” may soon become a privilege rather than a presumption, as transhumanist technologies are increasingly framed not just as options but as responsibilities.<sup>62</sup> As with more socially acceptable wellness practices, those who resist may be cast as irrational, negligent, or burdensome.<sup>63</sup> Perhaps, in the worst cases, they may be declared ineligible for public benefits.<sup>64</sup>

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<sup>52</sup> See Willie Drye, *Fountain of Youth*, NAT'L GEOGRAPHIC, <https://www.nationalgeographic.com/history/article/fountain-of-youth> (last accessed Oct. 29, 2025) (noting that Alexander the Great may have been looking for a version of the fountain of youth as early as 323 B.C.).

<sup>53</sup> See Huxley, *supra* note 8, at 73-76; see also P.D. HOPKINS, *supra* note 8.

<sup>54</sup> See Ferrando, *supra* note 8, at 27.

<sup>55</sup> See Aubrey D. N. J. de Grey, *Escape Velocity: Why the Prospect of Extreme Human Life Extension Matters Now*, 2 PLOS BIOLOGY 723, 723 (2004) (coining the term “longevity escape velocity”).

<sup>56</sup> See *id.* at 724.

<sup>57</sup> See KURZWEIL, *supra* note 3, at 68.

<sup>58</sup> See Cummings, *supra* note 20, at 237-40 (describing distinct “transhumanist eras”).

<sup>59</sup> O'CONNELL, *supra* note 31, at 134-159.

<sup>60</sup> *Id.*

<sup>61</sup> See LUPTON, *THE QUANTIFIED SELF*, *supra* note 31, at 68-69.

<sup>62</sup> See Lupton, *Quantifying the Body*, *supra* note 6, at 397.

<sup>63</sup> See *id.*

<sup>64</sup> See Weber, *supra* note 47.

Some scientists argue that there is no set limit to human lifespan.<sup>65</sup> But not all discussions of life extension probe these extremes so explicitly.<sup>66</sup> Instead, others argue that the appropriate scientific focus should simply be *healthspan*—the idea that we should improve the health of individuals at the end of life and eliminate the prolonged decline and disability often experienced before we die.<sup>67</sup> These interventions look more like commonly accepted notions of medical treatment, directly addressing age-related morbidity in ways insurance would plausibly cover. They also sound like a great idea. Who would not want to live their life like a lightbulb, shining brightly until the very end when, in an instant, things would just burn out—no drawn-out suffering, no institutionalized care, no pain?

But even the most palatable and mainstream approaches to longevity science can be a Trojan horse for others.<sup>68</sup> As healthspan—and general wellness—interventions become normalized and publicly accepted, they expand what counts as legitimate and expected self-maintenance. This creates space for more radical life-extension tools to enter under the banner of prevention, increased productivity, or improved quality of life. Public enthusiasm for delaying decline can easily be harnessed to justify other enhancement-based treatments, especially when those treatments are marketed using the same rhetoric of self-care and empowerment. Moderate longevity science sets the stage for transhumanist technologies in the same way as wellness by shifting cultural expectations, political priorities, and even regulatory frameworks.

Techno-oligarchs, particularly those in Silicon Valley, are at the forefront of this shift, promoting biohacking, longevity science, and self-experimentation not just as personal endeavors but as profitable industries.<sup>69</sup> These figures serve as a bridge between normalized wellness practices and more extreme forms of enhancement, using their influence to repackage transhumanist ideas as natural extensions of self-care.<sup>70</sup> Their vision of the future seamlessly blends

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<sup>65</sup> Nicholas J. L. Brown, Casper J. Albers & Stuart J. Ritchie, *Contesting the Evidence for Limited Human Lifespan*, 546 NATURE E6, E6-E7 (2017); see Joop de Beer, Anastasios Bardoutsos & Fanny Janssen, *Maximum Human Lifespan May Increase to 125 Years*, 546 NATURE E16, E16-E17 (2017); Bryan G. Hughes & Siegfried Hekimi, *Many Possible Maximum Lifespan Trajectories*, 546 NATURE E8, E8-E9 (2017); see Adam Lenart & James W. Vaupel, *Questionable Evidence for a Limit to Human Lifespan*, 546 NATURE E13, E13-E14 (2017); see Maarten P. Rozing, Thomas B. L. Kirkwood & Rudi G. J. Westendorp, *Is There Evidence for a Limit to Human Lifespan*, 546 NATURE E11, E11-E12 (2017).

<sup>66</sup> See Eric T. Juengst et al., *Antiaging Research and the Need for Public Dialogue*, 299 SCI. POL'Y F. 1323, 1323 (Feb. 28, 2003); Nic Fleming, *Scientists Up Stakes in Bet on Whether Humans Will Live to 150*, NATURE (Aug. 25, 2016), <https://www.nature.com/articles/nature.2016.20818>; LEON R. KASS & THE PRESIDENT'S COUNCIL ON BIOETHICS, *BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS* 157 (2003).

<sup>67</sup> See Kristin Kostick, Leah R. Fowler, & Christopher Thomas Scott, *A Matter of Life and Longer Life*, 50 J. AGING STUD., at 5 (Sept. 2019); see also Malene Hansen & Brian K. Kennedy, *Does Longer Lifespan Mean Longer Healthspan?*, 26 TRENDS CELL BIOLOGY 565, 566 (2016).

<sup>68</sup> See Eric T. Juengst et al., *Biogerontology*, "Anti-Aging Medicine," and the Challenges of Human Enhancement, 33 HASTINGS CTR. REP. 4, 21 (2003).

<sup>69</sup> See Johnson, *supra* note 1; Kosoff, *supra* note 2; KURZWEIL, *supra* note 3; Levy, *supra* note 3; Thomas, *supra* note 4; Paura, *supra* note 4, at 23-25; Ivanova, *supra* note 4; Torres, *supra* note 4; CALICO LABS, *supra* note 5; Milholland & Vijg, *supra* note 5, at 881.

<sup>70</sup> See Johnson, *supra* note 1.

transhumanist philosophy with consumerism, and their investment in the field makes this vision a reality. Their influential positions in the highest levels of government only add to the potential for transhumanist thought to permeate into health policy.<sup>71</sup>

As these expectations harden, the conceptual frameworks that once distinguished wellness from healthcare from enhancement erode, raising urgent questions for law and regulation. What begins with step counters and sleep trackers may soon extend to gene editing and neural implants. Transhumanism, then, is not an outlier. It is the culmination of consumer wellness culture. Perhaps we are all transhumanists already.

### III. WELLNESS WITHOUT LIMITS

Transhumanism is the logical endpoint of consumer wellness culture. Fitbits and meditation apps can slowly give way to gene editing and intensive, invasive anti-aging protocols, justified by the same goal of health optimization. However, as the spectrum of consumer wellness becomes normalized, traditional health law struggles to keep up. This Part turns to the legal implications of the wellness-transhumanism trajectory outlined in Part II. It focuses on how emerging technologies destabilize the regulatory categories that once reliably, if not imperfectly, anchored health law. The boundaries between treatment and enhancement, healthcare and consumer wellness, or medical patients and tech users are increasingly blurring. As these distinctions erode, regulatory oversight weakens, and legal accountability becomes harder to enforce.

#### A. A Categorization Crisis

When a drug or device developer seeks approval from the Food and Drug Administration (FDA), a patient sees a healthcare provider, or a research subject enrolls in a clinical trial, they do so within a complex web of laws and regulations.<sup>72</sup> These regulations have long depended on a series of binary categorizations—treatment versus enhancement,<sup>73</sup> evidence-based medicine versus experimentation,<sup>74</sup> healthcare versus wellness,<sup>75</sup> and patient versus consumer,<sup>76</sup> to name a few. That is not to say that the healthcare system works perfectly when things are neatly categorized. It is a system that, by most accounts, needs significant reform. However, as it stands, these categories underpin legal doctrines,

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<sup>71</sup> See Sorkin et al., *supra* note 17.

<sup>72</sup> See HEALTH LAW AS PRIVATE LAW: PATHOLOGY OR PATHWAY 1 (I. Glenn Cohen et al. eds. 2025).

<sup>73</sup> See Norman Daniels, *Normal Functioning and the Treatment-Enhancement Distinction*, 9 CAMBRIDGE Q. HEALTHCARE ETHICS 309, 309-310 (2000).

<sup>74</sup> See Barbara J. Evans, *Private Ordering Is Ubiquitous in Healthcare, but Why?*, in HEALTH L. AS PRIVATE L. 21, 27 (I. Glenn Cohen et al. eds. 2025).

<sup>75</sup> See Zabawa, *supra* note 7, at 682.

<sup>76</sup> See Nancy Tomes, *Merchants of Health: Medicine and Consumer Culture in the United States 1900-1940*, 88 J. AM. HIST. 519, 531 (2001); Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 647 (2008).

define responsibilities, and justify the application of different standards, protections, and oversight. In a relatively primitive wellness context, the implications of this breakdown are hard to appreciate. However, the risks of this disconnect become apparent when viewed through the lens of more sophisticated transhumanist technologies.

Consider the distinction between health and wellness. The FDA, for example, evaluates drugs and devices primarily based on intended use: whether a product is intended to treat, mitigate, or prevent a diagnosable condition.<sup>77</sup> As a result, it guarantees some level of review of the safety and efficacy of drugs<sup>78</sup> and devices before they hit the market.<sup>79</sup> But interventions targeting “normal” aging often fall outside the agency’s purview because the FDA does not currently consider aging to be a disease or condition.<sup>80</sup> Instead, to obtain FDA approval, a drug must target a disease associated with the aging process, but not aging itself.<sup>81</sup> Further, the FDA exercises enforcement discretion over low-risk wellness products and does not regulate products intended to “maintain or encourage” a healthy lifestyle at all.<sup>82</sup> As a result, companies can often sidestep oversight by labeling

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<sup>77</sup> See 21 U.S.C. §§ 321(b), (g)-(h), 331 (stating that to be within the FDA’s jurisdiction, a product both must meet the definition of a drug or device and it (or one of its components) must move in interstate commerce); see also *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014) (finding the required intersection with interstate commerce for an autologous stem cell intervention).

<sup>78</sup> See 21 U.S.C. § 321(g)(1) (“The term ‘drug means’ (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C) . . .”).

<sup>79</sup> See 21 U.S.C. § 321(h)(1) (“The term ‘device’ . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”).

<sup>80</sup> Matt Quinn, *FDA and the Fountain of Youth: Regulatory Hurdles in the Longevity Biotech Community*, WOMBLE, BOND & DICKINSON (Sept. 17, 2024), <https://www.womblebonddickinson.com/us/insights/blogs/fda-and-fountain-youth-regulatory-hurdles-longevity-biotech-community>.

<sup>81</sup> Amy Baker, *Classifying Aging as a Disease Could Speed FDA Drug Approvals*, HILL (Dec. 21, 2022), <https://thehill.com/opinion/healthcare/3774286-classifying-aging-as-a-disease-could-speed-fda-drug-approvals/>.

<sup>82</sup> See 21st Century Cures Act, Pub. L. No. 114-255, § 3060(a), 130 Stat. 1033, 1130-32 (2016) (codified as amended at 21 U.S.C. § 360j(o)) (noting Section 3060(a) of the 21st Century Cures Act amended Section 520 of the Food, Drug, and Cosmetics Act (FDCA) removed certain software functions from the FDCA definition of a device, including those that “maintain[] or encourage[] a healthy lifestyle.”); *id.* (noting other functions removed included: (A) to provide “administrative support [for] a healthcare facility,” (B) to “serve as electronic patient records,” and (C) to “transfer, store, or display data, or to convert data formats.”).

their products as cosmetics,<sup>83</sup> supplements,<sup>84</sup> or general wellness tools.<sup>85</sup> This labeling allows firms to avoid pre-market clearance or approval and more rigorous clinical testing to establish safety or efficacy, relying instead on marketing strategies that intentionally blur the line between health and wellness.<sup>86</sup>

Drug and device regulation is not the only place where categories no longer neatly fit. The universe of rights and protections is different depending on whether you are a patient or merely a consumer. An emergency room cannot simply turn you away without treatment or stabilization because you are unable to pay.<sup>87</sup> In a medical encounter, the standard of care is defined by professional norms and enforced through malpractice liability.<sup>88</sup> Patients generally cannot simply waive their right to sue for medical negligence.<sup>89</sup> Informed consent, though imperfect, helps address information asymmetries in medical care and federally funded scientific research.<sup>90</sup> Meanwhile, a private company is not obligated to help you achieve wellness, improve your healthspan, or even necessarily sell you a product that works.

Further, the development pipeline for longevity products looks different than other types of biomedical research, and this difference reinforces the broader legal challenges. With limited oversight, many longevity initiatives operate in a space with minimal transparency, reduced public accountability, and limited liability exposure. These conditions encourage speculative ventures and erode the safeguards traditionally associated with biomedical research.<sup>91</sup> Many initiatives are privately funded. Consider, for example, how Calico describes itself: “We are not

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<sup>83</sup> See Sven Bulterijs et al., *It's Time to Classify Biological Aging as a Disease*, 6 FRONTIERS IN GENETICS, June 2015, at 3.

<sup>84</sup> See DONNA V. PORTER, CONG RSCH. SERV., 94-965 SPR, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 4 (2020) (“The Act allows the ingredients in a supplement to be excluded from regulation as a food additive or drug, which both require premarket approval.”).

<sup>85</sup> See Pub. L. No. 114-225, § 3060(a), 130 Stat. 1033, 1130–32 (2016) (codified as amended at 21 U.S.C. § 360j(o)).

<sup>86</sup> See David A. Simon, Carmel Shachar, & I. Glenn Cohen, *Skating the Line Between General Wellness Products and Regulated Devices: Strategies and Implications*, 22 J.L. & BIOSCIS., July–Dec. 2022, at 9.

<sup>87</sup> Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd (2020).

<sup>88</sup> Larry S. Stewart, *The New Medical Malpractice Restatement*, 51 AM. J. L. & MED. 1, 1 (2025) (describing the new *Restatement (Third) of Torts* with a designated section on medical malpractice).

<sup>89</sup> See Nadia N. Sawicki, *Choosing Medical Malpractice*, 93 WASH. L. REV. 891, 918–20 (2018); Matthew Lawrence, *In Search of an Enforceable Medical Malpractice Exculpatory Agreement*, 84 N.Y.U.L. REV. 850, 851–52 (2009); *Tunkl v. Regents of Univ. of California*, 383 P.2d 441, 442 (Cal. 1963) (en banc); RESTATEMENT (SECOND) OF CONTRACTS § 195 (1979).

<sup>90</sup> See Valerie Gutmann Koch, *Reimagining Informed Consent: From Disclosure to Comprehension*, 14 U. C. IRVINE L. REV. 894, 898-903 (2024) (describing the legal doctrine of informed consent to treatment); Sara Manti & Amelia Licari, *How to Obtain Informed Consent for Research*, 14 BREATHE 145, 145–46 (2018); see also Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 610 (2007) (explaining 21 C.F.R. § 56.109 (2005), which requires that research being prepared for FDA review and involving human subjects be approved by an Institutional Review Board).

<sup>91</sup> See, e.g., Jacob Metcalf, *Implications of the Common Rule Revision for Private Enterprise*, ETHICAL RESOLVE (Jan. 15, 2016), <https://www.ethicalresolve.com/blog/commonrulerevisions.html> (“[P]rivate companies are not bound by the Common Rule insofar as they do not receive government funding.”).

a traditional biotechnology company, nor are we an academic institution. We have combined the best parts of both without the constraints of either.”<sup>92</sup>

These laws and regulations, along with many others, reflect the fact that healthcare implicates public interests, involves unique risks and vulnerable individuals, and requires special protections. Yet, as transhumanist technologies emerge following wellness’s well-trodden path, they largely operate outside these traditional safeguards.<sup>93</sup> While some protections do still apply, they are often weak, underenforced, patchy, or inapplicable.<sup>94</sup> They also, perhaps rightfully, operate under the assumption that wellness is less serious and less worthy of regulation than medicine. As a result, consumers are instead bound by hard-to-find and even harder-to-read click-through terms of service, often full of disclaimers, limited warranties, and mandatory arbitration agreements.<sup>95</sup>

Supporters of consumer-driven health tools celebrate this disruption.<sup>96</sup> Some envision a future in which personalized wellness platforms and biohacking replace traditional medicine and the regulations that accompany it. We welcome this shift because our healthcare system is expensive and broken, and consumer-facing products are often frictionless, personalized, and undeniably convenient. But the excitement about this “creative destruction”<sup>97</sup> overlooks the simultaneous erosion in the legal infrastructure built to protect vulnerable subjects, reduce information asymmetries, and manage collective health risks.

Legal protections tied to outdated distinctions are increasingly incoherent in a world where individuals can obtain unregulated gene therapies,<sup>98</sup> make their

<sup>92</sup> CALICO LABS, <https://www.calicolabs.com/> (last visited Oct. 17, 2025).

<sup>93</sup> See, e.g., Thomas T. Perls, *Anti-Aging Quackery: Human Growth Hormone and Tricks of the Trade—More Dangerous Than Ever*, 59A, No. 7 J. GERONTOLOGY 682, 682 (2004).

<sup>94</sup> See, e.g., Federal Trade Commission Act, 15 U.S.C. § 45 (authorizing the Federal Trade Commission (FTC) to regulate health claims in advertising, and unfair or deceptive acts or practices); 15 U.S.C. § 52 (prohibiting the dissemination of any false or misleading advertisement in or affecting commerce “for the purpose of inducing, or which is likely to induce . . . the purchase of food, drugs, devices, services, or cosmetics . . .”). *Advertising and Marketing Basics*, FED. TRADE COMM’N ADVICE, <https://consumer.ftc.gov/business-guidance/advertising-marketing/advertising-marketing-basics> (last visited Oct. 14, 2025) (requiring that claims in advertising “be truthful, cannot be deceptive or unfair, and must be evidence-based.”); 15 U.S.C. § 53(b) (authorizing the FTC to file suit to “enjoin” an “act or practice” that violates these provisions); *The Enforcers*, FED. TRADE COMM’N, <https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/enforcer#:~:text=States,for%20Coordination%20in%20Merger%20Investigations%20> (last visited Oct. 28, 2025) (noting that state attorneys generally have similar consumer protection powers over deceptive trade practices within their jurisdictions).

<sup>95</sup> See Daniel J. Solove, *Privacy Self-Management and the Consent Dilemma*, 126 HARV. L. REV. 1880, 1898–99 (2013); Margaret Jane Radin, *Boilerplate Today: The Rise of Modularity and the Waning of Consent*, 104 MICH. L. REV. 1223, 1231 (2006); Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PENN. L. REV. 647, 657 (2011); Cynthia Estlund, *The Black Hole of Mandatory Arbitration*, 96 N.C. L. REV. 679, 681 (2018); Judith Resnik, *Diffusing Disputes: The Public in the Private of Arbitration, the Private in Courts, and the Erasure of Rights*, 124 YALE L.J. 2804, 2810 (2015).

<sup>96</sup> See, e.g., ERIC TOPOL, *THE CREATIVE DESTRUCTION OF MEDICINE: HOW THE DIGITAL REVOLUTION WILL CREATE BETTER HEALTHCARE* 10–11 (2012).

<sup>97</sup> *Id.*

<sup>98</sup> Orianna Rosa Royle, *Bryan Johnson Is Being Used as a Human Guinea Pig in Unproven Gene*

own insulin,<sup>99</sup> or implant RFID chips into their hands to sense magnetic fields.<sup>100</sup> The result is a growing mismatch between the assumptions baked into health law and the realities of contemporary consumer health technologies. The law still treats medicine as exceptional, bound by fiduciary duties, and subject to professional norms. But health tools born of the wellness market are shaped by consumer choice, economic incentives, and private ordering. As these technologies grow more sophisticated, the distinctions at the center of health law no longer hold.

### B. Caveat Immortalis

Life-extension and enhancement technologies exist in a legal gray zone that reflects and reinforces their uncertain, and occasionally indescribable, identity. As these technologies advance under the banner of wellness, they slip between regulatory categories, challenging the boundaries of both health law and consumer protection.<sup>101</sup> The result is a sprawling, hybrid marketplace full of quackery where products that promise longer life and better health are governed not by health law but by private contracts.<sup>102</sup>

Terms of service and user agreements have become the default governance structures for consumer wellness products—and, by extension, transhumanist technologies. These documents are typically hard to read, non-negotiable, replete with disclaimers, waivers, and arbitration clauses, and determine the legal landscape in which consumers must operate.<sup>103</sup> They are also subject to unilateral amendment, so even if you read and understand the terms, they might change without notice.<sup>104</sup> Courts have largely upheld these agreements, even in cases involving potentially misleading or harmful health claims.<sup>105</sup>

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*Therapy Injections Worth \$25,000 a Pop in an Island off Honduras*, FORTUNE (Dec. 21, 2023, 7:19 AM), <https://fortune.com/2023/12/21/bryan-johnson-human-guinea-pig-unproven-tests-reprogram-human-genes-follistatin-roatan-island-honduras/>.

<sup>99</sup> See OPEN INSULIN FOUND., <https://openinsulin.org/> (last visited Oct. 16, 2025).

<sup>100</sup> See Popper, *supra* note 51.

<sup>101</sup> See Quinn, *supra* note 80.

<sup>102</sup> See Perls, *supra* note 93, at 690; *but see* Patricia J. Zettler et al., *Regulating Genetic Biohacking*, SCI., July 5, 2019, at 35–36 (noting that although the FDA does not currently take an active role in regulating biohacking, it has the jurisdiction and power to do so).

<sup>103</sup> See Yannis Bakos et al., *Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts*, J. LEGAL STUD., Jan. 2014, at 1, 32; Ben-Shahar & Schneider, *supra* note 95, at 657–58; *see generally* Florencia Marotta-Wurgler, *Will Increased Disclosure Help? Evaluating the Recommendation of the ALI's "Principles of the Law of Software Contracts,"* 78 U. CHI. L. REV. 165 (2011) (discussing potential avenues for increasing readership in end use license agreements of software sold online); *see generally* Ian Ayres & Alan Schwartz, *The No-Reading Problem in Consumer Contract Law*, 66 STAN. L. REV. 545 (2014) (arguing that consumer protection laws should focus on “term optimism” situations in which consumers expect more favorable terms than they actually receive).

<sup>104</sup> Leah R. Fowler, Jim Hawkins & Jessica L. Roberts, *Uncertain Terms*, 97 NOTRE DAME L. REV. 1, 1 (2021).

<sup>105</sup> See *Tompkins v. 23andMe, Inc.*, 840 F.3d 1016, 1033 (9th Cir. 2016) (class of plaintiffs brought claims against 23andMe for unfair business practices, breach of warranty, and misrepresentations about the health benefits); *McLellan v. Fitbit, Inc.*, No. 3:16-CV-00036, 2018 WL 2688781, at \*1

Unregulated interventions are offered abroad in regulatory havens where custom, industry-friendly legal frameworks limit liability.<sup>106</sup> Even cryonics—one of the most speculative and extreme life-extension technologies—operates through private membership contracts that disclaim any guarantee of success and shield providers from standard malpractice claims.<sup>107</sup>

In this environment, the distinction between healthcare and consumer tech collapses—and with it, the infrastructure of legal accountability in health. While some interventions are framed as empowering lifestyle choices, and many are indeed low risk, they can occasionally carry risks that resemble even the most invasive and risky medical treatments. One need not speculate about what this looks like when taken to its most extreme. Privatized jurisdictions that explicitly reject traditional state regulatory models in favor of contract-based governance already exist and offer a vision of our transhumanist future.<sup>108</sup>

#### IV. TO OLDLY GO

As wellness logic blurs the lines between healthcare and enhancement, so does the infrastructure of public oversight. This Part explores the legal future that could emerge in their place. It begins with innovation zones like Próspera, Honduras, where transhumanist technologies are offered under bespoke legal regimes designed to minimize accountability and maximize autonomy. It then zooms out to consider the increasing dominance of contract law as the default framework for governing enhancement. Ultimately, these technological and legal developments may be neutral or beneficial. But we must confront head-on whether our existing frameworks are satisfactorily equipped to govern the pursuit of immortality.

##### A. Innovating in Galt's Gulch

If transhumanism is a logical extreme of an already pervasive wellness movement, it raises the question of what a society that explicitly fosters transhumanism looks like. One need not speculate: a real-life example exists in the Galt's-Gulch-esque<sup>109</sup> free economic zone of Próspera, Honduras.<sup>110</sup> This

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(N.D. Cal. June 5, 2018) (plaintiffs claimed that Fitbit's popular heart-rate tracker did not work as advertised).

<sup>106</sup> See discussion *infra* Section IV.A.

<sup>107</sup> See Alexandra Mullock & Elizabeth Chloe Romanis, *Cryopreservation and Current Legal Problems: Seeking and Selling Immortality*, 10 J.L. & BIOSCI., July–Dec. 2023, at 21, <https://doi.org/10.1093/jlb/lpad028>.

<sup>108</sup> See discussion *infra* Section IV.A.

<sup>109</sup> See generally AYN RAND, ATLAS SHRUGGED (Signet 1996) (1957) (Galt's Gulch is a capitalist haven in Ayn Rand's *Atlas Shrugged*); see Alan Clardy, *Galt's Gulch: Ayn Rand's Utopian Delusion*, 23 UTOPIAN STUDIES 238 (2012).

<sup>110</sup> PRÓSPERA, <https://www.prospera.co/en> (last visited Oct. 19, 2025); see also DON'T DIE (Netflix 2025) (depicting Bryan Johnson's trip to Próspera to receive follistatin gene therapy); Royle, *supra* note 98.

libertarian techno-utopia clearly shows what those pursuing immortality think makes it possible: private, for-profit cities governed by terms of service.

Próspera is a Zone for Employment and Economic Development (ZEDE) and “charter city”<sup>111</sup>—a semiautonomous jurisdiction founded by a Delaware-based company in 2017.<sup>112</sup> ZEDEs are legally distinct from ordinary municipal structures in that they operate under their own regulatory frameworks and enjoy significant autonomy from the host nation’s laws and courts.<sup>113</sup> They are empowered to set their own tax, labor, and business policies, and, in some cases, even establish independent judicial systems.<sup>114</sup> Silicon Valley venture capitalists like Peter Thiel, Sam Altman, and Marc Andreessen (all transhumanists or singularitarians)<sup>115</sup> also help fund Próspera.

Próspera’s unique governance structure allows it to offer largely unregulated services, including medical services and clinical trials that function outside traditional constraints.<sup>116</sup> And it is a direct result of large companies—often Big Tech—growing weary of repeated clashes with government oversight.<sup>117</sup> In Próspera, the transhumanist imagination can run wild. Biohackers offer products to “cure Alzheimer’s and suppress all tumors,” while others offer implants that “turn people into self-sovereign cyborgs.”<sup>118</sup> Events for innovators call to “make death optional.”<sup>119</sup> And if inventors cannot market the therapies they develop in Próspera as drugs or devices in the United States, they can still create the most cutting-edge consumer-marketed products for those willing to travel and pay for a chance at immortality.<sup>120</sup>

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<sup>111</sup> Michael R. Castle Miller, *The Ciudades Modelo Project: Testing the Legality of Paul Romer’s Charter Cities Concept by Analyzing the Constitutionality of the Honduran Zones for Employment and Economic Development*, 22 WILLAMETTE J. INT’L L. & DISP. RESOL. 271, 273–74 (2015).

<sup>112</sup> Rachel Corbett, *The For-Profit City That Might Come Crashing Down*, N.Y. TIMES MAG. (Aug. 28, 2024), <https://www.nytimes.com/2024/08/28/magazine/prospera-honduras-crypto.html>.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> Kosoff, *supra* note 2; Alexander Beiner, *Get Ready for AI Religions: Sam Altman, Transhumanism, and the Merge*, KAINOS (Oct. 2, 2024), <https://beiner.substack.com/p/get-ready-for-ai-religions-sam-altman>; Edward Ongweso, Jr., *Silicon Valley’s Quest to Build God and Control Humanity*, NATION (July 13, 2023), <https://www.thenation.com/article/economy/silicon-valley-artificial-intelligence/> (discussing Marc Andreessen as a leader in a particular strain of transhumanist thought); Elke Schwarz, *Conjuring the End: Techno-eschatology and the Power of Prophecy*, OPINIOJURIS (Jan. 1, 2025), <https://opiniojuris.org/2025/01/30/conjuring-the-end-techno-eschatology-and-the-power-of-prophecy/>; Emile P. Torres, *Digital Eugenics and the Extinction of Humanity*, TECH POL’Y PRESS (July 11, 2025), <https://www.techpolicy.press/digital-eugenics-and-the-extinction-of-humanity/>; *see also* Corbett, *supra* note 112 (noting Thiel, Altman, and Andreessen among Próspera’s funders).

<sup>116</sup> Corbett, *supra* note 112.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *See* Laurie Clarke, *This Biohacking Company Is Using a Crypto City to Test Controversial Gene Therapies*, MIT TECH. REV. (Feb. 13, 2023), <https://www.technologyreview.com/2023/02/13/1068330/minicircle-prospera-honduras-biohacking-follistatin-gene-therapy/>.

A key feature of charter cities like Próspera is the legal and regulatory flexibilities that create a testbed for radical innovation.<sup>121</sup> This also extends to legal systems more generally, as these cities can establish their own dispute-resolution mechanisms.<sup>122</sup> In Próspera, this takes the form of mandatory arbitration, which further removes traditional legal and government oversight from the equation.<sup>123</sup>

Próspera's experiment in governance aligns with the vision of a self-sustaining, innovation-first society. Minimizing regulatory barriers and fostering a techno-libertarian environment provides an unprecedented opportunity for transhumanists to build the world they envision. If successful, Próspera may pave the way for a new era of self-directed human enhancement outside the reach of slow-moving regulatory bodies, risk-averse governments, and legal liability. It, and zones like it, enable what Quinn Slobodian would call a "perforation" of democratic authority, in this case over health, via a deliberate reallocation of governance away from public oversight and toward private ordering.<sup>124</sup>

Próspera demonstrates that if traditional nation-states cannot adapt to rapid technological change, billionaire technology giants may build a competitor micronation that will. And they may not have to go so far as Honduras. Some argue that the Constitution permits the creation of domestic prosperity zones in the United States through the Compact Clause, found in Article I, Section 10, or as purely a matter of state law.<sup>125</sup> Traditionally, interstate compacts require congressional consent only if they encroach upon federal supremacy or alter the balance of federal-state power.<sup>126</sup> However, under prevailing Supreme Court interpretations, such as *Virginia v. Tennessee* and *U.S. Steel v. Multistate Tax Commission*, states may enter into agreements coordinating internal governance so long as they do not undermine federal authority.<sup>127</sup> Prosperity Zones could leverage this flexibility.<sup>128</sup> For example, multiple states could enter into a compact establishing low-regulation, market-oriented jurisdictions within their borders, which would be insulated from ordinary state and local laws.<sup>129</sup> Congressional

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<sup>121</sup> *See id.*

<sup>122</sup> *See id.*

<sup>123</sup> Corbett, *supra* note 112 ("In order to enter the jurisdiction, I was told I needed to sign an 'agreement of coexistence' binding myself to 4,202 pages of rules . . . subject to the jurisdictional authority of the arbitration center.").

<sup>124</sup> QUINN SLOBODIAN, *CRACK-UP CAPITALISM: MARKET RADICALS AND THE DREAM OF A WORLD WITHOUT DEMOCRACY* 3 (2023).

<sup>125</sup> U.S. CONST., art. I, §10, cl. 3; Nick Dranias, *The Prosperity Zone Compact: Leveraging the Power and Promise of Interstate Compacts to Bring Back the American Dream*, COMPACT FOR AM., Policy Brief No. 10 at 4-5 (July 21, 2016), [https://www.compactforamerica.org/\\_files/ugd/e48202\\_708bc0df86ac47b092daacc9abf807b4.pdf](https://www.compactforamerica.org/_files/ugd/e48202_708bc0df86ac47b092daacc9abf807b4.pdf) (explaining how Prosperity Zones are consistent with the Compact Clause or, in the alternative, do not implicate the Compact Clause at all).

<sup>126</sup> *Virginia v. Tennessee*, 148 U.S. 503, 517-18 (1893); *U.S. Steel v. Multistate Tax Comm'n*, 434 U.S. 452, 473-78 (1978).

<sup>127</sup> *Virginia*, 148 U.S. at 517-18; *U.S. Steel*, 434 U.S. at 473-78.

<sup>128</sup> *See* Dranias, *supra* note 125.

<sup>129</sup> *See id.* at 2-3 (giving the examples of The Tahoe Regional Planning Compact and the Kansas and Missouri Metropolitan Culture District Compact as multi-state compacts that expand government power, but noting that the same logic "could also be used to create governing bodies to empower local communities to remove layers of government from the bottom-up for optimal regulation and free market economic development.").

consent, while advisable to fully entrench these zones, might not be strictly necessary for initial implementation if the compact merely exercises powers the states already possess independently.<sup>130</sup> Scholars have further argued that U.S. history—dating back to colonial charters and modern examples like foreign trade zones—demonstrates a robust tradition of geographically limited regulatory carve-outs.<sup>131</sup> This tradition persists. In 2021, Nevada introduced a proposal explicitly aimed at creating autonomous “Innovation Zones” that would function similarly to special economic jurisdictions, though the legislative effort ultimately stalled amid controversy over local governance implications.<sup>132</sup> However, whether these cities will truly become utopias or dystopias, and the role of wellness and transhumanism within them, remain open questions.

### B. [Re]Defining the Terms

Próspera may be a glimpse of our own future, but it need not be inevitable. If we do nothing, it is possible that the categories that once structured health law will lose their coherence, and in their place, a legal regime grounded in private ordering will emerge.<sup>133</sup> Increasingly, contract law—not health law—will govern the boundaries of bodily risk and access. This shift reflects both a regulatory retreat and a deeper transformation in how we define health, personhood, and responsibility in an era of techno-optimization.

This privatization of health governance raises concerns worth considering. First, asymmetric bargaining power and the reality of terms of service and privacy policies leave most users with no meaningful alternative to consent.<sup>134</sup> Consumers seeking wellness or enhancement are rarely in a position to evaluate product risks, much less negotiate contractual terms.<sup>135</sup> Second, the enforceability of waivers and disclaimers undermines traditional duties of care—duties that exist for a good reason in medicine, where the harm can be physical and often irreversible.<sup>136</sup> Third,

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<sup>130</sup> See *id.* at 4-5; see also Ilya Shapiro, *Constitutionality of the Prosperity Zone Compact*, CATO INST. (Sept. 6, 2016), <https://www.cato.org/testimony/constitutionality-prosperity-zone-compact> (explaining why Congressional consent is not necessary).

<sup>131</sup> Tom W. Bell, *Special Economic Zones in the United States: From Colonial Charters to Foreign-Trade Zones Toward USSEZs*, 64 BUFF. L. REV. 959, 976-80 (2016); see also Shapiro, *supra* note 130 (“One of the earliest interstate compacts, predating the Constitution, reciprocally guaranteed the continued protection of existing property and contract rights in the adopting states from “any law which rendered those rights less valid and secure.”).

<sup>132</sup> Steve Sisolak, Governor of Nev., 2021 State of the State Address (Jan. 19, 2021) (proposing the creation of Innovation Zones in Nevada); Charlie Ban, *Nevada’s ‘Smart City’ Proposal Would Amputate County Land*, NAT. ASSOC. OF CNTYS. (Mar. 8, 2021), <https://www.naco.org/articles/nevada-%E2%80%98smart-city%E2%80%99-proposal-would-amputate-county-land> (criticizing the proposal); see also Jeffrey Mason, *An Analysis of Nevada’s Proposed Innovation Zones Law*, CHARTER CITIES INST. (Feb. 5, 2021), <https://chartercitiesinstitute.org/blog-posts/an-analysis-of-nevadas-proposed-innovation-zones-law/> (expressing disappointment in the proposal’s similarity to existing county government).

<sup>133</sup> See *supra* Part III.

<sup>134</sup> See Solove, *supra* note 95, at 1898-99; Radin, *supra* note 95, at 1231.

<sup>135</sup> See Ben-Shahar & Schneider, *supra* note 95, at 657.

<sup>136</sup> See Lawrence, *supra* note 89, at 851-52.

mandatory arbitration and limits on tort recovery shift disputes into opaque, private forums where public accountability is absent.<sup>137</sup> These concerns reveal that contract-based governance fails to account for the unique vulnerabilities of health-related transactions. As it stands now, this disconnect is tolerable. If wellness and transhumanism become increasingly invasive and risky, they may eventually create more significant problems.

This possibility raises important questions: can contract law handle transhumanism's social, ethical, and physical stakes? What counts as a legitimate medical intervention in a world where anything from a neural implant to a nootropic smoothie can be framed as self-care? Who gets to decide whether these products are safe or effective, and by what standards, especially when outcomes are long-term, speculative, or inherently unmeasurable? Can we meaningfully regulate health in a globalized, digitized, and deregulated health marketplace where legal jurisdictions compete to lower barriers to entry and technologies move faster than the institutions designed to oversee them? Should we accept the risks and welcome this transformation as a solution to our expensive, ineffective healthcare system, which has long been searching for answers?

Equally pressing is the role of wellness in this landscape. Increasingly, “wellness” functions as a legal loophole—an all-purpose justification that allows companies to market increasingly sophisticated enhancement technologies as harmless self-care while avoiding the obligations of medical oversight.<sup>138</sup> As these products proliferate, the line between informed choice and exploitation becomes harder to locate. Whether the product in question offers sleep optimization or synthetic immortality, the fundamental legal questions remain the same: Who will write the terms, and who will pay the price when they fail?

## V. CONCLUSION

Transhumanism is often treated as fringe science or speculative fiction. But as this Essay has shown, it is neither. It is the logical—and perhaps inevitable—extension of consumer wellness culture, shaped by the same ideologies of self-optimization, personal responsibility, and privatized health.

Wellness technologies are everywhere, subtly reshaping our expectations of health, responsibility, and risk. Because they appear ordinary, their influence is often overlooked. However, considering them at their logical extreme reveals how these practices are positioned to transform the legal and ethical terrain. The regulatory frameworks we rely on to safeguard health are based on outdated categories that are increasingly poor fits. As those distinctions erode, so do the protections we have painstakingly built around them.

Whether this trajectory leads to innovation or exploitation depends on how law and society respond. We have to decide whether private ordering can adequately ensure safety, equity, and accountability in a transhumanist landscape

<sup>137</sup> See Estlund, *supra* note 95, at 681; Resnik, *supra* note 95, at 2810.

<sup>138</sup> See discussion *supra* Section II.A; Perls, *supra* note 93, at 682-691; Zabawa, *supra* note 7, at 682; U.S. FOOD & DRUG ADMIN., FDA-2014-N-1039, GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES (2019).

defined by the rules of consumer wellness. We must identify the legal interventions—doctrinal, procedural, or structural—needed to prevent exploitation in a market that promises radically healthier and longer lives. And perhaps most urgently, we have to reckon with the possibility that the pursuit of immortality may mean the death of health law as we know it.

# SACRED WELLNESS

Haley Palfreyman Jankowski\*

“You can’t pray a lie.”<sup>1</sup>

## I. INTRODUCTION

When I get the flu, I go to the doctor to obtain treatment and prescriptions for medicines to treat my illness and associated symptoms. But this is a treatment protocol for an illness that has already manifested. What doctor should I call *before* I get sick, maybe to help me avoid getting sick in the first place? Part of this answer can also be given by my primary care provider at my annual “well check” appointment. To maintain a stable physical wellness, the U.S. government recommends what most doctors recommend: eat a healthy diet (i.e., plenty of fresh vegetables and fruits, rich protein foods, whole grains, and avoiding sugary and fatty foods), work out and prioritize an active lifestyle (i.e., walk or bike regularly, build muscle, etc.), and otherwise develop healthy habits.<sup>2</sup>

But physical wellness, while important, is only one piece of a person’s overall wellness. The Wellness Alliance<sup>3</sup> labels six dimensions of wellness: Emotional, Physical, Intellectual, Occupational, Spiritual, and Social:<sup>4</sup>

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<sup>1</sup> MARK TWAIN, *THE ADVENTURES OF HUCKLEBERRY FINN* 269 (Victor Fischer & Lin Salamo eds., Univ. of Cal. Press 2003) (1894).

<sup>2</sup> See *Physical Wellness Toolkit*, NAT’L INSTS. OF HEALTH (Jan. 21, 2025), <https://www.nih.gov/health-information/your-healthiest-self-wellness-toolkits/physical-wellness-toolkit>.

<sup>3</sup> See *About Us*, WELLNESS ALL., <https://www.wellnessalliance.org/about-us> (last visited July 1, 2025) (“The Wellness Alliance unites the strengths of the two most recognized and influential professional associations in the wellness industry: Wellness Council of America (WELCOA) and the National Wellness Institute (NWI).”).

<sup>4</sup> *The Six Dimensions of Wellness*, WELLNESS ALL., <https://nationalwellness.org/resources/six-dimensions-of-wellness/> (last visited July 1, 2025).



Another version of this comes from the “Wholeness Wheel.”<sup>5</sup> Some versions of this “wholeness wheel” delineate “Spiritual Wellness” as the center or core axle of the wheel:



This Essay does not debate the question of whether “Spiritual Wellness” is equal to the other wellness dimensions or should be prioritized as the core and most

<sup>5</sup> See *The Wholeness Wheel*, PORTICO, <https://porticobenefits.org/the-wholeness-wheel/> (last visited July 1, 2025).

significant aspect of a person's wellness, because under either view, a person's "Spiritual Wellness" is a significant part of their overall wellness.<sup>6</sup>

"Spiritual Wellness" can be developed in a variety of ways, including participating in organized religion or engaging in personal meditation and mindfulness.<sup>7</sup> This Essay focuses on the former, in an overall effort to incorporate the First Amendment's built-in constitutional protections for freedom of religion into the field of Wellness Law. In other words, this Essay contends that if we are making space for mandating wellness provisions, such allowances must include options for people to practice their religious beliefs. Numerous studies have shown that participation in a religious group has an overall positive impact on a person's happiness.<sup>8</sup> And it is this truth that motivated this Essay to connect the freedom of religion protections and incorporate them into the emerging field of wellness law.

## II. WHAT IS WELLNESS LAW?

Is wellness a human right that must be legally protected? What would it look like, for example, to require employers to safeguard the wellness of their employees? What even *is* wellness? Legal scholars are beginning to grapple with these questions and more to determine how the legal landscape of "wellness law" should look.<sup>9</sup> Professor Barbara J. Zabawa is at the forefront of this process. "Wellness," Zabawa says, "means different things to different people, but at its

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<sup>6</sup> What if, one might query, someone contends that his or her wellness does not have a spiritual component at all? This is a valid viewpoint to hold, and I believe that all people can choose to "worship [or not worship] how, where, or what they may." The Pearl of Great Price, *Articles of Faith* 1:11 (The Church of Jesus Christ of Latter-day Saints 1981). Accordingly, this Essay is not at all intended to state that everyone must engage in some form of spiritual wellness or to mandate spirituality for anyone. But the fact remains that many leading sources on wellness include spirituality as at least a component to a person's overall wellness.

<sup>7</sup> However, while meditation and mindfulness can be undertaken at an individual level and without subscribing to an organized religion, even these practices are rooted in the customs of ancient Asian religions like Buddhism. See Jeffrey M. Greeson et al., *Changes in Spirituality Partly Explain Health-Related Quality of Life Outcomes After Mindfulness-Based Stress Reduction*, 34 J. BEHAV. MED. 508, 508 (2011) ("Buddhist teachings include the development of mindfulness as one of five spiritual faculties, along with faith, effort, concentration, and wisdom.").

<sup>8</sup> See Michael Wright, *Unveiling the Advantage: How Attending a Christian University Equips You for Success in a Secular World*, EMBASSY INT'L UNIV. (Dec. 6, 2024), <https://www.eceiuniversity.org/post/unveiling-the-advantage-how-attending-a-christian-university-equips-you-for-success-in-a-secular-wo>; *Religion's Relationship to Happiness, Civic Engagement and Health Around the World*, PEW RSCH. CTR. (Jan. 31, 2019), <https://www.pewresearch.org/religion/2019/01/31/religions-relationship-to-happiness-civic-engagement-and-health-around-the-world/> [hereinafter *Religion's Relationship to Happiness*].

<sup>9</sup> See Barbara Zabawa, *Defining the Field of Wellness Law*, SSRN 1 (Aug. 10, 2024), <https://ssrn.com/abstract=5006986>.

root wellness emphasizes a personal striving for holistic health optimization in one's physical, emotional, social, spiritual, and intellectual states of being."<sup>10</sup>

Whenever "wellness" is mentioned colloquially, it is often grouped with the related term, "health."<sup>11</sup> A natural instinct for approaching "wellness law," therefore, would be to view it as a subset of "health law." But they are not the same, and their differences warrant different legal treatment and categories. "Health" focuses on the treatment and management of diseases, as well as on efforts to *prevent* the imminent onset of such diseases.<sup>12</sup> "Wellness" sets itself apart by focusing not on the prevention of specific, imminent diseases but on incorporating and maintaining lifestyle changes that contribute to a healthier overall lifestyle.<sup>13</sup>

In Professor Zabawa's pilgrimage to identify and carve out a "wellness law" field, she "start[s] at the very beginning, a very good place to start:"<sup>14</sup> with "federal statutes, cases or guidance that use the words 'wellness,' or 'health promotion' to describe a key feature of the law or factual context in which the law operates," including "the Internal Revenue Code (IRC), the federal Food, Drug and Cosmetic Act (FDA), the Affordable Care Act (ACA), the Americans with Disabilities Act (ADA), the Genetic Information and Discrimination Act (GINA), lawsuits involving the ACA, ADA and GINA, and the Medicare Annual Wellness Visit provision."<sup>15</sup> She proceeds to explain the wellness law components of each legal source.<sup>16</sup>

Worth highlighting here is the ACA's groundbreaking focus on medical coverage for prevention and wellness care. Before the ACA, the earliest version of Medicare enacted in 1965 only covered expenses that were "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member."<sup>17</sup> The ACA's "emphasis on prevention and wellness required all insurers, both public and private, to cover preventive services with no cost sharing."<sup>18</sup> The ACA maps out incentive structures for

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<sup>10</sup> *Id.* at 3.

<sup>11</sup> See e.g., *Health & Wellness*, TODAY, <https://www.today.com/health> (last visited July 11, 2025) (noting Today's news section focusing on health and wellness).

<sup>12</sup> See Maxwell Gregg Bloche, *The Invention of Health Law*, 91 CALIF. L. REV. 247, 308 (2003) (defining the four aims of health law as health promotion and restoration, rescue, support and comfort, and personal dignity).

<sup>13</sup> See Anna Kirkland, *What Is Wellness Now?*, 38 J. HEALTH POL., POL'Y & L. 957, 961 (2015) (stating that wellness practices aim to ameliorate long-term (and sometimes inevitable) problems such as chronic diseases, aging, and physical disability and are carried out far in advance of any such problems manifesting—also labeling the focus of wellness as "the holistic person striving for self-improvement on his or her own, without expert intervention and highly technical guidance.").

<sup>14</sup> JULIE ANDREWS, *Do-Re-Mi, on The Sound of Music* (Rodgers & Hammerstein Holdings 1965).

<sup>15</sup> Zabawa, *supra* note 9, at 9-10.

<sup>16</sup> See *id.* at 10, 14, 17, 19, 21.

<sup>17</sup> Kirsten J. Colello & Sarah A. Lister, CONG. RSCH. SERV., RL40978, MEDICARE COVERAGE OF CLINICAL PREVENTIVE SERVICES 4 (2010).

<sup>18</sup> Zabawa, *supra* note 9, at 17; see Leighton Ku, Julia Paradise & Victoria Thompson, *Data Note: Medicaid's Role in Providing Access to Preventive Care for Adults*, KAISER FAM. FOUND. 2 (May 2017), <https://www.kff.org/medicaid/data-note-medicoids-role-in-providing-access-to-preventive-care-for-adults/>.

employers to offer employees based on wellness practices. But a key component of these incentive rules “is that once an employer decides to implement a worksite wellness program, the Act gives the employer wide discretion on how to structure the wellness program.”<sup>19</sup>

Workplace wellness “is the currently dominant variation of wellness in the United States.”<sup>20</sup> But workplace wellness programs must be “voluntary,” which, according to the EEOC Enforcement Guidance, means they must not require employees to provide health information or punish them for opting out.<sup>21</sup> Whether an employer’s wellness program is sufficiently “voluntary” has been the subject of much litigation.<sup>22</sup> Professor Zabawa analyzes these cases and surmises that the problem they have in common “is whether and how employees can be incentivized to engage in wellness activities while still preserving a sense of autonomy and choice.”<sup>23</sup> In that same vein, she says workplace wellness programs are “mislabelled” as wellness programs because they allow employers to dictate the wellness terms that qualify for the employees instead of offering employees flexibility and meaningful choices with how to promote their own wellness:

If wellness is about self-actualization and achieving something beyond a baseline health status, then workplace wellness programs that offer a pre-set menu of activities or just collect health data are likely not contributing to employee wellness goals, regardless of any incentives tied to those activities. Worksite wellness should not be a top-down benefit at all, but that is how it is currently structured. Instead, . . . employers could use the legal flexibility offered by the ACA, ADA, and GINA when designing workplace wellness programs to find ways to empower employees to engage in self-determination efforts. Rather than dictating lifestyle changes, employers should examine and remove the barriers that prevent employees from improving. . . . Addressing these “social determinants of health” (SDOH) through “autonomy-enhancing policies” would better

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<sup>19</sup> Zabawa, *supra* note 9, at 20; *see* Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33158, 33162 (June 3, 2013) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. 2590; 45 C.F.R. pts. 146–47) (permitting flexibility for the program development of group health plans and expressly declining to require accreditation or evidence-based clinical standards for such programs).

<sup>20</sup> Kirkland, *supra* note 13, at 958.

<sup>21</sup> *See* 42 U.S.C. § 12112(d)(4)(B) (2009); 29 C.F.R. § 1635.8(b)(2)(i)(A) & (B) (2019); U.S. EQUAL EMP. OPPORTUNITY COMM’N, EEOC 915.002, ENFORCEMENT GUIDANCE ON DISABILITY RELATED INQUIRIES AND MEDICAL EXAMINATIONS OF EMPLOYEES UNDER THE ADA (2000).

<sup>22</sup> *See* *Seff v. Broward Cnty.*, 691 F.3d 1221 (11th Cir. 2012) (class action alleging that Broward County’s wellness program violated the ADA by requiring medical exams for employees and a compelled disclosure of disability-related responses); *see also* *AARP v. EEOC*, 267 F. Supp. 3d 14 (D.D.C. 2017) (alleging that the employer-sponsored wellness programs that tied a thirty percent incentive level to disclosing confidential medical information violated the AA and GINA “voluntary” provisions).

<sup>23</sup> Zabawa, *supra* note 9, at 34.

align with the spirit of wellness than cookie-cutter workplace wellness activities.<sup>24</sup>

Zabawa then offers some examples of “autonomy-enhancing policies,” including “bringing healthy food choices to the worksite so that those who live in food deserts or food swamps have one less barrier to eat healthy” and “ensuring that the workplace is free from discrimination, or offering accessible fitness facilities.”<sup>25</sup> These are great examples of options that employers could take to broaden their wellness-plan offerings. But I wish to propose another example, one that covers an entirely different section of the “wholeness wheels” referenced in the Introduction:<sup>26</sup> Employers should offer a spiritual and religious component as part of their overall wellness plans and options.

### III. LEGAL CARVEOUTS FOR WELLNESS SHOULD INCLUDE RELIGIOUS OPTIONS

Importantly, Zabawa’s wellness law framework relies on employees’ freedom of choice for its sustainability: “[P]olicies should facilitate healthy behaviors by giving individuals access to meaningful choices and leaving space for individuals to flourish on their own.”<sup>27</sup> To the extent we are protecting wellness practices and trying to create an “ideal environment for employees to engage in self-actualization and make the best decisions to improve their wellbeing,”<sup>28</sup> this Essay contends that religious avenues for wellness must be included among the overall wellness options. And if wellness continues to be incentivized in the workplace, employees should be allowed to select religious wellness options in lieu of or in addition to physical wellness options.

An individual’s spiritual health is vital to their overall wellness.<sup>29</sup> And this spiritual well-being often manifests itself through participation in a religion. Several studies have confirmed that people who are active in religious congregations are happier and even tend to live longer than those who are not.<sup>30</sup> “Religious affiliation and regular church attendance are near the top of the list for most people in explaining their own happiness and serve as good predictors of who

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<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 35.

<sup>26</sup> *See supra* Part I.

<sup>27</sup> Zabawa, *supra* note 9, at 46.

<sup>28</sup> *Id.*

<sup>29</sup> *See* Kirkland, *supra* note 13, at 960 (“Spirituality is at the center of the visual depiction of the wheel of wellness.”).

<sup>30</sup> *See Religion’s Relationship to Happiness, supra* note 8; *see also* Kirkland, *supra* note 13, at 959 (“In the nineteenth-century United States, religious and spiritual movements such as *New Thought* and *Christian Science* were founded on the idea that individuals’ bodily health derives from their own achievement of a proper state of mind, usually understood as morally virtuous and often explicitly religious, not from outside medical intervention.”); Michael Conklin, *Religious Law Schools, Rankings, and Bias: Measuring the Rankings Penalty at Religious Law Schools*, SSRN 15-16 (Feb 23, 2025), <https://ssrn.com/abstract=5150673> (noting that religiously affiliated educational institutions offer great benefits, such as a strong sense of community, an emphasis on service, and the value of commitment).

is most likely to have this sense of well-being.”<sup>31</sup> These studied truths, or at a minimum correlations between religious practices and overall wellness, beg the question of how religious options could be left out of a wellness smorgasbord and, furthermore, if spiritual wellness are offered, what shape those options would take?

First, religious avenues of wellness could be incorporated into existing wellness incentive plans by adding religious-based options as a way to earn the monthly or annual incentive packages. For example, if employees are rewarded with a monthly bonus for reaching 10,000 steps each day for the entire month,<sup>32</sup> another option could be added in lieu of the steps whereby employees receive the same bonus for attending church services of their own choosing each week of the month.

A second avenue for incorporating religious or spiritual wellness options would take the form that Professor Zabawa credits “libertarian paternalists” with, as a “nudge.”<sup>33</sup> “Nudges can be laws or policies that encourage an individual to alter their behavior while maintaining their freedom to choose;” they “should be ‘easy and cheap to avoid.’”<sup>34</sup> A wellness nudge with a religious bent to it could be a weekly carve-out of time for employees to attend worship services, or it could be opening up a prayer/meditation room available for employees to use during work hours. Each of these examples would be easy for employees to take advantage of, but would never be perceived as a mandate, exactly the parameters that a libertarian paternalism theory would support.

These are just a few examples of how religious options could be worked into workplace wellness plans. The goal of this Essay is not to prescribe all potential options for religious wellness avenues, but to promote the notion that wellness should include more than just physical health considerations and should reach spiritual health as well through religious wellness choices. To be clear, these spiritual options should be *optional* in that they are merely offered as alternatives or other ways people can meet an overall wellness goal. This way, anyone who would not wish to participate in a spiritual wellness activity could still participate in the overall wellness program through other offered means, likely via physical wellness pathways.

Again, this Essay does not intend to lay out a comprehensive framework for what a wellness program with spiritual options would look like. Instead, the narrower goal here is to urge that religious wellness is not forgotten as we move forward into a new wellness law world.

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<sup>31</sup> HERITAGE FOUNDATION, WHY RELIGION MATTERS: THE IMPACT OF RELIGIOUS PRACTICE ON SOCIAL STABILITY 6 (1996), <https://www.heritage.org/civil-society/report/why-religion-matters-the-impact-religious-practice-social-stability>.

<sup>32</sup> See Andrea Bartz, *This Healthcare Company Is Determined to Have the Healthiest Employees in the World*, JOHNSON & JOHNSON (Feb. 25, 2018), <https://www.jnj.com/innovation/how-johnson-johnson-is-improving-workplace-wellness-for-healthiest-employees> (noting Johnson & Johnson’s 2017 Goal Getters step challenge that rallied employees all across the company to log at least 10,000 steps per day—the employees in this challenge did not get a monthly bonus but got to vote on which charitable organizations would receive donations from the company).

<sup>33</sup> Zabawa, *supra* note 9, at 40.

<sup>34</sup> *Id.* (citing Jessica L. Roberts & Leah Fowler, *How Assuming Autonomy May Undermine Wellness Programs*, 27 HEALTH MATRIX 101, 114 (2017)).

#### IV. CONCLUSION

“Congress shall make no law respecting an establishment of *religion*, or prohibiting the free exercise thereof . . . .”<sup>35</sup> The Continental Congress was so concerned about the relationship between the brand new federal government and religion that this was the very first right dealt with in the amendments to the Constitution, placed even before the other fundamental rights listed in the First Amendment (i.e., freedom of speech, right to peaceably assemble, and petition the Government for redress of grievances). Our Founding Fathers guarded against mirror concerns regarding religion: (1) the concern that the government would ever establish a state-sponsored religion, which would take away the people’s religious freedom, and (2) the concern that the government would prohibit any American’s free exercise of his own religion. This Essay focuses more on the latter concern in its plea to include religious avenues as part of a person’s overall package of wellness options.

Scholarship discussing the scope of the Constitution’s “free exercise” protection typically (and appropriately) stays solidly in its First Amendment lane.<sup>36</sup> For example, articles will argue whether government policies, practices, or laws run afoul of the Free Exercise Clause.<sup>37</sup> Or they will argue that certain actions by litigants should be protected by the Free Exercise Clause.<sup>38</sup> This Essay does neither.

Instead, this Essay takes the concept and right of the Free Exercise of religion and pivots to the wellness law field. The point here is not that the federal government must protect the free exercise of religion as a constitutional matter—a worthy argument but best left to my colleagues who are First Amendment experts—but rather that a person’s free exercise of religion embodies a critical part of her overall wellness for the *very same reasons* our Founders enshrined the Free Exercise Clause in the First Amendment to the Constitution.

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<sup>35</sup> U.S. CONST. amend. I.

<sup>36</sup> See Sherif Girgis, *Unfinished Liberties, Inevitable Balancing*, 125 COLUM. L. REV. 531, 575–76 (2025); see also Stephanie H. Barclay, *Replacing Smith*, 133 YALE L.J. F. 436, 438–39 (2023) (“[F]ree-exercise rights (like any other rights) as a conceptual matter can receive two types of doctrinal protections: (1) presumptive protection (a rebuttable presumption against government limitations that can be overcome when the government makes the requisite showing), or (2) absolute protection (a no-limits rule wherever the rights-holder demonstrates his or her relevant activity falls within the scope of the right).”).

<sup>37</sup> See Elizabeth A. Clark, *A Non-Categorical Approach to Free Exercise Rights*, 98 NOTRE DAME L. REV. REFLECTION 124, 128 (2023) (proposing a flexible framework to better assess whether government conditions infringe religious exercise); Note, *Constitutional Constraints on Free Exercise Analogies*, 134 HARV. L. REV. 1782, 1782 (2021) (criticizing various courts’ analogical approach to COVID-19 restriction cases as legally unpredictable and potentially violative of the Free Exercise protections).

<sup>38</sup> See Zalman Rothschild, *Individualized Exemptions, Vaccine Mandates, and the New Free Exercise Clause*, 131 YALE L.J. F. 1106, 1114 (2022) (using the COVID-19 vaccine exemption cases to demonstrate how “a new Free Exercise Clause” that views free exercise “as an expansive equality right,” drastically expands the reach of this protection); see also Christopher C. Lund, *Second-Best Free Exercise*, 91 FORDHAM L. REV. 843 (2022) (examining how the Roberts Court has continuously expanded the Free Exercise Clause by permitting religious exemptions in numerous cases).

George Washington said that “[t]he liberty enjoyed by the People of these States, of worshipping Almighty God agre[e]able to their Consciences, is not only among the choicest of their Blessings, but also of their Rights.”<sup>39</sup> James Madison defended a fierce protection of religious liberty in the Federalist Papers by arguing that although “Liberty is to faction what air is to fire,” such freedom to disagree (about religion or any matter) must not be abolished because it would fuel the flames of factions.<sup>40</sup> Finally, George Washington’s Farewell Address contained the following statement, likely penned by his Secretary of the Treasury and overall “Right Hand Man,”<sup>41</sup> Alexander Hamilton:<sup>42</sup> “Of all the dispositions and habits which lead to political prosperity, religion and morality are indispensable supports.”<sup>43</sup> Evidently, religion has been a key part of one’s overall wellness since the Founding, long before anyone publicized diagrams for wellness wheels or worked on their own wellness goals in therapy.

For me, religion is not merely a theoretical piece of an abstract wellness puzzle. My faith, religious beliefs, and practices are at the heart of my personal wellness. I am a member of The Church of Jesus Christ of Latter-day Saints, and I have held these beliefs my entire life, even before my official baptism on my eighth birthday. One of our Articles of Faith resonates with the First Amendment’s Free Exercise Clause, stating: “We claim the privilege of worshiping Almighty God according to the dictates of our own conscience, and allow all men the same privilege, let them worship how, where, or what they may.”<sup>44</sup> Thus, from a religious and constitutional standpoint, I have always believed in the sacred right of free agency concerning religious practices.

My story may seem static, but it is not. I wake up every morning on a faith journey; I try to make good choices because I believe they will lead me to happiness; when I make mistakes, I try to repent often and, in so doing, return back to God. With so much daily sadness and pain in the world and in my own life, it is my faith in our Savior Jesus Christ that helps me get out of bed most mornings. Without the fundamental belief that Jesus saved me and that through His Atonement I can change for the better, I would not be well.

And for me, my spiritual wellness extends beyond organized religion and can be found through personal prayer. Prayer is important if only for the simple

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<sup>39</sup> GEORGE WASHINGTON, *Letter from George Washington to the Society of Quakers*, in THE PAPERS OF GEORGE WASHINGTON 266 (W.W. Abbot & Dorothy Twohig eds., Univ. Press of Va. 1993) (1789).

<sup>40</sup> THE FEDERALIST NO. 10, at 58 (James Madison) (Jacob E. Cook ed., 1961) (“Liberty is to faction what air is to fire, an aliment without which it instantly expires. But it could not be less folly to abolish liberty, which is essential to political life, because it nourishes faction, than it would be to wish the annihilation of air, which is essential to animal life, because it imparts to fire its destructive agency.”).

<sup>41</sup> LIN-MANUEL MIRANDA, *Right Hand Man*, on Hamilton: An American Musical (CD, Atlantic Records Sep. 25, 2015).

<sup>42</sup> ALEXANDER HAMILTON, *Draft of George Washington’s Farewell Address* (July 1796), in ALEXANDER HAMILTON PAPERS: SPEECHES AND WRITINGS FILE, <https://www.loc.gov/item/mss246120240/>.

<sup>43</sup> GEORGE WASHINGTON, *Farewell Address* (Sept. 19, 1796), in WRITINGS OF GEORGE WASHINGTON 214 (Fitzpatrick & Matteson eds., U.S. Gov. Printing Office 1940) (1796).

<sup>44</sup> The Pearl of Great Price, *supra* note 6.

truth that Mark Twain's fictional character Huck Finn realized when he found himself incapable of praying for his friend Jim's recapture into slavery:

I was trying to make my mouth *say* I would do the right thing and the clean thing [in turning in Jim to his enslaver, Miss Watson] . . . but deep down in me I knowed it was a lie—and He knowed it. You can't pray a lie—I found that out.<sup>45</sup>

In other words, achieving a sense of spiritual and religious wellness through prayer has the added benefit of integrity and honesty to oneself. Huck could not bring himself to turn Jim in because he knew it was not the “right” or the “clean” thing, whatever society may be telling him in the early Nineteenth Century; he could not pray the lie or carry it out. Like in Huck's case, prayer helps me reach an honest answer talking to God even when I am struggling to be honest with myself.

It is this personal reflection on my own core wellness makeup that prompted this Essay. Realizing how much my own wellness leans on the twin pillars of organized religion and personal prayer, I felt strongly that this perspective ought to be aired. In my view, workplace wellness programs and wellness law in general are woefully incomplete if they forget to factor in the spiritual wellness that is critical for me and so many others. If you cannot pray a lie, you can honestly reflect on what needs work in all the wellness areas of your wholeness wheel.

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<sup>45</sup> TWAIN, *supra* note 1, at 269.

# SHOULD ALL ENTRY POINTS TO WELLNESS BE REGULATED EQUALLY? WHAT MAPPING EXISTING AND EMERGING ENTRY POINTS REVEALS

Tanya E. Karwaki\*

## I. INTRODUCTION

Americans are interested in wellness, with 84% of Americans prioritizing wellness in their daily lives.<sup>1</sup> Described as a “lifestyle,”<sup>2</sup> wellness services and products come in many forms. Many of these services, such as fitness wearables, meditation, and mobile device application sleep trackers are familiar to Americans. IV wellness therapies, delivering vitamins and supplements via an intravenous needle, are also popular, helped, in part by celebrities like Madonna and Gwyneth Paltrow.<sup>3</sup> Wellness tourism, incorporating established wellness routines into travel or providing an opportunity for refocusing on health and wellness, is a growing sector of the wellness industry.<sup>4</sup> Yet other components of the wellness industry, such as brain wellness clinics, where individuals may use psychedelic drugs as treatment, are in their infancy.<sup>5</sup> Regardless of which particular wellness services

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<sup>1</sup> *The \$2 Trillion Global Wellness Market Gets a Millennial and Gen Z Glow-up*, MCKINSEY & CO. (May 29, 2025), <https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/future-of-wellness-trends>.

<sup>2</sup> *E.g., Trending - Understanding Health, Wellness, and Medicine*, MICH. STATE UNIV. (Mar. 4, 2025), <https://cris.msu.edu/news/dietary-supplements/trending-understanding-health-wellness-and-medicine/>.

<sup>3</sup> Sara Youngblood Gregory, *IV Vitamin Therapy: Understanding the Lack of Proven Benefit and Potential Risks of This Health Fad*, MAYO CLINIC (Oct. 3, 2024), <https://mcpres.mayoclinic.org/living-well/iv-vitamin-therapy-understanding-the-lack-of-proven-benefit-and-potential-risks-of-this-health-fad/> (describing the risks and benefits of IV vitamin therapy); *see also* Jennifer L.W. Fink, *Medical Spas and Wellness IV Therapy*, 125 AM. J. NURSING 18 (2025) (describing the use of wellness IV therapy to “increase energy, aid weight loss, ease hangovers, improve immunity, and boost beauty.”).

<sup>4</sup> *See* Roger Sands, *Global Wellness Tourism Surges Toward the \$1 Trillion Mark*, FORBES (Jan. 17, 2025, 7:46 AM), <https://www.forbes.com/sites/rogersands/2025/01/16/global-wellness-tourism-surges-toward-the-1-trillion-mark/> (estimating that the global wellness tourism market will increase over 100% between 2022 and 2028); *see also* Alana K. Dillette et al., *Dimensions of Holistic Wellness as a Result of International Wellness Tourism Experiences*, 24 CURRENT ISSUES TOURISM 794, 796 (2021) (contrasting wellness tourism, or staying at a facility specifically aimed at contributing to one’s wellness journey that healthy people proactively engage in to improve their wellness with medical tourism that ill individuals reactively engage in to receive high quality care at a lower price).

<sup>5</sup> Anna Wexler & Dominic Sisti, *Brain Wellness “Spas” – Anticipating the Off-Label Promotion of Psychedelics*, 79 JAMA PSYCHIATRY 748 (2022) (anticipating the creation of brain wellness “spas” where psychedelic drugs may be used by individuals).

or products an individual uses, Americans demonstrate a growing demand for wellness and a world where they may feel “seen” rather than scolded.<sup>6</sup>

Broadly, “wellness can be defined as ‘the active pursuit of activities, choices, and lifestyles that lead to a state of holistic health.’”<sup>7</sup> As the wellness movement continues growing, organizations and scholars are distinguishing wellness from health. For instance, the Wellness Alliance defines wellness as “functioning optimally within your current environment.”<sup>8</sup> In order to “thrive amidst life’s challenges,” individuals should focus on the six dimensions of wellness: emotional, physical, intellectual, occupational, spiritual, and social.<sup>9</sup> Overall, wellness is associated with living one’s best life<sup>10</sup> and is characterized by a strong element of personal striving for wellness.<sup>11</sup>

McKinsey and Company report that the American wellness market is worth \$500 billion in annual spending and growing approximately 4-5% a year.<sup>12</sup> The younger generations are more likely to spend money on wellness products and services.<sup>13</sup> Millennials and Generation Z-ers make up 36% of the United States’ (U.S.) adult population, but they account for over 41% of the annual spending on wellness.<sup>14</sup> In contrast, the 35% of the U.S. adult population that is fifty-eight years of age or older drives only 28% of wellness spending.<sup>15</sup>

The wellness movement is growing in America, and while scholars are analyzing various components of the wellness environment, such as professional standards for wellness practitioners<sup>16</sup> and trade-offs in insurance wellness programs,<sup>17</sup> there is little scholarship on the entry points individuals use to enter the wellness space.<sup>18</sup> Entry points matter because different motivators reflect different needs that individuals hope to have met by entering the wellness space. While the wellness industry may meet some individuals’ needs, perhaps helping them become more physically active, the wellness industry may not fully meet

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<sup>6</sup> Elaine Godfrey, *The Wellness Women Are on the March*, ATLANTIC (Dec. 13, 2024), <https://www.theatlantic.com/politics/archive/2024/12/wellness-rfk-washington/680977/>.

<sup>7</sup> Bradley McDaniels et al., *A Prescription for Wellness in Early PD: Just What the Doctor Ordered*, 36 J. GERIATRIC PSYCHIATRY & NEUROLOGY 461, 463 (2023) (citing *What Is Wellness?*, GLOB. WELLNESS INST., <https://globalwellnessinstitute.org/what-is-wellness/> (last visited Feb. 6, 2026)).

<sup>8</sup> *Wellness Defined*, WELLNESS ALL., <https://wellnessalliance.org/resources-and-tools/wellness-defined> (last visited Feb. 6, 2026).

<sup>9</sup> *Six Dimensions of Wellness*, WELLNESS ALL., <https://nationalwellness.org/resources/six-dimensions-of-wellness/> (last visited Feb. 6, 2026).

<sup>10</sup> Barbara J. Zabawa, *Defining the Field of Wellness Law*, 53 HOFSTRA L. REV. 491, 498 (2025).

<sup>11</sup> *Id.*

<sup>12</sup> MCKINSEY & CO., *supra* note 1, at 2.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 4.

<sup>15</sup> *Id.*

<sup>16</sup> See generally Barbara J. Zabawa, *No More Wild West: The Need for Wellness Professional Standards*, 50 AM. J.L. & MED. 74 (2024) (proposing a private standard for regulating wellness industry professionals instead of existing methods of licensure).

<sup>17</sup> See generally Anya E.R. Prince, *Hidden Trade-offs in Insurance Wellness Programs*, 2021 MICH. ST. L. REV. 341 (2021) (arguing for insurance regulations to provide baseline standards).

<sup>18</sup> Zabawa, *supra* note 16, at 78-79 (describing, briefly, who uses wellness products and why).

others' needs, such as those seeking Lyme disease treatment.<sup>19</sup> Examining existing entry points, as well as foreseeable new entry points catalyzed by the Make America Health Again (MAHA) movement's approach to health and wellness,<sup>20</sup> points to the need for a broader policy discussion considering whether to encourage or discourage specific entry points.

This Article, in Part II, identifies and categorizes the existing prime entry points into wellness. These entry point categories are a self-driven decision, through culture, as part of, or in response to, our health care delivery system, or through a wellness program. Part III considers the MAHA movement's position and its likely creation of new entry points into wellness. Some of these new entry points may include dietary modifications, such as organic diets and raw milk consumption, and natural immunity rather than vaccination. Finally, Part IV advocates for policy choices either supporting or discouraging entry points into wellness, rather than only regulating the wellness industry. Such an approach permits a more nuanced approach to regulation, ideally helping to relieve some of the tension between health and wellness and better aligning individual needs with appropriate resources.

## II. CURRENTLY: IDENTIFYING AND CATEGORIZING KEY EXISTING ENTRY POINTS INTO WELLNESS

There is no single entryway for individuals seeking wellness products and services. For instance, an individual could attend a wedding incorporating wellness into the celebration,<sup>21</sup> receive a direct-to-consumer (DTC) genetic test as a gift,<sup>22</sup> or participate in a university's summer Passport to Wellbeing challenge.<sup>23</sup> The "wellness curious" could take a wellness retreat that includes wellness activities

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<sup>19</sup> Sara Berg, *Lyme Disease Misinformation has Physicians Searching for Guidance*, AM. MED. ASS'N (Jan. 12, 2023), <https://www.ama-assn.org/delivering-care/public-health/lyme-disease-misinformation-has-physicians-searching-guidance> (describing how some patients spend "thousands of dollars on extensive testing and unproven treatments and are still experiencing debilitating symptoms.").

<sup>20</sup> Pamela Herd, *MAHA Will Not Make Americans Healthy Again: The Politicization of U.S. Federal Health Agencies During the Second Trump Administration*, 51 J. HEALTH POL., POL'Y & L. 261 (2026) (describing the MAHA movement's prioritization of individual responsibility for health, rejection of existing scientific research on public health efforts such as vaccines, and alignment with the wellness industry).

<sup>21</sup> E.g., Sarah Lyon, *Starting a New Life Together, With Wellness Top of Mind*, N.Y. TIMES (Apr. 3, 2025, 5:00 AM), <https://www.nytimes.com/2025/04/03/style/wellness-mindfulness-wedding.html> (listing different types of available wellness elements welcome bags containing vitamin supplements and events such as "candlelit floating sound baths, acupuncture happy hours . . . spiritual growth sessions, botanical tea making and strength-training workshops.").

<sup>22</sup> See David Olmos, *Received an At-Home DNA Test as a Holiday Gift? Proceed with Caution*, UNIV. CAL. (Jan. 10, 2018), <https://www.universityofcalifornia.edu/news/received-home-dna-test-holiday-gift-proceed-caution>.

<sup>23</sup> See e.g., *Passport to Well-Being: Let Your Wellness Journey Take Flight This Summer*, UNIV. WASH.: WHOLE U (June 9, 2025), <https://thewholeu.uw.edu/2025/06/09/passport-to-well-being-the-whole-u-summer-wellness-challenge/> (exploring four wellness destinations: mental health, physical activity, connection, and nourishment, and earn miles and stamps for your wellness passport at the University of Washington).

and travel adventure.<sup>24</sup> Alternatively, an individual could attend a wellness event such as the “Well Festival” held by the New York Times in May 2025.<sup>25</sup> Although there are many different possible entry points into wellness, this Part categorizes the primary existing entry points based on whether an individual enters only solely of their own volition and autonomy, as part of their culture, as part of, or in response to, the health care delivery system, or through a discrete wellness program. The entry points described and categorized in this Part are not intended to be exhaustive, rather they are some of the key ways individuals enter the wellness space.

### A. A Self-Driven Decision

Many individuals make a self-driven, autonomous decision to improve their wellness and so enter the wellness space seeking services and products to help them in their endeavors. Such individuals may track their wellness through wearables, purchase IV wellness therapies, or participate in wellness tourism, among other activities. These individuals are, as Barbara Zabawa describes, “seeking self-actualization”<sup>26</sup> so that they may live their “best life.”<sup>27</sup> And the wellness space may provide what they seek. This may be greater personalization or more time with practitioners. Wearables and other technologies might help an individual work more successfully towards their individual wellness goals.

Artificial intelligence (AI),<sup>28</sup> neurotechnology, and DTC genetics, technologies personalizing an individual’s journey towards wellness, are likely to fuel significant growth in the number of individuals embarking on a self-driven pathway towards wellness. AI and neurotechnology are already part of the consumer personal wearables market.<sup>29</sup>

Many DTC genetic tests and services are marketed as part of wellness. For example, nutrigenetic DTC genetic tests provide diet and lifestyle advice to the test-

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<sup>24</sup> Sands, *supra* note 4.

<sup>25</sup> *The Well Festival*, N.Y. TIMES (May 7, 2025), <https://www.nytimes.com/events/wellfestival#overview> (inviting people to join “for a day of live journalism about living your healthiest life . . . diving deep into topics from sleep and nutrition to happiness and aging.”).

<sup>26</sup> Zabawa, *supra* note 10, at 491.

<sup>27</sup> *Id.* at 498.

<sup>28</sup> See Ramanakar Reddy Danda, *Generative AI for Enhanced Engagement in Digital Wellness Programs: A Predictive Approach to Health Outcomes*, 33 J. COMPUTATIONAL ANALYSIS & APPLICATIONS 788, 788 (2024); see also Yadong Chen et al., *Transforming Health and Wellness: Exploring the Captivating Convergence of Rehabilitation, Exercise, and Cutting-edge Health Gadgets in the Rapidly Evolving Tech-driven World*, 81 TECH. SOC’Y 7 (2025) (describing personalized virtual reality workouts that engage the user, making exercise more enjoyable); see generally e.g., AESCAPE, <https://app.aescape.com> (last visited Feb. 6, 2026) (describing how individuals in several parts of the U.S., including some New York City fitness gyms, can now locate and book a massage from an AI-powered massage table).

<sup>29</sup> See e.g., Kate Irwin, *Fitbit Using Google Gemini for New AI That Could Become Your Fitness Coach*, PC MAG. (Mar. 19, 2024), <https://www.pcmag.com/news/fitbit-using-google-gemini-for-new-ai-that-could-become-your-fitness-coach>; see Jeremy Ben Merkelson et al., *Neurotechnology Works Its Way Forward*, 48 SEATTLE U. L. REV. ONLINE 57, 63-64 (2025) (listing personal wellness wearables already using neurotechnology such as sleep monitoring headbands, headsets increasing focus, and goggles balancing the left and right sides of the brain to lessen chronic pain).

taker.<sup>30</sup> Other companies, such as 10X HealthSystem offer genetic testing to determine one's "current well-being."<sup>31</sup> Consumers can purchase a precision genetic test to discover what diet and workout plan will work for them.<sup>32</sup> For individuals who have already received their DNA data from a vendor such as 23andMe, Ancestry, or Family Tree DNA Analysis, their DNA data can be uploaded to LifeDNA to begin their "wellness transformation" with "personalized insights."<sup>33</sup> A "13 Methylation Genes Report plus Wellness Test Bundle" can be ordered, including seven reports: nutrition, vitamins, wellness, fitness, sleep, skincare, and personality and cognition.<sup>34</sup> Individuals on a self-driven pathway towards wellness, however, are not alone, there are other entry ways into wellness.

## B. Culture and Wellness

Individuals may embark on a pathway to wellness as part of their culture and heritage. For instance, those in and from the Mediterranean region may adhere to a Mediterranean diet.<sup>35</sup> Additionally, Indigenous peoples may enter the wellness space as part of their cultural practices.

Indigenous peoples have been described as having a spiritual desire to "live life to the fullest,"<sup>36</sup> which is similar to individuals in the wellness world being described as wanting to live their "best life."<sup>37</sup> Indigenous peoples holistic understanding of health and wellness "seeks balance between the physical, mental, emotional, and spiritual aspects of an Indigenous person in reciprocal relationships with their families, communities, the land, the environment, their ancestors, and future generations."<sup>38</sup> As one member of the Menominee Wellness Initiative, which works to promote the health and wellness of the Menominee Nation members, stated, "culture is prevention," particularly with respect to the

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<sup>30</sup> See Sarah Duranske, *This Article Makes You Smarter! (Or, Regulating Health and Wellness Claims)*, 43 AM J.L. & MED. 7, 11, 17 (2025) (presenting the example, DNAFit, providing nutrition and fitness information).

<sup>31</sup> *Genetic Testing*, 10XHEALTH, <https://10xhealthsystem.com/genetest/> (last visited Feb. 6, 2026) (appealing to potential purchasers that "[i]f you're seeking to improve your wellbeing or elevate your wellness, then you MUST take this test.").

<sup>32</sup> *Precision Genetic Testing*, 10XHEALTH, <https://10xhealthsystem.com/precision-genetic-testing/> (last visited Feb. 6, 2026).

<sup>33</sup> *Discover The Ultimate DNA Testing for Methylation and Complete Wellness*, LIFE DNA, <https://lifedna.com> (last visited Feb. 6, 2026).

<sup>34</sup> *Unlock Deep Insights Into Your MTHFR Gene, Methylation, And Overall Wellness*, LIFE DNA, <https://lifedna.com/plans> (last visited Feb. 6, 2026).

<sup>35</sup> See Anka Trajkovska Petkoska et al., *Mediterranean Diet: From Ancient Traditions to Modern Science – A Sustainable Way Towards Better Health, Wellness, Longevity, and Personalized Nutrition*, 17 SUSTAINABILITY 4187 (2025), <https://www.proquest.com/docview/3203263824/fulltextPDF/DE87A9A9881944B3PQ/1?accountid=14589&source=Scholarly%20Journals>.

<sup>36</sup> Udoka Okpalauwaekwe et al., *Enhancing Health and Wellness By, For and With Indigenous Youth in Canada: A Scoping Review*, 22 BMC PUB. HEALTH 1, 23 (2022) (quoting Elder Jim Dumont).

<sup>37</sup> Zabawa, *supra* note 10, at 498.

<sup>38</sup> Okpalauwaekwe et al., *supra* note 36, at 2.

Menominee youth.<sup>39</sup> In Canada, Makoyoh'sokoi, or Wolf Trail, focuses on the health and wellness needs of Indigenous women, prioritizing cultural safety.<sup>40</sup>

### C. As Part of, or in Response to, the Health Care Delivery System

The health care delivery system and health care providers themselves may influence an individual to begin on a pathway towards wellness. Individuals may enter the wellness space through interactions with the health care delivery system either as part of the services provided within the health care delivery system or in response to not receiving the care they hoped for from the health care delivery system or a health care provider.

#### 1. As Part of the Healthcare Delivery System

Individuals may enter the wellness environment as part of their engagement with the health care delivery system. For instance, an individual may choose to have a Medicare annual wellness visit, work with a health and wellness coach, or fill a social prescription. When seeking wellness services and products, individuals may be influenced by their health care providers. This influence may be the result of a trusting provider-patient relationship in which the individual values their provider's recommendations of a given wellness service or product.<sup>41</sup> Millennials and Generation Z-ers, often more digitally savvy, may seek wellness advice from a health care provider, but they are also more likely to be influenced by social media than other generations.<sup>42</sup> Moreover, some wellness influencers are physicians,<sup>43</sup> which may further influence individuals considering a wellness service or product.

##### a. Medicare Annual Wellness Visits

Participating in an available Medicare benefit, a Medicare annual wellness visit, is one way numerous Medicare beneficiaries enter the wellness space. Since

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<sup>39</sup> Amy Hilgendorf et al., *Language, Culture, and Collectivism: Uniting Coalition Partners and Promoting Holistic Health in the Menominee Nation*, 46 HEALTH EDUC. & BEHAV. 81S, 84S (describing how cultural identity helped youth be proud of their heritage); see also Jodi D. Barnett et al., *A Pilot Evaluation of Culture Camps to Increase Alaska Native Youth Wellness*, 21 HEALTH PROMOTION PRAC. 363 (2020) (evaluating youth culture camps' impact on increasing wellness among Alaska native youth).

<sup>40</sup> Levi Fehlich et al., *Spread of Makoyoh'sokoi (Wolf Trail) a Community Led, Physical Activity-based, Holistic Wellness Program for Indigenous Women in Canada*, 42 J. HEALTH, POPULATION & NUTRITION 1, 2 (2023).

<sup>41</sup> See *What Is the Future of Wellness?*, MCKINSEY & CO. 1, 2 (Nov. 20, 2024), <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-the-future-of-wellness#/>.

<sup>42</sup> MCKINSEY & CO., *supra* note 1, at 7 (categorizing Gen Z and millennials as maximalist optimizers, who will research and experiment with wellness product to find what works well for them).

<sup>43</sup> See Rachel O'Neill, *Rethinking the 'Wellness Influencer': Medical Doctors, Lifestyle Expertise and the Question of Credentials*, INT'L J. CULTURAL STUD. 1, 685, 687 (2025) (analyzing three prominent UK wellness influencers who are also physicians).

the passage of the Affordable Care Act (ACA), Medicare covers an annual optional wellness visit for Medicare beneficiaries.<sup>44</sup> Every year Medicare beneficiaries, who are beyond their first year of Medicare enrollment, may have a wellness visit without copayment.<sup>45</sup> As part of this visit, the health care provider supplies personalized referrals to educational services or programs promoting wellness in areas such as nutrition, physical activity, tobacco-use cessation, social engagement, and weight loss.<sup>46</sup> With 45% of Medicare beneficiaries living in the community in 2020 having a wellness visit,<sup>47</sup> this type of visit may be a significant entry point into the wellness space for Medicare beneficiaries.

### b. Health and Wellness Coaching

As of 2024, health and wellness coaching,<sup>48</sup> estimated to be a \$4.89 billion industry in the U.S., is expected to increase to \$9.45 billion by 2034,<sup>49</sup> and is attractive to many individuals seeking wellness. Health and wellness coaches motivate and empower individuals to “achieve long-term positive behavior changes through self-discovery and meaningful goal setting.”<sup>50</sup> These coaching sessions, may be for an individual or a group.<sup>51</sup> Regardless of the individual or group format, health and wellness coaches provide time and guidance for individuals making lifestyle choices; time that typically cannot be allocated by a health care provider.<sup>52</sup> For instance, while a primary care physician may only spend 13-16 minutes with a patient,<sup>53</sup> a health and wellness coaching session may last 30 to 60 minutes. A 4-year retrospective study evaluating the impact of providers prescribing health and wellness coaching using an integrated clinical workflow

<sup>44</sup> Cf. Annual Wellness Visits Providing Personalized Prevention Plan Services: Conditions for and Limitations on Coverage, 42 C.F.R. 410.15 (2024).

<sup>45</sup> Kimberly E. Lind et al., *Persistent Disparities in Medicare’s Annual Wellness Visit Utilization*, 57 MED. CARE 984 (2019) (presenting a brief history of the Medicare Annual Wellness Visit).

<sup>46</sup> See Annual Wellness Visits Providing Personalized Prevention Plan Services: Conditions for and Limitations on Coverage, 42 CFR 410.15(a)(ix) (2024).

<sup>47</sup> Medicare Current Beneficiary Survey, *Preventive Care Among the Medicare Population*, CTRS. MEDICARE & MEDICAID SERVS. (Sept. 2023), <https://www.cms.gov/files/document/mcbs-use-preventive-care-services-infographic.pdf>.

<sup>48</sup> See generally Kasey R. Boehmer et al., *The Impact of Health and Wellness Coaching on Patient-Important Outcomes in Chronic Illness Care: A Systematic Review and Meta-Analysis*, 117 PATIENT EDUC. & COUNSELING 1, 2, 3 (2023) (explaining how health and wellness coaching is becoming the standard term for what has previously been termed “health coaching,” “life coaching,” and “wellness coaching”).

<sup>49</sup> *Health Coach Market Size, Share, and Trends 2024 to 2034*, PRECEDENCE RSCH. (Oct. 22, 2024), <https://www.precedenceresearch.com/health-coach-market>.

<sup>50</sup> Dustan Watkins et al., *Successful Coaching Behaviors: Challenges and Opportunities in Relationships*, AM. J. LIFESTYLE MED. 1, 1 (2025).

<sup>51</sup> E.g., Ruth Q. Wolever et al., *Group Health & Wellness Coaching: Development and Validation of the Required Competencies*, 24 BMC HEALTH SERV. RES. 1 (2024) (developing and validating competencies for group health and wellness coaching).

<sup>52</sup> See Abd Moain Abu Dabrh et al., *Health & Wellness Coaching Services: Making the Case for Reimbursement*, AM. J. LIFESTYLE MED. 1, 2 (2024) (estimating that individuals spend about 5000 hours per year making independent lifestyle choices).

<sup>53</sup> Debra Wood, *Average Time Doctors Spend with Patients*, AMN HEALTHCARE (June 23, 2023), <https://www.amnhealthcare.com/blog/physician/locums/average-time-doctors-spend-with-patients/>.

found improved patient engagement and successful completion of coaching programs.<sup>54</sup> Such success may encourage an individual to continue their wellness journey.

### c. Social Prescriptions for Wellness

Social prescribing practices also provide a means for individuals to enter the wellness space. Social prescribing is an innovative method<sup>55</sup> for health care providers to encourage the building of community relationships which in turn may improve an individual's health and wellness.<sup>56</sup> These social prescriptions may be for community-based classes like boxing, yoga, cycling and dancing,<sup>57</sup> an organized nature program,<sup>58</sup> an art or cultural outing<sup>59</sup> or other activity. Some social prescriptions target loneliness, which may contribute to depression or other mental health concerns.<sup>60</sup> Using social prescribing, health care providers align patients with resources aimed at building community connections and improving patient health and wellness.<sup>61</sup>

These prescriptions may direct the patient to act on their own resources, such as walk, or engage with a wellness mobile device application, or use a health care system's internal resources, such as physical therapy, or a wellness program, or use external resources like a community center or gym.<sup>62</sup> One social prescription service, "Exercise is Medicine," measures an individual's physical activity at every healthcare encounter and uses this information to prescribe physical activity.<sup>63</sup> Another type of social prescribing is nature prescribing, where health care providers use a "nonpharmacologic intervention to encourage patients to spend time in nature."<sup>64</sup> Other social prescriptions may provide access to a wellness

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<sup>54</sup> See Michael D. Parkinson et al., *Impact of Physician Referral to Health Coaching on Patient Engagement and Health Risks: An Observational Study of UPMC's Prescription for Wellness*, 34 AM. J. HEALTH PROMOTION 366 (2020).

<sup>55</sup> Note that other innovative prescription programs such as a fresh food prescription program, delivering produce and meals to individuals living in under-resourced communities are reported to also improve participants' physical and financial well-being, mental health, and decrease participants' feelings of loneliness. See, e.g., Rachel Zimmer et al., *Exploring Perceptions of a Fresh Food Prescription Program during COVID-19*, 19 INT'L J. ENV'T RES. & PUB. HEALTH 1 (2022).

<sup>56</sup> McDaniels et al., *supra* note 7.

<sup>57</sup> See e.g., *id.* at 465.

<sup>58</sup> Christina Rariden & Alison Kuhn, *An Introduction to Nature Prescribing: Health Benefits of Nature*, 20 J. NURSE PRAC. 1, 2 (2024).

<sup>59</sup> Michele Cohen Marill, *A Promising Prescription for Older Adults: Social Connection*, 44 HEALTH AFF. 518, 520 (2025).

<sup>60</sup> McDaniels et al., *supra* note 7, at 463.

<sup>61</sup> *Id.* at 465.

<sup>62</sup> Kelly R. Ylitalo, *A Prescription for Wellness: Exercise Referrals at a Federally Qualified Health Center*, 11 J. PRIMARY CARE & CMTY. HEALTH 1, 2 (2020).

<sup>63</sup> *Id.* (Analyzing the effect of prescriptions to a federally qualified health center's Wellness Center, designed to support an individual's physical activity and reduce barriers to physical activity for those living in an exercise desert).

<sup>64</sup> Rariden & Kuhn, *supra* note 58, at 2.

resource at no cost to the individual. For instance, Art Pharmacy, is used to prescribe “a dose of arts and culture every month for twelve months.”<sup>65</sup>

By “filling” a social prescription, and engaging in the prescribed activity, individuals may improve their wellness through increased physical activity and greater social supports, potentially lowering the risk of diabetes, coronary heart disease and stroke,<sup>66</sup> as well as the risk of depression and anxiety.<sup>67</sup> Social prescriptions should be tailored to each individual’s need and may have far-reaching benefits.<sup>68</sup> For instance, a community dancing class may increase an individual’s movement, as well as provide “social benefits and spiritual benefits, emotional benefits and cognitive benefits.”<sup>69</sup>

## 2. In Response to a Patient’s Negative Experience with the Health Care Delivery System or a Health Care Provider

Individuals may also enter the wellness space in response to not receiving the care they hoped for from the health care delivery system or a health care provider. One way this outcome may occur is if an individual does not like the short, often rushed, office visits they have with their primary care provider and opts to become a patient at a concierge practice. Another way this may occur is if an individual experiences dismissive medicine or medical gaslighting. Individuals generally distrustful of experts, particularly medical professionals,<sup>70</sup> may be more likely to respond to dismissive care by entering the wellness space.

### a. Concierge Practice

Concierge practices arose in the 1990s as patients and providers became increasingly frustrated with the long wait times for short visits experienced in the health care delivery system.<sup>71</sup> In a concierge practice, model patients pay a membership fee, or retainer, and in return they typically experience short wait times for appointments, such as same day or next-day appointments, and lengthier appointments, such as fifty minutes.<sup>72</sup> These lengthier appointments permit greater time for wellness promotion,<sup>73</sup> which most concierge practices include as part of

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<sup>65</sup> Marill, *supra* note 59, at 518.

<sup>66</sup> *Id.* at 518.

<sup>67</sup> McDaniels et al., *supra* note 7, at 465.

<sup>68</sup> Marill, *supra* note 59, at 520.

<sup>69</sup> *Id.*

<sup>70</sup> O’Neill, *supra* note 43, at 689 (summarizing some scholars arguments that the “popularity of wellness influencers symptomizes widespread mistrust of experts generally and medical professionals especially.”).

<sup>71</sup> Brian Eastwood, *What Is Concierge Medicine? How Does It Improve Outcomes?*, HEALTH TECH (Dec. 27, 2022), <https://healthtechmagazine.net/article/2022/12/concierge-medicine-creates-better-patient-outcomes-perfcon>.

<sup>72</sup> James Stathopoulos, *Concierge Medicine: Quality Care for a Price*, 19 ANNALS HEALTH L. ADVANCE DIRECTIVE 155, 156-61 (2010).

<sup>73</sup> Salman Alhawshani & Safeer Khan, *A Literature Review on the Impact of Concierge Medicine Services on Individual Healthcare*, 13 J. FAMILY MED. PRIMARY CARE 2183, 2184 (2024).

their services. This may take the form of a wellness program,<sup>74</sup> or an individualized wellness plan,<sup>75</sup> an emphasis on diet and lifestyle changes,<sup>76</sup> or a focus on longevity.<sup>77</sup> In some practices, all the team members are trained health and wellness coaches in order to provide sustainable support to patients working to achieve their wellness goals.<sup>78</sup>

Concierge practices are currently a small part of the U.S. health care delivery system, with an estimated 1-2.5% of active physicians in the U.S. practicing in this type of care model.<sup>79</sup> However, the ability of a concierge practice to emphasize and work with individuals on wellness goals, makes this care model ripe for expansion as Americans' interest in wellness grows. This growth in wellness interest may occur across generations, including Baby Boomers, interested in preserving quality of life,<sup>80</sup> millennials, interested in long-term wellness,<sup>81</sup> and Generation Z, interested in improving their health, sleep and appearance.<sup>82</sup>

### b. Dismissive Care

Individuals may enter the wellness space after experiencing what they consider to be dismissive care. Patients describe dismissive providers as skeptical about the credibility of their illnesses, disregarding patient perspectives, and suggesting a psychological cause for symptoms.<sup>83</sup> Individuals may also feel dismissed if they believe their providers lack sufficient knowledge about treatment.<sup>84</sup>

Medical gaslighting, a type of dismissive medicine, occurs when patient experiences are “minimized, doubted, questioned, second-guessed, or outright denied.”<sup>85</sup> Medical gaslighting may have psychological implications as patients describe having self-doubts and questioning their own experience.<sup>86</sup> The diseases where medical gaslighting has been reported include inflammatory bowel disease, long COVID, and Lyme disease.<sup>87</sup> A study published in 2025 analyzing the medical gaslighting experiences of Black women in Canada, notes that as a result

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<sup>74</sup> E.g., MDVIP, <https://www.mdvip.com> (last visited Feb. 6, 2026).

<sup>75</sup> Dorthy Cohen Serna, *Lifestyle Medicine in a Concierge Practice: My Journey*, AM J. LIFESTYLE MED. 367, 368 (2019).

<sup>76</sup> E.g., *The AIM Metabolic Reset: Diet and Weightloss*, ALPINE INTEGRATED MED., <https://aim4healthnw.com/weight-loss/> (last visited Feb. 6, 2026).

<sup>77</sup> E.g., PARTNERMD, <https://www.partnermd.com> (last visited Feb. 6, 2026).

<sup>78</sup> E.g., Serna, *supra* note 75, at 368.

<sup>79</sup> See Eastwood, *supra* note 71 (describing the future outlook of the concierge medicine model).

<sup>80</sup> Eva Kahana & Boaz Kahana, *Baby Boomers' Expectations of Health and Medicine*, 16 VIRTUAL MENTOR 380, 380-384 (2014).

<sup>81</sup> Serna, *supra* note 75, at 369.

<sup>82</sup> MCKINSEY & CO., *supra* note 1, at 4.

<sup>83</sup> Gillie Gabay, *Dismissive Medicine and Gaslighting of Patients by Physicians – A Bioethics Lens*, 134 PATIENT EDUC. & COUNSELING 1, 1 (2025).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 1-2.

<sup>86</sup> *Id.* at 1.

<sup>87</sup> *Id.* at 2.

of these experiences, such women may seek alternate care.<sup>88</sup> While this study involved pregnant women who may not have sought wellness care as an alternative to medical care, it seems probable that in other situations an individual who believes they are being dismissed may turn to wellness care.

One area ripe for an individual's entry to wellness is women's health. Women with dysmenorrhea<sup>89</sup> or undergoing menopause may become frustrated with the lack of support from the health care system and turn to wellness services and products.<sup>90</sup> Yoga has been suggested for dysmenorrhea,<sup>91</sup> while some women approach menopause by taking a menopause retreat.<sup>92</sup> Some health and wellness coaches specialize in coaching women through menopause.<sup>93</sup> While further research is needed to determine the extent to which dismissive medicine may lead individuals to enter the wellness space, it is an entry point for some individuals.

#### D. Through a Wellness Program

Individuals may also enter the wellness space through different types of wellness programs. Employer sponsored wellness programs have been offered by employers for over 50 years.<sup>94</sup> But employers are not the only ones offering wellness programs, insurers also offer wellness programs to both group and individual beneficiaries.

Some individuals may enter the wellness space by participating in an employer sponsored wellness program. Employer sponsored wellness programs typically focus on lifestyle choices and "behaviors that individuals can theoretically control."<sup>95</sup> Some employers anticipate their wellness program will reduce the employer's health care costs by encouraging employees to learn and

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<sup>88</sup> Priscilla N. Boakye et al., *Anti-Black Medical Gaslighting in Healthcare: Experiences of Black Women in Canada*, 7 CANADIAN J. NURSING RSCH. 59, 66 (2025).

<sup>89</sup> Sara Sanchez-Lopez et al., *A Mixed Method Study of Menstrual Health in Spain: Pain, Disorders, and the Journey for Health*, FRONTIERS PUB. HEALTH 1, 1 (2025) (defining dysmenorrhea as "painful menstrual cramps of uterine origin . . . characterized by abdominal pain before or during menstruation.").

<sup>90</sup> See *id.* at 10 (reporting that some women with dysmenorrhea sought care from nutritionists); Jamie Cooper, *Examining Factors that Influence a Woman's Search for Information About Menopause Using the Socio-Ecological Model of Health Promotion*, 116 MATURITAS 73, 77 (2018) (reporting that some women found their primary care physician expertise "lacking in this area" and their gynecologist/obstetrician "was the least helpful person I spoke to and much less helpful than friends and web sources.").

<sup>91</sup> E.g., *Yoga for Period Pain*, NATIONWIDE CHILD.'S HOSP., <https://www.nationwidechildrens.org/family-resources-education/health-wellness-and-safety-resources/helping-hands/yoga-exercises-and-menstrual-cramps> (last visited Feb. 6, 2026).

<sup>92</sup> See e.g., Lilit Marcus, *Menopause Retreats Are the Next Big Thing in Wellness*, CNN: TRAVEL (July 17, 2024, 10:45 PM), <https://www.cnn.com/travel/menopause-retreats-hotels-spas-wellness>.

<sup>93</sup> *11 Different Types of Health Coaches Explained: From Weight Loss Coach to Emotional Wellness Coach*, HEALTHCOACHERY (Feb. 26, 2025), <https://www.healthcoachery.com/types-health-coaches/>.

<sup>94</sup> Kristin Madison, *Employer Wellness Incentives, the ACA, and the ADA: Reconciling Policy Objectives*, 51 WILLAMETTE L. REV. 407, 411 (2015) (detailing the history of employer wellness programs beginning with their rise in the 1980s).

<sup>95</sup> Prince, *supra* note 17, at 353.

maintain healthy behaviors.<sup>96</sup> Yet, personal responsibility and autonomy remain central to these employer sponsored wellness programs. An individual wanting to strive for wellness by working out in a gym may even proactively seek employment with an employer whose wellness program provides gym access.<sup>97</sup>

Other individuals may enter the wellness space through health, life, or long-term care insurers' wellness programs. These programs are like employer sponsored wellness programs but are available through an insurance plan and not tied to employment status.<sup>98</sup> Both group and individual health insurers may include wellness programs in their policies.<sup>99</sup> Policyholders may be offered discounts on vision needs, gym membership, and nutrition.<sup>100</sup> Wellness-linked life insurance policies encourage individual policyholders to adopt healthier lifestyles.<sup>101</sup> The incentives offered to promote wellness include premium adjustments or refunds,<sup>102</sup> options to earn a free or subsidized wearable,<sup>103</sup> discounts on wellness products,<sup>104</sup> as well as genetic testing.<sup>105</sup> Even long-term care insurers are increasingly including wellness programs.<sup>106</sup>

### III. IN THE SHORT-TERM: THE MAKE AMERICA HEALTH AGAIN MOVEMENT'S LIKELY EXPANSION OF ENTRY POINTS INTO WELLNESS

The MAHA movement will likely increase national interest and participation in the wellness movement. In addition to the existing entry points into wellness, it is likely that the MAHA movement, which emphasizes wellness, will create additional entry points into wellness. This Part analyzes the responsibilities and initial report of the MAHA Commission, created by executive order, and the role the U.S. Department of Health and Human Services (HHS) has taken in

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<sup>96</sup> Rachele M. Hendricks-Sturupp, *A Qualitative Study to Develop a Privacy and Nondiscrimination Best Practice Framework for Personalized Wellness Programs*, 10 J. PERSONALIZED MED. 1, 2 (2020) (qualitatively analyzing public and legislative stakeholders to determine key themes of promoting a culture of trust and wellness).

<sup>97</sup> *But see* Zabawa, *supra* note 10, at 528-29 (cautioning that by virtue of the employer functioning as an intervening authority and undercutting the individual's self-actualization, these programs are mislabeled as wellness).

<sup>98</sup> *See* Prince, *supra* note 17, at 344 (arguing for greater regulation to protect consumers participating in insurer wellness programs).

<sup>99</sup> *See id.* at 357.

<sup>100</sup> *See e.g., id.*

<sup>101</sup> An Chen & Stefan Schelling, *Exploring Health Improvement Incentives Through Wellness-Linked Products* 3, (July 29, 2024), <https://ssrn.com/abstract=4908866> (analyzing the viability of wellness-linked insurance products to align financial incentives with wellness behaviors).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> Prince, *supra* note 17, at 358.

<sup>105</sup> *Id.* at 359.

<sup>106</sup> *See* Nolan B. Tully & Jamie M. Campisi, *Long-Term Care Insurance: Wellness Program Impacts on Claims and Health Outcomes*, LEXISNEXIS: PRAC. GUIDANCE (2022), <https://www.faegredrinker.com/-/media/files/insights/pubs/2022/longterm-care-insurance-wellness-program-impacts-on-claims-and-health-outcomes.pdf?rev=ebaddf09ba8949f78cf3139525c28fc1>.

supporting the MAHA agenda.<sup>107</sup> It highlights the areas and examples where the MAHA movement will likely lead to new pathways into wellness.

### A. The MAHA Commission

In February 2025, President Trump issued Executive Order 14212 establishing a multiagency MAHA Commission (Commission).<sup>108</sup> Through this executive order, President Trump seeks to “ensure our healthcare system promotes health rather than just managing disease.”<sup>109</sup> Health, as it is used here, includes wellness as evidenced by the call for “fresh thinking on nutrition, physical activity, [and] healthy lifestyles.”<sup>110</sup> Moreover, all agencies addressing health or health care must “ensure the availability of *expanded treatment options* and the flexibility for health insurance coverage to provide benefits that support *beneficial lifestyle changes* and disease prevention.”<sup>111</sup> While no examples of “expanded treatment options” are provided, this could include treatment provided by wellness providers, both inside and outside of the traditional health care delivery system. And “beneficial lifestyle changes” implies a strong wellness component.

The Commission’s initial mission is to address childhood chronic diseases.<sup>112</sup> In carrying out its mission, the Commission was required to study the possible contributing causes to childhood chronic diseases including lifestyle, medical treatments, and diet.<sup>113</sup> And it must report on best practices preventing childhood health issues, such as “proper nutrition and the promotion of healthy lifestyles.”<sup>114</sup>

In May 2025, the Commission’s first report required under Executive Order 14212, the Make Our Children Healthy Again Assessment (Assessment) was published and began clarifying some of the MAHA movements links to wellness.<sup>115</sup> The Assessment found that childhood chronic diseases are likely driven by factors such as food, exposure to chemicals, medications, and “various changes to their lifestyle and behavior, particularly those related to physical activity, sleep and the use of technology.”<sup>116</sup> The Assessment emphasized the need for research on any correlation between childhood disease and the childhood vaccine schedule.<sup>117</sup> And the next steps detailed in the Assessment include calling

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<sup>107</sup> See, e.g., Matthew Mpoke Bigg, *Justice Department Drops Case Against Plastic Surgeon over Fake Covid-19 Cards*, N.Y. TIMES (July 13, 2025, 2:05 PM) (reporting the Justice Department’s dismissing charges against a physician accused of selling fake COVID-19 vaccine cards and stating the physician “gave his patients a choice when the federal government refused to do so.”).

<sup>108</sup> Exec. Order No. 14212, 90 Fed. Reg. 9833 (Feb. 19, 2025).

<sup>109</sup> *Id.* at 9834.

<sup>110</sup> *Id.* at 9833-34.

<sup>111</sup> Exec. Order No. 14212, *supra* note 108, at 9834.

<sup>112</sup> *Id.*

<sup>113</sup> *See id.*

<sup>114</sup> *Id.* at 9835.

<sup>115</sup> MAKE AMERICA HEALTHY AGAIN COMMISSION, THE MAHA REPORT: MAKE OUR CHILDREN HEALTHY AGAIN: ASSESSMENT 1 (May 22, 2025).

<sup>116</sup> *Id.* at 16.

<sup>117</sup> *See id.* at 63-64.

for a large-scale lifestyle intervention initiative addressing “movement, diet, light exposure, and sleep timing.”<sup>118</sup>

As evidenced by the Commission’s Assessment, and language in the Executive Order 14212, the Commission can be anticipated to maintain a strong focus on wellness. This focus may create additional entry points into wellness, as the MAHA movement wields its governmental and political powers encouraging individuals to pursue wellness. Beginning with children, this shift towards wellness will likely create new entry points into wellness, including dietary modifications, medication changes, and natural immunity.

### B. The U.S. Department of Health and Human Services

HHS broadcasts its support and commitment to the MAHA movement in the “Big Wins” section of its website,<sup>119</sup> which chronologically lists the MAHA “big wins” including phasing out petroleum-based dyes from food, updating dietary guidelines, and minimizing the risks of fluoride.<sup>120</sup> In addition to large scale reductions in workforce, consolidation of divisions, and reduction of regional offices, HHS has recently created the Administration for a Health America (AHA).<sup>121</sup> AHA combines existing agencies to focus on primary care, maternal and child health, mental health, environmental health, HIV/AIDS, and workforce development.<sup>122</sup>

Many elements of the MAHA movement resemble parts of the wellness movement. For instance, both movements may be skeptical, if not distrustful of mainstream medicine,<sup>123</sup> and both movements promote individual choices, like dietary choices,<sup>124</sup> and personal responsibility for health and wellness. The leaders of HHS, in particular, the Secretary of HHS, the Administrator of the Centers for

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<sup>118</sup> *Id.* at 72.

<sup>119</sup> *Celebrating Big Wins of the Trump Administration*, U.S. DEP’T. HEALTH & HUM. SERVS., <https://www.hhs.gov/hhs-big-wins-maha/index.html> (last visited Oct. 17, 2025).

<sup>120</sup> *Id.*

<sup>121</sup> *HHS Announces Transformation to Make America Healthy Again*, U.S. DEP’T HEALTH & HUM. SERVS. (Mar. 27, 2025), <https://www.hhs.gov/press-room/hhs-restructuring-doge.html>.

<sup>122</sup> *Id.*

<sup>123</sup> See Shiela McClear, *The Perilous Spread of the Wellness Craze*, ATLANTIC (May 29, 2025), <https://www.theatlantic.com/books/archive/2025/05/how-health-became-luxury-commodity/682957/> (available on Westlaw) (reviewing *How to Be Well: Navigating Our Self-Care Epidemic, One Dubious Cure at a Time*, a new book reveals how health-care inequality fueled the spread of anti-science conspiracy theories); Nicholas Florko, *The MAHA Takeover Is Complete*, ATLANTIC (May 8, 2025), <https://www.theatlantic.com/health/archive/2025/05/casey-means-surgeon-general-maha/682747/> (highlighting part of Dr. Means’ book, *Good Energy*, where she writes that people should not trust physicians “because the medical establishment makes more money when you are sick and does not understand how to treat the root causes of chronic disease.”).

<sup>124</sup> Alex McDonald, *MAHA Movement: Pseudoscience Over Evidence-Based Medicine*, PHYSICIAN’S WKLY. (May 26, 2025), <https://www.physiciansweekly.com/post/maha-sounds-good-but-thats-about-it>.

Medicare and Medicaid (CMS), and the Surgeon General, all demonstrate a focus on wellness that will likely catalyze new entry points into wellness.<sup>125</sup>

### 1. The Secretary of HHS

As HHS Secretary, Robert F. Kennedy, Jr. manages HHS, whose mission is “to enhance the health and well-being of all Americans.”<sup>126</sup> Kennedy, claiming familiarity with health from both a “conventional and alternative perspective,”<sup>127</sup> is working to align his knowledge with the public interest.<sup>128</sup> On the alternative health side of the equation, Kennedy favors governmental support of supplements and exercise.<sup>129</sup> He has an anti-vaccine stance, dismissing the entire CDC vaccine advisory panel in June 2025, stating it “has become little more than a rubber stamp for any vaccine.”<sup>130</sup> In addition to incorporating these beliefs into his HHS leadership role, Kennedy is also in a position to promote lifestyle changes rather than preventive services.

Under the ACA preventive care became accessible and affordable.<sup>131</sup> In *Kennedy v. Braidwood*,<sup>132</sup> the Court held that the Secretary of HHS can review and prevent or delay the U.S. Preventive Services Task Force (Task Force) recommendations from going into effect and requiring insurers to cover the services without cost sharing.<sup>133</sup> Justice Kavanaugh specified ways that the Secretary of HHS could stop a Task Force recommendation from being covered. These include removing and replacing Task Force members who refuse to take a specific action, such as withdrawing a recommendation with which the Secretary does not agree,<sup>134</sup> and establishing a formal review process preventing any Task Force recommendation from taking effect unless reviewed and approved by the Secretary of HHS.<sup>135</sup>

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<sup>125</sup> See Florko, *supra* note 123.

<sup>126</sup> *About HHS*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/about/index.html> (last visited Oct. 14, 2025).

<sup>127</sup> *Robert F. Kennedy, Jr.*, DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/about/leadership/robert-kennedy.html> (last visited Oct. 14, 2025).

<sup>128</sup> *Id.*

<sup>129</sup> E.g., Brendan Borrell, *He Built a Wellness Empire While Adventuring with Robert F. Kennedy Jr.*, N.Y. TIMES (Dec. 18, 2024), <https://www.nytimes.com/2024/12/18/health/mark-hyman-rfk-jr-functional-medicine.html> (noting Kennedy’s statement that “he would like to see an end to what he sees as the government’s “suppression” of supplements and exercise.”).

<sup>130</sup> Robert F. Kennedy Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines>.

<sup>131</sup> Rebecca Morris, *The Potential Effects of Braidwood Management v. Becerra and Impact on Community Health Centers*, 50 AM. J.L. & MED. 128, 131 (2024).

<sup>132</sup> *Kennedy v. Braidwood Management, Inc.*, 660 U.S. 748 (2025); see generally Katie Keith et al., *Supreme Court Upholds Preventative Services Requirement Under ACA*, HEALTH AFFS. (July 1, 2025), <https://www.healthaffairs.org/content/forefront/supreme-court-upholds-preventive-services-requirement-under-aca> (explaining Braidwood’s litigation pathway, which is beyond the scope of this article).

<sup>133</sup> *Braidwood*, 660 U.S. 748.

<sup>134</sup> *Id.* at 765.

<sup>135</sup> *Id.* at 768.

It remains unclear if or to what extent Kennedy may act on this broad authority. But if he does use this authority, it is possible that rather than promote preventive health services, such as vaccines or cancer screenings, HHS and MAHA may encourage individuals to rely on lifestyle choices for wellness.

Overall, Kennedy has tremendous potential to create new entry points into wellness—individuals may be encouraged by the federal government to take supplements, drink raw milk, and follow an organic diet. They may also be encouraged to use wearables. In the June 23, 2025, House of Representatives Committee on Energy and Commerce’s Subcommittee on Health, Kennedy declared his vision of all American’s “wearing a wearable within four years.”<sup>136</sup> In addition to Kennedy, other leaders in HHS are also supportive of wellness and their work will also likely result in new wellness entry points.

## 2. The Administrator of Centers for Medicare and Medicaid

Lead by Dr. Mehmet Oz, the Centers for Medicare and Medicaid (CMS) is also working to advance the MAHA movement and wellness. Prior to serving as the leader of CMS, Dr. Oz hosted The Dr. Oz Show, offering health and wellness advice and promoted products such as iHerb, an online retailer of vitamins and supplements.<sup>137</sup> The wellness component of the MAHA movement is evidenced in the CMS Innovation Center’s new strategy to “make America health again.”<sup>138</sup> This strategy aligns CMS with the MAHA agenda in each of its three pillars: promoting evidence-based prevention, empowering people to achieve their health goals, and driving choice and competition.<sup>139</sup>

Under the first pillar, promoting evidence-based prevention, CMS *may* pilot “lifestyle education and services (e.g. exercise and nutrition support), or offer access to evidence-based alternative medicine.”<sup>140</sup> The second pillar also provides possible examples of wellness focused models which *may* use “mobile device applications, shared decision-making tools, and health education materials” to empower individuals to improve their health and wellness.<sup>141</sup> Unlike the first two pillars, where the wellness component of future CMS models is suggested, but not required, the third pillar definitively includes wellness in a future CMS model. Under the third pillar, driving choice and competition, models “*will* be designed to

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<sup>136</sup> Puya Singh, *US Health Secretary Kennedy Says HHS to Launch Campaign to Encourage Wearable Devices*, REUTERS (June 24, 2025, 5:01 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-secretary-kennedy-says-hhs-launch-campaign-encourage-wearable-devices-2025-06-24/>.

<sup>137</sup> See Anne Flaherty & Will McDuffie, *Dr. Oz Agrees to Stop Promoting Health and Wellness Products If Confirmed, Trump Transition Says*, ABC NEWS (Dec. 6, 2024, 3:44 PM), <https://abcnews.go.com/Politics/dr-oz-agrees-stop-promoting-health-wellness-products/story?id=116525334>.

<sup>138</sup> Abe Sutton, *CMS Innovation Center Strategy to Make America Healthy Again*, U.S. CTRS. MEDICARE & MEDICAID SERVS. (May 13, 2025), <https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again>.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* (emphasis added).

level the playing field for providers practicing independently and outside of health system[s].”<sup>142</sup>

### 3. The Surgeon General of the Public Health Service

President Trump’s Surgeon General of the Public Health Service nominee, Dr. Casey Means, has been described as a “media-savvy wellness entrepreneur,”<sup>143</sup> and a “woo-woo wellness influencer.”<sup>144</sup> Having earned her M.D. from Stanford,<sup>145</sup> she left the health care system after seeing how “broken and exploitative”<sup>146</sup> it was during surgical training.<sup>147</sup> She wanted to “devote her life to tackling the root cause of why Americans are sick.”<sup>148</sup> Reflective of her decision not to remain in the health care system, Dr. Means lacks an active medical license.<sup>149</sup>

The Surgeon General is responsible for protecting and improving the health of Americans by issuing advisories and reports and communicating directly with the public.<sup>150</sup> Past examples of public health issues addressed by Surgeon Generals include smoking<sup>151</sup> and obesity.<sup>152</sup> If Dr. Means is confirmed by the U.S. Senate,<sup>153</sup> and becomes our next Surgeon General, it remains to be seen what specific public health issues Dr. Means will emphasize and how she will communicate with the public about these issues. Given her background, including running a wellness blog and other wellness-related activities,<sup>154</sup> it is likely that she will focus her efforts on wellness. Based on her book, *Good Energy*, her public health efforts will likely include lifestyle and dietary choices. The specific issues

<sup>142</sup> *Id.* (emphasis added).

<sup>143</sup> Sheryl Gay Stolberg, *Far-Right Activist Targets Surgeon General Pick as Kennedy Pushes Back*, N.Y. TIMES (May 11, 2025), <https://www.nytimes.com/2025/05/08/us/politics/means-loomer-trump-surgeon-general.html>.

<sup>144</sup> *Id.* (noting that “Rolling Stone called her a ‘woo-woo wellness influencer’”).

<sup>145</sup> *Metabolic Health Is Good Energy*, CASEY MEANS MD, <https://www.caseymeans.com/goodenergy> (last visited Oct. 16, 2025).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> Ashleigh Fields, *RFK Jr.: Casey Means ‘Walked Away from Traditional Medicine Because She Was Not Curing Patients,’* HILL (May 9, 2025, 9:19 AM), <https://thehill.com/policy/healthcare/5291915-rfk-jr-defends-trump-nominee-surgeon-general/>.

<sup>150</sup> *About the Office of the Surgeon General*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/surgeongeneral/about/index.html> (last visited Oct. 16, 2025).

<sup>151</sup> *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service*, U.S. DEP’T OF HEALTH, EDUC., & WELFARE, PUB. HEALTH SERV. (1964), <https://www.govinfo.gov/content/pkg/GPO-SMOKINGANDHEALTH/pdf/GPO-SMOKINGANDHEALTH.pdf>.

<sup>152</sup> OFFICE OF THE SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUM. SERVS., PUB. HEALTH SERV., *THE SURGEON GENERAL’S CALL TO ACTION TO PREVENT AND DECREASE OVERWEIGHT AND OBESITY* (2001), <https://www.ncbi.nlm.nih.gov/books/NBK44206/#:~:text=To%20achieve%20these%20goals%2C%20The,with%20regular%20physical%20activity%20to.>

<sup>153</sup> See generally PN730-47, 119th Cong. (2025-2026) (on January 13, 2025, the U.S. Senate received President Trump’s nomination of Dr. Casey Means and referred the nomination to the Committee on Health, Education, Labor, and Pensions).

<sup>154</sup> CASEY MEANS MD, *supra* note 145.

she promotes could range from eating well, walking, and improved sleep to using supplements and questioning childhood vaccine safety.<sup>155</sup>

Overall, the MAHA movement will likely add new entry points into wellness and encourage more Americans to enter the wellness space. MAHA may further modify wellness by framing wellness not just as a personal choice, but as a partisan and ideological choice.

#### **IV. IN THE LONG TERM: REGULATION SHOULD SUPPORT OR DISCOURAGE SPECIFIC ENTRY POINTS INTO WELLNESS**

##### **A. Entry Point Regulation Permits Finer Tailoring to Entry Point Motivators and Gaps in the U.S. Health Care System**

Regulators should support or discourage specific entry points into wellness. Doing so allows policy makers to better tailor regulations to the motivators and needs of individuals using these entry points, as well as remedy gaps in our health care system. This is analogous to California's regulatory approach to some of the entry points into universities. California has opted to support access to community colleges.<sup>156</sup> This support helps the state address different access gaps, including improving high school student preparation for college, increasing the number of successful transfers from a community college to the California State University or the University of California.<sup>157</sup> California also restricts legacy preference in admissions, or "considering an applicant's relation to an alumni."<sup>158</sup> Community college transfers and legacy admissions are two possible entry points into universities, with differing student motivations, which the California legislature regulates differently. Regulators can use a similar approach to differentiate among entry points into wellness.

While regulating the wellness industry, composed of various wellness services and products is a possible alternative option, it is not as suitable for responding to the various motivators propelling an individual through a specific entry point. Industry regulation may be useful in regulating wellness practitioners,<sup>159</sup> and making the wellness environment safer for participants, but it fails to consider why a person seeks to enter the wellness space and if there are gaps that would benefit from filling in our health care delivery system. Industry regulation and the regulation of specific entry points are not mutually exclusive, they may both be feasible policy alternatives, but with different goals.

In the case of wellness, self-driven, cultural, and social prescription entry points may be among those entry points fostered or at least not suppressed. Self-driven, seems the least likely to be regulated due to the great weight placed on autonomy in health and wellness issues. Cultural and social prescriptions may be encouraged, if part of evidence-based practice. In both instances, the entry points

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<sup>155</sup> Florko, *supra* note 123, at 4.

<sup>156</sup> CAL. EDUC. CODE § 76396.1 (Deering 2025).

<sup>157</sup> *Id.*

<sup>158</sup> CAL. EDUC. CODE § 66018.4 (Deering 2025).

<sup>159</sup> Zabawa, *supra* note 16.

lessen existing gaps in access to wellness, such as cultural safety and community building. On the other hand, dismissive care and employer wellness programs may be among those entry points requiring closer consideration and possible discouraging. Patients responding to what they consider dismissive care have different motivations than someone autonomously researching and choosing wellness. Moreover, this entry points suggests a gap in our health care system, that if addressed, may provide individuals with a truer choice between health, wellness, or both. Employer wellness programs may be misaligned with employees' wellness aims, and thus open to regulatory adjustment. Ideally, regulating entry points into wellness will better align individual needs with appropriate resources.

### **B. Entry Point Regulation Permits Greater Responsiveness to New Entry Points**

In addition to the existing entry points into wellness, new entry points are likely to emerge. These include the probable entry points created by the MAHA movement and encouraged by the federal government. Additionally, there will be other entry points in the future. Entry point regulation allows greater responsiveness to an evolving wellness environment.

Policy makers could also be proactive, encouraging a group entry point and helping to lessen the cost barrier to wellness. Individuals enter the wellness space at different ages and with different resources. Like most products and services, the extent to which an individual can successfully acquire wellness products and services depends, in part, on the individual's capacity to pay for these items. Unlike in health, where providers bear the principal responsibility for our achieving health and health insurers bear the primary responsibility for paying for what we need to achieve health, in wellness patients bear both the responsibility for striving for wellness *and* the financial costs associated with working towards wellness. The financial cost of wellness services and products is likely to pose a significant barrier to many individuals striving for wellness.<sup>160</sup> For example, health and wellness coaches may charge fifty to two-hundred dollars per hour depending on the coach's credentials, experience, coaching format, location and specialization.<sup>161</sup> And DTC genetic tests for wellness can cost \$1,299.<sup>162</sup>

Wellness could be encouraged as part of a group or community, like many of the examples where culture leads to an entry into wellness. An individual lacking sufficient resources to enter the wellness space alone, does not need to be excluded from a shared community approach to wellness. For instance, individuals can participate in group yoga or fitness classes with a lower cost than a private

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<sup>160</sup> Other types of access barrier, which are beyond the scope of this article, could also exist, including: transportation barriers, cultural and social barriers, and work schedule conflicts.

<sup>161</sup> Logan Sides, *How Much Does Wellness Coaching Cost?*, EV MOTION THERAPY (Jan. 10, 2025), <https://www.ewmotiontherapy.com/blog/wellness-coaching-cost>.

<sup>162</sup> *10X Health Precision Genetic Test*, 10X HEALTH SYSTEM, [https://shop.10xhealthsystem.com/products/10x-precision-genetic-test?utm\\_source=homepage&utm\\_medium=mainnav&utm\\_campaign=website](https://shop.10xhealthsystem.com/products/10x-precision-genetic-test?utm_source=homepage&utm_medium=mainnav&utm_campaign=website) (last visited Oct. 17, 2025).

session. Or they may engage in group health and wellness coaching<sup>163</sup> or group Medicare wellness visits.<sup>164</sup>

## V. CONCLUSION

Wellness is a growing industry, and Americans are eager to embrace it. With numerous existing entry points into wellness and new ones on the horizon, policy makers and other decision-makers should consider regulating entry points into wellness. This will facilitate a more nuanced response to the motivators and health care system gaps revealed by the various entry points.

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<sup>163</sup> Wolever et al., *supra* note 51, at 2 (suggesting that group health and wellness coaching is a potentially cost-effective method of enhancing wellness accessibility and empowering individuals while also using the community to engage and motivate individuals to improve their wellness).

<sup>164</sup> Charis Wiltshire et al., *Group Medicare Wellness Visits: A Pilot Exploration of an Approach to Wellness and Preventive Medicine for Older Adults*, 36 PREVENTIVE MED. REPS. 1, 3 (2023) (finding that a pilot program for group Medicare wellness visits has the added benefit of facilitating interactions among similar individuals, sharing of perspectives, and exchanges of wellness information).

# ILLNESS/WELLNESS, ABLEISM & PERFECTIBILITY IN THE TAX CODE

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## I. INTRODUCTION

The concept of “wellness” presents a variety of challenges to existing law and policy, including tax law. Because wellness requires an articulation of some notion of human well-being, it implicates some of the same concerns as those raised by critical disability theory. The basic claim is that wellness law must advance disability justice. However, most discussions of wellness, like the discussions of health care, medical care, and the tax treatment of medical expenses, marginalize and subordinate disabled and chronically ill people—when they are considered at all. The evolution of new law around wellness is an opportunity to do better: To center the needs and experiences of disabled and chronically ill people in an area of law of vital concern to them. In Part II, I introduce some key principles and perspectives of critical disability theory. In Part III, I articulate the notion of “perfectibility,” a form of ableism that typifies some common ways of thinking about wellness. Part IV lays out some relevant components of existing tax law in relation to medical care. While the tax treatment of medical care is familiar, the integration of wellness into medical care has both disability studies and tax consequences that have not been widely explored. Part V is an evaluation of Leigh Osofsky’s “Wellness and the Tax Law,”<sup>1</sup> especially from the point of view of critical disability theory. Part VI offers some concluding thoughts.

## II. CRITICAL DISABILITY THEORY

Human bodies and minds are wonderfully diverse and changeable. Individual bodies and minds differ from one another in myriad ways; one’s own body and mind also change over the life course. Some of these changes are positive or benign; others involve pain and debility. Some alterations are temporary or cyclic (such as a fracture that heals, or symptoms that “flare up”); others are permanent. Some reflect natural processes; some happen by accident or through the actions of others. Some changes can be ameliorated by various interventions, some cannot. Some alterations may be voluntarily undertaken, even if they involve risk. Some changes are welcomed by those who undergo them; other people dread the same changes. Some alterations better suit a person to function in the society of which they are a part, and to pursue and achieve their own goals. Others make those things more difficult or even impossible.

The foregoing observations have deliberately avoided terms like “disease,” “illness,” “health,” “impairment,” “wellness,” “medical care,” and “disability.” Using insights gained from medical anthropology and critical disability studies, I aim to begin from as neutral and non-essentialist a stance as

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<sup>1</sup> Leigh Osofsky, *Wellness and the Tax Law*, 59 GA. L. REV. 443 (2025).

possible about bodily changes and states as various as puberty; growing or losing hair; gain or loss of muscle or fat; pregnancy, childbirth, and lactation; blindness; deafness; missing limbs; increased or decreased mobility; chronic pain; processes like cancer, diabetes, or Alzheimer's; vaccines; cosmetic surgery; and the recreational use of intoxicants and other substances. If we include mental and psychological changes and conditions associated with all of the above, along with things like schizophrenia, anxiety, ADHD, and other mind/brain conditions, the breadth of the topic feels almost staggering.

For some of us, certain changes and conditions of body and mind have such a powerful positive or negative valence that it requires a genuine effort to consider them in a more neutral frame of mind, one that does not already rest upon ableist assumptions. This includes a belief as foundational, and perhaps seemingly obvious, as the idea of illness and disability as misfortune, to be avoided or prevented. Critical disability theory interrogates the idea of illness and disability as sources of nothing but suffering; it rejects the classification of groups of people or bodies as defective.<sup>2</sup> It does this by encouraging us to consider, for example, what it would mean to choose disability; for example, whether deaf parents should use assisted reproductive technology to select for deafness,<sup>3</sup> or whether intersex infants require medical intervention at all.<sup>4</sup> Critical disability scholars of science fiction point out and critique how often authors in this genre imagine a utopic future as one in which disease and disability have disappeared; and then query what it means to live in a society whose idea of utopia includes no one like you.<sup>5</sup>

The specific method I employ here also draws on Critical Race Theory and intersectional theory in at least two distinct ways. First, I seek to “demarginalize” the experience of disabled and chronically ill persons, by “placing those who are currently marginalized in the center” in the way pioneered by Black feminists like bell hooks and Kimberlé Crenshaw.<sup>6</sup> I deliberately center the evaluation of wellness law and policy, including its tax dimensions, on how those laws and policies affect (and theorize) the disabled and chronically ill.

Beyond this centering move, I also aim to include and amplify the works of disabled and chronically ill critical disability theorists themselves. In so doing, I draw on the work of Mari Matsuda, who argued “that those who have experienced

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<sup>2</sup> See, e.g., DOUGLAS BAYNTON, DEFECTIVES IN THE LAND: DISABILITY AND IMMIGRATION IN THE AGE OF EUGENICS (2016); LENNARD J. DAVIS, ED., THE DISABILITY STUDIES READER (5th ed. 2017) 4, 7; Douglas Baynton, *Disability and the Justification of Inequality in American History*, 17, 19-20 in DAVIS, THE DISABILITY STUDIES READER.

<sup>3</sup> See, e.g., Melissa Seymour Fahmy, *On the Supposed Moral Harm of Selecting for Deafness*, BIOETHICS 1 (2009).

<sup>4</sup> See, e.g., *What is Intersex?*, INTERACT ADVOCATES FOR INTERSEX YOUTH, <https://interactadvocates.org/> (last visited Feb. 28, 2026).

<sup>5</sup> See, e.g., Matthew Holder, *Imagining Accessibility: Theorizing Disability in Disabled People Destroy Science Fiction*, 40 DISABILITY STUD. Q. (2020).

<sup>6</sup> BELL HOOKS, FEMINIST THEORY: FROM MARGIN TO CENTER (1984); Kimberlé Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, 1989 U. CHI. LEGAL F. 139, 167 (1989).

discrimination speak with a special voice to which we should listen.”<sup>7</sup> In disability studies, something akin to this is expressed by the slogan, “Nothing about us without us.”<sup>8</sup> Matsuda explains the value of this approach: “Looking to the bottom . . . can assist critical scholars in the task of fathoming the phenomenology of law and defining the elements of justice.”<sup>9</sup> As with other groups who have experienced discrimination, disabled and chronically ill people have unique insights and are entitled to speak for themselves about their experience of disability and illness in relationship to law. Disability justice thus requires not only evaluating law and policy with regard to the impact it will have on the disabled and chronically ill, but also taking their own points of view into account, a demarginalizing move in itself.

Crenshaw, hooks, and Matsuda do not advocate this approach based on simple-minded principles of inclusivity or representation. The hope and expectation are that it will generate substantively different results. As Matsuda puts it, “The method of looking to the bottom can lead to concepts of law radically different from those generated at the top.”<sup>10</sup> This is so in part because, according to Matsuda, “The normative intuitions of those on the bottom are often different from the intuitions of those on top.”<sup>11</sup> Crenshaw describes how “bottom up” analysis is essential to “efforts to restructure the distribution of opportunity” beyond “minor adjustments within an established hierarchy.”<sup>12</sup> She urges those concerned with multidimensional antidiscrimination to begin “with addressing the needs and problems of those who are most disadvantaged and with restructuring and remaking the world where necessary,” to the benefit of others as well.<sup>13</sup>

Although she was writing specifically about the treatment of Black women, both as employment discrimination plaintiffs, and in feminism and anti-racism more generally, there is an analogy here. It remains to be seen whether centering disabled and chronically ill persons in the analysis of wellness law will reveal different normative intuitions or lead to radically different concepts of law than what is found in law generated by and for the able-bodied/able-minded. But it is only thanks to critical disability scholars that we even begin to question such deep-seated ableist normative assumptions as the idea that illness/disability is always a misfortune, or that illness/disability would never be chosen, or that the elimination of illness/disability is a utopic aim, universally shared. These thought-provoking and even troubling challenges to our usual ways of thinking contain the potential for a new angle of view on our topic.

A basic principle of critical disability theory is that all persons have value apart from their ability to contribute “productively” to the functioning of a market

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<sup>7</sup> Mari J. Matsuda, *Looking to the Bottom: Critical Legal Studies and Reparations*, 22 HARV. C.R.-C.L. L. REV. 323, 324 (1987).

<sup>8</sup> See, e.g., JAMES I. CHARLTON, *NOTHING ABOUT US WITHOUT US: DISABILITY OPPRESSION AND EMPOWERMENT* (1998).

<sup>9</sup> Matsuda, *supra* note 7.

<sup>10</sup> *Id.* at 326.

<sup>11</sup> *Id.* at 360.

<sup>12</sup> Crenshaw, *supra* note 6, at 145.

<sup>13</sup> *Id.* at 167.

economy at any given time or ever.<sup>14</sup> This is a challenging, provocative, and even radical thought for many of us (particularly tax scholars!). Critical disability studies is often, though not necessarily, anti-capitalist in its economics.<sup>15</sup> But whatever one's stance on large-scale macroeconomic and political questions, critical disability theory rejects the idea that the goal of human life is optimal economic productivity and especially repudiates the corrosive dehumanizing devaluation of those seen as unproductive. It is possible to endorse the aspirations of those who wish to contribute, to be productive, to be taxpayer-citizens, while not mistaking this for the measure of human worth or entitlement to concern as a co-equal member of our polity.

A further basic principle of critical disability theory is the recognition of the social construction of “disability” as a category. To the extent that disability (including chronic illness) becomes social, political, and economic disadvantage, this consequence reflects social processes and structures, rather than individual choices or facts located inside the body-mind of the disabled person.<sup>16</sup> Here, it is important to acknowledge that among the bodily differences and conditions often classified as disabilities are some that create pain and debility. There is no suggestion that this is “unreal” in some way. At the same time, critical disability theory emphasizes those aspects of disability that are not the necessary consequences of bodily or mental conditions and are instead susceptible to social intervention—and it further demands, in the name of disability justice, that those interventions take place.

For example, consider an example drawn from what is called “universal design.”<sup>17</sup> A person who uses a wheelchair should not be understood as “unable” to enter a building with stairs but no ramps or elevators, or with doorways too narrow to get through. The defect is in the building or the building codes, not the person. The defect rests on the false assumption that everyone (who matters) will enter and negotiate the building by walking. Lack of access to the built environment results in educational, housing, recreational, and employment disadvantage.<sup>18</sup> But none of these harms should be seen as the inevitable product or consequence of the mobility impairment itself. The mobility impairment is “real”: the person cannot walk, unassisted, a sufficient distance to access the

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<sup>14</sup> See Anwesha Majumder & Jessica Mason, *Workers with Disabilities Continue to Benefit from Expanded Workplace Flexibility, but Are Suffering from Trump's Attacks*, NAT'L P'SHIP WOMEN & FAMS. (Feb 25, 2025), <https://nationalpartnership.org/workers-with-disabilities-continue-to-benefit-from-expanded-workplace-flexibility-but-are-suffering-from-trumps-attacks> (“[W]hile employment is a primary source of income for many people, our inherent value is not based on our ability to work.”).

<sup>15</sup> See, e.g., MARTHA RUSSEL, *CAPITALISM AND DISABILITY: SELECTED WRITINGS* (Keith Rosenthal, ed. 2019).

<sup>16</sup> See, e.g., Tom Shakespeare, *The Social Model of Disability* 195, in DAVIS, *supra* note 2.

<sup>17</sup> For an in-depth discussion of “universal design,” see *About Universal Design*, CTR. FOR EXCELLENCE IN UNIVERSAL DESIGN, <https://universaldesign.ie/about-universal-design> (last visited Jan. 28, 2026).

<sup>18</sup> See, e.g., Patricia R. Lawrence & Raeda K. Anderson, *Poverty and Disability: A State-Level Geospatial Analysis*, 33(5) *CLINICAL NURSE RSCH.* 344, 344-54 (2024).

building as currently constructed. But the *disadvantage* that results is a social choice, and it is open to us to make different choices.

Similarly, a privatized health insurance system, linked to employment, structures the experience of disability and chronic illness in ways that have nothing to do with those conditions themselves. This system dramatically affects who receives treatment or care, and the material consequences of different disabilities or chronic illnesses. When scholars discuss how much it “costs” to treat some illness or condition, this should not be regarded as a medical or natural fact. Economic processes, and not disease processes alone, determine whether various disabilities or illnesses are financially “catastrophic” or not.

This Essay is an exploration in the genre of critical and intersectional disability antidiscrimination law. The analysis offered here is not a full-fledged intersectional one, which would also necessarily take race, sex/gender, and sexual orientation/gender identity into account along with disability.<sup>19</sup> However, this analysis does address intersectional issues of disability and class. It centers disabled and chronically ill taxpayers within the larger classes of, on the one hand, all taxpayers; and on the other, all persons who experience serious medical events with economic consequences, due to the costs of treatment in our privatized healthcare system, as well as their effects on employability and earning potential.

### III. PERFECTIBILITY

I use the term “perfectibility” to refer to the set of ableist norms that come together around an ideal of physical and mental health and wellness towards which all people are expected to strive, and against which all people are expected to measure themselves, though everyone will inevitably come up short. As a normative ideal, it operates in part by producing guilt and shame in those who fail to embody it, who are then regarded as “defective” in some way. It creates a sense of personal failure for those who are unable to achieve it or unwilling to strive tirelessly towards it. Disabled and chronically ill people are especially damaged by law and policy organized around an aspirational state they know they can never achieve.

Against perfectibility, critical disability theory challenges us to embrace an inclusive idea of benign human variation and to take claims of human equality and dignity genuinely seriously. It rejects any simple binary dividing the able-bodied/able-minded from the disabled, any treatment of any group of people as defective, along with an exclusionary and intersectional hierarchy of race, sex/gender, and able-bodied/able-mindedness.

Beyond neutrality and anti-essentialism about illness/wellness and disability, critical disability theory and disability justice demand that we identify, examine, and critique ableist beliefs and principles that structure law and policy wherever we find them, and consider what genuinely non- or anti-discriminatory law and policy would look like. This includes evaluating how antidiscrimination law in the disability context compares to other antidiscrimination law.

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<sup>19</sup> See, e.g., Majumder & Mason, *supra* note 14.

Civil rights laws in the U.S. generally prohibit differential treatment of persons based on their membership in one or more protected categories.<sup>20</sup> However, these abstract principles of inclusion/non-discrimination frequently fail to attend to differences between bodies, a central aspect of disability. This is well-documented in the case of gender. For example, women were permitted in combat roles in the U.S. Air Force beginning in 1993; twenty-five years later, the Air Force finally acknowledged that their uniforms and gear did not fit women.<sup>21</sup> This inattention to bodily difference, and the male norm at its center, helps explain why NASA originally proposed sending Sally Ride into space with 100 tampons for a six-day mission.<sup>22</sup> Non-discrimination against women meant permitting women into a male space; it did not include what we might call epistemic equality: insuring that decision-makers possessed basic knowledge of differences between male and female bodies.

A female body is not the same as a disabled body.<sup>23</sup> But these examples from the sex/gender context illustrate the consequences of placing an often-unacknowledged idealized (White, male, cisgendered) able-bodied/able-minded person (worker, taxpayer) at law's normative and epistemic center. The law embeds the knowledge that allows it to attend to and provide for that body. Inclusion generally means participation on the terms already in place for those who fit the norm. This ideal creates an exclusionary and intersectional hierarchy of race, sex/gender, and able-bodied/able-mindedness.

Examples drawn from universal design help demonstrate that another approach is possible, if the lived experience of all people is taken into account from the beginning. But the history of disability law is otherwise. Consider the Americans with Disabilities Act (ADA).<sup>24</sup> Unlike the basic nondiscrimination principles of most U.S. civil rights laws, which by their own terms flatly prohibit exclusion and differential treatment in most cases,<sup>25</sup> the ADA does not begin from a premise of basic equality.<sup>26</sup> Instead, it measures a person's distance from an able-bodied/able-minded norm and asks how much "accommodation" can reasonably be demanded (of an employer, the owner of premises, etc.), in light of possibly countervailing "business necessity" or "undue burden." Disability accommodations are assumed to impose a cost that may or may not be worth

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<sup>20</sup> See, e.g., Title VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e—2000e-17 (2022).

<sup>21</sup> Jeff Schogol, *Air Force Finally Acknowledges Its Uniforms and Gear Are Not Made to Fit Women*, TASK & PURPOSE (Mar. 29, 2018), <https://taskandpurpose.com/news/air-force-gear-does-not-fit-women/>.

<sup>22</sup> Ted Radio Hour, *That Time When NASA (Almost) Sent Sally Ride to Space with 100 Tampons*, NPR at 0:25 (June 3, 2022), <https://www.npr.org/transcripts/1102635355>.

<sup>23</sup> Notwithstanding a historical tradition, from Aristotle on down, of understanding femaleness in precisely that way! See ARISTOTLE, ON THE GENERATION OF ANIMALS bk. II, ch. 3 (Arthur Platt, trans.) ("For the female is, as it were, a mutilated male."); THOMAS AQUINAS, SUMMA THEOLOGICA pt. I, q. 92, a.1, Obj. 1 ("[T]he female is a misbegotten male.").

<sup>24</sup> 42 U.S.C. §§ 12101-12213 (1990).

<sup>25</sup> In some cases, bodily differences can permit discrimination, where those differences are a "bona fide occupational qualification" ("BFOQ"). 42 U.S.C. § 2000e-2 (1990).

<sup>26</sup> See U.S. Dep't of Just. Civ. Rts. Div., *Americans with Disabilities Act of 1990*, as Amended, <https://www.ada.gov/law-and-regs/ada/>.

bearing; the burden of demonstrating their reasonableness is on the disabled person and is always in doubt. Inclusion is precarious and contingent.

This landmark civil rights act may have improved the material conditions of many disabled persons' lives in the United States,<sup>27</sup> but its basic approach reflects a tolerance for disability exclusion and disability subordination that goes far beyond what is deemed acceptable with respect to race and gender, at least as a formal matter. It reflects what Crenshaw, in the intersectional race/gender context, described evocatively as “a markedly decreased political and emotional vigilance toward barriers” confronting certain people.<sup>28</sup> Put another way, it regards disabled people as less important, as inherently a burden on others, and places a lesser value on remediating the discrimination they suffer. Critical disability theory does not hesitate to point this out.

Similarly, to the extent that emerging definitions and understandings of wellness, or distinctions between healthcare and wellness, in the tax Code or elsewhere, further entrench ableist ideas, or exclude or further disadvantage the disabled or chronically ill through perfectibility norms, they are appropriately critiqued, because they worsen, perhaps inadvertently, these existing forms of inequity and injustice.

#### IV. TAX LAW

One of the most challenging aspects of evaluating the tax law treatment of disability and chronic illness is their scattershot and shadowy presence throughout the Internal Revenue Code. While every Code provision is race- and gender-neutral by its own terms (if not in their effects<sup>29</sup>), many disability-proximate terms and concepts *do* appear in the Code, but not in any organized or coherent way. For example, blind taxpayers are entitled to an additional standard deduction.<sup>30</sup> Though the amount is relatively small (a few thousand dollars), no other sensory condition is treated similarly.<sup>31</sup> Some provisions that do not address illness or disability explicitly can be shown, with analysis, to create or exacerbate structural disadvantage experienced by disabled or chronically ill taxpayers. Here, I address

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<sup>27</sup> The data are equivocal. Compare, e.g., *Did the ADA Reduce Employment of the Disabled?*, DIGEST (Nov. 1, 2004), <https://www.nber.org/digest/nov04/did-ada-reduce-employment-disabled>, with Michelle Maroto & David Pettinicchio, *Twenty-Five Years After the ADA: Situating Disability in America's System of Stratification*, 35 DISABILITY STUD. Q. (2015), <https://dsq.sds.org/index.php/dsq/article/view/4927/4024>.

<sup>28</sup> Crenshaw, *supra* note 6, at 161.

<sup>29</sup> See, e.g., Grace Blumberg, *Sexism in the Code: A Comparative Study of Income Taxation of Working Wives and Mothers*, 21 BUFF. L. REV. 49 (1971); Beverly I. Moran & William Whitford, *A Black Critique of the Internal Revenue Code*, 1996 WIS. L. REV. 751.

<sup>30</sup> I.R.C. § 63(c)(3).

<sup>31</sup> See IRS, *Topic No. 551, Standard Deduction*, <https://www.irs.gov/taxtopics/tc551> (last visited Feb. 28, 2026).

just two tax Code provisions that are especially relevant for a critical disability analysis of wellness.<sup>32</sup>

### A. Section 213 and “Deductible” Medical Expenses

Section 262(a) states that “no deduction shall be allowed for personal, living, or family expenses.” This language does not expressly refer to medical expenses, health care, or wellness expenditures. However, Section 213 creates a deduction for uninsured “medical care” expenses, available to taxpayers who itemize deductions.<sup>33</sup> Section 213(d) expansively defines medical care expenses to include “amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body.”<sup>34</sup> This includes “durable medical equipment,” such as wheelchairs and diabetes supplies, items used by many disabled and chronically ill people.<sup>35</sup> Deduction of medical care expenses under Section 213 is subject to a “floor”; taxpayers may deduct only expenses exceeding 7.5% of adjusted gross income.<sup>36</sup>

At first glance, this Section would appear very helpful and favorable to persons who regularly incur substantial medical expenses for the treatment or management of chronic illnesses and disabilities. However, the Regulations, particularly Treasury Regulation § 1.213-1(e)(1)(ii), contain some very significant limitations.<sup>37</sup> Two of these limitations are especially significant in relationship to wellness. Regulation § 1.213-1(e)(1)(ii) instructs that “Deductions . . . will be *confined strictly* to expenses incurred *primarily* for the prevention or alleviation of a physical or mental defect or illness.”<sup>38</sup> It distinguishes a deductible expense from “an expenditure which is *merely beneficial* to the general health of an individual, such as an expenditure for a vacation,” which does not qualify for deduction.<sup>39</sup> Finally, the Regulation provides that “Amounts expended for illegal operations or treatments are not deductible.”<sup>40</sup> These Regulations are also echoed in a variety of other forms of guidance the IRS issues to taxpayers.<sup>41</sup> As will be explored below because of its significance for wellness, the line between expenditures “primarily for the prevention or alleviation” of disease and those “merely beneficial” to health

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<sup>32</sup> See also Osofsky, *supra* note 1, at 461-65.

<sup>33</sup> I.R.C. §§ 213(a), 213(d)(1)(A).

<sup>34</sup> *Id.*

<sup>35</sup> See Medicare.gov, *Durable Medical Equipment (DME) Coverage*, <https://www.medicare.gov/coverage/durable-medical-equipment-dme-coverage> (last visited Feb. 28, 2026).

<sup>36</sup> I.R.C. § 213(a).

<sup>37</sup> See also Osofsky, *supra* note 1, at 447 et seq.

<sup>38</sup> Treas. Reg. § 1.213-1(e)(1)(ii) (emphases added). As Osofsky describes, this is also drawn from the legislative history and was clearly the Congressional intent of the statute when first enacted in 1942, although this restriction did not find its way into the statutory language. Osofsky, *supra* note 1, at 452-53.

<sup>39</sup> Treas. Reg. § 1.213-1(e)(1)(ii) (emphasis added).

<sup>40</sup> *Id.*

<sup>41</sup> See Osofsky, *supra* note 1, at 454-55.

more generally is not easy either to draw or to justify, and generated a good deal of litigation over the years.<sup>42</sup>

These Regulations, together with all the Regulations drafted and promulgated by the Internal Revenue Service, are not mere suggestions, but form a part of what tax scholars have typically understood to be “tax law.”<sup>43</sup> Since *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, decided in 1984, Treasury Regulations have enjoyed a nearly-statutory status.<sup>44</sup> As one textbook expressed it, “If the IRS has issued regulations, but not addressed the specific area desired by the taxpayer, unless the IRS’s position in the regulation is contrary to the plain meaning of the statute, a court is not free to replace that clear language with its own interpretation.”<sup>45</sup> As a result, for many years, Section 213 has been interpreted to permit deduction of much less than the statute’s language might suggest.

But a blockbuster 2024 U.S. Supreme Court decision has thrown all of this into doubt. In *Loper Bright Enterprises v. Raimondo*, the Supreme Court overturned so-called “*Chevron* deference” to agency regulations.<sup>46</sup> Under *Loper Bright*, “Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority,” rather than deferring to any reasonable agency interpretation of ambiguous statutes.<sup>47</sup> Though the decision was not completely unexpected,<sup>48</sup> it still sent shock waves through administrative law,<sup>49</sup> including tax law.<sup>50</sup> *Loper Bright* leaves the current status of Treasury Regulations unclear.

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<sup>42</sup> See, e.g., *Adler v. Comm’r*, 330 F.2d 91 (9th Cir. 1964); *Fiedziuszko v. Comm’r*, T.C. Memo. 2018-75 (2018); *Green v. Comm’r*, T.C. Memo. 2010-109 (2010); *Gardner v. Commissioner*, T.C. Memo. 1983-541; *Borgmann v. Commissioner*, 438 F.2d 1211 (9th Cir. 1971), *aff’g* T.C. Memo. 1969-129. (Note: These are a few examples of the 35 cases that come up when searched on Westlaw).

<sup>43</sup> See, e.g., *Osofsky*, *supra* note 1, at 443 (emphasis added) (“The tax law nonetheless disallows subsidies for wellness expenditures under the theory that they are ‘merely beneficial to general health.’”).

<sup>44</sup> *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984).

<sup>45</sup> JONI LARSON, DAN SHEAFFER & CATHERINE MCCOLLUM, *FEDERAL TAX RESEARCH* 111 (3d ed. 2022), citing *Hillman v. Comm’r*, 263 F.3d 338 (4th Cir. 2001), *reversing and remanding* 114 T.C. 103 (2000).

<sup>46</sup> *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 413 (2024).

<sup>47</sup> *Id.* at 412-13.

<sup>48</sup> See Diane Klein, *Gorsuch, Gutierrez, and Goodbye, Chevron*, DORF ON L. (Feb. 1, 2017), <https://www.dorfonlaw.org/2017/02/gorsuch-gutierrez-brizuela-and-goodbye.html>; Kristin Hickman, *To Repudiate or Merely Curtail? Justice Gorsuch and Chevron Deference*, 70 ALA. L. REV. 733, 735 (2019); Beckett Cantley & Geoffrey Dietrich, *Loper v. Raimondo: The U.S. Supreme Court’s Potential Extension of Its Anti-Regulatory Direction to Overturning Chevron Deference*, 39 J. LAND USE & ENV’T L. 79, 81 (2023).

<sup>49</sup> John-Paul S. Mantone, *A Tale of Two Agencies: Contrasting How the Loss of Chevron Deference Will Impact the Department of Defense and the Environmental Protection Agency*, 61 CAL. W. L. REV. 491, 495 (2025); Teague I. Donahey, *The End of Chevron Deference and Its Impact on Intellectual Property Law*, IDAHO STATE BAR (Dec. 30, 2024); Jack Beermann, *Chevron Deference Is Dead, Long Live Deference*, 2023-2024 CATO SUP. CT. REV. 31, 55 (2024).

<sup>50</sup> Marie Sapirie, *Chevron Is Dead. Long Live Skidmore and the APA?*, TAX NOTES (July 15, 2024) <https://www.taxnotes.com/featured-analysis/chevron-dead-long-live-skidmore-and->

Especially if we do not regard Section 213 as an “ambiguous” statute, it seems at least possible that a taxpayer seeking to deduct an expensive vacation, clearly beneficial to their health but not primarily undertaken for that purpose, might successfully challenge Regulation § 1.213-1(e)(1)(ii). However, in the sixty-five years since it was first promulgated, no one has yet done so. Of the thirty-five or so reported cases in which courts addressed whether a claimed deduction was disallowed under Regulation § 1.213-1(e)(1)(ii)’s “merely beneficial” standard, none involved challenges evaluated under either *Chevron* or the prior standard, *Skidmore*.

Regulation § 1.213-1(e)(1)(ii) actually predates *Chevron*. It was part of a large group of regulations promulgated in 1960,<sup>51</sup> and was first applied in *Levy v. Commissioner* in 1961 to deny a deduction for a “nursemaid” hired to care for the Levys’ daughters.<sup>52</sup> At that time, the judicial standard applied to review of regulations was *Skidmore v. Swift and Co.*, which demanded “respect,” if not deference, from courts.<sup>53</sup> Applying the Regulation, pre-*Chevron* cases regularly denied deductions for expenditures that today we might define as “wellness,” such as dancing lessons,<sup>54</sup> summer camp,<sup>55</sup> shopping excursions,<sup>56</sup> a cruise,<sup>57</sup> and a stay at La Costa (a luxury spa).<sup>58</sup> In some cases, the courts acknowledged the health benefits of the expenditure and still denied its deductibility. For example, in one of the dancing cases, the Tax Court said, “Doctors often recommend a course of personal conduct and personal activity which, if followed, could result in health benefits to the patient, but the expenses therefor are generally to be considered ordinary personal expenses.”<sup>59</sup> In the shopping excursion case (*Rabb v. Comm’r*), the Tax Court, denying the deduction, observed that “We may take judicial notice of the generally therapeutic effect that shopping with unlimited charge accounts offers a housewife, even one in Betty’s obviously ill state.”<sup>60</sup> Although there is some suggestion that the Tax Court was not quite in earnest, the point is that “generally therapeutic effect” was insufficient for deductibility, even in the pre-*Chevron* world. In the cruise case, the Tax Court reiterated that “Not every activity which benefits health is permitted as a medical care deduction section 213.”<sup>61</sup> Thus, the fact that Section 213 by its own terms might seem to permit deductions of expenses for preventive care; expenses incurred primarily for pleasure (like a

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apa/2024/07/12/7kgn1 (“Two Supreme Court decisions released within days of each other in late June and early July [*Loper Bright* and *Corner Post*] are likely to usher in a new wave of litigation and reshape the way that tax regulations and guidance are challenged.”).

<sup>51</sup> 25 Fed. Reg. 11201-12162 (Nov. 26, 1960).

<sup>52</sup> *Levy v. Comm’r*, T.C. Memo. 1961-74, 1, 3-4 (1961).

<sup>53</sup> See *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944).

<sup>54</sup> *Adler v. Comm’r*, 330 F.2d 91, 93 (9th Cir. 1964); *Fr. v. Comm’r*, T.C. Memo. 1980-215, at \*1, 6-7 (U.S. Tax Ct. 1980).

<sup>55</sup> *Weinberg v. Comm’r*, T.C. Memo. 1969-3, 2, 5 (1969).

<sup>56</sup> *Rabb v. Comm’r*, T.C. Memo. 1972-119, 1, 10-11 (1972).

<sup>57</sup> *Mizl v. Comm’r*, T.C. Memo. 1980-227, 1, 12 (1980).

<sup>58</sup> *Murray v. Comm’r*, T.C. Memo. 1982-269 (1982).

<sup>59</sup> *Fr.*, T.C. Memo. 1980-215, 1, 7-8 (1980).

<sup>60</sup> *Rabb*, T.C. Memo. 1972-119, 1, 10-11 (1972).

<sup>61</sup> *Mizl*, T.C. Memo. 1980-227, 1, 12 (1980).

vacation), and only secondarily or incidentally for the prevention or alleviation of illness; expenses demonstrably beneficial to “general health” though not undertaken at the specific direction of a physician; or even illegal operations or treatments, may not matter very much.

At the same time, the extension of the very large standard deduction, first enacted in 2017 in the Tax Cuts and Jobs Act (TCJA) and now extended by the One Big Beautiful Bill Act (OBBA), arguably renders Section 213, with or without the limitations of § 1.213-1(e)(1)(ii), largely moot. Put simply, almost no one takes the medical expense deduction (anymore). When Osofsky says that “The combination of the AGI and the itemized deduction limitation narrow the reach of the medical expense deduction,”<sup>62</sup> she is vastly understating the case. Even before the TCJA, relatively few taxpayers itemized deductions (about 31%), a prerequisite for taking the medical expense deduction.<sup>63</sup> Since the TCJA went into effect, the standard deduction has dramatically increased, and even fewer taxpayers have itemized since then (about 9% in 2020).<sup>64</sup> Between 2017 and 2018, the standard deduction nearly doubled, rising to \$12,000 for a single filer (and \$24,000 for a married couple), and it has risen every year since then.<sup>65</sup>

In 2022, the most recent year for which the IRS has made data available, more than 161 million returns were filed.<sup>66</sup> Of the fifteen million returns with itemized deductions in 2022, fewer than four million took the medical expense deduction.<sup>67</sup> Although this resulted in a tax “subsidy” (that is, foregone tax revenue) of nearly \$10 billion, the medical expense deduction still ranked 20th among itemized deductions, far behind the SALT deduction, the home mortgage interest deduction, and the charitable deduction.<sup>68</sup> Section 213 deductions amounted to 1/240th of total individual income tax revenues in 2022, or four-tenths of one percent.<sup>69</sup> For the 2025 tax year, the standard deduction is \$15,570 for a single filer (\$31,500 for married couples).<sup>70</sup> Deductible medical expenses would have to exceed those very significant sums (well beyond the statutory “floor” of deductibility for most filers) in order for it to make sense for taxpayers *actually* to deduct them. All of which is to say that Section 213 is increasingly a purely

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<sup>62</sup> Osofsky, *supra* note 1, at 459.

<sup>63</sup> *How Did the TCJA and OBBA Change the Standard Deduction and Itemized Deductions?*, TAX POL’Y CTR. (Sept. 2025), <https://taxpolicycenter.org/briefing-book/how-did-tcja-change-standard-deduction-and-itemized-deductions>.

<sup>64</sup> *Id.*

<sup>65</sup> TAX POL’Y CTR., STANDARD DEDUCTION AMOUNT, TAX YEARS 1970-2024 (Jan. 24, 2024), [https://taxpolicycenter.org/sites/default/files/statistics/pdf/standard\\_deduction\\_4.pdf](https://taxpolicycenter.org/sites/default/files/statistics/pdf/standard_deduction_4.pdf) [hereinafter TAX POL’Y CTR.].

<sup>66</sup> IRS, SOI TAX STATS – INDIVIDUAL STAT, TABLES BY SIZE OF ADJUSTED GROSS INCOME, [https://www.irs.gov/statistics/soi-tax-stats-individual-statistical-tables-by-size-of-adjusted-gross-income#\\_grp2](https://www.irs.gov/statistics/soi-tax-stats-individual-statistical-tables-by-size-of-adjusted-gross-income#_grp2) (last visited Feb. 28, 2026).

<sup>67</sup> *Id.*

<sup>68</sup> Osofsky, *supra* note 1, at 459 nn. 73–74.

<sup>69</sup> See Cong. Budget Off., *The Federal Budget in Fiscal Year 2022* (Mar. 2023), <https://www.cbo.gov/publication/58891>.

<sup>70</sup> IRS, *IRS Releases Tax Inflation Adjustments for Tax Year 2025*, IR-2024-273 (Oct. 22, 2024), <https://www.irs.gov/newsroom/irs-releases-tax-inflation-adjustments-for-tax-year-2025>.

symbolic deduction, and most scholarship about it is rapidly becoming a matter of predominantly historical interest.

In light of this, it might seem that there is little to be said about Section 213's treatment of disabled and chronically ill taxpayers, or taxpayers with disabled and chronically ill dependents, either from a critical disability point of view or any other. But that would not be quite right. Among other reasons, the definitions contained in Section 213(d) are used throughout the Code in provisions related to a variety of subsidies for medical care apart from the medical expense deduction itself.<sup>71</sup>

At the same time, the structure of the deduction encodes an ableist norm, according to which large medical expenses are presumed to be an unusual, short-lived, and transitory occurrence in the earning life of a taxpayer—sometimes referred to as “extraordinary” medical expenses.<sup>72</sup> This erasure of disability and chronic illness is reflected by several aspects of Section 213. First, even when the standard deduction was much lower, taxpayers whose medical expenses were regular and significant, but beneath the percentage floor (perhaps because the person was a relatively high earner notwithstanding their ongoing medical expenses), obtained no tax benefit whatsoever from Section 213, despite having less ability to pay than their similarly-situated but non-disabled/chronically ill counterparts.

Consider two taxpayers in 2016, each with an AGI of \$100,000, the first of whom regularly incurred \$6,000 in annual uninsured medical expenses and the second of whom did not (either because they had health insurance, including employer-provided health insurance, or because they did not obtain any medical care). (In that year, the standard deduction was \$6,300<sup>73</sup>). Their tax bill is the same, but the second taxpayer is able to save or invest or simply consume that sum each year, with potentially significant long-term financial and quality of life consequences. For example, the second taxpayer could use the money to cover a larger mortgage, on a home more likely to appreciate in value. With the increased standard deduction, this discrepancy is even larger. A taxpayer with regular medical expenses of \$15,000 a year *still* will not deduct them or obtain any tax benefit, because the amount falls short of the standard deduction, and itemizing will therefore not reduce their tax bill. Thus, the parenthetical claim in the Senate Budget Committee materials that “It is possible that the [Section 213] deduction assists taxpayers with one-off, unanticipated medical expenses (*or chronic*

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<sup>71</sup> See Osofsky, *supra* note 1, at 459-65 (identifying “many other places where the tax law provides a subsidy for medical expenses . . . and makes the subsidy depend on the definition of medical care that derives from § 213(d).”).

<sup>72</sup> See *id.* at 458 (“Practically, the AGI threshold means that a taxpayer will only be able to take the medical expense deduction if the taxpayer has *extraordinary*, unreimbursed medical expenses in a given year, relative to the taxpayer’s income.”), *id.* at 494 (“It is hard, if not impossible, to justify many of today’s subsidized medical care expenses as compulsory expenses that rectify an *extraordinary* medical loss.”) (emphases added).

<sup>73</sup> TAX POL’Y CTR., *supra* note 65.

conditions that are expensive, relative to AGI),” makes no sense.<sup>74</sup> The deduction precisely *fails* to assist taxpayers with expensive chronic conditions, “relative to AGI,” if those expenses fall below the bloated standard deduction. The two taxpayers just described will have the same tax bill and the same after-tax income—but one of them will be spending \$15,000 a year of it on the medical expenses associated with their disability or chronic illness.

Making matters worse, Section 213 deductions may only be taken in the year in which the expenses were incurred and thus can only be set off against that year’s income. Even if someone’s medical expenses exceed both 7.5% of AGI and the standard deduction, if the medical events are significant enough that they severely and negatively impact income that year, the tax benefit disappears forever.<sup>75</sup> These problems also apply, of course, to non-disabled persons who have catastrophic medical expenses in a particular year, but their long-term structural effects are felt most acutely by those who have significant medical expenses year over year.

It is safe to say that Section 213, with or without the limitations of Regulation § 1.213-1(e)(1)(ii) in a post-*Loper Bright* environment, does not center the experience or needs of a taxpayer whose ability to pay is regularly impacted by the need to bear uninsured medical expenses, perhaps in order to continue working. Merely acknowledging the existence of chronic conditions, “expensive, relative to AGI,” is not nearly enough, if the substantive tax law does not aim to put that taxpayer on an equal footing with their non-disabled fellow citizens in a way that reflects the economic reality of their lives. The medical expense deduction frustrates, rather than facilitates, the full and equal economic participation of disabled and chronically ill taxpayers. An apparently helpful and generous change in the tax law—the increase in the standard deduction—is not only *not* beneficial but affirmatively harmful to a large class of disabled and chronically ill taxpayers. These never-deducted medical expenses, no matter how squarely they seem to fit within the statutory definition of deductibility, amount to a tax on disability itself.<sup>76</sup>

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<sup>74</sup> S. Comm. on the Budget, 116th Cong., *Tax Expenditures: Compendium of Background Material on Individual Provisions* 880–82 (S. Prt. No. 116-53, Comm. Print 2020) (prepared by the Cong. Rsch. Serv.).

<sup>75</sup> I have addressed this timing issue in detail in Diane Kemker, *Reforming the Medical Expense Income Tax Deduction to Better Reflect “Crip Time,”* 58 U. MICH. J. L. REFORM CAVEAT 1 (2025).

<sup>76</sup> The hashtag #CripTax has been used on social media by disabled people to identify, inter alia, “medical expenses not covered by health insurance, extra costs of living in an accessible neighborhood, extra costs associated with public transportation, pass-through expenses from private businesses (i.e., #handicapitalism), additional costs for specially-prepared food, and the cost of lost productivity due to time spent advocating for accessibility.” Stephen McGarity, Abstract Withdrawn, “#CripTax Taketh Away, but Does Not Giveth:” *A Thematic Analysis of Twitter Conversations on the Extra Costs of Living with a Disability* (Soc’y for Soc. Work & Res., 24th Ann. Conf. — Reducing Racial & Econ. Inequality, Jan. 17, 2020), <https://sswr.confex.com/sswr/2020/webprogram/Paper40656.html>; see also Ryan Boren, *Crip Tax*, STIMPUNKS FOUND. (Aug. 30, 2022), <https://stimpunks.org/glossary/crip-tax/>.

## B. Non-Inclusion In Income of Employer-Paid Health Insurance Premiums

Entirely separate from Section 213, which at least theoretically permits the deduction of uninsured medical expenses, is another seemingly-helpful policy that operates *sub silentio* to the detriment of disabled and chronically ill taxpayers. Under Section 106(a), the value of employer-provided health insurance (premiums paid by the employer) is not included in taxable income.<sup>77</sup> This is “tax law’s most costly benefit,” meaning it results in the greatest loss of revenue.<sup>78</sup> According to Osofsky, “The exclusion from income of employer contributions for medical insurance premiums and medical care is the biggest expenditure in the tax law, estimated to cost the government approximately \$225 billion in lost revenue in 2022.”<sup>79</sup> This policy choice, to subsidize (by not taxing) employer-provided health insurance, not only represents a huge amount of foregone tax revenue and operates regressively (favoring the higher tax-bracket taxpayers)<sup>80</sup>; it also has ableist consequences, once we take into account longstanding lower rates of employment for disabled persons.

Although the statistics are somewhat inconsistent depending on the source, employment rates for disabled people, especially White women and people of color, are dramatically lower than for non-disabled people. At the lower end, according to the National Partnership for Women and Families, “In 2024, 22.7 percent of disabled people ages 16-64 were employed, a historic high that is nonetheless abysmally low compared to nondisabled people (65.5 percent).”<sup>81</sup> According to their data, some disabled groups do even worse; “only 19.4 percent of Asian people with disabilities are employed.”<sup>82</sup> More favorable numbers come from the American Association of People with Disabilities, which reports that “employment rates for people with disabilities *do* rise, fall, and rise again over time, [but] the percentage of disabled people employed has always been only around 30-40 percent, compared to more like 70 percent for non-disabled people.”<sup>83</sup>

This has at least two separate but related consequences. First, it means disabled people are simply less likely to *have* employer-provided health coverage at all. Currently, only about half of *all* working Americans have employer-

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<sup>77</sup> 26 USC 106(a) (“Except as otherwise provided in this section, gross income of an employee does not include employer-provided coverage under an accident or health plan.”); see also *How Does the Tax Exclusion for Employer-Sponsored Health Insurance Work?*, TAX POL’Y CTR. (Jan. 2024), <https://taxpolicycenter.org/briefing-book/how-does-tax-exclusion-employer-sponsored-health-insurance-work>.

<sup>78</sup> Osofsky, *supra* note 1, at 460.

<sup>79</sup> *Id.* at 460 n.78 (and sources cited therein).

<sup>80</sup> See *id.* at 450 & text accompanying n.18, 480-84 (discussion of Surrey’s critique of the regressivity of medical care deductions).

<sup>81</sup> Majumder & Mason, *supra* note 14.

<sup>82</sup> *Id.*

<sup>83</sup> Andrew Pulrang, *Why Is the Employment Gap for People with Disabilities So Consistently Wide?*, FORBES (Nov. 17, 2022), <https://www.aapd.com/why-is-the-employment-gap-for-people-with-disabilities-so-consistently-wide/>.

provided health insurance.<sup>84</sup> While some scholars identify the tax-free character of employer-paid health insurance premiums as a major tax subsidy, the significantly lower overall rates of employment for the disabled mean that this subsidy goes overwhelmingly to non-disabled people, further exacerbating the economic disadvantage of those who frequently need health insurance the most. Disabled people are therefore more likely to be paying out of pocket for medical expenses (or going without it), bearing an additional expense (for coverage) (or again, doing without it), and losing both tax advantages: the subsidy in the form of tax-free health insurance premiums, and less income from which to pay or deduct otherwise-deductible uninsured medical expenses, if it even makes economic sense to deduct them at all (for the reasons described above).

Here again, we encounter a policy that seems generous and well-intentioned at first glance. Exclusion of employer-paid health insurance premiums from income is popular and tax-beneficial for those who receive it. But it is not neutral or irrelevant to those who do *not*, precisely because what those excluded health insurance premiums pay for—health care—is something those with less access to that benefit are likely to need and use more than others. It is an “upside-down” subsidy not only because it is regressive, but because it seems obviously to have been adopted with no consideration whatsoever for its effect on disabled and chronically ill people. Just as discrimination and redlining reduced homeownership for people of color, which in turn produced long-term wealth inequality for families of color,<sup>85</sup> discrimination resulting in underemployment of disabled people cuts many of them off from the tax and other benefits of employer-provided health insurance, further impoverishing those who are already economically disadvantaged.

### C. Employer-Sponsored “Wellness” Programs

Although they are not generally tax-favored, employment-sponsored “wellness” programs also operate in relation to the Section 213(d) definition of medical care. More specifically, many, perhaps most, of the current wellness program offerings do *not* qualify for deductibility (and thus cannot be paid for

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<sup>84</sup> 2024 *Employer Health Benefits Survey: Summary of Findings*, KFF (Oct. 9, 2024), <https://www.kff.org/report-section/ehbs-2024-summary-of-findings/> (finding that 53.7% of workers have employer-sponsored coverage); Osofsky, *supra* note 1, at 460 n.81 (and sources cited therein) (finding 47%).

<sup>85</sup> Dorothy Brown et al., *The Racist History That Helps Explain Our Present Wealth Gap*, CTR. FOR PUB. INTEGRITY (Mar. 15, 2022), <https://publicintegrity.org/inequality-poverty-opportunity/the-geist/racist-history-wealth-gap-redlining-maps/>; Rashawn Ray et al., *Homeownership, Racial Segregation, and Policy Solutions to Racial Wealth Equity*, BROOKINGS INST. (Sept. 1, 2021), <https://www.brookings.edu/articles/homeownership-racial-segregation-and-policies-for-racial-wealth-equity/>.

using tax-favored arrangements such as Healthcare Spending Accounts), contrary to some marketing by providers.<sup>86</sup> As Osofsky notes:

The fact that the IRS Commissioner himself would weigh in on the issue [of deductibility] underscores the importance of the inherently medical/merely beneficial to general health distinction in the tax law. This distinction, which arose in the limited context of the medical expense deduction, is now deeply rooted in and essential across the most extensive framework of subsidies that exists in the tax law.<sup>87</sup>

Regardless of their precise tax status, however, employment-based programs disproportionately exclude disabled and chronically ill people due to the employment discrimination and underemployment they experience. It is, therefore, important to be sensitive both to definitional and practical barriers to the participation of disabled and chronically ill people in wellness programs, however defined (and regardless of their tax consequences). If such programs exist primarily inside of employment situations where disabled and chronically ill people are not present, that is a form of exclusion with which it is appropriate to be concerned.

#### D. Summary

The analyses offered here are intended to familiarize the reader with tax Code provisions of special relevance to the situation of disabled and chronically ill taxpayers, and to demonstrate how these tax Code provisions look when we put disabled and chronically ill people at the center of the analysis of laws that profoundly affect them—and when we don't. What becomes clear is that these provisions have not been designed with disabled and chronically ill people in mind, and perhaps unsurprisingly, do not serve them well as a result.

#### V. LEIGH OSOFSKY, “WELLNESS AND THE TAX LAW”

In “Wellness and the Tax Law,” Leigh Osofsky undertakes a quite thorough “reappraisal” (her term) of the medical expense deduction in the tax Code (Section 213 and other related provisions), and ultimately concludes that the current subsidy (all the provisions in the tax Code that reduce revenue by favorable treatment of medical expenditures) cannot be justified, primarily because it is both incoherent at a theoretical level, and regressive at a practical one.<sup>88</sup> To take its place, Osofsky proposes, in a preliminary way, a refundable progressive tax credit with an income phase out. She does not explicitly address how well either the existing subsidy, or her reform proposal serves disabled and chronically ill people.

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<sup>86</sup> I.R.S. Off. Chief Couns. Mem. 202323006 (June 6, 2023); I.R.S. News Release IR-2024-65 (Mar. 6, 2024).

<sup>87</sup> Osofsky, *supra* note 1, at 468.

<sup>88</sup> *See id.* at 443.

In this section, I review her critique of existing law, and her proposal, from a critical disability theory point of view.

Osofsky argues that the current medical expense subsidy regime (including the medical expense deduction itself, as well as other tax provisions that rely on the Section 213(d) definition of medical care) is incoherent. First, she shows that no sharp and medically defensible distinction can be made between (deductible) expenditures undertaken to treat (or especially, to prevent) illness and those that are pure (nondeductible) wellness-related “consumption.” Quite simply, as she puts it, “modern understandings of wellness illustrate that things we have long viewed as pure consumption treat or prevent disease. In this way, wellness more than blurs the lines between tax law’s definition of medical care, on the one hand, and consumption, on the other; it collapses the distinction between them.”<sup>89</sup>

So long as medical care is defined functionally, wellness cannot be usefully distinguished from it, because “medical science now teaches that a variety of wellness expenditures prevent or treat disease.”<sup>90</sup> [T]hese understandings around wellness, in combination with changes to tax law’s subsidy over time, pose fundamental problems in justifying the entire medical care subsidy regime.”<sup>91</sup> More specifically, “if the definition of medical care is that it treats or prevents disease, many wellness expenses should qualify, despite the fact that tax authority has long relegated them as merely being beneficial to general health.”<sup>92</sup> But if they did, an already overlarge subsidy would grow even larger (and more regressive). Meanwhile, an equally wide variety of expenditures that do not fit nearly as well

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<sup>89</sup> *Id.* at 489. By contrast, Barbara Zabawa offers an approach to the entire field of wellness law that crucially depends on successfully distinguishing medical care/health care from wellness and furthers a perfectibilist “self-actualization” ideal. See Barbara Zabawa, *Defining the Field of Wellness Law*, 53 *HOFSTRA L. REV.* 491 (2025). A full critique of Zabawa’s approach is beyond the scope of this Essay, but among Zabawa’s key analytic steps are (1) a binary division between the “vulnerable” patient seeking healthcare and the “empowered” consumer obtaining wellness products and services, *id.* at 493; (2) an internal tension between her attempt to describe healthcare as meeting only “imminent” threats, *id.* at 491, and then defining that as “the presence, or possible future presence, of disease or illness,” *id.* at 497, a universal human condition that would seem to leave no room for wellness at all; (3) a definition of healthcare as restoration to “an acceptable status quo” vs. wellness as health “optimization,” *id.* at 492, which would seem to foreclose wellness for the disabled and chronically ill. Zabawa’s overall approach is also consumerist, in ways that are problematic for those critical of the commodification and privatization of both medical care and wellness, and perfectibilist in its celebration of “self-actualization through lifestyle changes,” *id.* at 498, going so far as to say, “Wellness should be *exclusively* about the choice to engage in self-actualization and improvement . . .” *Id.* at 543 (emphasis added).

<sup>90</sup> Osofsky, *supra* note 1, at 469. Of course, it is not the wellness *expenditures* that have this effect, but rather, the wellness activities or products themselves (just as medical *care*, not medical care *expenditures*, treat disease). From within a privatized and commodified system of healthcare and wellness, this imprecision is understandable but should still be noticed. How much it costs to treat an illness, and who pays it, is not solely (or even primarily) a direct result of any disease process. It is an economic, not a medical, phenomenon. When a generic drug becomes available, for example, the cost of curing an illness drops dramatically, but the *illness* doesn’t change at all.

<sup>91</sup> Osofsky, *supra* note 1, at 469.

<sup>92</sup> *Id.* at 474.

into the statutory language of Section 213 have nevertheless been deemed deductible.<sup>93</sup> Attempts to find a principled basis for this are in vain.

The notion of expenses for products or procedures that are “inherently medical,” at least as that is defined by the IRS, solves the problem. While such a standard might work in theory, it has not operated consistently in practice. Instead, as Osofsky again carefully demonstrates, the IRS “is engaging in an incoherent subsidy of some types of consumption but not others,”<sup>94</sup> often driven by politics or lobbying efforts, rather than a consistent standard.<sup>95</sup>

Nor will a notion of compulsoriness/voluntariness rescue the existing approach. First, other than the most extreme emergency situations, most medical care is in some sense voluntary. No expense is “compulsory” if you cannot pay it, and describing almost any medical care as “compulsory” ignores the consequences for those unable to pay.<sup>96</sup> Second, some entirely voluntary health-related expenditures are nevertheless deductible (like smoking-cessation programs).<sup>97</sup>

Although Osofsky painstakingly demonstrates the underinclusiveness of the current deduction, with examples such as exercise and nutrition, most contemporary people will not have a hard time being persuaded of the medical benefits of wellness.<sup>98</sup> In fact, as shown above, by the 1960s and 1970s courts also were ready to concede the health benefits of many non-deductible wellness-type expenses. When Osofsky says that “practices we have long thought of as pure consumption actually treat or prevent disease,”<sup>99</sup> few judges would have disagreed even decades ago. Judges in these cases were less concerned with finding a consistent theoretical justification for the medical care deduction than they were with following the law. And it was the law, including the plain language of statutes and Regulations, not an underdeveloped medical understanding, that precluded the deductibility of health-benefiting expenses like dancing<sup>100</sup> and organic food.<sup>101</sup> Down to today, as Osofsky aptly summarizes, “The Treasury, the IRS, and the

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<sup>93</sup> See *id.* at 456, 492-93 (discussing how the IRS has used the alternate second criterion for deductibility found in Section 213—that the expense be for something that “affect[s] the structure or function of the body”—to declare lactation supplies deductible, while gym memberships underwrite activities with that consequence, but are not deductible) (citing I.R.S. Announcement 2011-14, 2011-9 I.R.B. 532 (“The Internal Revenue Service has concluded that breast pumps and supplies that assist lactation are medical care under § 213(d) of the Internal Revenue Code because, like obstetric care, they are for the purpose of affecting a structure or function of the body of the lactating woman.”)).

<sup>94</sup> Osofsky, *supra* note 1, at 492.

<sup>95</sup> See *id.* at 492-93 (discussing the changing tax treatment of lactation supplies).

<sup>96</sup> *Id.* at 502-04 (discussing Kelman’s critique of Andrews and observing that few real-world medical expenses are truly compulsory, outside of the paradigm case—emergency life-saving care) (citing Mark G. Kelman, *Personal Deductions Revisited: Why They Fit Poorly in an “Ideal” Income Tax and Why They Fit Worse in a Far from Ideal World*, 31 STAN. L. REV. 831, 865-66 (1979)).

<sup>97</sup> Osofsky, *supra* note 1, at 476.

<sup>98</sup> See *id.* at 469-78, 490 (addressing meditation, social connection, vacations, and gym memberships, which also “affect the structure or function of the body,” a separate criterion for deductibility under Section 213).

<sup>99</sup> *Id.* at 450.

<sup>100</sup> See, e.g., *Adler v. Comm’r*, 330 F.2d 91 (9th Cir. 1964); *France v. Comm’r*, 40 T.C.M. (CCH) 508 (1980).

<sup>101</sup> *Becher v. Comm’r*, 53 T.C.M. (CCH) 683 (1987).

courts have made clear that, across the tax law, medical care excludes expenses that promote general health. Excluded expenses thus include many wellness expenses, like gym memberships, dance lessons, and nutrition counseling.”<sup>102</sup>

Before presenting her own proposal, Osofsky takes the reader through the leading justifications for the medical care deduction. Osofsky first describes William Andrews’ 1972 argument that medical care expenses should not be thought of as (non-deductible) consumption expenses, but as

compulsory expenses to restore a taxpayer’s state of well-being relative to the loss that resulted in the medical expenses. In this way, medical expenses are not spending on personal pleasure or regular personal maintenance; they are not a form of consumption, and they should therefore be deducted from the taxpayer’s income in the tax system’s measurement and taxation of relative wellbeing.<sup>103</sup>

From a critical disability theory point of view, what stands out most is not whether these expenses are “consumption” or not, or even the problem with “compulsoriness,” as described above. Rather, it is the idea that the deduction is justified only insofar as these expenditures “restore” a state of health that may not be available to the disabled or chronically ill person, coupled with the idea that significant medical expenses are not part of a person’s “regular personal maintenance.” What if the expenditures only maintain someone in a state of chronic illness, and do not restore wellbeing? What if the expenses are part of someone’s regular personal maintenance? Should they then *not* be deductible? Even as Andrews defends a general rule for deductibility that might be favorable for disabled and chronically ill people, he does so from an ableist standpoint that excludes their lived reality, and that cannot, therefore, be a justification *for them*.

In illustrating Andrews’ point, Osofsky takes the reader through an example like the one above, comparing two taxpayers, who Osofsky calls the “Big Spender” and the (unfortunately named) “Tragic Medical Patient.” The “Big Spender” undertakes a \$100,000 kitchen renovation, while the “Tragic Medical Patient” is “diagnosed with a terrible medical disease and must pay \$100,000 to treat it.”<sup>104</sup> Fact patterns and nicknames like this not only encourage us to think of the paradigm case as a high earner experiencing a one-time “tragedy,” but also treat all disease as temporary and curable (if expensive), characterize disease only as “terrible” and “tragic,” and naturalize a healthcare system in which people “must pay” exorbitant sums for care. The return to “well-being” is assumed to be possible and achievable; the assumption that treatment of disease is an expense to be individually borne is unquestioned (“the loss *that resulted in* the medical expenses,” as if this connection is ineluctable).

Mark Kelman’s 1979 article developed the idea, *contra* Andrews, that medical expenses *cannot* be sharply distinguished from consumption choices, because medical care often includes an element of consumption. To illustrate

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<sup>102</sup> Osofsky, *supra* note 1, at 466.

<sup>103</sup> *Id.* at 486.

<sup>104</sup> *Id.* at 486-87.

Kelman's thesis, Osofsky presents two versions of the same stereotyped character, "wealthy Tragic Medical Patient, [who] for instance, can pay for a tax-deductible private hospital room, along with the highest quality meals, whereas a poor Tragic Medical Patient is likely to receive less personally satisfying care."<sup>105</sup> Wherever one comes out on whether Kelman or Andrews got it right ("Kelman argued [that] it can be difficult to distinguish between consumption choices about how to spend one's income (which should be included in the tax base) and medical care (which, in Andrews's seminal defense of the medical deduction, should not)"<sup>106</sup>), an air of unreality hovers around the entire discussion. In the United States, where the median net worth is currently \$192,000,<sup>107</sup> medical expenses amounting to more than half of that do not just mean a less fancy hospital room. The person without the means to treat an illness for which the drug or surgery (or hospitalization) costs \$100,000 does not merely "receive less personally satisfying care." They borrow to pay for care and are bankrupted by it<sup>108</sup>; or they receive no care; and perhaps they die or are permanently disabled by the "terrible medical disease" they cannot afford to treat in our privatized health care system.

While Osofsky is correct, with Kelman, in arguing that medical expenses very frequently have or might have a consumption element, and that the justification for the medical expense deduction therefore cannot rest upon a concept of medical expenses as non-consumption per se, this argument is not advanced by examples so disconnected from real experience (ironically, a charge Kelman levels at Andrews<sup>109</sup>). Importantly, Osofsky goes still further than Kelman. As she puts it, "The science around wellness teaches us that consumption is not fundamentally distinct from medical care, at least as the tax law defines medical care, because consumption often *is* medical care."<sup>110</sup> In other words, whether expenditures on traditional medical care, or on "inherently medical" procedures or products, also include an element of consumption is to some degree beside the point (even if true); the more fundamental problem with defining medical expenses to exclude consumption expenses is that some expenses regarded as a paradigmatically consumption also have medical benefits that seem to bring them within the ambit of Section 213. Once the teachings of the new science of wellness are understood, it becomes clear that there is no way the law can

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<sup>105</sup> *Id.* at 488.

<sup>106</sup> *Id.*

<sup>107</sup> See, e.g., Emily Sherman & Jessica Walrack, *What Is the Average American Net Worth by Age?*, U.S. NEWS & WORLD REP. (May 23, 2025), <https://money.usnews.com/money/personal-finance/articles/what-is-the-average-american-net-worth-by-age>.

<sup>108</sup> Edwin Woods, Jr., *Health Care Costs Number One Cause of Bankruptcy for American Families*, AM. BANKR. INST. (Jan. 20, 2017), <https://www.abi.org/feed-item/health-care-costs-number-one-cause-of-bankruptcy-for-american-families> (providing that according to the American Bankruptcy Institute, "health care costs are the #1 cause of bankruptcy" in the United States); see also John August, *Healthcare Insights: How Medical Debt Is Crushing 100 Million Americans*, SCHEINMAN INST. ON CONFLICT RESOL. BLOG (Oct. 21, 2024), <https://www.ilr.cornell.edu/scheinman-institute/blog/john-august-healthcare/healthcare-insights-how-medical-debt-crushing-100-million-americans>.

<sup>109</sup> Osofsky, *supra* note 1, at 488.

<sup>110</sup> *Id.* at 489 (emphasis in original).

meaningfully, usefully, and accurately “distinguish between consumption and medical care as a general matter.”<sup>111</sup>

The current medical understanding of the health-enhancing value of wellness practices, together with the incoherence and expense of the current medical care subsidy, presents two paths forward, from Osofsky’s point of view. We might include wellness practices in the deduction (subsidy), so long as they satisfy Section 213(d), meaning they demonstrably treat or prevent illness, or affect the structure or function of the body. This approach has a variety of undesirable fiscal, administrability and regressivity problems.<sup>112</sup> Despite the fact that many wellness practices in fact seem to satisfy the language of Section 213, Osofsky already sees the deduction as having “ballooned” well beyond what can be justified and does not defend enlarging it.<sup>113</sup>

The second option is to shrink the subsidy in some way. Though it is tempting to draw a line around the “inherently medical” that does not rely on a consumption concept or focus on outcomes (such as preventing illness) or respond to politics, it seems unlikely. Alternatively, one could narrow the deduction “to more closely match justifiable goals, such as insuring against catastrophic medical expenses.”<sup>114</sup> Osofsky explains,

The idea would be that perhaps the tax law should subsidize medical care expenses that are truly catastrophic and compulsory, but not others. This would protect taxpayers from having to pay taxes that do not reflect their true ability to pay when they have suffered real, and very large, medical losses.<sup>115</sup>

Ultimately, Osofsky rejects this approach—but as with Kelman’s defense, it is not for the right reasons, from a critical disability theory point of view. Osofsky explains further,

The way to do this would be to: (a) scale back tax subsidies other than the medical expense deduction, while ensuring that the deduction remains subject to a high-AGI floor so that tax law only considers catastrophic costs; and (b) scale back the definition of medical care to only include compulsory expenses.<sup>116</sup>

The idea that some (especially rare or one-time) medical expenses are “catastrophic” reflects the background ableist assumption that the paradigmatic taxpayer almost never has such expenses; ignores the background way healthcare is financed, that makes “very large medical losses” all too common; and by defending the high-AGI floor ignores the supervening significance of the standard

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<sup>111</sup> *Id.* at 490.

<sup>112</sup> *See id.* at 499-500 (regressivity). Though Osofsky rightly rejects this approach, her concerns about changing the Regulations, expressed at 496, are superseded by *Loper Bright*, discussed *supra*.

<sup>113</sup> *Id.* at 494.

<sup>114</sup> *Id.* at 495.

<sup>115</sup> Osofsky, *supra* note 1, at 501.

<sup>116</sup> *Id.*

deduction. As noted above, describing such expenses as somehow “compulsory” ignores the consequences for those unable to pay them. The “loss” framing treats large medical expenses negatively impacting ability to pay taxes as inherently rare occasions, followed by “restoration” to full health and earnings (it is a perfectibility framing). It fails to take account of the experience of those for whom these are the baseline costs of self-care in a country with privatized health insurance. And even a more narrowly-defined deduction would still be subject to all the timing problems already addressed.<sup>117</sup>

Ultimately Osofsky rejects both of these approaches, in favor of a novel proposal, a progressive wellness credit that would replace the medical expense deduction, or in a still more radical form, as an unconditional payment modeled on universal basic income.<sup>118</sup> In tax law, a “credit” is applied against any tax owed, giving full dollar value, unlike a deduction, whose value varies depending on the taxpayer’s tax bracket. In tax law terminology, if it is possible to receive this payment without owing any tax, or to receive it even if it exceeds any tax due, it is called (perhaps confusingly) a “refundable credit” (even though nothing is being “refunded”). Although Osofsky does not explicitly call her proposal a “refundable” credit, the tables she presents makes clear that this is what she has in mind, as a taxpayer with no income at all still receives the full amount.<sup>119</sup> She presents two versions of the credit, one with and one without “phaseouts” for higher incomes, to achieve differing degrees of progressivity.<sup>120</sup>

The goal of this proposal is to “respond to the major problems inherent in today’s medical care subsidy: its incoherence and regressivity.”<sup>121</sup> Many of the benefits of such a credit, like uniform basic income, are enhancements to health and well-being, including in ways especially beneficial to disabled and chronically ill people. For example, simply being able to pay bills and make small consumption choices is demonstrably beneficial to mental health.<sup>122</sup> A crucial feature of this approach is that it makes many expenditures which would be deductible available even to those who lack “the privilege of having salary, insurance, or healthcare accounts that entitle them to the subsidy.”<sup>123</sup> The idea of a medical care tax program structured like UBI or a refundable credit is one that the critical disability theorist can applaud: “the payments to program participants enabled them to engage in the types of consumption that can prevent or treat disease, on a more even playing field with high-income individuals, and in contrast to tax law’s existing, regressive subsidy regime.”<sup>124</sup>

However, her recommendation to “*replac[e]* tax law’s medical expense deduction with a credit,” because “a credit eliminates the regressivity inherent in a

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<sup>117</sup> See Part II, *supra*; Diane Kemker, *supra* note 75.

<sup>118</sup> See Osofsky, *supra* note 1, at 504-05.

<sup>119</sup> *Id.* at 505-14 (Taxpayer A). She also cites approvingly to Batchelder’s discussion of the benefits of refundable tax credits, specifically.

<sup>120</sup> See *id.* at 513-14 (Taxpayers B and C).

<sup>121</sup> *Id.* at 514.

<sup>122</sup> See *id.* at 509-11.

<sup>123</sup> *Id.* at 511.

<sup>124</sup> Osofsky, *supra* note 1, at 511.

deduction,”<sup>125</sup> has quite a significant problem she does not address. The annual credit she suggests, \$2400, is chosen deliberately to be a “modest” amount, compared to UBI proposals of \$6000 to \$12000 per year.<sup>126</sup> But this small amount makes it inadequate as a true replacement for Section 213. What of the taxpayer who actually *has* deductible medical expenses in excess of \$15,000, once or year after year? Even for those without significant medical expenses, if Section 106(a) were repealed, and taxpayers were required to include employer-paid health insurance premiums in income, this would be a significant tax increase for many, greatly in excess of the \$2400 credit. Alternatively, if Osofsky doesn’t actually mean to fully replace Section 213, then detailed reform proposals are needed in order to avoid effectively expanding a subsidy Osofsky already regards as excessive (as well as regressive). If, as seems likely, her suggestion would be to limit Section 213 to the “compulsory” and “catastrophic” expenses she describes, the problems with that approach reappear.

However, whether we endorse Osofsky’s progressive refundable wellness credit or not, she is surely correct that existing law “is rooted in a traditional paradigm, which imagines a limited set of medical interventions that restore taxpayers to good health.”<sup>127</sup> While Osofsky’s primary objection to this paradigm is that it only works if “it is possible to distinguish easily between medical care and consumption,”<sup>128</sup> critical disability theory also points out the perfectibility norm expressed by the centrality of “restoration to good health.” Osofsky is correct that medical care and consumption cannot be neatly separated, and moreover, many consumption-like “wellness” expenditures are for products and activities that in fact treat and prevent disease (or, as the case may be, affect the structure and function of the body), and often do so less expensively than recognized deductible medical expenses. The current deductibility rules do not make sense. The current subsidy regime cannot be justified. What critical disability theory adds to critiques based on incoherence and regressivity is that the current approach conceptualizes illness and medical care in ways that especially disserve disabled and chronically ill people, resulting in further disadvantage to those already living with recurring significant medical expenses and staggering underemployment.

The tax Code expresses collective judgments about who deserves care and concern, as do reform proposals. These judgments operate at both the level of theory and of practice. When the justification for a large medical deduction from taxable income is that the expenses incurred to treat or cure it are “compulsory,” those unable to afford those expenses disappear from view. When the justification is that a taxpayer’s ability to pay may be affected in a given year by large medical expenses, persons who pay such expenses every year are made invisible. “Favorable” tax provisions for some exacerbate privation and inequality for others. The exclusion of employer-provided health insurance from taxable income is a “tax break” for many—but it is a regressive subsidy that only makes those who are

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<sup>125</sup> *Id.* at 505 (emphasis added).

<sup>126</sup> *See id.* at 512.

<sup>127</sup> *Id.* at 515-16.

<sup>128</sup> *Id.* at 516.

not employed, or whose employers do not provide this benefit, worse off. A dramatic increase in the standard deduction may be popular, but those with regular medical expenses falling just below it benefit least, and in fact are made worse off in relative terms. Osofsky's refundable progressive wellness credit responds to many shortcomings in the current approach, but even more is called for if we seek substantive, material improvement in the economic status of the disabled and chronically ill.

## VI. CONCLUSION

Ableism in the tax Code's medical care subsidy and in our conceptions of wellness harm everyone, by marginalizing and subordinating disabled and chronically ill people, perpetuating damaging norms about perfectibility, and through conceptions of health and illness that are, at best, partial. When illness is consistently theorized as treatable and curable, it is easy to believe that all illness "ought" to be treated and cured, and that the failure to "get better" is a personal failing. This individualized model is exacerbated by a privatized system of health care, in which access to care depends on a combination of employment status and personal/familial resources, and thus reflects other structural forms of inequality, including racism and sexism. When illness is exclusively conceived of as misfortune, even "catastrophe," it is difficult to theorize a dignified life as a disabled or chronically ill person and to avoid thinking of such persons as defective and less worthy of care. Critical disability theory demands that we do better.

# THE WELLNESS DATA CONUNDRUM: PRIVACY, POWER, AND REGULATION BEYOND HIPAA

Gary Hsuanyu Liu\*

## I. INTRODUCTION

When GoodRx paid a \$1.5 million FTC penalty in 2023 for sharing patient prescription histories with Facebook and Google,<sup>1</sup> the case exposed an uncomfortable truth about American health privacy. This “pixel affair” revealed that however vast the wellness data ecosystem, from fitness trackers to workplace programs, most of it operates beyond HIPAA’s reach.<sup>2</sup> Privacy protection has eroded silently outside HIPAA’s perimeter. Not in hospitals or clinics, where HIPAA still guards those gates—but in the unregulated wilderness where most Americans now seek health.

The global wellness economy has surged to a \$6.3 trillion industry, with the North American market alone accounting for \$2.2 trillion. With 84% of Americans prioritizing wellness more than ever,<sup>3</sup> digital health tools pervade daily life. Yet unlike HIPAA-governed hospitals, wellness companies operate in regulatory chaos. Who controls wellness-generated data? What deletion rights exist? What duties bind companies? In this chaos, valuable health data can flow freely to tech companies with minimal oversight, leaving consumers vulnerable to privacy invasions and discrimination that healthcare privacy law was designed to prevent.

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<sup>1</sup> Compl. ¶¶ 40–46, *FTC v. GoodRx Holdings, Inc.*, No. 23-cv-460 (N.D. Cal. filed Feb. 1, 2023) [hereinafter *GoodRx Complaint*]; see Thomas Germain, *GoodRx Saves Money on Meds—It Also Shares Data with Google, Facebook, and Others*, CONSUMER REPS. (Mar. 6, 2020), <https://www.consumerreports.org/health/health-privacy/goodrx-saves-money-on-medsit-also-shares-data-with-google-facebook-and-others-a6177047589/>.

<sup>2</sup> *GoodRx Complaint*, *supra* note 1, ¶ 1; Stipulated Order at 4, *FTC v. GoodRx Holdings, Inc.*, No. 23-cv-460 (N.D. Cal. Feb. 17, 2023) [hereinafter *GoodRx Stipulated Order*] §§ II–III; see Press Release, Fed. Trade Comm’n, *FTC Enforcement Action to Bar GoodRx from Sharing Consumers’ Sensitive Health Info for Advertising* (Feb. 1, 2023) [hereinafter *FTC GoodRx Press Release*], <https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising>.

<sup>3</sup> See Anna Pione et al., *The Future of Wellness Trends Survey 2025*, MCKINSEY & CO. (May 29, 2025), <https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/the-future-of-wellness-trends-survey-2025> (analyzing consumer wellness priorities).

This Article proposes an integrated legal framework. Building on Richards, Cohen, and Solove's insights, I contend that absent federal guidelines undermine consumer autonomy and health equity. Recent enforcement against GoodRx, BetterHelp, and Flo,<sup>4</sup> plus novel litigation over hospital tracking pixels,<sup>5</sup> illustrate tangible harms. Confusion about HIPAA's boundaries, particularly when wearable data meets clinical records, exacerbates vulnerability and disrupts care continuity.

I advance the following thesis: A "Tiered Integration Framework" can bridge these gaps through three interlocking mechanisms: (1) a federal data fiduciary duty imposing loyalty-based care obligations on wellness platforms; (2) a baseline-flexible model preserving stronger state privacy laws while establishing federal minimums; and (3) an FDA "risk gate" clarifying when wellness products require medical device regulation. This framework curbs information-driven power asymmetries<sup>6</sup> while fostering innovation under clear rules.

I develop these claims in four parts. Part II maps the doctrinal fault lines that constitute the wellness data gap. First Amendment constraints, jurisdictional limits, and outdated tort doctrines. Part III develops a federal wellness data fiduciary duty grounded in loyalty and care principles,<sup>7</sup> sketching a statutory blueprint with four core duties and demonstrating why this framework survives First Amendment scrutiny as content-neutral conduct regulation.<sup>8</sup> Part IV proposes federal floor preemption (analogous to GLBA<sup>9</sup>) and an FDA two-gate risk test delineating high-risk wellness products requiring device regulation. Part V

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<sup>4</sup> See, e.g., FTC GoodRx Press Release, *supra* note 2 (noting the first use of the Health Breach Notification Rule; GoodRx shared consumers' prescription data with Facebook and Google, resulting in a \$1.5 million penalty and a prohibition on such disclosures); Press Release, Fed. Trade Comm'n, FTC to Ban BetterHelp from Revealing Consumers' Data, Including Sensitive Mental Health Information, to Facebook and Others for Targeted Advertising (Mar. 2, 2023) (online therapy platform BetterHelp shared users' mental-health data for advertising; settlement imposed \$7.8 million in fines and requires opt-in consent) [hereinafter FTC BetterHelp Press Release]; Press Release, Fed. Trade Comm'n, Developer of Popular Women's Fertility-Tracking App Settles FTC Allegations That It Misled Consumers About the Disclosure of Their Health Data (Jan. 13, 2021) (Flo Health app shared sensitive cycle and pregnancy data despite privacy promises; FTC order requires user notice and consent) [hereinafter FTC Flo Press Release]; see also *Doe v. Google LLC*, 741 F. Supp. 3d 828 (N.D. Cal. 2024) (allowing claims that a hospital's use of tracking pixels on a patient portal violated privacy and wiretap laws).

<sup>5</sup> Steve Alder, *Google Must Face Healthcare Class Action Lawsuit over Tracking Technology*, HIPAA J. (Mar. 30, 2023), <https://www.hipaajournal.com/google-tracking-technology-healthcare-class-action/>.

<sup>6</sup> FTC GoodRx Press Release, *supra* note 2; see generally JULIE E. COHEN, *BETWEEN TRUTH AND POWER* (Oxford Univ. Press 2019) (analyzing information-driven power asymmetries).

<sup>7</sup> See Neil M. Richards, Woodrow Hartzog & Jordan Francis, *A Concrete Proposal for Data Loyalty*, 37 HARV. J.L. & TECH. 1335 (2023).

<sup>8</sup> See *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011); see *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980); see *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 707 (1986); Jack M. Balkin, *Information Fiduciaries and the First Amendment*, 49 U.C. DAVIS L. REV. 1183, 1208–12 (2016) (analyzing content-neutral conduct regulation).

<sup>9</sup> See Gramm–Leach–Bliley Act, 106th Cong. Pub. L. No. 106-102, 113 Stat. 1338 (1999) (federal financial privacy law allowing stronger state laws) [hereinafter Gramm–Leach–Bliley Act].

addresses implementation via the FTC's amended Health Breach Notification Rule<sup>10</sup> and phased compliance.

The wellness-healthcare divide creates a privacy paradox: Data are protected in the clinic, but exposed in the app. This Article proposes bridging that chasm before market forces render privacy obsolete.

## II. THE WELLNESS DATA GAP

### A. Doctrinal Fault Lines

The Constitution, as currently interpreted, shields data commodification while constraining privacy protection, a tension that *Sorrell v. IMS Health* brought into sharp relief. Vermont's ban on selling prescriber data fell to First Amendment challenges, with the Court deeming medical data commerce "protected expression."<sup>11</sup> The decision transformed health information into a tradeable commodity, holding that the law imposed a "burden based on the content of speech" that the State's justifications could not withstand. This precedent erected a formidable constitutional barrier: privacy rules now risk strict scrutiny as speech restrictions. Medical disclosures face similar challenges, while data-mining limits encounter constitutional roadblocks.<sup>12</sup>

Alexander Tsesis captures the resulting paradox: The Free Speech Clause has morphed into a "deregulatory tool" that invalidates even modest consumer protections.<sup>13</sup> The practical implications are unsettling. A state law barring fitness tracker data sales to brokers could crumble under *Sorrell's* logic. Laws that treat health data as commodity enjoy constitutional protection; laws that treat health data as sensitive face immediate suspicion. This constitutional fault line fundamentally tilts the playing field: companies invoke "free speech" to monetize heart rate data while privacy advocates struggle to justify basic protections. Below, Part III.C will demonstrate how carefully crafted fiduciary duties can navigate *Sorrell's* constraints through content-neutral conduct regulation.<sup>14</sup>

Beyond constitutional constraints lies a jurisdictional maze that leaves wellness data in regulatory limbo. The FTC attempts oversight through consumer protection mandates, but *LabMD v. FTC* exposed critical limits: When the Eleventh Circuit vacated an order against a cancer testing lab for lax security, it condemned the FTC's attempt to enforce an "indeterminable standard of

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<sup>10</sup> See Morrison & Foerster, *FTC Issues Final Rule to Expand Health Breach Notification Requirements* (May 14, 2024), <https://www.mofo.com/resources/insights/240514-ftc-issues-final-rule-to-expand> (expanding breach notification to health apps and devices).

<sup>11</sup> See *Sorrell*, 564 U.S. 552 (holding that the sale of prescriber-identifying data is protected speech under the First Amendment).

<sup>12</sup> See Jane Bambauer, *Is Data Speech?*, 66 STAN. L. REV. 57, 63–64 (2014); see Nat'l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA), 585 U.S. 755 (2018).

<sup>13</sup> See Alexander Tsesis, *The Free Speech Clause as a Deregulatory Tool*, 153 DAEDALUS 208 (2024), <https://direct.mit.edu/daed/article/153/3/208/123989/The-Free-Speech-Clause-as-a-Deregulatory-Tool>.

<sup>14</sup> See *Sorrell*, 564 U.S. 552; Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980); *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 707 (1986).

reasonableness” without clear standards.<sup>15</sup> This precedent signals judicial skepticism toward expansive FTC authority in data security. Moreover, FTC jurisdiction covers only commercial entities; nonprofit wellness programs, employer health challenges, and university research slip through statutory cracks.

HIPAA’s boundaries prove equally rigid and increasingly obsolete. The Banner Health settlement, which imposed \$1.25 million in penalties after hackers accessed 2.81 million patient records through a third-party food service vendor exploiting network connections, illustrates the problem with precision.<sup>16</sup> When hackers accessed 2.81 million patient records through a third-party food service vendor exploiting network connections, HIPAA stretched to cover the hospital’s extended ecosystem. Yet consider the absurdity: identical data—names, conditions, treatments—collected by an independent wellness app faces zero HIPAA oversight. The law creates a binary regulatory world where protection depends not on data sensitivity but on collector identity. This pattern, which I call the “collector-identity paradox,” structures the entire regulatory failure: inside HIPAA’s walls are robust safeguards; outside lies a patchwork of weak state laws and limited FTC authority.<sup>17</sup>

Traditional tort and contract doctrines fail conspicuously when confronting modern wellness data harms. *Bartis v. Biomet* reveals this doctrinal awkwardness.<sup>18</sup> When hip implant plaintiffs battled over Fitbit discovery, the court struck a curious balance: It compelled step-count production (relevant to mobility claims) while protecting heart rate, sleep, and location data as “not relevant . . . and rais[ing] privacy concerns.”<sup>19</sup> This recognized privacy interests only in discovery’s procedural context, and offered zero substantive protection against breaches or misuse. No freestanding tort exists for “wellness data privacy invasion”; existing privacy torts demand unreasonably high bars like “highly offensive conduct.”<sup>20</sup> Contract law fares no better in this mismatched legal landscape. Privacy policies routinely reserve sweeping company rights while disclaiming meaningful liability.<sup>21</sup> When devices malfunction or unlawfully share data, plaintiffs resort to product liability theories to recover for physical harm. *Smith v. Apple* exemplifies this doctrinal poverty: consumers alleged Apple Watch

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<sup>15</sup> See *LabMD, Inc. v. FTC*, 894 F.3d 1221, 1236 (11th Cir. 2018).

<sup>16</sup> See U.S. DEP’T OF HEALTH & HUM. SERVS., *Banner Health Resolution Agreement and Corrective Action Plan*, <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/banner-health-ra-cap/index.html> (last visited July 13, 2025).

<sup>17</sup> GoodRx Complaint, *supra* note 1, ¶¶ 1, 40–46; FTC GoodRx Press Release, *supra* note 2; see Germain, *supra* note 1.

<sup>18</sup> See Doug Austin, *Court Grants Defendants’ Motion to Compel Plaintiff’s Fitbit Data*, *EDISCOVERY TODAY* (June 1, 2021), <https://ediscoverytoday.com/2021/06/01/court-grants-defendants-motion-to-compel-plaintiffs-fitbit-data-ediscovery-case-law/>.

<sup>19</sup> See *Bartis v. Biomet, Inc.*, No. 4:13-CV-00657-JAR, 2021 WL 2092785, at \*3 (E.D. Mo. May 24, 2021).

<sup>20</sup> See *id.* (finding location data “raises privacy concerns”).

<sup>21</sup> See, e.g., Lauren Henry Scholz, *Fiduciary Boilerplate: Locating Fiduciary Relationships in Information Age Consumer Transactions*, 46 J. CORP. L. 143, 158 (2020) (noting firms’ use of unilateral change-of-terms clauses); see also Class Action Complaint at 24, *Albano v. Amazon.com, Inc.*, No. 2:25-cv-00261 (W.D. Wash. Feb. 10, 2025) (alleging data collection occurred without meaningful consent despite policy terms).

screens shattered, causing physical injury. The \$20 million settlement addressed purely physical product defects, not privacy rights, leaving data vulnerabilities without meaningful redress, acting as a Band-Aid on a gaping wound.<sup>22</sup>

Yet *Doe v. Google* offers a partial opening through innovative statutory theories.<sup>23</sup> Patients whose hospital portal interactions were secretly tracked by Google's analytics pixel survived dismissal by invoking wiretap statutes and invasion of privacy. Judge Chhabria's reasoning proved crucial: Google "intended to receive communications containing individually identifiable health information" before issuing 2023 remedial guidance. Patients never consented to this interception.<sup>24</sup> Such victories remain exceptional, however, because they demand egregious facts (covert hospital website tracking) and plaintiff-friendly jurisdictions. Even then, proving "interception" or concrete harm remains daunting.

State legislation represents another emerging battlefield. Washington's My Health My Data Act defines "consumer health data" expansively to include any information revealing health status or service-seeking behavior.<sup>25</sup> *Maxwell v. Amazon* tests these boundaries aggressively.<sup>26</sup> The suit alleges Amazon's mobile SDK collected precise geolocation from third-party apps, potentially revealing visits to addiction clinics or fertility centers. Whether location data can qualify as protected health information when indicating healthcare seeking pushes legal definitions to their outer limits. Courts have yet to embrace such expansive interpretations, and only Washington and a handful of other states even provide statutory causes of action.

The legal void surrounding de-identified wellness data deserves separate attention. Under HIPAA, de-identification removes all regulatory protection, a loophole growing more dangerous as re-identification techniques advance. *Dinerstein v. Google* starkly illustrates this gap's consequences. When a hospital shared thousands of "anonymized" medical records with Google for AI development, the Seventh Circuit affirmed dismissal for lack of concrete injury; the plaintiff could not plausibly allege re-identification or misuse.<sup>27</sup> This holding crystallizes a disturbing principle: Large-scale transfers of sensitive health records escape legal remedy absent proven identity theft or tangible harm.

These doctrinal strands converge on a single pattern. Taken together, today's legal doctrines treat wellness data exposures as "no harm, no foul" events,

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<sup>22</sup> See Final Approval Order at 1–2, *Smith v. Apple Inc.*, No. 4:21-cv-09527-HSG (N.D. Cal. May 1, 2025) (approving physical defect settlement); STACY-ANN ELVY, *A COMMERCIAL LAW OF PRIVACY AND SECURITY FOR THE INTERNET OF THINGS* 160–61, 322 (Cambridge Univ. Press 2021) (noting product liability limitations).

<sup>23</sup> See *Doe v. Google LLC*, 741 F. Supp. 3d 828 (N.D. Cal. 2024); see Alder, *supra* note 5.

<sup>24</sup> Alder, *supra* note 5.

<sup>25</sup> See WASH. REV. CODE § 19.373.010(8) (2024) (defining consumer health data).

<sup>26</sup> *Maxwell v. Amazon.com, Inc.*, No. 2:25-cv-00261 (W.D. Wash. filed Feb. 10, 2025) [hereinafter *Maxwell Complaint*]; Steve Alder, *Lawsuit Filed Against Amazon Alleging Unlawful Collection of Health & Location Data*, HIPAA J. (Oct. 26, 2023), <https://www.hipaajournal.com/amazon-sdk-privacy-lawsuit-washington-my-health-my-data/>.

<sup>27</sup> *Dinerstein v. Google, LLC*, 73 F.4th 502 (7th Cir. 2023) (holding that plaintiffs lacked standing absent a plausible showing of reidentification or misuse of the "anonymized" data).

forcing litigants to squeeze privacy grievances into ill-fitting categories: product defects, property loss, anything but privacy violations. The chasm between subjective privacy invasion—that visceral feeling when your intimate data is misused—and objective legal injury required by courts grows ever wider. This doctrinal mismatch leaves millions exposed, their most personal information monetized without recourse.

### B. Enforcement Gaps and Patchwork Responses

Three recent FTC enforcement actions against wellness apps reveal both the agency's creative reach and the structural limits of case-by-case enforcement. The FTC's recent trilogy—GoodRx, BetterHelp, and Flo—exposes both the agency's creativity and its limitations as wellness data's de facto guardian.

GoodRx's conduct exemplified the gap between privacy promises and commercial practice. Despite promising users their personal health information would never be shared, the company secretly fed medication and condition data to Facebook and Google's advertising machines.<sup>28</sup> The FTC's response marked history: the first-ever Health Breach Notification Rule enforcement, yielding \$1.5 million in penalties and unprecedented injunctive terms. GoodRx must now cease health data advertising shares, obtain explicit consent for any disclosures, delete third-party data, and implement comprehensive privacy programs.<sup>29</sup> The FTC heralded this as putting digital health companies "[on] notice[.]"<sup>30</sup> Yet the action's very novelty reveals a troubling truth: such practices had thrived unchecked until investigative journalism and innovative legal theories finally caught up.<sup>31</sup>

BetterHelp's violation involved arguably more sensitive information, striking at the foundations of therapeutic trust. The online therapy platform shared subscribers' most vulnerable moments—email addresses and intake responses revealing depression, anxiety, trauma—with Facebook, Snapchat, and others for targeting.<sup>32</sup> The \$7.8 million settlement, the FTC's first returning money to health privacy victims, reflected the egregious nature of mental health data misuse.<sup>33</sup> The consent order demands affirmative consent before any future disclosures and robust protective implementations.<sup>34</sup> Notably, BetterHelp's penalty dwarfed GoodRx's, signaling the agency's view that mental health breaches warrant harsher consequences.

Flo Health's case foreshadowed post-*Dobbs* dangers. The menstrual tracking app shared millions of users' intimate details—cycle data, pregnancy status—with analytics firms including Facebook and Google, despite privacy

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<sup>28</sup> GoodRx Complaint, *supra* note 1, ¶¶ 19, 42, 45; CAL. CIV. CODE § 1798.140 (2025) (defining "sell" and "sharing" to include data transfers for cross-context behavioral advertising).

<sup>29</sup> GoodRx Stipulated Order, *supra* note 2, §§ II–III; FTC GoodRx Press Release, *supra* note 2.

<sup>30</sup> FTC GoodRx Press Release, *supra* note 2.

<sup>31</sup> *See id.*

<sup>32</sup> *See* FTC BetterHelp Press Release, *supra* note 4, at 1–2.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

assurances.<sup>35</sup> While the 2021 consent order imposed notice requirements, user consent obligations, and twenty-year privacy audits, Flo paid no monetary penalty due to the FTC’s limited fining authority absent rule violations.<sup>36</sup> The case illuminated reproductive data’s vulnerability and presaged concerns that period-tracking apps could expose pregnancies or abortions to scrutiny.

These actions reveal a fundamental weakness: reactive, piecemeal enforcement targeting individual bad actors rather than establishing industry-wide standards. Each case hinges on deception (broken promises) or narrow breach reporting duties, not general data protection mandates. The FTC stretches existing authorities creatively but cannot substitute for proactive regulation.

State innovation offers both promise and fragmentation. California’s Consumer Privacy Rights Act regulations demonstrate granular thinking: businesses must not disclose medical identification numbers in access requests while informing consumers they possess such information “with sufficient particularity[.]”<sup>37</sup> This practical rule protects sensitive identifiers while preserving awareness rights. California also grants broad deletion rights, though with necessary exceptions.<sup>38</sup> However, ambiguities persist—if consumers input their own health metrics, the question whether this constitutes “medical information” under state law remains unresolved. HIPAA-covered entities enjoy exemptions, creating additional regulatory gaps.

Missouri’s proposed Biometric Information Privacy Act (S.B. 554) would strengthen individual rights over biometric identifiers such as fingerprints and facial scans. The bill mandates prior informed consent, prohibits biometric sales, requires reasonable security, and creates private enforcement with \$1,000–\$5,000 liquidated damages.<sup>39</sup> Following the pattern of Illinois’s Biometric Information Privacy Act (BIPA), it would empower direct lawsuits.<sup>40</sup> Yet as of this writing, industry opposition and preemption concerns have stalled progress—a pattern repeated across states acknowledging gaps but failing to act.

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<sup>35</sup> FTC Flo Press Release, *supra* note 4.

<sup>36</sup> *Id.*

<sup>37</sup> See CAL. CODE REGS. tit. 11, § 7024(d) (2024) (prohibiting businesses from disclosing a consumer’s medical identification number in a data access response but requiring the business to inform the consumer “with sufficient particularity” that such information was collected); see also 4 COLO. CODE REGS. § 904-3-4.04(E) (2023) (similarly exempting medical ID numbers from access disclosures but obligating controllers to confirm their collection “with sufficient particularity”).

<sup>38</sup> See CAL. CIV. CODE § 1798.105(a), (d) (West 2024) (granting consumers a right to request deletion of personal information, subject to enumerated exceptions such as completing a transaction or complying with law); see also CAL. CIV. CODE § 1798.145(c)(1)(A) (exempting any “medical information” governed by California’s CMIA, as well as any protected health information under HIPAA — i.e., HIPAA-covered data is excluded from these deletion rights).

<sup>39</sup> See S.B. 554, 103d Gen. Assemb., 1st Reg. Sess. §§ 1.566, 1.569 (Mo. 2025) (proposed) (setting liquidated damages amounts) [hereinafter Mo. S.B. 554].

<sup>40</sup> See *id.* § 1(1)–(8), (14) (this bill would enact a “Biometric Information Privacy Act” requiring notice and consent for biometric collection, prohibiting sale of biometric identifiers, mandating reasonable data protection, and allowing private lawsuits with \$1,000–\$5,000 in damages per violation); see also 740 ILL. COMP. STAT. 14 (2008 & Supp. 2024) (Illinois’s BIPA, requiring informed written consent and a retention policy before collecting biometrics, forbidding sale/profit from biometric data, and allowing \$1,000 or \$5,000 liquidated damages per violation).

Washington succeeded where others stalled. Its My Health My Data Act expansively defines “consumer health data” to include any information reasonably linked to a person revealing health status or service-seeking behavior.<sup>41</sup> Location data indicating healthcare visits explicitly receives protection. The law mandates collection and sharing consent while enabling deletion rights.<sup>42</sup> Crucially, it provides private enforcement through consumer protection statutes. *Maxwell v. Amazon* tests these boundaries: does a phone’s pharmacy location ping constitute protected “health data”? If so, Washingtonians enjoy rights virtually no other Americans possess—controlling their whereabouts’ health profiling potential. Yet this pioneering law faces potential *Sorrell* challenges if framed as restricting data use, plus Dormant Commerce Clause issues affecting interstate data flows.

Federal agencies issue “soft guidance” that clarifies boundaries while effectively abdicating regulatory responsibility. The FDA’s 2022 Medical Device Data Systems guidance distinguishes regulated hardware “Device MDDS” from unregulated “Non-Device MDDS”—software merely storing or transmitting medical data without controlling or analyzing it.<sup>43</sup> Similarly, FDA policy exempts low-risk wellness products promoting healthy lifestyles from device regulation.<sup>44</sup> While providing clarity, these guides effectively cede vast consumer device markets to the unregulated realm. A fitness smartwatch tracking steps and heart rate escapes oversight; adding ECG features diagnosing atrial fibrillation triggers regulation. Manufacturers deliberately avoid “diagnosis or treatment” claims to evade FDA authority. This risk-based safe harbor sensibly avoids overregulating harmless gadgets but abandons privacy and security oversight to either company self-governance or inadequate laws.

Government reports spotlight mounting stakes. The GAO’s March 2024 wearables study noted concerns about employee tracking and device vulnerabilities stemming from weak encryption and delayed updates.<sup>45</sup> A

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<sup>41</sup> See WASH. REV. CODE § 19.373.010(8) (2024) (defining consumer health data).

<sup>42</sup> See *id.* § 19.373.010(8)(a), (b)(xi) (2023) (defining “consumer health data” under the My Health My Data Act to include personal information reasonably linkable to a person’s physical or mental health status or to seeking health services, expressly including precise location data showing health-service visits); *id.* § 19.373.030(1)–(2) (requiring affirmative consent before collecting or sharing consumer health data, with limited exceptions); *id.* § 19.373.040(1)(c) (granting consumers the right to deletion of their health data on request); *id.* § 19.373.090 (making violations an unfair or deceptive act under Washington’s Consumer Protection Act); *cf.* Maxwell Complaint, *supra* note 26, at 22 (alleging that Amazon’s in-app tracking software collected precise location data—visits to pharmacies and clinics—without consent, violating the My Health My Data Act).

<sup>43</sup> See *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices*, U.S. FOOD & DRUG ADMIN. 5–6 (Sept. 28, 2022), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices> (guidance document exempting data transfer software) [hereinafter *Medical Device Data Systems*].

<sup>44</sup> See *General Wellness: Policy for Low Risk Devices*, U.S. FOOD & DRUG ADMIN. 2 (Jan. 6, 2026), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices> (exempting low-risk wellness products).

<sup>45</sup> See U.S. Gov’t Accountability Office, *Science & Tech Spotlight: Wearable Technologies in the Workplace*, GAO-24-107303, at 1–2 (Mar. 4, 2024) (finding that wearable devices may be vulnerable to hackers due to weak encryption, and noting that employees have raised concerns about being tracked by such devices) [hereinafter *Science & Tech Spotlight*]; U.S. Gov’t Accountability Office,

December 2024 follow-up found stakeholders voicing data ownership, privacy, and security concerns even as companies rapidly deploy productivity-enhancing technologies.<sup>46</sup> The GAO observed no comprehensive federal law addressing these issues—only OSHA’s physical safety rules and sectoral privacy laws’ patchwork. Their conclusion was unequivocal: current privacy laws have “gaps” requiring Congressional action.<sup>47</sup>

The cumulative picture resembles triage rather than preventive care. The FTC bandages the worst wounds, states experiment with treatments, and agencies provide reassurance without remedies. Meanwhile, a consumer wellness industry surpassing \$1.8 trillion sees its data appetite growing unchecked. This predicament is not merely academic; it affects millions of consumers whose fitness, fertility, genomic, sleep, and nutrition data are constantly collected and monetized without the protections they might assume exist. Reactive enforcement, fragmented state laws, and guidance documents cannot substitute for the comprehensive federal framework explored in Part III.

### III. A FEDERAL WELLNESS DATA FIDUCIARY DUTY

#### A. Normative Foundation for Fiduciary Privacy

The case for imposing fiduciary loyalty on wellness data collectors rests on a deceptively simple premise: companies that harvest intimate health information occupy positions of trust analogous to those of physicians. Richards and Hartzog’s influential proposition—treating data handlers as fiduciaries—strikes at modern privacy law’s core weakness.<sup>48</sup> Their vision transforms passive “notice and consent” into active loyalty obligations, requiring companies to limit “wrongful self-dealing” through enforceable “best interests” rules.<sup>49</sup> This resonates powerfully in wellness contexts where users entrust intimate details—menstrual cycles, moods, genetic markers—expecting improvement, not exploitation.

The trust asymmetry is stark. When uploading fertility data to tracking apps, users seek reproductive insights, not insurance discrimination. Yet companies routinely monetize this vulnerability, selling predictions to advertisers or insurers who weaponize intimate knowledge against users’ interests. A fiduciary duty would flip this script: instead of users defending themselves through

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*Technology Assessment: Wearable Technologies — Potential Opportunities and Deployment Challenges in Manufacturing and Warehousing*, GAO-25-107213, at 1 (Dec. 12, 2024) (reporting stakeholders’ “concerns about data ownership, privacy, and security” as workplace wearables proliferate) [hereinafter *Technology Assessment: Wearable Technologies*]; cf. U.S. Gov’t Accountability Office, *Internet Privacy: Additional Federal Authority Could Enhance Consumer Protection*, GAO-19-52, at 30 (2019) (concluding that existing consumer privacy laws have “gaps” and recommending Congress strengthen the legal framework) [hereinafter *Internet Privacy*].

<sup>46</sup> See *Science & Tech Spotlight*, *supra* note 45, at 1–2; *Technology Assessment: Wearable Technologies*, *supra* note 45, at 1; cf. *Internet Privacy*, *supra* note 45, at 30.

<sup>47</sup> *Internet Privacy*, *supra* note 45, at 30.

<sup>48</sup> See Richards et al., *supra* note 7, at 1335 (advocating a “data loyalty” fiduciary duty for companies).

<sup>49</sup> *Id.* at 1338.

incomprehensible privacy policies, companies bear legal obligations to act as data trustees.<sup>50</sup>

Solove and Citron’s privacy harm typology reinforces this need. They document how violations cause diffuse injuries—behavioral chilling, reputational anxiety, trust erosion—that courts dismiss as trivial.<sup>51</sup> These scholars construct a framework recognizing that privacy harms “do not fit well with existing cramped judicial understandings[.]”<sup>52</sup> When fertility app data leaks, the harm defies easy quantification yet cuts deep, undermining health tech trust and reinforcing inequalities where premium privacy becomes a luxury.<sup>53</sup> Their thesis demands focusing on preventing wrongs, not just compensating harms. Fiduciary duties align with this logic precisely: if sharing data violates loyalty, the breach itself warrants redress without awaiting identity theft.<sup>54</sup>

Julie Cohen adds crucial political economy dimensions. She critiques informational capitalism’s commodification of personal data, which entrenches knowledge and power asymmetries.<sup>55</sup> In *Between Truth and Power*, Cohen analogizes data to Polanyi’s land and labor—resources appropriated by 21st-century capitalism.<sup>56</sup> Platforms excel at “legal entrepreneurship,” exploiting regulatory gaps to claim de facto data ownership.<sup>57</sup> Meditation apps compile anxiety profiles, constructing predictive algorithms for third-party sale. Users remain oblivious, lacking negotiation leverage. Cohen calls this systematic “datafication” of human experience.<sup>58</sup>

Her analysis points toward stronger interventions. Fiduciary models requiring loyalty and minimization strike at commodification’s heart. Companies cannot freely monetize wellness data as property; they must act as trustees for data subjects.<sup>59</sup> This reframes the relationship from extraction to stewardship.

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<sup>50</sup> *Id.* at 1346.

<sup>51</sup> Danielle Keats Citron & Daniel J. Solove, *Privacy Harms*, 102 B.U. L. REV. 793, 841–42 (2022); Sandra Fulton, *Pay-for-Privacy Schemes Put the Most Vulnerable People at Risk*, FREE PRESS (May 10, 2016), <https://www.freepress.net/blog/pay-privacy-schemes-put-most-vulnerable-people-risk>.

<sup>52</sup> Citron & Solove, *supra* note 51, at 794; *see also* DANIELLE KEATS CITRON, *THE FIGHT FOR PRIVACY: PROTECTING DIGNITY, IDENTITY, AND LOVE IN THE DIGITAL AGE* 83 (W.W. Norton & Co. 2022) [hereinafter *THE FIGHT FOR PRIVACY: PROTECTING DIGNITY, IDENTITY, AND LOVE IN THE DIGITAL AGE*].

<sup>53</sup> Stacy-Ann Elvy, *Paying for Privacy and the Personal Data Economy*, 117 COLUM. L. REV. 1367, 1409–14 (2017).

<sup>54</sup> *See* Woodrow Hartzog & Neil Richards, *The Surprising Virtues of Data Loyalty*, 71 EMORY L.J. 985, 992–95 (2022) [hereinafter *Data Loyalty*].

<sup>55</sup> *See* BETWEEN TRUTH AND POWER, *supra* note 6, at 5–6; *see also* Julie E. Cohen, *What Privacy Is For*, 126 HARV. L. REV. 1904, 1915–16 (2013) [hereinafter *What Privacy Is For*] (analyzing knowledge and power asymmetries in informational capitalism).

<sup>56</sup> BETWEEN TRUTH AND POWER, *supra* note 6, at 8.

<sup>57</sup> *See* *What Privacy Is For*, *supra* note 55, at 1927–28.

<sup>58</sup> BETWEEN TRUTH AND POWER, *supra* note 6, at 15–16; *see also* Julie Cohen *Speaks on Her New Book “Between Truth and Power,”* YALE L. SCH. (Feb. 19, 2019), <https://law.yale.edu/yls-today/news/julie-cohen-speaks-her-new-book-between-truth-and-power>.

<sup>59</sup> *See* Balkin, *supra* note 8, at 1209 (coining the term “information fiduciary”); *see also* Neil M. Richards & Woodrow Hartzog, *Taking Trust Seriously in Privacy Law*, 19 STAN. TECH. L. REV. 431, 435 (2016) (applying fiduciary principles to digital platforms); *Data Loyalty*, *supra* note 54, at 990; *id.* at 994 (arguing that wellness data should be governed by fiduciary duties); *see, e.g.*, Thomas

Danielle Citron's *The Fight for Privacy* illuminates the dignitary stakes surrounding intimate data.<sup>60</sup> Privacy violations involving health information represent not mere economic injuries but affronts to identity, dignity, and equality. Post-*Dobbs*, if period-tracking apps reveal pregnancy status without consent, they jeopardize autonomy over personal decisions and risk legal exposure, harms touching personhood's core.<sup>61</sup> Citron advocates treating intimate information with bodily privacy's sanctity.<sup>62</sup>

A wellness fiduciary duty would operationalize this vision. By elevating care standards for sensitive data and recognizing intangible harms, the law would acknowledge that privacy invasions wrong individuals even absent financial loss. The betrayal of trust itself violates human dignity.

These theoretical strands weave together compellingly. Loyalty prevents self-serving data misuse.<sup>63</sup> Recognition of non-economic privacy harms validates subjective experiences.<sup>64</sup> Critique of commodification challenges power imbalances.<sup>65</sup> Protection of intimate dignity safeguards personhood.<sup>66</sup> Together, they establish why wellness companies—mediating our bodies' most personal aspects—should bear fiduciary-like duties analogous to those imposed on professionals handling confidential property or sensitive affairs.

This normative foundation also addresses the failures documented in Part II directly. Where *Sorrell* privileged data commerce over privacy, fiduciary duties rebalance toward user protection. Where tort law demanded tangible injuries, loyalty breaches create actionable wrongs. Where contracts failed through adhesion and power disparities, fiduciary obligations override one-sided terms. Where the collector-identity paradox left identical data unprotected outside clinical settings, fiduciary duties follow the data regardless of who holds it. The normative case is clear: Those profiting from intimate health data must serve users' interests, not exploit their vulnerability.

## B. Statutory Blueprint of the Duty

Translating fiduciary principles into operative statutory language requires transplanting HIPAA's definitional precision into consumer contexts while

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Hardjono & Alex Pentland, *Data Cooperatives: Towards a Foundation for Decentralized Personal Data Management* 2 (2019), <https://arxiv.org/pdf/1905.08819> (describing a collective data fiduciary model).

<sup>60</sup> See THE FIGHT FOR PRIVACY: PROTECTING DIGNITY, IDENTITY, AND LOVE IN THE DIGITAL AGE, *supra* note 52, at 5–6.

<sup>61</sup> Danielle Keats Citron, *Intimate Privacy in a Post-Roe World*, 75 FLA. L. REV. 1037, 1040–41 (2023).

<sup>62</sup> Jane Kelly, *This Peerless Expert is Leading the Charge on Online Privacy*, UVA TODAY (Feb. 25, 2022), <https://news.virginia.edu/content/inside-uva-peerless-expert-leading-charge-online-privacy>.

<sup>63</sup> Richards et al., *supra* note 7, at 1342.

<sup>64</sup> Citron & Solove, *supra* note 51, at 841–42.

<sup>65</sup> BETWEEN TRUTH AND POWER, *supra* note 6, at 72; see *What Privacy Is For*, *supra* note 55, at 1932.

<sup>66</sup> See Danielle Keats Citron, *Sexual Privacy*, 128 YALE L.J. 1870, at 1878 (2019) (advocating recognition of sexual privacy as a fundamental right).

overlying transformative duties that rebalance power between users and companies.

Scope and Definitions: The statute should escape HIPAA’s “covered entity” straitjacket that protects identical data differently based solely on who holds it—the collector-identity paradox identified in Part II. The absurdity is plain: a user’s heart rhythm data enjoys robust protection in a cardiologist’s office but none in your fitness app. The analysis begins with HIPAA’s foundation—“individually identifiable health information” encompassing data about health status, healthcare provision, or payment when linked to identifying details.<sup>67</sup> However, unlike HIPAA’s entity-based limitations, the proposed law would reach any “Wellness Data Controller”: private entities that, in the ordinary course of business, collect, use, or share personal data relating to physical or mental health, biometric information, or wellness activities.

This definition captures the modern wellness ecosystem: app developers, device manufacturers (regarding collected data), fitness and dietary programs, genomics services, and corporate wellness vendors. Small entities or those handling exclusively de-identified data could receive exemptions to avoid burdening local yoga studios’ email lists. Richards’ framework proves instructive: when consumers supply health information expecting benefits like tracking or advice, trust relationships triggering fiduciary duties emerge.<sup>68</sup>

The statute should enumerate health data categories extending beyond HIPAA’s clinical focus. Traditional medical information remains covered, but modern wellness data demands explicit inclusion: exercise routines, sleep patterns, heart rate variability, fertility markers, genetic traits, mood tracking, meditation frequency, nutrition logs, and, crucially, algorithmic inferences. That last category matters immensely: when apps categorize users as “high anxiety risk” based on usage patterns, they create health data deserving protection. Washington’s My Health My Data Act offers guidance by covering information “reasonably associated” with health status or service-seeking.<sup>69</sup> Following California’s approach of listing specific categories prevents ambiguity while providing flexibility for emerging technologies.<sup>70</sup> Definitions of “sell or share” should encompass not merely monetary transactions but disclosures for cross-context behavioral advertising or analytics benefits.<sup>71</sup>

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<sup>67</sup> 45 C.F.R. § 160.103 (2024) (defining “health information,” “individually identifiable,” and HIPAA “covered entities”).

<sup>68</sup> See Richards et al., *supra* note 7, at 1348.

<sup>69</sup> WASH. REV. CODE § 19.373.010(8)(a) (2023) (defining “consumer health data” under Washington’s My Health My Data Act); see also Alder, *supra* note 26.

<sup>70</sup> CAL. CIV. CODE § 1798.140(ae) (West 2024) (listing specific categories of sensitive personal information).

<sup>71</sup> GoodRx Complaint, *supra* note 1, ¶¶ 19, 42, 45; see CAL. CIV. CODE § 1798.140.

## 1. Four Core Duties Transform Data Relationships

### a. The Duty of Loyalty

First, the Duty of Loyalty would prohibit wellness providers from using or disclosing data in ways furthering their interests to users' detriment.<sup>72</sup> This would bar monetization for unrelated purposes absent informed consent after full risk disclosure. Under this duty, fertility tracking apps could not share data with brokers or leverage it for unrelated advertising, such self-dealing would be inherently disloyal. Richards' model statute provides the framework: outlawing "any processing of user data not in the best interests of the user" subject to narrowly tailored exceptions.<sup>73</sup>

GoodRx's secret monetization of prescription data exemplifies precisely the conduct this duty would prohibit. Consent retains importance for genuinely mutual benefits—users wanting apps to share with their doctors or opting into research studies. However, consent cannot become *carte blanche* for pure company benefit. The distinction matters: sharing exercise data with a physician serves the user's health interests; selling it to data brokers serves only corporate profits.<sup>74</sup> Companies would be required to act as faithful data stewards, not opportunistic monetizers.

### b. The Duty of Care

Second, the Duty of Care would mandate exercising reasonable safeguards against loss, breach, or improper access while avoiding negligent data handling.<sup>75</sup> This mirrors HIPAA's Security Rule philosophy while focusing on outcomes over prescriptive checklists. Entities collecting sensitive health information should implement industry-standard protections: end-to-end encryption, role-based access controls, third-party partner vetting, and prompt security patching. The GAO's findings about wearables' vulnerability to hackers due to weak encryption underscore this need.<sup>76</sup>

Care extends beyond security to accuracy and integrity. If wellness data drives decisions—even simple personalized recommendations—companies should ensure data remains unaltered and accurate as provided. Technical minimization overlaps here: collecting only data necessary for the promised service. A meditation app needs session frequency for habit tracking but not location data unless explicitly providing location-based features.

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<sup>72</sup> See Neil Richards & Woodrow Hartzog, *A Duty of Loyalty for Privacy Law*, 99 WASH. U. L. REV. 961, 965 n.7 (2021) (proposing anti-detriment duty).

<sup>73</sup> Richards et al., *supra* note 7, at 1374.

<sup>74</sup> See generally *id.* at 1360–62 (distinguishing consent for mutual benefit from consent for purely company-beneficial purposes).

<sup>75</sup> See *LabMD, Inc. v. FTC*, 894 F.3d 1221, 1230-31 (11th Cir. 2018) (linking negligence to unfairness).

<sup>76</sup> See *Science & Tech Spotlight*, *supra* note 45, at 1–2; *Technology Assessment: Wearable Technologies*, *supra* note 45, at 16; cf. *Internet Privacy*, *supra* note 45, at 30.

### c. The Duty of Transparency

Third, the Duty of Transparency would compel honest, clear communication about data practices in understandable terms. Today's privacy policies hide behind vague legalese while reserving sweeping rights. Under fiduciary obligations, companies would be required to explicitly state what data they collect, how they use it, and who receives it. Material uses or disclosures beyond core services would require heightened disclosure and likely explicit opt-in consent.

California's CPRA Regulation § 7024 provides helpful benchmarks: businesses responding to access requests must inform consumers "with sufficient particularity" about sensitive information categories collected.<sup>77</sup> Generic statements like "we collect health data" would become insufficient. The standard would demand: "we collect heart rate, daily step count, sleep duration, and weight[.]"<sup>78</sup> Users deserve knowing whether their anxiety levels feed advertising algorithms. Importantly, transparency would transform from today's liability shield into enforceable duty—misrepresentations or material omissions would create independent violations.

### d. The Duty of Minimization

Fourth, the Duty of Minimization would implement purpose limitation by restricting collection, use, and retention to amounts reasonably necessary for user-requested services.<sup>79</sup> Aligning with GDPR principles, companies would need to map data requirements during product design, not accumulate speculatively for future monetization. This duty particularly constrains Silicon Valley's "collect everything" mentality.

Retention limits would prevent indefinite storage. Colorado's privacy rules mandate that controllers conduct reviews ensuring continued retention necessity, even requiring annual assessments for sensitive biometric data justifying ongoing storage.<sup>80</sup> The proposed law would similarly demand periodic deletion or anonymization once data no longer serves user purposes, subject to narrow exceptions for legal obligations or explicit user requests for long-term tracking history.<sup>81</sup> Purpose limitation dovetails with loyalty: data use must benefit users or align with clearly disclosed purposes.

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<sup>77</sup> CAL. CODE REGS. tit. 11, § 7024 (requiring businesses to omit medical ID numbers in access disclosures but to inform the consumer "with sufficient particularity" of their collection).

<sup>78</sup> See CAL. CIV. CODE § 1798.100(a)(1) (West 2023) (requiring disclosure of categories); *id.* § 1798.140(ae)(2) (defining sensitive information).

<sup>79</sup> Rachel Marmor, *Preparing for Compliance with the Colorado Privacy Act Rules*, PRACTICAL L. 4 (2023) (outlining new data minimization and retention rules in Colorado).

<sup>80</sup> *Id.* at 5.

<sup>81</sup> See COLO. REV. STAT. § 6-1-1308(3)(a) (2023) (imposing data minimization and retention requirements).

### e. Enforcement Mechanisms

Effective enforcement requires multiple avenues. The FTC would treat violations as unlawful trade practices, while state attorneys general could bring parallel actions. A private right of action for certain violations would prevent companies from treating occasional fines as mere business costs. A calibrated approach might allow private suits for willful or reckless violations, or where actual harm occurs, potentially with statutory damages following Illinois BIPA's \$1,000/\$5,000 structure for negligent versus intentional violations.<sup>82</sup>

Clear compliance standards and safe harbors could prevent litigation floods. Companies adhering to FTC-approved codes of conduct or achieving third-party certifications might enjoy rebuttable presumptions of compliance. This would incentivize proactive privacy programs while providing legal certainty.

### f. Constitutional Design

The framework's constitutional resilience depends on its content-neutral character. It would regulate commercial data-handling conduct rather than expression, managing information arising from service transactions rather than public discourse. As Richards demonstrates, privacy laws governing how businesses collect and use information avoid First Amendment conflicts by regulating commercial practices, not speech content.<sup>83</sup>

Loyalty duties concern conduct—preventing misuse of entrusted data—without dictating particular messages or viewpoints. The law would apply equally whether data relates to heart rates or dietary preferences, demonstrating content agnosticism. This careful design anticipates and neutralizes potential *Sorrell* challenges by avoiding speaker- or content-specific targeting while generally requiring responsible data stewardship.

This blueprint transforms wellness data from unprotected commodity to protected trust asset, addressing each failure identified in Part II. Where the collector-identity paradox left data exposed, comprehensive definitions would capture all wellness ecosystem participants. Where traditional tort law failed, statutory duties would create clear, enforceable obligations. The framework translates Part III.A's normative vision through concrete legal architecture.

## C. Constitutional Fit and First Amendment Considerations

A federal wellness fiduciary duty must navigate the constitutional landscape shaped by *Sorrell*, where the Court treated *Vermont's* prescriber data restrictions as impermissible speech regulation.<sup>84</sup> Yet properly framed, the

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<sup>82</sup> See Mo. S.B. 554, *supra* note 39; see also 740 ILL. COMP. STAT. 14/5, 14/10, 14/15, 14/20.

<sup>83</sup> Neil M. Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. REV. 1149, 1156–58 (2005); see also ELVY, *supra* note 22, at 293.

<sup>84</sup> *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011).

proposed law regulates conduct with only incidental speech effects, subjecting it to intermediate scrutiny it can readily satisfy.

*Sorrell's* fatal flaw was viewpoint discrimination. Vermont targeted pharmaceutical marketers and marketing use specifically, triggering heightened scrutiny for disfavoring certain speakers and content.<sup>85</sup> By contrast, the wellness fiduciary law proposed here would apply neutrally across all data handlers and uses, save those directed by consumers. This general applicability avoids *Sorrell's* content-based trap. Like GLBA's financial privacy provisions—never struck down despite restricting bank data sharing—our law would regulate business practices, not messages.<sup>86</sup>

Richards anticipated these challenges in *Why Data Privacy Law Is (Mostly) Constitutional*.<sup>87</sup> Privacy laws typically regulate personal data processing as economic conduct, imposing duties resembling professional confidentiality that courts historically uphold.<sup>88</sup> If every data restriction violated free speech, absurd results would follow: credit card fraud laws and confidentiality agreements would crumble.<sup>89</sup> Courts properly recognize that privacy regulations satisfy intermediate scrutiny when serving substantial interests while preserving ample speech channels.

Here, protecting personal health privacy and preventing exploitation constitutes not merely substantial but compelling interests. The narrow tailoring is evident: the proposed law does not ban public dissemination or media reporting; it restricts commercial collectors' non-consensual uses. Consumer protection has long justified commercial speech regulation; drug side-effect disclosures and telemarketing bans face no serious constitutional challenge.<sup>90</sup>

Potential challengers might argue that the transparency duty compels speech through required disclosures or consent procedures. However, *Zauderer* permits factual commercial disclosures that are not unduly burdensome. Requiring apps to state "We will not sell your data without consent" or obtain agreement for secondary uses prevents deception—squarely within *Zauderer's* safe harbor.<sup>91</sup>

Bambauer's critique warrants consideration. She argues that privacy laws impede truthful information dissemination, warranting First Amendment scrutiny.<sup>92</sup> Yet even Bambauer concedes that entrenched privacy rules like professional confidentiality survive because they regulate relationships, not public

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<sup>85</sup> *Id.*

<sup>86</sup> See 15 U.S.C. §§ 6801–6809 (2018) (GLBA provisions coexisting with First Amendment requirements).

<sup>87</sup> Richards, *supra* note 83, at 1156.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 1152–53, 1156–58; Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People from Speaking About You*, 52 STAN. L. REV. 1049, 1050–52 (2000) (cautioning that broad privacy rights may suppress truthful speech).

<sup>90</sup> See *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976) (holding that commercial speech can be regulated for consumer protection).

<sup>91</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); see also CAL. CODE REGS. tit. 11, § 7024 (exemplifying factual disclosure requirements).

<sup>92</sup> Bambauer, *supra* note 12, at 57.

expression. The proposed law explicitly anchors itself in fiduciary concepts; doctors and lawyers maintain confidentiality without constitutional crisis.<sup>93</sup>

Tsisis supplies the broader framework: The First Amendment was never a deregulatory trump against general welfare laws. Data fiduciary duties resemble product safety regulations; companies must handle data carefully as they handle chemicals. Balkin’s influential work on information fiduciaries reinforces the same point: such duties are “like product-safety regulations that only ‘incidentally’ affect speech[.]”<sup>94</sup>

Practical precedent further supports this constitutional position. The Fair Credit Reporting Act restricts credit information disclosure except for enumerated purposes, granting consumers access and correction rights. Despite data brokers’ challenges, courts uphold FCRA by treating credit reports as regulated commodities, not protected public speech.<sup>95</sup> If credit histories receive such treatment, surely heart rate logs deserve similar protection. Post-*Dobbs*, some states restrict reproductive health data disclosure to law enforcement—impinging on sharing interests yet serving compelling privacy objectives likely to survive scrutiny.<sup>96</sup>

Under *Central Hudson*’s intermediate scrutiny framework, even assuming some speech interest exists, the proposed law prevails.<sup>97</sup> The substantial interest (privacy, preventing misuse) is undeniable. The law directly advances that interest through binding practices—unlike failed notice-and-consent regimes. The tailoring is precise: permitted uses would align with consumer welfare or genuine consent; prohibited uses would involve exploitation or non-consensual monetization. This balance exemplifies constitutional tailoring.

The design is also prophylactic. By characterizing the law as content-neutral conduct regulation focused on marketplace practices, it avoids most First Amendment obstacles. Legislative findings should emphasize parallels to financial privacy and consumer protection necessities. Courts reviewing challenges would likely apply rational basis or intermediate scrutiny, not strict scrutiny reserved for content-based speech restrictions.

The wellness fiduciary duty is, to echo Richards, “mostly constitutional.”<sup>98</sup> The duty leverages content-neutral obligations, addresses documented privacy harms, and preserves traditional public discourse. Rather than censoring viewpoints or speakers, it channels commercial data practices toward consumer protection. The First Amendment permits—indeed, historically has permitted—

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<sup>93</sup> See *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981) (affirming that the attorney–client privilege serves important public interests).

<sup>94</sup> Tsisis, *supra* note 13, at 213–14 (explaining that the Free Speech Clause “was never meant to immunize general-purpose regulations”); see also Balkin, *supra* note 8, at 1213 (analogizing data fiduciary duties to product-safety regulations that only “incidentally” affect speech).

<sup>95</sup> See *TransUnion LLC v. Ramirez*, 594 U.S. 413, 417–25 (2021) (treating credit reporting as regulated commercial activity).

<sup>96</sup> See, e.g., CONN. GEN. STAT. § 19a-906 (restricting disclosure of reproductive health data).

<sup>97</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980); see also *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011); see also *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 707 (1986).

<sup>98</sup> Richards, *supra* note 83, at 1156–58.

such economic regulation despite tangential speech effects.<sup>99</sup> This constitutional resilience clears Congress's path to legislate without fearing judicial invalidation fears.

#### IV. STATE HARMONIZATION AND FDA CLARITY

##### A. A “Baseline-Plus” Model for State Laws

The preemption question—whether federal privacy law displaces or preserves state innovation—shapes the practical viability of any comprehensive framework. The answer shapes whether California's privacy leadership and Washington's health data protections survive federal action. I propose federal baseline protections—a floor via wellness fiduciary duties—while preserving states' ability to build higher. This mirrors GLBA's approach: federal financial privacy standards preempt only “inconsistent” state laws, explicitly preserving stronger state protections.<sup>100</sup>

Why preserve state experimentation? States have proven themselves privacy laboratories, pioneering protections that set de facto national standards. California's deletion rights reflect GDPR principles. Illinois's biometric law sparked nationwide awareness. Crushing this innovation through broad preemption would freeze privacy law at federal minimums, preventing adaptation to emerging threats.

Under the proposed framework, the Wellness Data Fiduciary Act would state explicitly: federal standards preempt only state provisions contradicting or undercutting federal requirements. States offering equal or greater protection would remain untouched. If federal law grants deletion rights, states cannot negate them but could mandate faster timelines (fifteen days versus thirty) or extend coverage beyond federal scope.<sup>101</sup>

California exemplifies productive state innovation. Civil Code § 1798.105 grants consumers deletion rights with enumerated exceptions. This parallels the proposed federal right, creating reinforcing protections. California's regulations add nuance: businesses must withhold sensitive identifiers like medical numbers from access disclosures while confirming their collection “with sufficient particularity[.]”<sup>102</sup> Federal law might omit such procedural details; California's extra safeguard would stand as supplemental protection ensuring security without sacrificing transparency.

Colorado pushes boundaries further through granular obligations: data protection assessments for sensitive processing and opt-in consent requirements.<sup>103</sup>

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<sup>99</sup> See *id.* at 1173–74 (classifying privacy rules as economic regulation).

<sup>100</sup> Gramm–Leach–Bliley Act, *supra* note 9.

<sup>101</sup> See 15 U.S.C. § 6807 (GLBA provision preserving more protective state laws).

<sup>102</sup> CAL. CIV. CODE § 1798.105(a), (d) (establishing consumers' right to request deletion of personal information, subject to the exceptions in that provision); see also CAL. CODE REGS. tit. 11, § 7024(d) (requiring businesses, when responding to data access requests, to withhold medical ID numbers but to inform the consumer “with sufficient particularity” of their collection).

<sup>103</sup> See Marmor, *supra* note 79.

Remarkably, Colorado defines “sensitive data inferences” requiring consent before inferring health conditions from other data.<sup>104</sup> Under baseline-plus, Colorado would continue enforcing these heightened standards. Wellness companies operating nationally would comply with federal loyalty duties while obtaining additional consent in Colorado for health inferences from smartwatch data.<sup>105</sup>

Missouri’s legislative trajectory illustrates the tension between expanding and constraining private enforcement. The 2025 proposal, S.B. 554, sought to impose robust rules—notice, consent, and private enforcement with \$5,000 damages. While federal law generally covers biometric health data, this model specifically targets commercial misuse. However, more recent 2026 initiatives like S.B. 1359 suggest a legislative pivot toward limiting liability through safe harbors rather than expanding private rights of action.<sup>106</sup>

Critics may fear compliance nightmares from fifty different regimes. However, baseline-plus actually simplifies compliance by establishing uniform minimums. Companies know federal duties apply everywhere; state additions typically strengthen existing obligations rather than contradict them. Environmental law proves instructive: federal Clean Air standards set minimums while California’s stricter emissions rules push innovation without chaos.<sup>107</sup>

To prevent operational conflicts, federal law should include GLBA-style provisions explicitly authorizing states to exceed federal protections in specified domains (biometrics, genetic data, children’s wellness).<sup>108</sup> That way, states could not declare “no consent required for wellness data sales” (undermining federal loyalty) but could mandate “wellness data sales prohibited entirely” or “opt-in required always” (stricter protection).

Coordination mechanisms could smooth implementation. An oversight council reviewing state laws for consistency could designate them as providing “greater protection” (safe from preemption) or identify conflicts requiring resolution. The FTC already performs similar functions under GLBA, evaluating whether state financial privacy laws exceed federal standards.<sup>109</sup>

Health-specific niches where states lead deserve particular attention. Mental health app data might receive elevated state protection—for example, if states bar sharing self-assessment results without explicit per-instance consent (exceeding federal requirements), that stricter rule would stand. Reproductive

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<sup>104</sup> See *Processing Sensitive Personal Information Under U.S. State Privacy Laws*, GREENBERG TRAURIG (May 23, 2023), <https://www.gtlaw-dataprivacydish.com/2023/05/processing-sensitive-personal-information-under-u-s-state-privacy-laws/>.

<sup>105</sup> See generally COLO. REV. STAT. § 6-1-1308(1)(a)(I)–(II); see generally 4 COLO. CODE REGS. § 904-3-7.05(A)–(B) (defining “sensitive data inferences” as inferences about health, sex life, ethnicity, etc., and requiring consumer opt-in consent before processing such inferred data).

<sup>106</sup> See Mo. S.B. 554, *supra* note 39, §§ 1.566, 1.569 (detailing retention schedules and providing liquidated damages of “5,000 or actual damages” for reckless violations); 740 ILL. COMP. STAT. 14/15, 14/20 (2024). *But see* S.B. 1359, 103d Gen. Assemb., 2d Reg. Sess. (Mo. 2026) (proposing a “safe harbor” to limit liability for private entities compliant with retention and security standards).

<sup>107</sup> See 42 U.S.C. § 7543 (Clean Air Act waiver provision for California).

<sup>108</sup> See generally Gramm–Leach–Bliley Act, *supra* note 9, at Sec. 507.

<sup>109</sup> 16 C.F.R. § 313.17 (FTC rule regarding the relation of federal privacy requirements to state laws).

health data post-*Dobbs* demands particular sensitivity; states restricting disclosure to law enforcement would complement federal loyalty duties.<sup>110</sup>

Political realities make baseline-plus essential for passage. Industry seeks preemption for compliance ease. Privacy advocates and progressive states resist rollbacks. Floor preemption offers compromise: explicitly preserving laws meeting or exceeding federal protections while preempting only those permitting what federal law forbids. This parallels civil rights laws—states add rights, never subtract them.

Harmonization, then, means enacting uniform federal duties (loyalty, care, transparency, minimization) while letting states supplement with stricter obligations, shorter deadlines, or enhanced enforcement. Consumers would receive guaranteed minimum protection nationwide with additional shields in forward-thinking states. Companies would face one core rulebook with state variations rewarding better behavior—imperfect uniformity, but reasonable for achieving strong protections without stifling innovation. Over time, successful state experiments could inform federal amendments, as California’s auto emissions standards influenced EPA policy.<sup>111</sup>

## B. Clarifying FDA’s Role: A Two-Gate Risk Test

The line between wellness tracker and medical device has grown dangerously blurred. The FDA’s deliberate restraint, while avoiding innovation stifling, has left critical ambiguities. Products with serious health implications could escape oversight simply by labeling themselves “wellness.” A Two-Gate Risk Test would establish clearer boundaries without crushing beneficial technologies.

### 1. Gate 1: Physiological Specificity Asks Whether Products Target Specific Diseases or Conditions.

This distinction already shapes FDA thinking but lacks clear implementation. The 2022 MDDS guidance illustrates the principle: Pure data transfer/storage software remains unregulated “Non-Device MDDS,” while software analyzing physiological data for clinical purposes becomes regulated.<sup>112</sup> Many wellness products deliberately straddle this line to avoid oversight. The spectrum the FDA already recognizes illuminates the distinction. A general fitness tracker encouraging daily movement remains unregulated wellness technology. However, a wristband specifically claiming to detect atrial fibrillation crosses into medical device territory requiring FDA approval. The FDA’s General Wellness

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<sup>110</sup> See, e.g., WASH. REV. CODE § 9.02.120 (restricting disclosure of reproductive health data).

<sup>111</sup> See generally *Massachusetts v. EPA*, 549 U.S. 497, 532 (2007) (recognizing states as “laboratories” of environmental policy).

<sup>112</sup> *Medical Device Data Systems*, *supra* note 43; U.S. Food & Drug Admin., *Examples of Software Functions that Are Not Medical Devices* (Feb. 11, 2022), <https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-are-not-medical-devices> [hereinafter *Examples of Software Functions*].

Policy articulates this framework—products promoting general healthy living escape device regulation provided they avoid referencing specific diseases or conditions.<sup>113</sup> An app encouraging regular hydration stays in wellness territory; claiming it prevents kidney stones triggers device classification.

Gate 1 would formalize and clarify this approach. Products marketed or intended for specific medical purposes—diagnosing, treating, or monitoring identified conditions—would face FDA regulation unless qualifying for explicit exemptions. Conversely, products making only generic wellness claims (“improves sleep quality” without disease references) would pass through Gate 1 as non-devices. This would preserve FDA’s current risk-based philosophy while providing manufacturers clearer guidance about regulatory boundaries.

## **2. Gate 2: Decision Impact Examines Whether Reliance on the Product Could Affect Clinical Decisions or Serious Health Outcomes.**

This risk-based assessment captures products that, despite “wellness” marketing, function as de facto medical tools in practice. Even without explicit disease claims, some products create risks demanding oversight.

The FDA’s 2023 Clinical Decision Support guidance provides the conceptual framework. Software offering recommendations to healthcare providers can escape device regulation only if clinicians can independently review the basis for those recommendations.<sup>114</sup> Black-box algorithms requiring blind trust—where providers cannot understand or verify the logic—demand FDA oversight as devices.

Applying this principle to wellness contexts reveals hidden risks. An AI-powered diet app analyzing users’ genomic data and laboratory blood test results that recommends personalized nutrition plans for “optimal wellness” illustrates the problem. The app carefully avoids disease claims, positioning itself as lifestyle enhancement. Yet if users or even healthcare providers begin relying on its recommendations to manage pre-diabetes or metabolic conditions, it functions as a medical intervention. Gate 2 would capture such situations: When wellness products generate outputs likely used in health decisions where inaccuracy could cause harm, FDA regulation becomes appropriate.

Technical standards reinforce this risk-based approach. IEEE Standard 2933-2024 emphasizes Trust, Identity, Privacy, Protection, Safety, and Security (TIPPSS) principles for clinical Internet of Things (IoT) devices.<sup>115</sup> When wellness devices enter clinical ecosystems—such as smartwatches automatically feeding ECG data into electronic health records—they should meet medical-grade

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<sup>113</sup> *Examples of Software Functions*, *supra* note 112.

<sup>114</sup> *Id.*

<sup>115</sup> See IEEE, IEEE/UL Std 2933-2024, Standard for Clinical Internet of Things (IoT) Data and Device Interoperability with TIPPSS—Trust, Identity, Privacy, Protection, Safety, and Security §§ 1.1, 4.1 (2024) [hereinafter IEEE Std 2933] (defining the TIPPSS framework to “reduce risk to the data, device, patient, and provider”). The standard defines the “Internet of Things” as an “[i]nfrastructure of interconnected people, devices, systems, and information resources . . . that process and react to information from the physical world and virtual world.” *Id.* § 3.1.1 (quoting ISO/IEC 20924:2021).

requirements for accuracy and reliability. Similarly, the AMA's Code of Medical Ethics Opinion 3.2.4 cautions against granting data companies unfettered access to medical records due to confidentiality and accuracy concerns.<sup>116</sup> Wellness apps performing quasi-diagnostic functions or integrating with clinical workflows edge into territory where medical ethics and FDA standards should apply.

Gate 2 essentially implements a practical risk assessment: what happens if users rely incorrectly on this product? Step counters encouraging general activity pose minimal risk; minor inaccuracies might lead to slightly more or less walking. By contrast, home hormone tests marketed for “wellness optimization” that incorrectly identify imbalances could lead users to take harmful supplements or delay necessary medical care. The FDA's established regulatory science would classify the latter as higher risk, potentially requiring validation studies and premarket review.

### **3. Borderline Cases Illuminate the Framework's Nuanced Application.**

Mental health chatbots present complex challenges. They typically claim general wellness benefits—stress reduction, mood improvement—while avoiding specific disorder treatment claims. Gate 1 analysis: no explicit disease claims, so they pass as non-devices. Gate 2 analysis reveals significant risks: users might substitute AI chatbots for professional therapy, receiving inadequate or harmful advice that worsens conditions. Because the FDA specifically excludes products that prompt clinical action from general wellness safe harbors, these chatbots occupy a gray zone, potentially triggering device classification if their functionality implies medical management.

The framework also accommodates technological evolution through existing standards. IEEE 2621-2022 establishes cybersecurity requirements for wireless diabetes devices.<sup>117</sup> If wellness products cross Gate 1 into glucose monitoring—some wearables now track blood glucose for “dietary optimization”—IEEE 2621 compliance should become mandatory. Since FDA has already adopted this as a recognized device standard,<sup>118</sup> products meeting its requirements effectively acknowledge their medical device status.

### **4. Implementation Could Proceed Through Multiple Pathways.**

The FDA could issue updated guidance within eighteen months clarifying the Two-Gate framework with concrete examples. “Policy for Device Software Functions and Mobile Medical Applications” could explicitly delineate both gates: Gate 1 focusing on intended use and disease claims, Gate 2 assessing decision

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<sup>116</sup> Am. Med. Ass'n, 3.2.4 *Access to Medical Records by Data Collection Companies*, AMA Code of Medical Ethics, <https://code-medical-ethics.ama-assn.org/ethics-opinions/access-medical-records-data-collection-companies>.

<sup>117</sup> IEEE, *IEEE/UL Std 2621.2-2022, Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions* (2022), [https://standards.ieee.org/ieee/2621.2-2022\\_UL\\_2621-2/10602/](https://standards.ieee.org/ieee/2621.2-2022_UL_2621-2/10602/).

<sup>118</sup> 88 Fed. Reg. 50870, 50875–76 (Aug. 2, 2023) (noting FDA recognition of IEEE 2621 standards).

impact and risk profile. Real-world examples would provide clarity—consumer blood oxygen monitors would face regulation only if marketed for medical purposes beyond general fitness awareness. Congress could later codify these distinctions, providing FDA clear authority over emerging technologies like AI health coaches that blur traditional boundaries.

The Two-Gate framework would achieve multiple objectives. It would protect against regulatory arbitrage where companies self-declare “wellness” status to avoid oversight despite creating medical-grade risks. Gate 1 efficiently would filter truly low-risk general wellness products. Gate 2 would capture products that, regardless of marketing labels, present risks equivalent to medical devices through their practical use and reliance patterns. Genuine innovation would continue for meditation apps, basic fitness trackers, and similar low-risk technologies. Consumer safety would improve when wellness technology performing medical functions faces appropriate oversight.

This FDA framework complements rather than replaces the fiduciary duty structure proposed in Part III. The fiduciary duty addresses data privacy and security obligations for all wellness data handlers, regardless of FDA regulatory status. FDA oversight ensures performance accuracy and safety for products functioning as health devices. Privacy law alone cannot guarantee a heart rhythm monitor provides accurate readings. FDA regulation alone cannot prevent a user’s heart rate data from being sold to advertisers. Together, they create the comprehensive protective framework consumers deserve—addressing both data exploitation risks and product safety concerns.

## V. OPERATION AND OBJECTIONS

### A. Implementation Road Map

Existing enforcement tools, particularly the FTC’s revamped Health Breach Notification Rule, offer an immediate foundation for broader reform even before Congress acts.

The HBNR transformation provides this foundation. In September 2021, the FTC declared any unauthorized health data disclosure by non-HIPAA entities constitutes a reportable “breach.”<sup>119</sup> The 2023–24 updates explicitly cover health apps, fitness trackers, and similar technologies, removing prior ambiguities.<sup>120</sup> This groundwork means wellness companies already face notification obligations for breaches or reckless sharing.

Implementation begins by leveraging HBNR reporting as an oversight mechanism. When companies file breach notices—a meditation app hack, for instance—the FTC could require not just notification but fiduciary duty audits. Was the breach caused by inadequate security (violating care duty)? Did prior data

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<sup>119</sup> FTC, *Policy Statement on Breaches by Health Apps and Other Connected Devices* 8 (Sept. 15, 2021); *see also* Germain, *supra* note 1.

<sup>120</sup> Morrison & Foerster, *supra* note 10.

misuse create vulnerability (breaching loyalty)? HBNR becomes a funnel catching worst actors while building precedent for comprehensive duties.

Legislative action should grant FTC expanded rulemaking authority or establish a dedicated health data bureau. The FTC already demonstrates capability through GoodRx and BetterHelp enforcement.<sup>121</sup> Congress could mandate FTC rulemaking within one year defining loyalty, care, transparency, and minimization duties for wellness controllers. This parallels COPPA's successful implementation model. Alternatively, a new Data Protection Agency could lead, though leveraging FTC's existing infrastructure accelerates deployment.

### **1. Phased Compliance Prevents Market Disruption While Ensuring Rapid Progress.**

Year One targets “Large wellness platforms”—defined for the purposes of this proposal as those with at least 5 million users, or those processing the health data of 100,000 or more individuals. Under this framework, market leaders like Google/Fitbit, Apple Health, Headspace, and MyFitnessPal would be required to implement compliance measures first.<sup>122</sup> These resource-rich companies often claim privacy leadership; early compliance sets industry standards while developing tools smaller firms later adopt.

Year Two expands coverage to mid-sized services (500,000+ users). Year Three reaches all regulated entities down to a floor exempting truly small businesses handling fewer than 10,000 individuals' data. This graduated approach avoids crushing garage startups while quickly reining in major aggregators.

### **2. Industry Self-Regulation Complements Enforcement.**

The law should authorize FTC-approved certification programs creating compliance presumptions. Wellness app consortiums could develop de-identification codes or consent standards earning FTC approval. Members following approved codes gain liability protection, incentivizing higher standards. This mirrors GDPR's sectoral code approach, leveraging industry expertise while maintaining oversight.

FDA implementation of the Two-Gate test proceeds through guidance initially. Within eighteen months, FDA could issue updated “Device versus Wellness Products Policy” clearly delineating Gate 1 (disease-specific claims) and Gate 2 (decision impact) criteria. Examples would clarify: consumer oximeters face regulation if marketed for medical use beyond fitness. Congress could later codify distinctions, granting FDA authority over emerging AI health coaches.

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<sup>121</sup> See FTC GoodRx Press Release, *supra* note 2; see also FTC BetterHelp Press Release, *supra* note 4, at 1–2.

<sup>122</sup> *Cf.* WASH. REV. CODE § 19.373.010(28) (2024) (defining a “Small business” exempt from certain immediate obligations as one processing consumer health data of fewer than 100,000 consumers). *Wellness Technology Market Size, Share and Trends 2026 to 2035*, PRECEDENCE RSCH. (Jan. 2, 2026), <https://www.precedenceresearch.com/wellness-technology-market> (listing Apple, Google/Fitbit, and Headspace as key market players).

### 3. Education Proves Crucial for Smooth Transition.

Many lean wellness startups lack privacy expertise. The FTC should release plain-language guides: “Essential Privacy Steps for Wellness Apps”—obtain affirmative consent, implement encryption, limit retention. App store partnerships could help; Apple and Google could require wellness apps demonstrating basic compliance, similar to current privacy label requirements. Market expectations evolve: users begin asking “Is this app a certified data fiduciary?” as routinely as checking HIPAA compliance for medical services.

Early enforcement should target egregious violators to establish precedent. First cases would likely pursue companies blatantly selling health data or suffering breaches from known negligence. Strong penalties—mirroring BetterHelp’s restitution model<sup>123</sup>—signal seriousness. Voluntary compliance programs could offer grace periods: companies self-auditing and fixing issues receive leniency except for actual harm incidents. This fix resembles regulatory rollouts encouraging self-improvement over immediate punishment.

By 2026–2027, this roadmap could transform wellness data governance. HBNR provides immediate hooks. Phased implementation gives industry adjustment time. Certification programs incentivize proactive compliance. Clear FDA guidance prevents device classification confusion. Together, these elements operationalize the comprehensive framework, moving from today’s largely unregulated landscape to tomorrow’s balanced ecosystem protecting innovation and privacy alike.

## B. Anticipated Critiques and Responses

The claim that privacy regulation kills innovation—industry’s most persistent refrain—deserves serious scrutiny alongside other predictable objections to comprehensive wellness data reform.

### 1. “Innovation and Economic Chill”

Industry advocates paint apocalyptic scenarios; fiduciary duties stifling startups, reducing U.S. competitiveness, and freezing wellness tech development. They claim compliance burdens and liability fears will deter entrepreneurs, slowing beneficial innovations reaching consumers. Yet evidence points decisively in the opposite direction. McKinsey’s 2025 analysis confirms the global wellness industry has reached \$2 trillion, with growth driven heavily by privacy-conscious millennials and Gen Z consumers.<sup>124</sup> These younger demographics remember Cambridge Analytica, Equifax, and countless breaches—they demand data protection alongside innovation. McKinsey reported a striking statistic: 30% of consumers would only use wearables if data remained exclusively with them, shared with no third parties.<sup>125</sup> This represents millions of potential users currently

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<sup>123</sup> See FTC BetterHelp Press Release, *supra* note 4.

<sup>124</sup> Anna Pione et al., *supra* note 3 (noting Gen Z drives forty-one percent of spend).

<sup>125</sup> See Shaun Callaghan et al., *The Trends Defining the \$1.8 Trillion Global Wellness Market in*

sitting on the sidelines, their privacy fears outweighing wellness benefits. Clear privacy protections could unlock this massive hesitant market segment. Rather than chilling innovation, regulation could catalyze growth by building trust.

History reinforces this counterintuitive truth. When HIPAA emerged, doomsayers predicted electronic health record adoption would collapse under compliance weight. Instead, HIPAA spawned an entire ecosystem of privacy-compliant health IT innovation—secure messaging platforms, encrypted databases, consent management systems. The market adapted and thrived. Similarly, wellness fiduciary duties would spark innovation in privacy-preserving analytics, differential privacy techniques, homomorphic encryption for health data, and intuitive consent UX design. McKinsey’s 2025 wellness report emphasizes earning customer trust as a paramount factor sustaining consumer engagement.<sup>126</sup> Companies credibly advertising robust privacy compliance gain competitive advantage—witness Apple’s privacy-centric marketing driving wearables sales rather than hindering them.

The “innovation chill” proves largely phantom upon examination. Wellness technology’s inherently data-rich nature ensures continued value creation even under ethical constraints. Companies will still analyze trends, personalize experiences, and improve products—they’ll simply do so respecting user interests. Moreover, uniform federal rules actually reduce compliance overhead compared to navigating fifty different state privacy regimes. Startups can plan coherent data strategies from inception rather than retrofitting for each jurisdiction.

## 2. “Compliance Costs for Small Businesses”

Skeptics warn about overwhelming expenses—hiring privacy officers, implementing new technology, retaining legal counsel. Small app developers supposedly cannot shoulder these burdens, leading to market consolidation favoring tech giants. Several responses deflate this concern.

The phased implementation structure deliberately gives smaller players extended timelines and potentially simplified obligations. Large platforms would implement first, developing tools and best practices that smaller firms later adopt at lower cost. On a practical level, many compliance measures involve one-time investments or automation. Implementing end-to-end encryption uses readily available open-source libraries. Consent management platforms offer plug-and-play solutions. Cloud services provide security features previously requiring massive infrastructure. GAO data confirms that privacy and security solutions have become increasingly affordable and scalable.<sup>127</sup>

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2024, MCKINSEY & CO. (Jan. 16, 2024), <https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/the-trends-defining-the-1-point-8-trillion-dollar-global-wellness-market-in-2024> (highlighting privacy concerns in wearable adoption).

<sup>126</sup> See Anna Pione et al., *supra* note 3 (identifying trust as a key imperative for growth); cf. Richards & Hartzog, *supra* note 72, at 965–67 (proposing fiduciary duties to supersede ineffective notice-and-choice models).

<sup>127</sup> See *Science & Tech Spotlight*, *supra* note 45, at 1–2; see *Technology Assessment: Wearable*

Existing realities further weaken this objection. Any wellness startup targeting European users already complies with GDPR. Those serving Californians navigate CCPA requirements. Rather than adding new burdens, federal law would streamline compliance by replacing the current patchwork with unified standards. Maintaining different privacy practices across markets costs more than implementing consistent protections.

Nicolas Terry's scholarship on "exceptionally thin regulation" reveals hidden costs of the status quo.<sup>128</sup> Lack of baseline standards creates its own expenses—catastrophic breach costs, legal uncertainty, and reputational damage from privacy scandals. Strong security mandated by fiduciary duties may prevent company-destroying breaches. The cost of implementing encryption pales against the cost of explaining to users why their mental health data appeared on the dark web. Preventive compliance proves cheaper than reactive damage control.

### 3. "First Amendment Absolutism"

Free speech maximalists deploy constitutional arguments against any data regulation. They claim that restricting collection or sharing violates First Amendment principles, invoking *Sorrell* to argue that data flows constitute protected expression. Any wellness privacy law supposedly faces strict scrutiny and inevitable invalidation. This fundamentally mischaracterizes both the law's design and constitutional doctrine.

The framework proposed here would regulate commercial conduct—data handling within service provision—not speech. This triggers at most intermediate scrutiny, which the law readily satisfies.<sup>129</sup> The framework does not target particular viewpoints or speakers but generally requires responsible data practices across all wellness companies. Richards explains how privacy laws governing business information practices avoid First Amendment conflicts by regulating marketplace conduct rather than expression.<sup>130</sup>

Precedent supports this distinction. The Video Privacy Protection Act<sup>131</sup> prevents video rental disclosure without constitutional crisis. No court has struck down this law despite its clear restriction on information sharing. FCRA comprehensively regulates credit information disclosure while surviving decades of potential challenges. Courts treat credit reports as commercial commodities subject to regulation, not protected public speech. If financial and entertainment records receive such treatment, surely intimate health data merits equal protection.

The First Amendment critique often conflates public information dissemination (core protected territory) with commercial data exploitation

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*Technologies*, *supra* note 45, at 1; *cf. Internet Privacy*, *supra* note 45, at 43.

<sup>128</sup> See Nicolas P. Terry, *Assessing the Thin Regulation of Consumer-Facing Health Technologies*, 48 J. L. MED. & ETHICS 94, 95 (2020) (arguing that the lack of regulation leads to hidden costs and risks).

<sup>129</sup> See Richards, *supra* note 83, at 1152–53, 1156–58.

<sup>130</sup> See *id.* at 1156–58; see Sarah McMahon, *Internet of Things: A Privacy Law Case Study* (SSRN, Scholarly Paper No. 2608473, 2015), <https://dx.doi.org/10.2139/ssrn.2608473>.

<sup>131</sup> Video Privacy Protection Act, 18 U.S.C. § 2710 (2018) (barring disclosure of video rental records).

(permissible economic regulation). The proposed law does not prevent journalists from reporting on wellness trends or academics from publishing research. It would prevent companies from betraying user trust through unauthorized commercialization. Legislative findings emphasizing consumer protection and parallels to accepted financial privacy regulations would further bolster constitutional defense.

#### 4. “Equity and Inclusion Concerns”

Critics raise important questions about unintended consequences for marginalized communities. Could regulation limit public health research benefiting underserved populations? Might forcing apps toward paid models exclude low-income users from wellness tools? These questions require serious engagement, not dismissal.

On the research front, the law should include carefully crafted public health exceptions mirroring HIPAA’s allowances. Anonymized wellness data contributing to CDC diabetes prevention studies or NIH health disparities research could proceed under narrow exceptions. These would ensure genuine public benefit while maintaining privacy safeguards—requiring true de-identification, prohibiting re-identification attempts, and limiting use to specified research purposes. IRB-approved academic studies could similarly access data under strict protocols.

Regarding the free-versus-paid services debate: yes, current models often subsidize “free” apps through data monetization. Privacy restrictions might prompt some shift toward subscription models. However, this framing misses crucial points. First, “free” apps are not truly free—users pay with their data, and psychological biases often obscure this cost. Second, evidence suggests that trust and data protection are high priorities for consumers, challenging the dominance of the “free” model. Third, legal and technical frameworks aimed at privacy-preserving loyalty enable sustainable models—such as contextual advertising that puts user interests first without sharing personal data externally.

Most importantly, examining equity through a data justice lens reveals that vulnerable populations suffer most under current unregulated regimes. Low-income users, often less aware of complex data practices, face greater exposure to predatory targeting.<sup>132</sup> Wellness data enables discriminatory insurance pricing, employment decisions, and targeted marketing of harmful products to vulnerable communities. Oliva’s pathbreaking work on prescription monitoring programs demonstrates how surveillance systems disproportionately flag and penalize marginalized patients, forcing medication tapering and chilling necessary care-seeking.<sup>133</sup>

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<sup>132</sup> See Mary Madden et al., *Privacy, Poverty, and Big Data: A Matrix of Vulnerabilities for Poor Americans*, 95 WASH. U. L. REV. 53, 66–67 (2017).

<sup>133</sup> Jennifer D. Oliva, *Dosing Discrimination: Regulating PDMP Risk Scores*, 110 CALIF. L. REV. 47, 49–52 (2022) (demonstrating that proprietary PDMP risk-scoring algorithms disproportionately flag and penalize marginalized patients—leading to forced tapering, prescription discontinuation, and patient abandonment, and thereby chilling necessary treatment); see also *An Act Regarding*

Strengthening privacy protections would help level the playing field. When wellness data cannot be weaponized for discrimination, equity improves. The law should incorporate explicit anti-discrimination provisions prohibiting wellness data use in insurance underwriting, employment decisions, housing, or credit—areas where bias runs rampant. Algorithmic accountability requirements would ensure that wellness AI does not perpetuate or amplify discrimination against protected classes.

These critiques, while raising legitimate concerns, prove ultimately manageable through careful statutory design and implementation. Innovation thrives under reasonable rules providing that provide certainty and build consumer trust. Compliance costs remain proportionate and decrease over time through technology and market adaptation. First Amendment concerns dissolve when one recognizes the distinction between regulating commercial data practices and restricting public discourse. Equity improves when vulnerable populations gain protection from exploitative data uses currently harming them most.

## VI. CONCLUSION

The smartphone on a patient's nightstand now captures resting heart rate data that the patient's physician never sees. This asymmetry—wellness apps harvesting intimate data beyond HIPAA's reach—captures the privacy paradox at the heart of this Article. Law remains frozen while technology races ahead.

Yet this transcends regulatory gaps. What confronts us is a fundamental mismatch between technological capability and legal protection. Identical health data receives fortress protection in hospitals but none in apps. Companies monetize fertility patterns while users assume confidentiality. Privacy violations inflict demonstrable harm, yet courts demand impossible proof. The system, as Part II documented, has failed.

The Tiered Integration Framework offers three concrete responses. Federal wellness data fiduciary duties would transform companies from data exploiters to data trustees, bound by loyalty, care, transparency, and minimization obligations. Baseline-plus state harmonization would establish national minimums while preserving innovative state protections. The FDA's Two-Gate Risk Test would capture wellness products functioning as medical devices without stifling genuine lifestyle tools.

Critics will resist. They will invoke innovation, costs, and constitutional concerns. Yet each objection crumbles under scrutiny. Privacy builds rather than breaks trust, enabling sustainable innovation. Compliance costs pale against breach risks and decrease through technology. Constitutional challenges fail when one recognizes that conduct regulation differs from speech restriction. The framework addresses real problems with practical solutions.

Historical analogy illuminates the stakes. The 1960s witnessed environmental degradation without coordinated response—until the EPA's

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*Controlled Substances Prescription Monitoring Activities: Testimony in Support of L.D. 1277* (Me. Legis. Apr. 11, 2025); see also McMahon, *supra* note 130, at 33-34.

creation and landmark legislation transformed American industry. Today, wellness data exploitation proceeds similarly unchecked, awaiting its regulatory watershed moment. Just as the Clean Air Act did not destroy manufacturing but channeled it responsibly, wellness privacy law would not kill innovation but guide it ethically.

The FTC's recent enforcement trilogy—GoodRx, BetterHelp, and Flo—demonstrates both current tools' potential and their limitations. Reactive penalties cannot substitute for proactive protection. State experiments like Washington's My Health My Data Act show promise but create fragmentation. The time has arrived for comprehensive federal action establishing "Wellness Law" as a coherent discipline.

The wellness data conundrum is a defining challenge, but it is solvable. By extending the fundamental values that underlie medical privacy—confidentiality, loyalty, and respect for persons—into the wellness tech ecosystem, lawmakers can ensure that individuals remain in control of their health narratives. This would not only protect rights and prevent harms but also enable the ethical and sustainable growth of wellness innovations.

The choice confronts us now. Continue the fiction that wellness data differs from health data? Or recognize that when apps predict mental health crises and fertility windows, the distinction collapses? This Article has charted a path. Whether Congress follows depends on recognizing that in the data age, health privacy cannot be selective.

# WELLNESS INFLUENCER SCIENCEPLOITATION: AN AMERICAN MEDICINE SHOW REVIVAL

Jennifer D. Oliva\*

## ABSTRACT

*This Article argues that modern wellness influencer marketing represents a digital revival of the American medicine show. From 19th-century patent medicine peddlers to today’s social media personalities hawking detox teas and gummy supplements, wellness fraud has exploited the same information asymmetries, regulatory gaps, and cultural anxieties—while leveraging new technologies that amplify both reach and harm. The Article traces this evolution across five Parts: the history of American wellness fraud and current regulatory frameworks; the rise of modern wellness influencers and “conspiratoriality”; COVID-19 pandemic health scams; the institutional capture of government health agencies by wellness industry interests; and a critique of existing regulatory approaches with recommendations for reform. These recommendations include reforming the Dietary Supplement Health and Education Act, enhanced platform transparency requirements modeled on the European Union Digital Services Act, strengthened Federal Trade Commission enforcement authority, and targeted amendments to Section 230 that would remove immunity for algorithmically promoted health misinformation. The story of American wellness regulation is not one of scientific progress triumphing over quackery, but of a complex dance between innovation, exploitation, and institutional adaptation. Understanding this history is essential to developing regulatory frameworks capable of addressing contemporary wellness fraud while respecting legitimate interests in health autonomy and free expression.*

## I. INTRODUCTION

The promise of health perfection and wellness optimization through purportedly miraculous tonics, tinctures, nutraceuticals, devices, and other remedies has captivated Americans for centuries.<sup>1</sup> From the patent medicine<sup>2</sup>

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<sup>1</sup> See, e.g., Meredith B. Linn, *Neither Snake Oils nor Miracle Cures: Interpreting Nineteenth-Century Patent Medicines*, 56 HIST. ARCHAEOLOGY 681, 681–82 (2022); see also Steven J. Jackson, Michael P. Sam, Marcelle C. Dawson & Daniel Porter, *The Wellbeing Pandemic: Outline of a Contested Terrain and a Proposed Research Agenda*, 7 FRONTIERS SOC., Dec. 2022, at 1 (explaining that “[w]ellbeing has emerged as a central, if not defining feature, of contemporary social life” and “new conceptualisations of wellbeing have emerged that have shifted the focus from primarily economic measures, such as . . . standard of living, to allegedly more holistic and progressive measures associated with quality of life”).

<sup>2</sup> The term “patent medicine” is misleading because often these products were not patented in the United States. Instead, they were proprietary medicines made of secret ingredients that were usually

peddlers of the 19th century to today’s Instagram, YouTube, and TikTok influencers who hawk recipes, guided meditation routines, fitness tips, detox teas, raw milk, and gummy supplements, the fundamental appeal remains unchanged: the hope that wellness can be purchased and optimized through unproven, hyper-individualistic self-care schemes.<sup>3</sup> Such autonomous paths to improved and sustained health are particularly seductive to many Americans distrustful of the conventional health care delivery system and its professional elites.<sup>4</sup> As *The Wellness Trap* author Christy Harrison explained in a recent interview: “American individualism and capitalism fit right in with wellness culture. Our health-care system makes so many people feel dismissed and unheard, and they feel the need to take things into their own hands.”<sup>5</sup>

There is no question that the U.S. healthcare delivery system has failed many Americans.<sup>6</sup> The U.S. grossly outspends other wealthy nations on healthcare per capita, yet it ranks poorly relative to those countries on key health indicators, such as life expectancy, rates of avoidable deaths, and infant and maternal mortality.<sup>7</sup> America is also the only country among its high-net-worth comparators that does not provide any form of universal healthcare.<sup>8</sup> That stated, beneath the enduring promise of wellness optimization lies a troubling pattern of exploitation,

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marketed under trademarked names. See, e.g., Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 664 (2006).

<sup>3</sup> See e.g., STEPHANIE ALICE BAKER, WELLNESS CULTURE: HOW THE WELLNESS MOVEMENT HAS BEEN USED TO EMPOWER, PROFIT AND MISINFORM 9–11 (2022); Ross D. Petty, *Pain-Killer: A 19th Century Global Patent Medicine and the Beginnings of Modern Brand Advertising*, 39 J. MACROMARKETING 287, 288–89 (2019); see also Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623 (1999); JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION (1961).

<sup>4</sup> BAKER, *supra* note 3, at 7–8; see also Lisa Miller, *3 Days of Healing, Hope, and ‘Snake Oil’ With the Wellness Elite*, N.Y. TIMES (Nov. 8, 2024), <https://www.nytimes.com/2024/11/08/well/eudemonia-summit-wellness-palm-beach.html> (explaining that “[t]he attendees were joined by the belief that the conventional health care system had largely failed to heal the sick, and that by heeding the teachers on their phones they’d do a better job healing themselves”).

<sup>5</sup> Danielle Cohen, *‘Wellness’ Was Never About Our Well-Being*, CUT (Apr. 20, 2023), <https://www.thecut.com/2023/04/christy-harrison-the-wellness-trap-book-interview.html>; see also Leah R. Fowler, Max N. Helveston & Zoe Robinson, *Influencer Speech-Torts*, 113 GEO. L.J. 415, 418 (2025) (recognizing that “it is easy to understand how even sensible people can turn away from the providers and institutions that have failed them and toward influencers and online communities with health experiences that mirror their own”); James Harvey Young, *Patent Medicines: An Early Example of Competitive Marketing*, 20 J. ECON. HIST. 648, 652 (1960) (stating that “[t]he two most important reasons for the rise of patent medicines were the unsatisfactory state of health in the nation, and the expansion of ways by which ailing citizens could be confronted with messages of hope”).

<sup>6</sup> See, e.g., David Blumenthal et al., *Mirror, Mirror: A Portrait of the Failing U.S. Health System*, COMMONWEALTH FUND (Sept. 19, 2024), <https://www.commonwealthfund.org/publications/fund-reports/2024/sep/mirror-mirror-2024>.

<sup>7</sup> *Id.*; see also Rebecca Pifer, *US Is Drastically Behind Other Wealthy Nations on Healthcare, Despite Spending the Most*, HEALTHCARE DIVE (Sept. 18, 2024), <https://www.healthcaredive.com/news/us-lags-nations-health-system-performance-commonwealth-fund/727423>.

<sup>8</sup> Pifer, *supra* note 7.

misinformation, and regulatory cat-and-mouse games that have evolved with technology while maintaining their essential character.<sup>9</sup>

The modern wellness industry, valued at over \$6.3 trillion globally in 2023, represents both the culmination of centuries-old health optimization desires and a new frontier for regulatory challenges.<sup>10</sup> Today's perpetually online wellness grifters operate in a landscape far more complex than their snake-oil predecessors, leveraging social media algorithms, influencer marketing, celebrity endorsements, sophisticated pseudoscientific language, and viral conspiracy theories to reach millions of consumers simultaneously.<sup>11</sup> These tactics were prominently featured during the height of the COVID-19 pandemic and anti-vaccination social media infodemic campaigns, deleterious to public health.<sup>12</sup> Understanding how we arrived at this moment requires examining the historical trajectory of wellness fraud in America, from the traveling medicine shows that instigated the enactment of the Pure Food and Drug Act of 1906<sup>13</sup> to the vast digital wellness ecosystem that challenges traditional regulatory frameworks today.<sup>14</sup>

This Article traces that evolution, exploring how each era's technological and cultural shifts created new opportunities for wellness exploitation while revealing the persistent inadequacies of our regulatory responses. More importantly, it examines why traditional regulatory approaches, designed for a world of centralized manufacturing and clear product categories, struggle to address the vast, decentralized, content-driven nature of modern wellness fraud.<sup>15</sup> As this Article explains, the story of American wellness regulation is not one of scientific progress triumphing over quackery, but of a complex dance between innovation, exploitation, and institutional adaptation.

This Article proceeds in five Parts. Part I provides a concise history of American wellness fraud, from the 19th-century patent medicine peddlers and

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<sup>9</sup> See Jaroslava Kankova, Alice Binder & Jorg Matthes, *Helpful or Harmful? Navigating the Impact of Social Media Influencers' Health Advice: Insights from Health Expert Content Creators*, 24 BMC PUB. HEALTH, Dec. 2024, at 2; Joshua J. Klein & Scott J. Schweikart, *Does Regulating Dietary Supplements as Food in a World of Social Media Influencers Promote Public Safety?*, 24 AMA J. ETHICS E396 (2022).

<sup>10</sup> *The Global Wellness Economy Reaches a New Peak of \$6.3 Trillion—And Is Forecast to Hit \$9 Trillion by 2028*, GLOB. WELLNESS INST. (Nov. 5, 2024), <https://globalwellnessinstitute.org/press-room/press-releases/the-global-wellness-economy-reaches-a-new-peak-of-6-3-trillion-and-is-forecast-to-hit-9-trillion-by-2028/>.

<sup>11</sup> See Emily Denniss & Rebecca Lindberg, *Social Media and the Spread of Misinformation: Infectious and a Threat to Public Health*, 40 HEALTH PROMOTION INT'L, Apr. 2025, at 3, 4; Fowler et al., *supra* note 5, at 419–20; Laura Paddison, *Wellness Influencers Fueled Pandemic Misinformation. Now They're Targeting Another Crisis*, CNN (Feb. 5, 2024, at 1:19 PM ET), <https://www.cnn.com/2024/02/04/climate/wellness-influencers-conspiracy-climate-intl>.

<sup>12</sup> Jennifer A. Sandlin & Alan Eladio Gomez, *Toward New Critical Pedagogies of Conspiratorial Consumption: Exploring and Combatting the COVID-19 New-Age Grifters*, 2023 NEW DIRECTIONS FOR ADULT & CONTINUING EDUC. 41, 41–42; see Israel Junior Borges do Nascimento et al., *Infodemics and Health Misinformation: A Systemic Review of Reviews*, 100 BULL. WORLD HEALTH. ORG. 544, 544 (2022).

<sup>13</sup> Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>14</sup> See, e.g., FED. TRADE COMM'N, HEALTH PRODUCTS COMPLIANCE GUIDANCE (Dec. 20, 2022).

<sup>15</sup> See DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 32–45 (2010).

snake oil salesmen to the deregulated dietary supplement hawkers of the late 20th Century. It also details the current regulatory frameworks that apply to social media influencer wellness marketing. Part II examines the rise of the modern wellness influencer, examines various online wellness scams, and explores the connection between wellness influencer marketing and conspiratoriality. Part III details the massive online health scams instigated by celebrities and other internet personalities during the COVID-19 pandemic, while Part IV explores the modern wellness-industrial complex and the threat to public health posed by wellness conspirators' institutional capture of government health agencies. Part V concludes the Article with a critique of current regulatory frameworks governing online wellness influencer marketing, an overview of the psychology of susceptibility to online fraud, and recommendations for a more robust and effective wellness regulatory scheme.

## II. THE AMERICAN WELLNESS INDUSTRY: FROM PATENT MEDICINE PEDDLERS TO SOCIAL MEDIA HEALERS

“The snake-oil salesmen of old have morphed into the deceptive, high-tech marketers of today, preying on people’s desires for easy solutions to difficult health problems—including Alzheimer’s, arthritis, cancer, diabetes, memory loss, sexual performance, weight loss, Coronavirus Disease 2019 (COVID-19), influenza and other infectious diseases.”<sup>16</sup>

### A. The Snake Oil Era: Foundations of American Wellness Fraud

The roots of American wellness fraud date back to the early colonial period,<sup>17</sup> but the phenomenon reached its apex in the post-Civil War era, when rapid industrialization, westward expansion, advances in printing technology that enabled widespread, sophisticated product advertising, and distrust of 19th-century medicine created the perfect conditions for the proliferation of patent medicines.<sup>18</sup>

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<sup>16</sup> U.S. FOOD & DRUG ADMIN., *6 Tip-Offs to Rip-Offs: Don’t Fall for Health Fraud Scams* (Mar. 4, 2021), <https://www.fda.gov/consumers/consumer-updates/6-tip-offs-rip-offs-dont-fall-health-fraud-scams>.

<sup>17</sup> See YOUNG, *supra* note 3, at 3–15.

<sup>18</sup> *Balm of America: Patent Medicine Collection*, SMITHSONIAN, <https://www.si.edu/spotlight/balm-of-america-patent-medicine-collection/history> (last visited Oct. 21, 2025) (noting that “[r]apid increases in industry and manufacturing, urban living, advertising in national newspapers and magazines, and the absence of drug regulation all contributed to a boom in the production and consumption of patent medicines”); see YOUNG, *supra* note 3, at 73 (explaining that “all the pamphlets, articles, and resolutions by the opponents of quackery were too small a dike to stem the mighty flood of patent medicine advertising”); see also Catherine Falzone, *Snake Oil Almanacs: Patent Medicine Advertising in the 19th Century*, N.Y. HIST. SOC’Y BLOG (Sept. 11, 2012), <https://www.nyhistory.org/blogs/snake-oil-almanacs-patent-medicine-advertising-in-the-19th-century> (explaining the significant role of patent medicine almanac advertising in the 19th Century); ANN ANDERSON, SNAKE OIL, HUSTLERS AND HAMBONES: THE AMERICAN MEDICINE SHOW 20 (2000) (pointing out that “[g]iven the state of the medical arts in the nineteenth century, self-dosing with a proprietary medicine was a reasonable as any other treatment”).

Although the popular term “snake oil salesman” derives from this period, the historical reality was far more complex than the stereotype suggests.<sup>19</sup> Actual snake oil, derived from Chinese water snakes and brought to America by Chinese railroad workers, contained beneficial omega-3 fatty acids and had legitimate therapeutic properties.<sup>20</sup> American entrepreneurs, however, quickly appropriated the concept, creating countless imitations using mineral oil, beef fat, and other cheap substitutes while claiming the mystique of exotic Eastern medicine.<sup>21</sup> This pattern—the appropriation and commercialization of traditional remedies stripped of their original context and efficacy—would become a recurring theme in American wellness culture.<sup>22</sup>

The medicine show emerged as the primary vehicle for patent medicine distribution, combining vaudeville acts, wild west revues, circus routines, minstrel-style entertainment, and their attendant “exotic” features with commerce in ways that prefigured modern infotainment marketing.<sup>23</sup> These traveling performances featured elaborate staging, testimonials from planted audience members, and charismatic pitchmen who understood that selling hope required more than just product claims—it required spectacle, community, the appearance of scientific authority, and, perhaps most important, the appeal to significant cultural anxieties and folk wisdom that, among other things, invoked idealized Indigenous naturalism.<sup>24</sup> Dr. William Radam’s “Microbe Killer,” Lydia Pinkham’s

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<sup>19</sup> See Lakshmi Gandhi, *A History of ‘Snake Oil Salesmen,’* NPR CODE SWITCH (Aug. 26, 2013, at 11:55 AM ET), <https://www.npr.org/sections/codeswitch/2013/08/26/215761377/a-history-of-snake-oil-salesmen>.

<sup>20</sup> *Id.*; see also Richard Kunin, *Snake Oil*, 151 W. J. MED. 208, 208 (1989).

<sup>21</sup> See, e.g., Domagoj Valjak, *In 19th Century, Clark Stanley Patented Snake Oil and Advertised It as a Painkiller, Saying He Had Studied Its Sonders with the Hopi Healers*, VINTAGE NEWS (Feb. 26, 2018), <https://www.thevintagenews.com/2018/02/27/snake-oil/>.

<sup>22</sup> See, e.g., ANDERSON, *supra* note 18, at 26–28; see also Emily Thornton, *When Healing Harms: Cultural Appropriation in the Wellness Industry*, NAT. INDIGENOUS TIMES (Apr. 18, 2025, at 9:20 AM ET), <https://nit.com.au/18-04-2025/17487/when-healing-harms-cultural-appropriation-in-the-wellness-industry>; Sarah Schrank, *The Trouble with Wellness*, 8 RACE & YOGA 35, 37 (2024); (pointing to criticisms of wellness culture, generally, and yoga, specifically, due to cultural misappropriating and arguing that other critiques “highlight[] a growing concern that wellness – now its own industry – preyed on women’s insecurities about their bodies, lent itself to disordered eating, was racist and exclusionary, and served as the perfect neoliberal tool through which workers could be underpaid yet offered free mindfulness classes to offset their stress and increase their efficiency”).

<sup>23</sup> Michael Ortiz-Castro, *Patent Medicines, Medicine Shows, and the Secret Life of Blackface*, YALE UNIV. HARVEY CUSHING/JOHN HAY WHITNEY MED. LIB. (Oct. 12, 2023), <https://library.medicine.yale.edu/news/patent-medicines-medicine-shows-and-secret-life-blackface>; ANDERSON, *supra* note 18, at 44 (explaining that “[r]acial anxiety was expressed openly and often in patent medicine advertising and ingrained stereotypes into the national consciousness”); Brooks McNamara, *The Indian Medicine Show*, 23 ED. THEATRE J. 431, 432 (1971) (explaining that “[m]any white Americans believed that the Indian was a natural physician, endowed with an iron constitution because he possessed secrets of healing unknown to the white man” and that the “Indian” medicine show traded on the “mystique” of Indigenous people).

<sup>24</sup> Ortiz-Castro, *supra* note 23; ANDERSON, *supra* note 18, at 48–49, 61–67. For additional information, the *Sawbones* podcast has recorded an entertaining three-part series featuring several of the more colorful 19th century patent medicine peddlers. SAWBONES: A MARITAL TOUR OF MISGUIDED MEDICINE, *Heroes of Patent Medicine: Vol. 1* (Apple Podcasts, Apr. 8, 2015);

Vegetable Compound, Hamlin’s Wizard Oil, Kick-a-poo Indian Sagwa, and countless other nostrums promised to cure everything from consumption to melancholy and often contained dangerous levels of alcohol, laudanum, cocaine, opium, or mercury.<sup>25</sup> Patent medicine distributors also marketed numerous tinctures and tonics to babies and young children, several of whom tragically died from ingesting products containing opium and morphine during the early 20th century.<sup>26</sup>

The patent medicine industry’s success rested on several factors that remain relevant to contemporary wellness fraud. First, the information asymmetry between sellers and consumers was enormous—most Americans had limited access to medical care and scientific education, making them vulnerable to authoritative-sounding claims.<sup>27</sup> Second, the medicines often produced immediate effects due to their alcohol or drug content, creating genuine testimonials from users who felt better temporarily.<sup>28</sup> Third, the industry exploited fundamental gaps in medical care, offering hope to those suffering from conditions that legitimate medicine could not yet treat effectively.<sup>29</sup>

Perhaps most importantly, patent medicine marketing pioneered techniques that modern wellness grifters still employ: the use of scientific-sounding language to lend credibility, the emphasis on “natural” ingredients as

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SAWBONES: A MARITAL TOUR OF MISGUIDED MEDICINE, *Heroes of Patent Medicine: Vol. 2* (Apple Podcasts, Apr. 15, 2015); SAWBONES: A MARITAL TOUR OF MISGUIDED MEDICINE, *Heroes of Patent Medicine: Vol. 3* (Apple Podcasts, Apr. 22, 2015).

<sup>25</sup> See Linn, *supra* note 1, at 687, 689; see also *Kickapoo Indiana Medicine Company*, AM. INST. HIST. PHARM., <https://aihp.omeka.net/exhibits/show/heritagemarket/kickapoo-company> (last visited Oct. 21, 2025); Rebecca Rego Barry, *Was Lydia E. Pinkham the Queen of Quackery?*, JSTOR DAILY (Nov. 22, 2017), <https://daily.jstor.org/was-lydia-e-pinkham-the-queen-of-quackery/>; Mark Benvenuto et al., *What’s in Century-Old “Snake Oil” Medicines? Mercury and Lead*, SMITHSONIAN MAG. (Nov. 15, 2013), <https://www.smithsonianmag.com/science-nature/whats-in-century-old-snake-oil-medicines-mercury-and-lead-16743639/>; Grace Hemmingson, Scottie Lynch, Nancy Fawkes Mason & E. Thomas Ewing, *Radam’s Microbe Killer: Advertising Cures for Tuberculosis*, NAT’L LIB. MED. (Oct. 9, 2015), <https://circulatingnow.nlm.nih.gov/2015/10/09/radams-microbe-killer-advertising-cures-for-tuberculosis/>; Donohue, *supra* note 2, at 664; ANDERSON, *supra* note 18, at 34–35; SARAH STAGE, FEMALE COMPLAINTS: LYDIA PINKHAM AND THE BUSINESS OF WOMEN’S MEDICINE 9–11 (1979).

<sup>26</sup> Carrie Scufari James, *FDA’s Homeopathic Risk-Based Enforcement: Compromised Consumer Protection or Stepped-Up Scrutiny?*, 70 SYRACUSE L. REV. 1115, 1117 (2020) (explaining that “[f]rom 1904 to 1906, thirteen babies died due to opium and morphine poisoning resulting from [patent medicines] that could be purchased without a physician’s advice or prescription”).

<sup>27</sup> See JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH-CENTURY AMERICA 15–30 (1967).

<sup>28</sup> See *id.* at 30–32; Bryan Denham, *Magazine Journalism in the Golden Age of Muckraking: Patent-Medicine Exposures Before and After the Pure Food and Drug Act of 1906*, 22 JOURNALISM & COMM’N MONOGRAPHS 100, 101 (2020) (noting that “[p]atent medicines often contained substances such as alcohol, cannabis, cocaine, and morphine, and a ‘cure’ frequently involved an altered state of consciousness and little else”); Maria Cunningham, *There’s a Cure for That: Historic Medicines and Cure-alls in America*, OR. HEALTH & SCI. UNIV., <https://www.ohsu.edu/historical-collections-archives/theres-cure-historic-medicines-and-cure-alls-america> (last visited Oct. 21, 2025) (explaining that “[w]hile [patent medicines] could provide temporary relief, this was largely due to the liberal use of alcohol and opiates”).

<sup>29</sup> See YOUNG, *supra* note 3, at 169; YOUNG, *supra* note 27, at 18–21.

inherently safer than synthetic alternatives, and the positioning of products as “holistic” alternatives to expensive, invasive, or ineffective conventional treatments.<sup>30</sup> These medicines were marketed not just as cures but as lifestyle choices that reflected the consumer’s wisdom, autonomy, and commitment to health optimization.<sup>31</sup>

The regulatory environment that allowed this industry to flourish was characterized by minimal federal oversight and a prevailing philosophy of *caveat emptor*.<sup>32</sup> Before 1906, the Supreme Court’s narrow interpretation of the Commerce Clause limited federal regulatory authority over intrastate economic activity while state and local efforts to police food and drug markets were uneven and often insufficient to curb unsafe or deceptive practices.<sup>33</sup> This created a regulatory vacuum that entrepreneurs were quick to exploit, establishing patterns of innovation-outpacing-regulation that persist today.<sup>34</sup>

## B. The Pure Food and Drug Act: America’s Initial Regulatory Response

The Progressive Era witnessed an expanding public awareness of industrial malfeasance and a corresponding demand for government intervention to protect consumers.<sup>35</sup> The catalyst for food and drug regulation came from

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<sup>30</sup> See Falzone, *supra* note 18; Nina L. Shapiro, *Quackery and Hype: Mesmerized by Wizards*, 85 SOC. RSCH. 889, 891–92 (2018); GRETE DE FRANCESCO, *POWER OF THE CHARLATAN* 3–4 (Yale Univ. Press 1939).

<sup>31</sup> Judy Z. Segal, *The Empowered Patient on a Historical-Rhetorical Model: 19th-Century Patent-Medicine Ads and the 21st-Century Health Subject*, 24 HEALTH 572, 580 (2020) (explaining that “[t]he historical health subject was addressed not only as a savvy sort of person but also as a vigilant one, who does not wait to get very sick before seeking treatment”); J. Worth Estes, *The Pharmacology of Nineteenth-Century Patent Medicines*, 30 PHARM. HISTORY 3, 7 (1988) (“Both patent medicines and alternative medical practices flowered in tandem, nourished by democratic principles advocated by Andrew Jackson’s supporters, who fostered the notions of freedom of choice and self-sufficiency which accompanied the westward movement of the American frontier” in the 1840s).

<sup>32</sup> Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces That Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 FOOD & DRUG L.J. 315, 336–41 (2014); MORTON KELLER, *REGULATING A NEW ECONOMY: PUBLIC POLICY AND ECONOMIC CHANGE IN AMERICA, 1900-1933* at 25–45 (1990); JAMES HARVEY YOUNG, *PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906* 42 (1989).

<sup>33</sup> See, e.g., *United States v. E.C. Knight Co.*, 156 U.S. 1 (1895) (holding that manufacturing was not “commerce” and therefore beyond Congress’s Commerce Clause power); see also Lainie Rutkow & Jon S. Vernick, *The U.S. Constitution’s Commerce Clause, the Supreme Court, and Public Health*, 126 PUB. HEALTH REP. 750, 750 (2011) (explaining that “in the decades preceding the New Deal, the Supreme Court, operating in a more laissez-faire social and economic environment, interpreted the scope of the Commerce Clause more narrowly, striking down numerous laws intended to protect the public’s health”); James Harvey Young, *The Long Struggle for the Law*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/110318/download?attachment> (last accessed Mar. 12, 2026).

<sup>34</sup> See YOUNG, *supra* note 27, at 149–50; McNamara, *supra* note 23, at 666.

<sup>35</sup> London, *supra* note 32, at 337–38; Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 334–35 (opining that “[t]he [Pure Food and Drugs] Act has long been understood as a key example of Progressivism, creating the first federal

multiple sources: Upton Sinclair's *The Jungle* exposed unsanitary conditions in meatpacking plants, Dr. Harvey Washington Wiley's "Poison Squad" experiments demonstrated the dangers of food additives, and investigative journalists documented the patent medicine industry's false claims and dangerous ingredients.<sup>36</sup>

The Pure Food and Drug Act of 1906, signed into law by President Theodore Roosevelt on June 30, 1906, represented America's first comprehensive attempt to regulate the wellness industry.<sup>37</sup> The law prohibited the interstate transport of unlawful food and drugs, defined as products that were mislabeled or adulterated, that is, contained harmful ingredients.<sup>38</sup> Crucially, it required that patent medicines containing alcohol, cocaine, opium, morphine, or other specified drugs list those ingredients on their labels.<sup>39</sup>

The 1906 Act's limitations, however, were immediately apparent and would presage many of the challenges facing modern wellness regulation.<sup>40</sup> The law focused primarily on labeling rather than efficacy, meaning that products could still make wild claims as long as they accurately listed a small set of enumerated ingredients.<sup>41</sup> It applied only to interstate commerce, leaving intrastate sales largely unregulated.<sup>42</sup> The law also delegated to manufacturers the decision of whether a drug was available by prescription or over the counter.<sup>43</sup> Most importantly, it placed the burden of proof on the government to demonstrate that products on the

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consumer agency in the glow of faith in science and expertise to solve market failures and better the human condition"); Elizabeth Sanders, *Rediscovering the Progressive Era*, 72 OHIO ST. L.J. 1281, 1282–84 (2011); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States*, 37 FOOD DRUG COSM. L.J. 310, 310 (1982).

<sup>36</sup> See PHILLIP J. HILTS, PROTECTING AMERICAS HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 48–49 (2003) (describing Sinclair's *The Jungle* as a significant provocation for the 1906 Act); Litman & Litman, *supra* note 35, at 318 (describing the impact of Dr. Wiley's "Poison Squad" food additive experiments); SAMUEL HOPKINS ADAMS, THE GREAT AMERICAN FRAUD: ARTICLES ON THE NOSTRUM EVIL AND QUACKERY (1905); *see also* UPTON SINCLAIR, THE JUNGLE (1906); HARVEY W. WILEY, THE HISTORY OF A CRIME AGAINST THE FOOD LAW (1929).

<sup>37</sup> Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed by 21 U.S.C. § 329(a) (1938)); *see also* Swanson, *supra* note 35, at 334–35 ("The 1906 Act has long been understood as a key example of Progressivism, creating the first federal consumer agency in the glow of faith in science and expertise to solve market failures and better the human condition."); C. C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3, 3–15 (1933).

<sup>38</sup> Pure Food and Drug Act, Pub. L. No. 59-384 § 2, 34 Stat. 768-69.

<sup>39</sup> Pure Food and Drug Act, Pub. L. No. 59-384 § 8, 34 Stat. 769.

<sup>40</sup> James, *supra* note 26, at 1124–33; RUTH DE FOREST LAMB, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS 278–79 (1936).

<sup>41</sup> *See, e.g., Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement> [hereinafter 1906 Food and Drug Act History].

<sup>42</sup> *Id.*; Mitchell Salem Fisher, *The Proposed Food and Drugs Act: A Legal Critique*, 1 LAW & CONTEMP. PROBS. 74, 75–76 (1933).

<sup>43</sup> McNamara, *supra* note 23, at 666–67.

market were harmful or mislabeled, rather than requiring manufacturers to prove their products were safe and effective before they could be sold to consumers.<sup>44</sup>

The enforcement of the Pure Food and Drug Act revealed both the potential and limitations of federal regulation.<sup>45</sup> The Bureau of Chemistry, the federal agency led by Dr. Wiley that would ultimately become the Food and Drug Administration (FDA), pursued numerous prosecutions against patent medicine manufacturers, achieving some notable successes.<sup>46</sup> Industry adaptation, however, was swift and sophisticated. Manufacturers reformulated products to comply with labeling requirements while maintaining their marketing claims, relocated operations to avoid interstate commerce regulations, and developed new advertising strategies that implied benefits without making explicit medical claims.<sup>47</sup>

The period between 1906 and 1938 demonstrated a pattern that would become familiar in wellness regulation: regulatory reforms triggered by well-publicized public health tragedies followed by industry adaptation and the emergence of new loopholes.<sup>48</sup> During this era, patent medicine advertising shifted from newspapers to radio, where the nascent Federal Trade Commission (FTC) had limited authority.<sup>49</sup> New product categories emerged that fell outside existing regulatory frameworks.<sup>50</sup> Most importantly, the industry began developing the rhetorical strategies that modern wellness companies still employ—emphasizing “support” rather than “cure,” using testimonials and celebrity endorsements rather than direct claims, and positioning products as food supplements rather than medicines.<sup>51</sup>

### C. Evolution Through the Mid-20th Century

The Food, Drug, and Cosmetic Act of 1938 (FDCA) significantly strengthened federal food and drug regulatory authority.<sup>52</sup> The law was enacted

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<sup>44</sup> See Pure Food and Drug Act, Pub. L. No. 59-384 § 4, 34 Stat. 768; Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 216 (2009).

<sup>45</sup> See 1906 Food and Drug Act History, *supra* note 41.

<sup>46</sup> YOUNG, *supra* note 27, at 6–12; James, *supra* note 26, at 1126–27.

<sup>47</sup> See YOUNG, *supra* note 3, at 236–52.

<sup>48</sup> CARPENTER, *supra* note 15, at 80–81.

<sup>49</sup> YOUNG, *supra* note 27, at 158–75.

<sup>50</sup> See *id.*; PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 31 (1980) (explaining that “to avoid the scope of the [1906 Act] entirely, [a manufacturer] could produce a nonnarcotic preparation, give it a novel name, and say little definite about it”). See generally CARPENTER, *supra* note 15, at 10 (highlighting the dynamic between regulatory frameworks and pharmaceutical companies).

<sup>51</sup> See Fisher, *supra* note 42, at 80–83; see also *United States v. Johnson*, 221 U.S. 488, 495 (1911) (holding that the technical term “misbranded” in the 1906 Act applied only to false statements regarding the identity and quality of foods and drugs and not to therapeutic or curative declarations). The holding in *United States v. Johnson* prompted Congress to amend the 1906 Act in 1912 with the Sherley Amendment, which prohibited “false and fraudulent” therapeutic representations. See Sherley Amendment, 37 Stat. 416 (1912); Fisher, *supra* note 42, at 80.

<sup>52</sup> See Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

primarily in response to the 1937 Elixir Sulfanilamide tragedy that killed over 100 people, most of whom were young children.<sup>53</sup> The 1938 FDCA required pharmaceutical manufacturers to notify the FDA that new drugs were safe before they could go to market, thereby transforming the FDA's role from post-market police officer to pre-market regulator.<sup>54</sup> The law further extended oversight of medical devices, cosmetics, and food to the FDA.<sup>55</sup> As will be explored in the following section of this Article, the FDCA created the long-criticized regulatory distinction between drugs and dietary supplements, the latter of which are generally policed post-market as food products rather than evaluated for pre-market safety like drugs, a distinction that continues to complicate wellness regulation today.<sup>56</sup> It is worth noting that, while the FDCA gave the FDA authority to regulate product labels, it specifically exempted medical journal advertising from the FDA's purview.<sup>57</sup> Congress instead opted to give the FTC jurisdiction to regulate false food, drug, and cosmetic advertising by passing the 1938 Wheeler-Lea Act.<sup>58</sup>

The post-World War II era brought new challenges and opportunities for wellness entrepreneurs.<sup>59</sup> Scientific advances in nutrition and pharmacology yielded legitimate breakthroughs that lent credibility to health-optimization claims.<sup>60</sup> The discovery of vitamins and their role in preventing nutrient deficiency diseases, such as scurvy, beriberi, rickets, and pellagra, suggested that targeted supplementation could enhance health beyond mere disease prevention.<sup>61</sup> Simultaneously, growing prosperity and leisure time created a market for products promising enhanced vitality, longevity, and performance.<sup>62</sup>

This period saw the emergence of what might be called “scientific wellness fraud” or “scienceploitation”—the marketing of products that

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<sup>53</sup> Van Tassel, *supra* note 44, at 223–24.

<sup>54</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1052 § 505 (1938); 21 U.S.C. § 355 (1938); NAT'L RSCH. COUNCIL COMM. ON THE FRAMEWORK FOR EVALUATING THE SAFETY OF DIETARY SUPPLEMENTS, DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY 27 (2005); *Developments in the Law - the Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 635 (1954); *see also* CARPENTER, *supra* note 15, at 10 (explaining that “[t]he difference between pre-market (ex ante) and post-market (ex post) regulatory power is crucial”).

<sup>55</sup> DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY, *supra* note 54, at 27; *Developments in the Law - the Federal Food, Drug, and Cosmetic Act*, *supra* note 54, at 635.

<sup>56</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1048 § 403(j) (1938); DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY, *supra* note 54, at 27–28 (explaining that “[t]he applicability of these provisions to products containing a vitamin, mineral, or botanical ingredient (e.g., whether the product was considered a drug or a food) depended on the product's intended use, as determined usually by the labeling and advertising claims for the product”).

<sup>57</sup> Charles J. Walsh & Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325, 1337–38 (1994).

<sup>58</sup> *See* Pub. L. No. 75-447, 52 Stat. 111 (1938). The provisions of the Wheeler-Lea Act are incorporated throughout the FTC Act. Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

<sup>59</sup> *See* YOUNG, *supra* note 27, at 200–30.

<sup>60</sup> *See id.*

<sup>61</sup> *See* Richard D. Semba, *The Discovery of Vitamins*, 82 INT'L J. VITAMIN NUTRITION RSCH. 310 (2012); KENNETH J. CARPENTER, *THE HISTORY OF SCURVY AND VITAMIN C* vii (1986).

<sup>62</sup> *See* BAKER, *supra* note 3, at 15–39.

appropriated legitimate scientific concepts and terminology to lend credibility to dubious claims.<sup>63</sup> Linus Pauling's advocacy for vitamin C supplementation as a cure-all, while controversial within the scientific community, provided a Nobel Prize winner's endorsement for the concept that targeted nutrition could prevent disease and enhance health.<sup>64</sup> This created space for entrepreneurs to make increasingly sophisticated claims about their products' mechanisms of action while maintaining plausible scientific deniability.<sup>65</sup>

Television advertising transformed wellness marketing by enabling direct-to-consumer advertising that could reach millions simultaneously.<sup>66</sup> However, broadcast media's regulatory oversight and mass market reach imposed some constraints on the most egregious claims.<sup>67</sup> The FTC's fairness doctrine and the FDA's marketing regulations created a relatively controlled information environment compared to what would emerge in the digital age.<sup>68</sup>

The 1960s counterculture movement added new dimensions to wellness fraud by emphasizing "natural" alternatives to conventional medicine and promoting skepticism toward established medical authority.<sup>69</sup> This cultural shift created opportunities for wellness entrepreneurs to position themselves as viable substitutes to what they characterized as a profit-driven, reductionist medical establishment.<sup>70</sup> The language of empowerment, autonomy, and holistic health that emerged during this period would become central to modern wellness marketing.<sup>71</sup>

The 1960s also witnessed significant federal reforms in pharmaceutical law and policy. The 1962 drug amendments to the FDCA, commonly known as the Kefauver-Harris Amendments, represented a watershed moment in drug regulation by fundamentally expanding the FDA's authority to require pre-market

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<sup>63</sup> See Jesse Ruse, *Why Do We Fall for Wellness Scams? Our Cultural Biases and Myths Are Often to Blame*, CONVERSATION (Feb. 25, 2025, at 8:24 PM ET), <https://theconversation.com/why-do-we-fall-for-wellness-scams-our-cultural-biases-and-myths-are-often-to-blame-250790>; Ross Pomeroy, *Exploring the Wild and Disturbing World of "Scienceploitation,"* BIG THINK (Feb. 13, 2025), <https://bigthink.com/thinking/scienceploitation/>; Rina Raphael, *How Fake Science Sells Wellness*, N.Y. TIMES (July 26, 2023), <https://www.nytimes.com/2023/07/26/well/live/wellness-products-false-claims.html>; Eric Bock, *Health Law Professor Advises Scientists Must Speak Up Against Misinformation*, NIH REC., Nov. 2021, at 4.

<sup>64</sup> Contrast LINUS PAULING, VITAMIN C AND THE COMMON COLD (1970), with Stephen Barrett, *The Dark Side of Linus Pauling*, QUACKWATCH (Sept. 14, 2014), <https://quackwatch.org/related/pauling/> (Pauling's book argues that high doses of Vitamin C cures colds while Barrett's article highlights the controversies); see also Sara Chodosh, *How a Nobel Prize Winner Spread the Vitamin C Myth*, POPULAR SCI. (June 26, 2021, at 1:00 PM ET), <https://www.popsoci.com/vitamin-c/>.

<sup>65</sup> See YOUNG, *supra* note 27, at 300–20.

<sup>66</sup> See DE FOREST LAMB, *supra* note 40, at 285–300.

<sup>67</sup> See e.g., *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367 (1969).

<sup>68</sup> See YOUNG, *supra* note 27, at 296–315.

<sup>69</sup> See BAKER, *supra* note 3, at 15–39; Shapiro, *supra* note 30, at 891–92; Michael Cohen & Mary Ruggie, *Integrating Complementary and Alternative Medical Therapies in Conventional Medical Settings: Legal Quandaries and Potential Policy Models*, 72 U. CIN. L. REV. 671, 671 (2003). See generally THEODORE ROSZAK, *THE MAKING OF A COUNTER CULTURE* (1969) (explaining how a counterculture comes into being).

<sup>70</sup> See YOUNG, *supra* note 27, at 320–45.

<sup>71</sup> See generally *id.* (showing examples of historical language of empowerment, autonomy, and holistic health that emerged in the 1900s).

proof of both safety and efficacy for new drugs.<sup>72</sup> Before 1962, the FDA could only require manufacturers to demonstrate that drugs were safe, following the 1938 FDCA response to the sulfanilamide tragedy.<sup>73</sup> The 1962 amendments were directly precipitated by the thalidomide crisis, in which a sedative widely used in Europe caused severe birth defects in thousands of children.<sup>74</sup> FDA medical officer Dr. Frances Kelsey's refusal to approve the drug largely spared Americans.<sup>75</sup>

Congress passed the 1962 drug amendments unanimously after extensive hearings led by Senator Estes Kefauver revealed widespread problems in the pharmaceutical industry, including the marketing of ineffective drugs at high prices and inadequate clinical testing procedures.<sup>76</sup> The legislation required pharmaceutical companies to submit substantial evidence of effectiveness through "adequate and well-controlled investigations" before receiving FDA approval, marking the first time in American history that drug efficacy became a legal prerequisite for market entry.<sup>77</sup> The amendments also mandated informed consent for clinical trial participants, established good manufacturing practices, and required FDA inspection of manufacturing facilities, creating the modern framework of pharmaceutical regulation that, at least in theory, emphasizes scientific rigor and patient protection over unfettered market freedom.<sup>78</sup>

#### D. The Dietary Supplement Revolution

The Dietary Supplement Health and Education Act of 1994 (DSHEA) represents perhaps the most consequential wellness law in American history, though not in the way its supporters likely intended.<sup>79</sup> Passed in response to the FDA's attempts to regulate vitamins and minerals as drugs in the 1980s, DSHEA

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<sup>72</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified at 21 U.S.C. § 355(d) (2025)).

<sup>73</sup> Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG. (Jan./Feb. 2006), <https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf>; Van Tassel, *supra* note 44, at 223–24.

<sup>74</sup> Bara Fintel et al., *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation*, HELIX (July 28, 2009), <https://www.helix.northwestern.edu/2009/07/28/the-thalidomide-tragedy-lessons-for-drug-safety-and-regulation/>.

<sup>75</sup> *Id.*

<sup>76</sup> Jeremy A. Greene & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals—The Kefauver Harris Amendments at 50*, 367 NEW ENG. J. MED. 1481, 1481–82 (2012); *see also* Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L.J. 185 (1971) (detailing the extensive legislative history of the Kefauver-Harris Amendments).

<sup>77</sup> Greene & Podolsky, *supra* note 76, at 1482.

<sup>78</sup> Meadows, *supra* note 73, at 3–4.

<sup>79</sup> Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. §§ 321, 331, 342, 343, 350b); *see also* Presidential Statement on Signing the Dietary Supplement Health and Education Act of 1994, 2 PUB. PAPERS 1872 (Oct. 25, 1994) (celebrating that "manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law" and contending that, "[w]ith perhaps the best of intentions[,] agencies of government charged with protecting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people").

created a separate regulatory category for dietary supplements that effectively exempted them from the pre-market safety and efficacy requirements that applied to pharmaceuticals.<sup>80</sup> As one commentator aptly noted, “supporters from across the spectrum championed [DSHEA] as a victory for consumer freedom, populist protection, and preventative medicine.”<sup>81</sup> The Center for Science in the Public Interest (CSPI), on the other hand, took a markedly different and more prescient tack, predicting that DSHEA would instigate “America’s Second Age of Quackery.”<sup>82</sup> Professor Margaret Gilhooley relatedly noted that “[t]he enactment of DSHEA became a harbinger of a new era of re-examination of the appropriate limits of regulatory power” and, consequently, “the term ‘being DSHEAed’ has become a byword for deregulation in some quarters.”<sup>83</sup>

DSHEA defines “dietary supplement” as “a product (other than tobacco) intended to supplement the diet” that contains one or more dietary ingredients enumerated in the statute, which includes, but is not limited to, vitamins, minerals, herbs, botanicals, and amino acids.<sup>84</sup> As that definition suggests, DSHEA regulates dietary supplements as foods rather than drugs, meaning manufacturers can market them without proving they are safe or effective, so long as they include disclaimers that their products have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent disease.<sup>85</sup> This lax regulatory framework created enormous opportunities for wellness entrepreneurs while imposing minimal obligations for scientific substantiation.<sup>86</sup> In fact, “[t]he multibillion dollar industry has invested exorbitant amounts of money on lobbyists to campaign against any increased regulatory control by the FDA” and, thereby, stalled any attempt for Congressional reform since 1994.<sup>87</sup>

The practical effect of DSHEA was to legalize much of what had been considered wellness fraud under previous regulatory frameworks.<sup>88</sup> DSHEA

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<sup>80</sup> Roseann B. Termini, Esq. & Vincent A. Sannuti, *A Look Back at the DSHEA—Over 25 Years Later: The Dangers of a Reactionary Approach to Dietary Supplement Regulation*, 22 QUINNIPIAC HEALTH L.J. 171, 180 (2019); Khatcheressian, *supra* note 3, at 625–30; Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 678–79 (1997).

<sup>81</sup> Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 246–47 (2005).

<sup>82</sup> *Id.* at 247.

<sup>83</sup> Gilhooley, *supra* note 80, at 666.

<sup>84</sup> 21 U.S.C. § 321(ff) (2025).

<sup>85</sup> Termini & Sannuti, *supra* note 80, at 181; Cohen & Ruggie, *supra* note 69, at 716.

<sup>86</sup> Cohen & Ruggie, *supra* note 69, at 716; *see also* Maggie Dickens, *Safe Until Proven Unsafe: Solving the Growing Debate Around Dietary Supplement Regulation*, 15 WAKE FOREST J. BUS. & INTELL. PROP. L. 576, 583 (2015) (noting that “[t]he lack of regulatory authority in the industry, for example, no prior approval required by the FDA, attracts businesses to the market”).

<sup>87</sup> Dickens, *supra* note 86, at 583–84.

<sup>88</sup> McCann, *supra* note 81, at 220 (providing that “[m]anufacturers are afforded wide latitude in product labeling and in product promotion; short of egregious misrepresentation or explicit promise to cure disease, supplement manufacturers possess broad autonomy in how they shepherd their product through the American economy”); Rajani R. Starr, *Too Little, Too Late: Ineffective Regulation of Dietary Supplements in the United States*, 105 AM. J. PUB. HEALTH 478, 479–80 (2015) (citing numerous government reports arguing that most supplements contain harmful contaminants,

permits supplement manufacturers to make “structure-function” claims about how their products affect normal body functions or structure, such as “calcium builds strong bones.”<sup>89</sup> The law does not allow supplement manufacturers to advance disease claims, such as “calcium cures cancer,” which would trigger drug regulation.<sup>90</sup> This distinction, however, has proved both legally significant and practically meaningless, as consumers struggle to distinguish between claims that a product “supports immune function” and claims that it “prevents illness.”<sup>91</sup> DSHEA also expressly permits supplement manufacturers to make “general well-being” product claims, such as “melatonin promotes healthy sleep,” so long as those claims are “truthful and not misleading.”<sup>92</sup>

DSHEA further established the current burden-of-proof framework, which requires the FDA to demonstrate that a supplement is unsafe before it can be removed from the market, rather than requiring manufacturers to prove safety before selling their wares to unsuspecting consumers.<sup>93</sup> This post-marketing policing scheme, which places the burden of proof for safety on the government, contrasts sharply with the rigorous premarket safety and efficacy vetting regime that applies to pharmaceuticals and has proven extremely difficult to enforce given the FDA’s limited resources and the supplement industry’s rapid growth.<sup>94</sup>

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including lead, arsenic, mercury, and pesticides; supplement manufacturers often do not comply with adverse event reporting requirements; and pointing out that “[s]everal deficiencies and potentially deceptive practices in supplement labeling have been documented in the literature”); Khatcheressian, *supra* note 3, at 630, 632–38 (chronicling post-DSHEA examples of supplement misrepresentation triggering enforcement and litigation).

<sup>89</sup> 21 U.S.C. § 343(r)(6)(A) (2025); *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2024), <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/structurefunction-claims>; see also Cohen & Ruggie, *supra* note 69, at 716; Khatcheressian, *supra* note 3, at 630. Federal law also permits supplement manufacturers to make FDA-authorized “health claims” supported by “significant scientific agreement,” such as “adequate calcium and vitamin D as part of a healthy diet may reduce the risk of osteoporosis in later life.” *Questions and Answers on Health Claims in Food Labeling*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2017), <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/questions-and-answers-health-claims-food-labeling> (explaining that “[h]ealth claims in food labeling are claims that have been reviewed by FDA and are allowed on food products to show that a food or food component may reduce the risk of a disease or a health-related condition”).

<sup>90</sup> See U.S. FOOD & DRUG ADMIN., SMALL ENTITY COMPLIANCE GUIDE ON STRUCTURE/FUNCTION CLAIMS (Jan. 2002) (explaining that “[d]isease claims require prior approval by FDA and may be made only for products that are approved drug products or for foods under separate legal provisions that apply to claims called ‘health claims’”).

<sup>91</sup> See McCann, *supra* note 81, at 247–49.

<sup>92</sup> 21 U.S.C. § 343(r)(6)(A)–(B) (2025).

<sup>93</sup> See, e.g., Starr, *supra* note 88, at 481 (“DSHEA places the burden of proving that a supplement is unsafe, or marketed without adequate notification or proof of safety, on the FDA.”).

<sup>94</sup> *Id.*; Kathy Talkington, *Stronger Federal Oversight of Dietary Supplements Will Protect Consumers from Unsafe Products*, PEW (Jan. 26, 2023), <https://www.pew.org/en/research-and-analysis/articles/2023/01/26/stronger-federal-oversight-of-dietary-supplements-will-protect-consumers-from-unsafe-products>; see also Khatcheressian, *supra* note 3, at 643 (“FDA is doing what it can to ensure the safety, if not the effectiveness, of supplement products, but when the laws require them to act only when they have information that a supplement actually is dangerous (rather than testing whether it is dangerous before allowing consumers to take it), there only is so much the agency can do.”); Vitoria Hawekotte, *FDA’s Minimal Authority over Dietary Supplements*, REGUL. REV.

Compounding enforcement difficulties, the FDA must prove that a supplement ingredient poses a “significant or unreasonable risk of injury” to remove it from the market.<sup>95</sup>

Notably, DSHEA’s supplement policing authority limits the FDA to assessing the manufacturer’s “intended use” of the supplement at issue.<sup>96</sup> In other words, the FDA is precluded from considering a supplement’s actual or unintended consumer uses in evaluating whether it poses a significant or unreasonable risk of injury.<sup>97</sup> FTC law, by contrast, “focuses not on the marketer’s intent, but on the consumer’s understanding.”<sup>98</sup>

The supplement industry’s response to DSHEA was swift and dramatic.<sup>99</sup> The number of available supplements exploded from approximately 4,000 in 1994 to over 100,000 today.<sup>100</sup> More importantly, the industry developed increasingly sophisticated marketing strategies that maximized DSHEA’s opportunities while minimizing its constraints.<sup>101</sup> Companies learned to make claims that sounded medical while technically qualifying as structure-function claims, to use third-party publications and testimonials to imply benefits they could not claim directly, and to position their products within broader lifestyle and wellness narratives rather than specific medical contexts.<sup>102</sup> As legal advocates have explained,

many companies skirt [the law] by using suggestive language and imagery implying their products have drug-like effects for conditions like obesity, erectile dysfunction, and arthritis pain. Terms like “clinically tested,” “scientifically formulated,” or “doctor-

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(Jan. 10, 2024), <https://www.theregreview.org/2024/01/10/hawekotte-fdas-minimal-authority-over-dietary-supplements/>; Jessie L. Bekker, Alex Flores & Michael S. Sinha, *Re-Regulating Dietary Supplements*, 19 J. FOOD L. & POL’Y 2, 4 (2023) (“By the FDA’s own admission, its post-market measures do not keep unsafe products out of consumers’ hands.”).

<sup>95</sup> 21 U.S.C. § 342(f)(1)(A) (2025).

<sup>96</sup> 21 U.S.C. § 321(ff) (2025); *see also* Marlys J. Mason, *Drugs or Dietary Supplements: FDA’s Enforcement of DSHEA*, 17 J. PUB. POL’Y & MKTG. 296, 297 (1998).

<sup>97</sup> *See* Mason, *supra* note 96.

<sup>98</sup> FED. TRADE COMM’N, HEALTH PRODUCTS COMPLIANCE GUIDANCE 5 (Dec. 2022).

<sup>99</sup> *See, e.g.*, Taylor C. Wallace & Igor Koturbash, *DSHEA 1994 – Celebrating 30 Years of Dietary Supplement Regulation in the United States*, 1 J. DIETARY SUPPS. 1, 2 (2025) (demonstrating the explosive growth in the industry since 1994); Bekker et al., *supra* note 94, at 2–3 (same).

<sup>100</sup> Wallace & Koturbash, *supra* note 99, at 2; Press Release, Sen. Dick Durbin, *Durbin Introduces Legislation to Improve Safety and Ensure Transparency of Dietary Supplements* (July 30, 2024), <https://www.durbin.senate.gov/newsroom/press-releases/durbin-introduces-legislation-to-improve-safety-and-ensure-transparency-of-dietary-supplements>.

<sup>101</sup> *See* Klein & Scott, *supra* note 9, at 397–98.

<sup>102</sup> *See Learn to Spot Common Health Scams*, FED. TRADE COMM’N CONSUMER ADVICE, <https://consumer.ftc.gov/articles/common-health-scams> (last accessed July 31, 2025) (explaining that “[u]nder federal law, no one can promote dietary supplements for the treatment of a disease. But dishonest companies often make false claims like ‘helps prevent Alzheimer’s disease,’ ‘stops arthritis pain forever,’ ‘cures eye disease,’ ‘is traditional remedy for heart disease, prostate cancer, erectile dysfunction,’ and ‘prevents allergies.’”); *Dangerous Dietary Supplements and False Advertising Claims: Safeguarding Consumer Health*, RYAN L. GRP. (Nov. 11, 2024), <https://theyanlawgroup.com/blog/dangerous-dietary-supplements-and-false-advertising-claims-safeguarding-consumer-health/>.

recommended” are frequently used to lend legitimacy to supplements despite a lack of reliable data to support usage claims.<sup>103</sup>

DSHEA’s lenient regulation of the booming dietary supplement industry has resulted in negative health outcomes for many Americans.<sup>104</sup> According to a 2015 study published in the *New England Journal of Medicine*, more than 23,000 people seek emergency room treatment every year due to adverse health reactions to supplements.<sup>105</sup> More recently, in 2019, the Pew Charitable Trusts conducted a national survey in which 1 in 8 adults reported that “they or an immediate family member had experience[d] extreme side effects—such as increased heart rate, high blood pressure, kidney problems, or liver damage—as a result of taking dietary supplements.”<sup>106</sup> The Pew study also demonstrated that more than half of the survey respondents were under the entirely false impression that supplements must be proven safe to the FDA’s satisfaction before they go on the market.<sup>107</sup> “Other underappreciated harms of alternative remedies arise from interactions with conventional medications and opportunity costs from delaying or not seeking evidence-based treatment, which is a particular concern in cancer patients.”<sup>108</sup>

Yale University School of Medicine Professor and clinical neurologist Dr. Steven Novella describes the easy-to-exploit American supplement regulatory scheme as follows:

The deal that DSHEA . . . made with the public was this: Let the supplement industry have free reign to market untested products with unsupported claims, and then we’ll fund reliable studies to arm the public with scientific information so they can make good decisions for themselves. This “experiment” (really just a gift to the supplement industry) has been a dismal failure. The result has been an explosion of

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<sup>103</sup> *Dangerous Dietary Supplements and False Advertising Claims: Safeguarding Consumer Health*, *supra* note 102.

<sup>104</sup> See, e.g., Ilisa B. G. Bernstein & Karin K. Bolte, *Is My Patient Taking and Unsafe Dietary Supplement?*, 24 *AMA J. ETHICS* E390, E392 (2022) (“Dietary supplements can have side effects; interact with medications, food, or other supplements; or be unsafe. These harms result due to the supplement’s being contaminated, tainted with at least one drug ingredient, or containing more than a labeled amount of ingredients.”); *Dietary Supplements: Dubious Value, Hidden Dangers*, HARV. MED. SCH. (Dec. 1, 2018), <https://www.health.harvard.edu/heart-health/dietary-supplements-dubious-value-hidden-dangers>; Andrew I. Geller et al., *Emergency Room Visits for Adverse Events Related to Dietary Supplements*, 373 *NEW ENG. J. MED.* 1531, 1531 (Oct. 15, 2015).

<sup>105</sup> Geller et al., *supra* note 104, at 1531.

<sup>106</sup> Talkington, *supra* note 94; see also *Americans Support Requiring Supplement Makers to Tell FDA About Their Products*, PEW (Dec. 18, 2019), <https://www.pew.org/en/research-and-analysis/fact-sheets/2019/12/americans-support-requiring-supplement-makers-to-tell-fda-about-their-products>.

<sup>107</sup> *Americans Support Requiring Supplement Makers to Tell FDA About Their Products*, *supra* note 106.

<sup>108</sup> Douglas MacFarlane, Mark J. Hurlstone & Ullrich K.H. Ecker, *Protecting Consumers from Fraudulent Health Claims: A Taxonomy of Psychological Drivers, Interventions, Barriers, and Treatments*, 259 *SOC. SCI. & MED.*, Aug. 2020, at 1, 2.

the supplement industry flooding the marketplace with useless products and false claims.<sup>109</sup>

The emergence of the internet in the 1990s and its mainstream adoption in the 2000s created unprecedented opportunities for wellness entrepreneurs while exposing the limitations of existing regulatory frameworks.<sup>110</sup> Unlike traditional media, the internet enabled anyone to publish health information to a global audience with minimal oversight or investment.<sup>111</sup> In addition, and unlike direct mail marketing, online content can be updated instantly and targeted precisely to interested consumers.<sup>112</sup> As Professor Alexandra J. Roberts recently pointed out:

Influencer advertising has enjoyed a meteoric rise. The industry is projected to reach \$10-20 billion in 2020, with close to 80% of brands participating. Consumers follow influencers on social media, engage with the content they post, and buy what they endorse, trusting the influencers they follow as much—or more than—their actual friends.<sup>113</sup>

The meteoric rise of online influencer-healers and their crafty adoption of medicine show tactics to promote under-regulated wellness products in under-regulated online environments is the subject of the following section of this Article.<sup>114</sup>

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<sup>109</sup> Steven Novella, *Herbs Are Drugs*, 37 SKEPTICAL INQ., Mar./Apr. 2013, <https://skepticalinquirer.org/2013/03/herbs-are-drugs/>.

<sup>110</sup> See Klein & Scott, *supra* note 9, at 396 (pointing out that “the regulatory environment for dietary supplements, which has been criticized as being inadequate in the face of hazards, has serious pitfalls when confronting promotion of these supplements by social media influencers”).

<sup>111</sup> See *id.* at 397–98; Susannah Fox & Maeve Duggan, *Health Online 2013*, PEW RSCH. CTR. (Jan. 15, 2013), <https://www.pewresearch.org/internet/2013/01/15/health-online-2013/> (acknowledging that as early as 2013, 59% of American adults “have looked online for health information in the past year” and more than “[o]ne in three American adults have gone online to figure out a medical condition”).

<sup>112</sup> See Jessica Apotheker et al., *In Influencer Marketing, Precision Wins*, BOS. CONSULTING GRP. (Apr. 21, 2025), <https://www.bcg.com/publications/2025/influencer-marketing-precision-wins>; Gregory M. Dickinson, *The Patterns of Digital Deception*, 65 B.C. L. REV. 2457, 2458 (2024) (explaining that “[o]nline tracking enables sellers to amass troves of historical data, apply machine-learning tools to construct detailed customer profiles, and target those customers with tailored offers that best suit their interests”); see also *id.* at 2461 (stating that “[i]n contrast with the mass emails of old, scammers now stalk and target their victims with expert precision”).

<sup>113</sup> Alexandra J. Roberts, *False Influencing*, 109 GEO. L.J. 81, 83–84 (2020).

<sup>114</sup> See John Powell & Tabitha Pring, *The Impact of Social Media Influencers on Health Outcomes: Systemic Review*, 340 SOC. SCI. & MED., Jan. 2024, at 1 (explaining that “[t]he prolific, largely unregulated, user-generated nature of social media means individuals can be exposed to misleading or dangerous health information”).

### III. THE RISE OF ONLINE WELLNESS INFLUENCERS, FRAUD, AND CONSPIRITUALITY

“Problems in medicine do not mean that homeopathic sugar pills work; just because there are problems with aircraft design, that doesn’t mean that magic carpets really fly.”<sup>115</sup>

#### A. The Internet Age: New Platforms, Old Promises

Early internet wellness fraud often resembled traditional direct marketing tactics translated to digital platforms—sales letters in blog posts or direct mail form promising quick fixes and miraculous “natural” cures, testimonial videos featuring supposedly recovered patients, and time-limited offers creating artificial urgency.<sup>116</sup> The internet’s unique characteristics soon enabled more sophisticated approaches. Search engine optimization encouraged wellness entrepreneurs to position their content prominently when consumers searched for health information.<sup>117</sup> Email marketing sustained ongoing relationship-building with potential customers.<sup>118</sup> Most importantly, the internet’s apparent democratization of information made questionable health claims seem more credible by positioning them alongside legitimate scientific content.<sup>119</sup>

The regulatory challenges posed by online wellness fraud were immediately apparent but difficult to address.<sup>120</sup> The borderless nature of the internet made jurisdiction ambiguous—was a website based where its servers were located, where its owner resided, or where its content was accessed?<sup>121</sup> The speed of digital publishing meant that regulatory responses were always reactive,

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<sup>115</sup> BEN GOLDACRE, *BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS* 358 (2013).

<sup>116</sup> See *6 Tip-Offs to Rip-Offs: Don’t Fall for Health Fraud Scams*, *supra* note 16; *Questions and Answers on Health Claims in Food Labeling*, *supra* note 89; *Health Fraud*, AM. ASS’N RETIRED PEOPLE (June 10, 2020), <https://www.aarp.org/money/scams-fraud/health-miracle-cures>.

<sup>117</sup> See *6 Tip-Offs to Rip-Offs: Don’t Fall for Health Fraud Scams*, *supra* note 16; *Health Fraud*, *supra* note 116; Bernie Garrett et al., *Internet Health Scams—Developing a Taxonomy and Risk-of-Deception Assessment Tool*, 27 HEALTH SOC. CARE COMM. 226, 227–28 (2019).

<sup>118</sup> *A Wellness Pro’s Guide to Small Business Email Marketing*, PRAC. BETTER (June 4, 2023), <https://practicebetter.io/blog/a-wellness-pros-guide-to-small-business-email-marketing>.

<sup>119</sup> See Gita Wirjawan, *The Paradox of the Internet* 1, 2 (Shorenstein Asia-Pac. Rsch. Ctr. working paper, Stan. Univ., Nov. 2024), <https://fsi.stanford.edu/publication/paradox-internet> (explaining that “the democratization of information has not led to a commensurate democratization of ideas” and that “[t]oday, digital content is increasingly being disseminated in ways that actively undermine respect for truth, facts, and critical thinking”); Steven Novella, *The Menace of Wellness Influencers*, SCI.-BASED MED. (Feb. 7, 2024), <https://sciencebasedmedicine.org/the-menace-of-wellness-influencers/>.

<sup>120</sup> See Cara Santa Maria, *Twenty Years of Health Scams and Wellness Trends*, 49 SKEPTICAL INQ., July/Aug. 2025, <https://skepticalinquirer.org/2025/06/twenty-years-of-health-scams-and-wellness-trends/>.

<sup>121</sup> See Roscoe B. Starek, III, Comm’r, Fed. Trade Comm’n, Speech at Australian National University’s Conference on Transborder Consumer Regulation and Enforcement (June 7, 1999) (discussing the difficulties in enforcing consumer protection laws in borderless markets, including the internet).

shutting down websites after they had already reached thousands or millions of consumers.<sup>122</sup> Worse yet, the ease and low cost of creating new websites meant that entrepreneurs could simply launch new domains when old ones were shuttered.<sup>123</sup>

Perhaps most importantly, the online environment's emphasis on infotainment and other content creation that attracts attention and generates clicks created new categories of wellness fraud that existing law struggled to contain.<sup>124</sup> Traditional regulations focused on the safety and marketing of specific, material products, but internet wellness entrepreneurs increasingly earn their living by posting information—recipes, diet tips, video courses, coaching programs—that promise to reveal secrets for achieving optimal health.<sup>125</sup> These informational products often fall outside existing regulatory frameworks while promoting many of the same questionable practices as traditional wellness products.<sup>126</sup>

The rise of search engines, and Google in particular, created new dynamics in the realm of wellness fraud.<sup>127</sup> Consumers increasingly turned to “Dr. Google” rather than healthcare providers for health information, creating opportunities for wellness entrepreneurs to position themselves as authoritative sources.<sup>128</sup> According to a 2023 brief published by the National Center for Health Statistics, “58.5% of adults used the [i]nternet to look for health or medical information” over just a one-year period.<sup>129</sup> In 2019, Google Health Vice President David Feinberg

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<sup>122</sup> See Harry Freeborough, *New Year, New Scams – Health Product Scam Campaigns Abusing Cheap TLDs*, NETCRAFT (Jan. 16, 2024), <https://www.netcraft.com/blog/health-product-scam-campaigns-abusing-cheap-tlds>; *FTC Warns That Rapid Expansion of Internet Domain Name System Could Leave Consumers More Vulnerable to Online Fraud*, FED. TRADE COMM'N (Dec. 16, 2011), <https://www.ftc.gov/news-events/news/press-releases/2011/12/ftc-warns-rapid-expansion-internet-domain-name-system-could-leave-consumers-more-vulnerable-online>.

<sup>123</sup> See Freeborough, *supra* note 122.

<sup>124</sup> Kyle Chayka, *How the Internet Turned Us into Content Machines*, NEW YORKER (June 4, 2022), <https://www.newyorker.com/culture/infinite-scroll/how-the-internet-turned-us-into-content-machines>.

<sup>125</sup> See, e.g., Agne Pelesinaite-Celedine, *The Top 32 Health Influences to Follow in 2025 for Total Wellness Inspiration*, BILLO (Dec. 30, 2025), <https://billo.app/blog/health-influencers/> (pointing out that many “top” wellness influencers share content-centric lifestyle information like workout routines, diet tips, nutrition plans, ebooks, health advice, and online instructional videos); Barbara Zabawa, *Health and Wellness Coaching: A Booming Industry in a Post-COVID19 World*, WELLNESS L. (Apr. 12, 2024), <https://wellnesslaw.com/blogs/health-wellness-coaches/health-and-wellness-coaching-a-booming-industry-in-a-post-covid19-world>.

<sup>126</sup> Zabawa, *supra* note 125 (explaining that wellness coaching is not regulated); Dickinson, *supra* note 112, at 2461 (pointing out that “[o]nline tricksters are everywhere, and the nation’s leading enforcer of consumer-protection laws, the Federal Trade Commission (FTC), has been playing catch-up”).

<sup>127</sup> See Carley Beauge, *Not Feeling Well? Don’t Rely on Dr. Google to Diagnose Your Condition*, ORLANDO HEALTH (Mar. 10, 2023), <https://www.orlandohealth.com/content-hub/not-feeling-well-dont-rely-on-dr-google-to-diagnose-your-condition>.

<sup>128</sup> See, e.g., Xiaoyun Jia, Yan Pang & Liangni Sally Liu, *Online Health Information Seeking Behavior: A Systematic Review*, 9 HEALTHCARE, Dec. 2021, at 1, 2.

<sup>129</sup> Xun Wang & Robin A. Cohen, *Health Information Technology Use Among Adults: United States, July–December 2022*, NCHS DATA BRIEF (Oct. 2022), <https://www.cdc.gov/nchs/data/databriefs/db482.pdf>.

conceded that approximately 7% of daily Google searches were health-related.<sup>130</sup> That may sound modest, but it translated into *70,000 health-related searches per minute* because, at the time, Google handled a billion searches per day.<sup>131</sup> Such astounding statistics are particularly disturbing, given that the vast online information landscape makes it difficult for consumers to distinguish between legitimate health information and marketing content, especially as wellness entrepreneurs have become more sophisticated at mimicking the appearance of scientific authority.<sup>132</sup>

### B. Social Media and the Democratization of Wellness Fraud

The emergence of social media platforms in the 2000s and their mainstream adoption in the 2010s represented another quantum leap in wellness fraud capabilities.<sup>133</sup> Unlike static websites, social media enables ongoing relationship building between wellness influencers<sup>134</sup> and their audiences.<sup>135</sup> Moreover, unlike traditional advertising, social media content can be shared organically by users, lending it credibility through social proof.<sup>136</sup> Most importantly, social media platforms' algorithmic content distribution systems can amplify wellness content to precisely targeted audiences while generating detailed data about user engagement and interests.<sup>137</sup> In 2023, social media influencer

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<sup>130</sup> Margi Murphy, *Dr Google Will See You Now: Search Giant Wants to Cash in on Your Medical Queries*, TELEGRAPH (Mar. 10, 2019, at 6:01 PM ET), <https://www.telegraph.co.uk/technology/2019/03/10/google-sifting-one-billion-health-questions-day/>.

<sup>131</sup> *Id.*

<sup>132</sup> See Novella, *supra* note 119.

<sup>133</sup> See Andreas M. Kaplan & Micheal Haenlein, *Users of the World, Unite! The Challenges and Opportunities of Social Media*, 53 BUS. HORIZONS 59, 61 (2010) (defining social media platforms as “a group of Internet-based applications that build on the ideological and technological foundations of Web 2.0, and that allow the creation and exchange of user-generated content”).

<sup>134</sup> See Roberts, *supra* note 113, at 89 (“Influencers are social media personalities paid to leverage their popularity to market products and shape consumer preferences. Although some are also offline celebrities who gained a substantial following after becoming known entities, others are purely online personalities who have established a loyal audience in a particular niche.” (internal citations omitted)).

<sup>135</sup> See Kankova et al., *supra* note 9, at 2; see also JOSÉ VAN DIJCK, *THE CULTURE OF CONNECTIVITY: A CRITICAL HISTORY OF SOCIAL MEDIA* 1–25 (2013).

<sup>136</sup> See, e.g., Leslie Poston, *Decoding Social Proof in Consumer Psychology*, FORBES (May 9, 2024, at 7:00 AM ET), <https://www.forbes.com/councils/forbescommunicationscouncil/2024/05/09/decoding-social-proof-in-consumer-psychology/>; Hermant Kothari et al., *Impact of Social Media Advertising on Consumer Behavior: Role of Credibility, Perceived Authenticity, and Sustainability*, 10 FRONTIERS COMM'N, May 2025, at 2–3; see also DANAH BOYD, *IT'S COMPLICATED: THE SOCIAL LIVES OF NETWORKED TEENS* 45–75 (2014) (highlighting the ways in which social media is intertwined with social lives).

<sup>137</sup> VAN DIJCK, *supra* note 135, at 4 (explaining that “[c]onnectivity quickly evolved into a valuable resource as engineers found ways to code information into algorithms that helped brand a particular form of online sociality and make it profitable in online markets—serving a global market of social networking and user-generated content” (italics omitted)); see also SHOSHANA ZUBOFF, *THE AGE OF SURVEILLANCE CAPITALISM: THE FIGHT FOR A HUMAN FUTURE AT THE NEW FRONTIER OF POWER* 125–75 (2019).

marketing was valued at \$17.4 billion, “with more than 80% of companies in the U.S. using influencers for marketing purposes.”<sup>138</sup>

Instagram, which hosts 64 million influencers,<sup>139</sup> became the platform of choice for wellness influencers due to its visual nature and centrality to influencer culture.<sup>140</sup> The platform’s emphasis on lifestyle content rather than explicit advertising allowed wellness influencers to embed product promotions within broader narratives about health, beauty, nutrition, and self-improvement.<sup>141</sup> As a pair of researchers recently explained:

Influencers are social media users who leverage their individual perspective to develop a ‘personal brand’ that is attractive to others. Influencers present idealised life experiences – showcasing the possessions and lifestyles that many people dream of having. Through the creation of high-quality and aspirational content, influencers garner a celebrity-like following and can monetise their popularity through product promotion.

. . .

Typical Instagram influencers capture a unique demographic that concurrently fulfils the role of peer and celebrity; often balancing everyday life, for example, as a housewife and mother, with celebrity-like follow and ‘like’ metrics. For influencers, engagement is essential to measuring success and is strategically maximized.<sup>142</sup>

The rise of “wellness influencers” created a new category of wellness entrepreneurs who monetized their personal brand and lifestyle rather than specific products, making traditional regulatory approaches even more challenging to apply.<sup>143</sup>

The case of Belle Gibson exemplifies the destructive potential of wellness fraud on Instagram and the platform’s role in enabling dangerous health

<sup>138</sup> Maximillian Beichert et al., *Revenue Generation Through Influencer Marketing*, 88 J. MKTG. 40, 41 (2024).

<sup>139</sup> Jason Hall, *Influencer Marketing: How to Target Gen Z*, FAST CO. (Apr. 5, 2024), <https://www.fastcompany.com/91070824/influencer-marketing-how-to-target-gen-z>.

<sup>140</sup> See Emily Lowe-Calverley & Rachel Grieve, *Do the Metrics Matter? An Experimental Investigation of Instagram Influencer Effects on Mood and Body Dissatisfaction*, 36 BODY IMAGE, Mar. 2021, at 1.

<sup>141</sup> Lowe-Calverley & Grieve, *supra* note 140, at 1; Zoe Brown & Marika Tiggemann, *A Picture is Worth a Thousand Words: The Effect of Viewing Celebrity Instagram Images with Disclaimer and Body Positive Captions on Women’s Body Image*, 33 BODY IMAGE 190, 198 (2020) (explaining that “Instagram users can edit and filter their photographs to achieve an ‘ideal’ look. Users can also post captions text with their photographs, which adds context to their photo.”).

<sup>142</sup> Lowe-Calverley & Grieve, *supra* note 140, at 1.

<sup>143</sup> See, e.g., Pierre-Yann Dolbec & Andrew N. Smith, *From Fame to Fortune: How Person-Brands Capture Value in the Creator Economy*, 42 INT’L J. RSCH. MKTG. 1264, 1265–68 (2025); Anna Gragert, *Modern-Day Snake Oil: How Wellness Influencers Gained the Power to Spread Health Misinformation*, CNET (Nov. 18, 2025, at 2:28 AM ET), <https://www.cnet.com/health/features/modern-day-snake-oil-how-wellness-influencers-gained-power-spread-health-misinformation/>; Lowe-Calverley & Grieve, *supra* note 140, at 1.

misinformation.<sup>144</sup> Gibson, an Australian wellness influencer, built a massive online following by documenting her supposed recovery from terminal—yet entirely fabricated—brain cancer through dietary changes and alternative treatments, promoting her story through the Instagram-integrated app *The Whole Pantry*, which was awarded Apple’s Best Food and Drink App in 2013, and a companion cookbook.<sup>145</sup> Her Instagram presence featured inspirational quotes, personal anecdotes, and carefully curated photographs that created parasocial relationships with followers seeking hope and alternative cancer treatments.<sup>146</sup> As one report about Gibson’s social media tactics aptly put it, “[f]aking a health crisis was a genius marketing strategy, winning her around 200,000 Instagram followers – an impressive count in the platform’s earliest days.”<sup>147</sup>

Gibson’s extensive Munchausen’s Syndrome by Social Media fraud, which she perpetrated under the account @healing\_belle and admitted to in 2015, revealed the sophisticated ways wellness influencers could exploit Instagram’s visual storytelling capabilities to spread dangerous medical misinformation.<sup>148</sup> She claimed to have rejected conventional cancer treatment in favor of nutrition, Ayurvedic treatments, and other “natural” therapies, positioning herself as an authentic alternative to the medical establishment while monetizing her fabricated

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<sup>144</sup> See generally BEAU DONNELLY & NICK TOSCANO, *THE WOMAN WHO FOOLED THE WORLD: THE TRUE STORY OF FAKE WELLNESS GURU BELLE GIBSON* (2017) (detailing the story of Belle Gibson).

<sup>145</sup> Elaine Xu & Terence Lee, *Illness Bloggers and Sickness Scams: Communication Ethics and the ‘Belle’ Gibson Saga*, 14 ETHICAL SPACE 72, 77 (2017).

<sup>146</sup> Stephanie Alice Baker, *Apple Cider Vinegar: How Social Media Gave Rise to Fraudulent Wellness Influencers like Belle Gibson*, CONVERSATION (Feb. 14, 2025, at 11:26 AM ET), <https://theconversation.com/apple-cider-vinegar-how-social-media-gave-rise-to-fraudulent-wellness-influencers-like-belle-gibson-249432> (“Gibson’s primary platform of communication was Instagram. She used the photo-and-video sharing app to build and engage with her followers through inspirational quotes, personal anecdotes and evocative photographs. . . . This persona allowed Gibson not only to achieve fame online, but to establish a parasocial relationship with her followers.”); Sophie Corbett, *What We Should Learn from the Belle Gibson Fraud*, MENTAL HEALTH DIETITIANS (Feb. 20, 2025), <https://www.mentalhealthdietitians.com/what-we-should-learn-from-the-belle-gibson-fraud/> (“A parasocial relationship is a one-sided emotional connection where an individual feels a strong bond or connection with a public figure that they do not have a real life relationship with. Belle [Gibson] used her story to encourage an emotional connection with her followers.”); see Kati Koivunen et al., *The Emergence of Cause-Oriented Influencers – Conceptualizing De-Influencing on Tik Tok*, 197 J. BUS. RSCH., Aug. 2025, at 1 (noting that “influencer theory explains how parasocial source credibility increases product purchasing”).

<sup>147</sup> Melanie McFarland, *“Apple Cider Vinegar” May Explain How “The Whole Pantry” Fraud was a Step on the Path to RFK, Jr.*, SALON (Feb. 7, 2025, at 12:01 PM ET), <https://www.salon.com/2025/02/07/apple-cider-vinegar-may-explain-how-the-whole-pantry-fraud-was-a-step-on-the-path-of-rfk-jr/>.

<sup>148</sup> Rosemary Counter, *How Cancer Scammer Belle Gibson Became “One of the Most Hated Women in Australia,”* VANITY FAIR (Feb. 5, 2025), <https://www.vanityfair.com/hollywood/story/cancer-scammer-belle-gibson-apple-cider-vinegar>; DONNELLY & TOSCANO, *supra* note 144, at 215 (suggesting Gibson suffered from “Munchausen’s by Internet”); Xu & Lee, *supra* note 145, at 76 (explaining “Munchausen’s Syndrome refers to a type of factitious disorder where ‘patients’ try to gain attention or sympathy by feigning sickness” and that such online cases “highlight the ease with which the resources of the internet can be manipulated to corroborate fictitious health claims”); *Australian Health Blogger Admits Faking Terminal Cancer*, BBC NEWS (Apr. 23, 2015), <https://www.bbc.com/news/world-australia-32420070>.

health journey.<sup>149</sup> Critics documented that Gibson had persuaded real cancer patients to forgo conventional medical treatment, demonstrating how Instagram wellness fraud could directly harm sick and vulnerable followers seeking medical advice.<sup>150</sup> In a subsequently deleted social media post, Gibson boasted that she had helped other people give up conventional treatment “countless times . . . along with leading them down natural therapy for everything from fertility, depression, bone damage and other types of cancer.”<sup>151</sup> As prominent Australian barrister Ian Freckelton aptly pointed out,

[Bell Gibson] was an internet sensation because she manipulated sympathies and took advantage of vulnerabilities of persons in the community (not just in Australia) keen to become healthier and, more significantly, to fight diseases to which conventional medicine was not providing the resolution to which they aspired. She profited mercilessly from people’s weaknesses and very quickly became wealthy.<sup>152</sup>

The Gibson case also highlighted the inadequacy of existing legal frameworks for addressing social media wellness fraud. Although Australian courts fined Gibson AU\$410,000 in 2017 for misleading and deceptive conduct, she has never paid the fine and faces no criminal charges despite admitting to concocting cancer claims and misappropriating charitable donations.<sup>153</sup> The case’s lack of resolution fueled ongoing public outrage and prompted Australia to overhaul its therapeutic health claims regulations in 2022, implementing new restrictions that prohibit paid testimonials for health products and prevent those claiming health expertise from endorsing commercial wellness products.<sup>154</sup> The Gibson case, recently dramatized in the Netflix series *Apple Cider Vinegar*,

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<sup>149</sup> See Baker, *supra* note 146; Stephanie Alice Baker & Chris Rojeck, *The Scandal that Should Force Us to Reconsider Wellness Advice from Influencers*, CONVERSATION (May 21, 2019, at 4:31 AM ET), <https://theconversation.com/the-scandal-that-should-force-us-to-reconsider-wellness-advice-from-influencers-117041>.

<sup>150</sup> Ian Freckelton, *The Woman Who Fooled the World: Belle Gibson’s Cancer Con*, by Beau Donnelly and Nick Toscano, 26 PSYCHIATRY PSYCH. & L. 332, 333 (2019) (reviewing BEAU DONNELLY & NICK TOSCANO, *THE WOMAN WHO FOOLED THE WORLD: THE TRUE STORY OF FAKE WELLNESS GURU BELLE GIBSON* (2017)).

<sup>151</sup> Beau Donnelly & Nick Toscano, *Backlash Over App Developer Belle Gibson’s Missing Charity Money*, AGE (Mar. 9, 2015, at 1:02 PM ET), <https://www.theage.com.au/technology/backlash-over-app-developer-belle-gibsons-missing-charity-money-20150309-13yzd4.html>.

<sup>152</sup> Freckelton, *supra* note 150, at 333.

<sup>153</sup> Charlotte Graham-McLay, *Wellness Blogger Belle Gibson Lied About Having Cancer. Years Later, Australia Is Still Chasing Her*, ABC27 (Feb. 21, 2025, at 1:09 AM ET), <https://www.abc27.com/news/health/ap-health/ap-wellness-blogger-belle-gibson-lied-about-having-cancer-years-later-australia-is-still-chasing-her/>.

<sup>154</sup> *Id.* (explaining that “Australia’s code governing therapeutic health claims was dramatically overhauled in 2022 and breaches can now be punished by millions of dollars in fines — changes some analysts attribute in part to Gibson’s conduct”); John Buckley, *No Vitamins, No Testimonials: Australian Wellness Influencers Face Tough New Laws*, VICE (Feb. 28, 2022, at 7:23 PM ET), <https://www.vice.com/en/article/no-vitamins-no-testimonials-australian-wellness-influencers-face-tough-new-laws/>.

illustrates how Instagram’s visual storytelling capabilities and algorithm-driven reach can amplify wellness fraud to unprecedented scales while traditional legal remedies prove inadequate to address health-harming outcomes.<sup>155</sup>

The influencer model overcame several traditional challenges faced by wellness entrepreneurs. Instead of making direct medical claims about their products, influencers rely on authenticity; they could share their personal experiences and transformations, positioning themselves as relatable peers rather than medical authorities.<sup>156</sup> Instead of investing in expensive advertising campaigns, they could build organic audiences through consistent content creation and algorithmic amplification.<sup>157</sup> Instead of maintaining inventory or handling customer service, they could promote affiliate products or create information-based offerings with minimal overhead.<sup>158</sup> Brands, in turn, realize impressive returns on investment in social media influencer marketing, with the “top 13% of brands earning up to \$20 for every \$1 spent.”<sup>159</sup>

TikTok’s emergence in 2016 added new dimensions to social media wellness fraud.<sup>160</sup> The platform “is the fastest growing social network in the post-pandemic era.”<sup>161</sup> TikTok’s short-form video format proved ideal for before-and-after transformations, quick health tips, and emotionally engaging testimonials.<sup>162</sup> Researchers have pointed out that TikTok “is a more natural and spontaneous platform than YouTube, with its longer videos, and Instagram, which features more static formats with a carefully constructed aesthetic (e.g., high-quality, filtered photographs . . . ).”<sup>163</sup>

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<sup>155</sup> See Olivia B. Waxman, *What to Know About the Wellness Guru Who Faked Cancer and Inspired Netflix’s ‘Apple Cider Vinegar,’* TIME (Feb. 6, 2025, at 11:58 AM ET), <https://time.com/7213216/apple-cider-vinegar-true-story-netflix/>.

<sup>156</sup> See Roberts, *supra* note 113, at 90-93; BROOKE ERIN DUFFY, (NOT) GETTING PAID TO DO WHAT YOU LOVE: GENDER, SOCIAL MEDIA, AND ASPIRATIONAL WORK 99-106 (2017) (providing examples and narrative behind what it means to be “relatable”).

<sup>157</sup> Cara Kelly, *Fyre Festival to Fashion Week, How Do Instagram Influencers Make So Much Money?*, USA TODAY (Feb. 13, 2019, at 4:44 PM ET), <https://www.usatoday.com/story/news/investigations/2019/02/12/instagram-youtube-influencer-rates-fyre-festival-fashion-week-money-rich-branding-ads-girls/2787560002/>; VAN DUICK, *supra* note 135, at 4.

<sup>158</sup> See Jennifer Dublino & Gretchen Grunburg, *Social Media Stars: How Much Do They Really Make*, BUSINESS.COM (Jan. 6, 2026), <https://www.business.com/articles/social-media-stars-how-much-do-they-really-make/>.

<sup>159</sup> *The Smart Way to Measure Influencer Marketing ROI*, ASPIRE, <https://www.aspire.io/blog/how-to-measure-influencer-marketing-roi-the-right-way> (last accessed July 31, 2025).

<sup>160</sup> See Koivunen et al., *supra* note 146, at 4; Keren Landman, *TikTok Is Full of Bad Health “Hacks.” Here’s How to Navigate Them*, VOX (June 30, 2024, at 7:00 AM ET), <https://www.vox.com/even-better/357645/misinformation-debunking-health-tiktok-youtube-instagram-weird-health-trick-hack>; Sergio Barta, Daniel Belanche, Ana Fernandez & Marta Flavian, *Influencer Marketing on TikTok: The Effectiveness of Humor and Followers’ Hedonic Experience*, 70 J. RETAILING & CONSUMER SERVS., Jan. 2023, at 1-2.

<sup>161</sup> Barta et al., *supra* note 160, at 1.

<sup>162</sup> See Koivunen et al., *supra* note 146, at 4; Barta et al., *supra* note 160, at 1-2; A.W. Ohlheiser, *How TikTok Profits off Dangerous Health Trends*, VOX (Oct. 5, 2023, at 11:30 AM ET), <https://www.vox.com/technology/23902094/tiktok-shop-wellness-trend-castor-oil>.

<sup>163</sup> Barta et al., *supra* note 160, at 2.

TikTok's algorithm, which prioritizes engagement over follower count, enabled wellness content to go viral rapidly, reaching millions of users within hours or days.<sup>164</sup> The platform's young user base proved particularly susceptible to wellness trends, creating viral phenomena around potentially unsafe practices like "dry scooping" pre-workout supplements or using unproven skincare ingredients.<sup>165</sup> Supplement "dry scooping" experiments documented on TikTok, for example, raised one social media user's blood pressure so extravagantly that, according to his physician, "it caused his brain to start to stroke in the form of a bleed."<sup>166</sup> The dry scooping supplement trend also caused twenty-year-old TikTok user Briatney Portillo to suffer a heart attack and be hospitalized, while another TikToker was captured choking and losing the ability to breathe on a platform video as a result of a similar experiment.<sup>167</sup>

In addition, numerous studies have raised concerns regarding the negative mental health issues experienced by young social media users who engage with Instagram and TikTok wellness influencers who post idealized and unrealistic health and fitness images and videos, as well as those who promote wellness disinformation and misinformation.<sup>168</sup> The Center for Countering Digital Hate

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<sup>164</sup> Lakshit Jain et al., *Exploring TikTok Use and Mental Health Issues: A Systematic Review of Empirical Studies*, 16 J. PRIMARY CARE & COMM. HEALTH 1, 2 (2025) ("TikTok maintains a superior engagement rate, receiving twice as many comments per post, enhancing the likelihood of virality. Such prolific content generation fuels the algorithm's learning process, reinforcing a positive feedback loop."); Chris Bates, *Understanding the TikTok Algorithm: What It Prioritizes and Why It Matters*, N. PENN. NOW CMTY. NEWS (Apr. 22, 2025), <https://northpennnow.com/news/2025/apr/22/understanding-the-tiktok-algorithm-what-it-prioritizes-and-why-it-matters/>; Sara Spruch-Feiner, *Wellness Brands are Winning on TikTok Shop, for Now*, GLOSSY POP NEWSL. (Apr. 11, 2025), <https://www.glossy.co/pop/glossy-pop-newsletter-wellness-brands-are-winning-on-tiktok-shop-for-now/>; Sammi Burke, *Understanding TikTok's Algorithm: Here's How to Go Viral*, BACKSTAGE (Sept. 25, 2024), <https://www.backstage.com/magazine/article/tik-tok-algorithm-explained-75091/>; see also Xin Wang & Qian Shang, *How Do Social and Parasocial Relationships on TikTok Impact the Well-Being of University Students? The Roles of Algorithm Awareness and Compulsive Use*, 248 ACTA PSYCHOLOGICA, June 2024, at 1–3; Litty Samuel, Katelynn Kuijpers & Amy Bleakey, *TherapyTok for Depression and Anxiety: A Quantitative Content Analysis of High Engagement TikTok Videos*, 74 J. ADOLESCENT HEALTH 1184, 1184–85, 1188 (2024).

<sup>165</sup> See Samantha Edwards, *TikTok's "Sephora Kids" are Embracing Expensive Skin Care – But These Routines Carry a Risk, Study Finds*, GLOBE & MAIL (June 20, 2025), <https://www.theglobeandmail.com/life/health-and-fitness/article-tweens-teens-tiktok-skin-care-sephora-kids/>; Erin Corbett, *Whatever You Do, Don't Try Dry Scooping, TikTok's Latest Wellness Trend*, REFINERY29 (June 4, 2021, at 12:20 PM ET), <https://www.refinery29.com/en-us/2021/06/10507634/what-is-dry-scooping-tiktok-trend-dangerous>; Daniel Davies, *People on TikTok Are Dry Scooping Pre Workout. You Really Shouldn't Do That*, MEN'S HEALTH (May 12, 2021), <https://www.menshealth.com/uk/health/a36404534/people-on-tiktok-are-dry-scooping-pre-workout/>.

<sup>166</sup> Kate Fowler, *The Dry Scooping Pre-Workout TikTok Trend Went Dangerously Wrong for These People*, NEWSWEEK (June 4, 2021, at 11:22 AM ET), <https://www.newsweek.com/dry-scooping-pre-workout-tiktok-trend-went-dangerously-wrong-these-people-1597622>.

<sup>167</sup> *Id.*

<sup>168</sup> See, e.g., Powell & Pring, *supra* note 114, at 1 (explaining that "[a] growing area of research is focusing on the intersection between social media and health, with particular focus on the health effects of social media on children and young people and more recently the potential harmful spread of health disinformation" and citing studies).

published a 2022 report detailing disturbing findings regarding the potentially health-harming impacts of algorithm-driven, negative body image and mental health TikTok content on young teenagers.<sup>169</sup> The researchers set up new TikTok accounts in the United States, United Kingdom, Canada, and Australia, posing as 13-year-olds (the youngest age permitted to create a TikTok account), then “paused briefly on videos about body image and mental health, and liked them.”<sup>170</sup>

The results were terrifying. The researchers reported that TikTok recommended (1) suicide content within 2.6 minutes; (2) eating disorders content within 8 minutes; and (3) body image and mental health videos every 39 seconds to young teenagers.<sup>171</sup> They further found that TikTok was twelve times more likely to recommend self-harm content to the teenage accounts the researchers characterized as particularly vulnerable to suicide and eating disorders.<sup>172</sup> In this connection, TikTok was recently sued by the parents of a Long Island high school junior who contend that their child died by suicide due to suggestive, targeted platform content.<sup>173</sup>

A 2022 systematic review of the literature catalogued the key psychological and behavioral influences, including boredom, loneliness, low self-esteem, neuroticism, procrastination, and depression, that exacerbate TikTok user mental health issues and enhance the risk of developing TikTok use disorder, that is, the compulsive, excessive, and problematic use of the platform.<sup>174</sup> As those researchers concluded, “[o]ur review reveals notable mental health concerns related to TikTok use, with multiple studies showing a clear link between excessive engagement on the platform and increased levels of anxiety, depression, and stress.”<sup>175</sup> Several other studies associated active social media use with problematic alcohol consumption and gambling behaviors in both adult and youth populations.<sup>176</sup>

Health experts also have criticized both TikTok and Instagram for hosting “legions” of wellness grifters who promote “the benefits of unpasteurized ‘raw’

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<sup>169</sup> CTR. FOR COUNTERING DIGITAL HATE, DEADLY BY DESIGN: TIKTOK PUSHES HARMFUL CONTENT PROMOTING EATING DISORDERS AND SELF-HARM INTO USERS’ FEEDS (Dec. 15, 2022), [https://counterhate.com/wp-content/uploads/2022/12/CCDH-Deadly-by-Design\\_120922.pdf](https://counterhate.com/wp-content/uploads/2022/12/CCDH-Deadly-by-Design_120922.pdf).

<sup>170</sup> *Id.* at 5.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> See *Nasca v. Bytedance Ltd.*, 2025 N.Y. Misc. LEXIS 2255 (N.Y. Sup. Ct. Apr. 14, 2025). TikTok succeeded in convincing the trial court to dismiss the plaintiffs’ complaint on the grounds that social media platforms are exempt from liability for the third-party behavior alleged under Section 230 of the Communications Act of 1934. *Id.*

<sup>174</sup> Jain et al., *supra* note 164, at 5–12.

<sup>175</sup> *Id.* at 26; see also *id.* (adding that “[o]ur review highlights patterns of excessive TikTok use, with several studies suggesting a connection between prolonged engagement on the platform and behaviors similar to those seen in addiction”).

<sup>176</sup> See, e.g., Iilina Savolainen & Atte Oksanen, *Keeping You Connected or Keeping You Addicted? Weekly Use of Social Media Platforms Associated with Hazardous Alcohol Use and Problematic Gambling Among Adults*, 59 ALCOHOL & ALCOHOLISM, Mar. 2024, at 1; Brandon Cheng et al., *A Systematic Review and Meta-Analysis of the Relationship Between Youth Drinking, Self-Posting of Alcohol Use and Other Social Media Engagement (2012-21)*, 199 ADDICTION 28, 28, 42 (2024); Raffaello Rossi & Agnes Nairn, *New Developments in Gambling Marketing: The Rise of Social Media Ads and Its Effect on Youth*, 9 CURR. ADDICT. REP. 385, 389 (2022).

milk, which has not been heated to kill off illness-causing microorganisms.”<sup>177</sup> Consuming unpasteurized raw milk contaminated with germs, such as *Salmonella*, *E. coli*, *Listeria*, and *Campylobacter*, can cause foodborne illness and is particularly dangerous for children and individuals with immunocompromised health conditions.<sup>178</sup> “According to the Centers for Disease Control and Prevention (CDC), from 1998 through 2018, there were 202 outbreaks linked to drinking raw milk. These outbreaks caused 2,645 illnesses and 228 hospitalizations.”<sup>179</sup>

YouTube’s long-form video format enables sophisticated wellness fraud, allowing entrepreneurs to create content that mimics educational or documentary formats while promoting specific products or services.<sup>180</sup> “YouTube hosts videos providing information on the pathogenesis, diagnosis, treatment, and prevention of various health conditions,” often posted by non-medical professionals.<sup>181</sup> The platform’s monetization system creates financial incentives for wellness content creation, while its recommendation algorithm often guides viewers from legitimate health content to increasingly questionable material.<sup>182</sup> As one group of experts pointed out, “YouTube’s search results are based on popularity, relevancy, and view history rather than content quality. This creates an issue for informal or

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<sup>177</sup> Julia Metraux, *TikTok’s Raw Milk Influencers Are Going to Give Us All Bird Flu*, MOTHERJONES (May 3, 2024), <https://www.motherjones.com/food/2024/05/raw-milk-influencers-h5n1-bird-flu-virus-social-media/>.

<sup>178</sup> See *The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk*, U.S. FOOD & DRUG ADMIN. (May 30, 2024), <https://www.fda.gov/food/buy-store-serve-safe-food/dangers-raw-milk-unpasteurized-milk-can-pose-serious-health-risk>; see also *Health Officials Investigating Salmonella Cases Linked to Raw Milk*, MINN. DEP’T OF HEALTH (July 27, 2023), <https://www.health.state.mn.us/news/pressrel/2023/salmonella072723.html>; Amanda Jackson, *Raw Milk Linked to Listeria Illness and Death*, CNN (Mar. 18, 2016, at 6:15 PM ET), <https://www.cnn.com/2016/03/18/health/raw-milk-listeria-millers-organic-farm-irpt>.

<sup>179</sup> *The Dangers of Raw Milk*, *supra* note 178.

<sup>180</sup> Wael Osman et al., *Is YouTube a Reliable Source of Health-Related Information? A Systematic Review*, 19 BMC MED. EDUC., May 2022, at 8 (contending “YouTube, the most visited media website worldwide, does not only host a significant portion of poor and misleading content but it also promotes these videos through its popularity-based system”); J. Qi et al., *Misinformation Is Prevalent in Psoriasis-Related YouTube Videos*, 22 DERM. ONLINE J. (2016), <https://escholarship.org/uc/item/7qc9z2m5> (concluding that “[u]seful videos were highest in quality but had similar viewership as misleading and patient view videos, with lower popularity and engagement of users compared to other categories”); Kapil Chalil Madathil et al., *Healthcare Information on YouTube: A Systematic Review*, 21 HEALTH INFORMATICS J. 173, 190 (2014) (explaining that “public service announcements from organizations, documentaries, and TV shows, and user-generated anecdotal content in which users discuss their perspectives and their experiences were the most commonly found sources” and “misleading information is found on YouTube, and the probability of healthcare consumers encountering such material during the information-seeking process is high”).

<sup>181</sup> Madathil et al., *supra* note 180, at 190.

<sup>182</sup> See Muhammad Haroon et al., *Auditing YouTube’s Recommendation System for Ideologically Congenial, Extreme, and Problematic Recommendations*, 120 PNAS, Dec. 2023, at 1–2; Anjana Susarla, *YouTube’s Algorithms Could Be Harming Users Looking for Health Information*, FAST CO. (July 15, 2020), <https://www.fastcompany.com/90527961/youtubes-algorithms-could-be-harming-users-looking-for-health-information>; Ben Popken, *As Algorithms Take Over, YouTube’s Recommendations Highlight a Human Problem*, NBC NEWS (Apr. 19, 2018, at 6:14 PM ET), <https://www.nbcnews.com/tech/social-media/algorithms-take-over-youtube-s-recommendations-highlight-human-problem-n867596>.

unguided learners who are increasingly exposed to unverified and partly misleading content that could promote unhealthy habits and activities.”<sup>183</sup> YouTube’s global reach enables wellness entrepreneurs to build international audiences while operating from jurisdictions with minimal regulatory oversight.<sup>184</sup>

The regulatory challenges posed by social media wellness influencers have proven even more complex than those created by the early internet.<sup>185</sup> Social media platforms are private companies with their own terms of service and content moderation policies, which constitute protected expression in the United States, creating a layer of quasi-regulation that operates independently of government oversight.<sup>186</sup> Platform algorithms determine which content reaches which audiences, but the algorithms are proprietary and constantly changing, making consistent enforcement difficult.<sup>187</sup>

### C. Expertise Skepticism and Wellness Conspiratoriality

Social media’s democratization of information sharing coincided with a broader cultural shift toward skepticism of traditional institutions, media, science, and expertise.<sup>188</sup> As a pair of experts recently pointed out, “[a]spirational lifestyle

<sup>183</sup> Osman et al., *supra* note 180, at 2.

<sup>184</sup> See Caleb N. Griffin, *Systemically Important Platforms*, 107 CORNELL L. REV. 445, 475 (2022) (explaining that “there are relatively few consumer protection laws applicable to digital platforms . . . . There is no equivalent to the Food and Drug Administration or Federal Trade Commission to vet the quality of digital platforms or to outlaw particularly harmful practices, leaving consumers more vulnerable to exploitation. In these ways, a digital user is in a far weaker position than a traditional customer.”); see also Roberts, *supra* note 113, at 129 (pointing out that, “[t]ypically, the social media platform on which advertising claims are published is exempt from liability under Section 230 of the Communications Act of 1934”).

<sup>185</sup> See, e.g., Julia Hornle, *The Jurisdictional Challenge of Internet Regulation*, OXFORD UNIV. PRESS BLOG (Mar. 24, 2021), <https://blog.oup.com/2021/03/the-jurisdictional-challenge-of-internet-regulation/> (noting that the “power of a state agent to act is limited to the territory of that state, but the internet’s reach is not so limited, jurisdiction is the fundamental legal concept behind many, if not most, of the troubles of effectively regulating the global internet.”).

<sup>186</sup> See, e.g., Beatriz Sampaio, *Meta’s Fact-Checking Rollback, Governance, Free Speech and User Safety*, BERKELEY TECH. L.J. BLOG (May 23, 2025), <https://btlj.org/2025/05/metasp-fact-checking-rollback-governance-free-speech-and-user-safety>.

<sup>187</sup> See, e.g., Haochen Sun, *The Right to Know Social Media Algorithms*, 18 HARV. L. & POL’Y REV. 1, 3 (2023) (contending that social media algorithms are developed, applied, and even legally protected as black boxes); Haroon et al., *supra* note 182, at 1 (explaining that “[o]ver 70% of content watched on YouTube is recommended by its algorithm, which is proprietary and opaque to users and regulators”).

<sup>188</sup> See Sangwon Lee et al., *Examining the Role of Distrust in Science and Social Media Use: Effects on Susceptibility to COVID Misperceptions with Panel Data*, 27 MASS COMM. & SOC’Y 653, 653 (2024) (pointing out that “[t]rust in scientific actors and institutions in the United States is at an all-time low” and arguing that “if people do not trust scientific information provided by scientists, they are likely to turn to social media to get alternative scientific information”); Claudia Deane, *Americans’ Deepening Mistrust of Institutions*, PEW (Oct. 17, 2024), <https://www.pew.org/en/trend/archive/fall-2024/americans-deepening-mistrust-of-institutions>; Ariel Hasell & Sedona Chinn, *The Political Influence of Lifestyle Influencers? Examining the Relationship Between Aspirational Social Media Use and Anti-Expert Attitudes and Beliefs*, 9 SOC. MEDIA & SOC’Y, Oct. 2024, at 2 (noting that many Americans “are highly skeptical of mainstream information sources, preferring information they find themselves”).

content on social media varies widely, but there is a common theme of skepticism of expertise in favor of intuition and doing one’s own research.”<sup>189</sup> The wellness community became particularly susceptible to what researchers have termed “conspirituality”—an online phenomenon where spiritual wellness practices intersect with conspiracy theories and anti-establishment sentiment.<sup>190</sup> This convergence proved especially potent because wellness culture’s emphasis on individual intuition, natural alternatives, and distrust of “Big Pharma” created fertile ground for more extreme forms of institutional skepticism.<sup>191</sup>

Wellness influencers leverage this skepticism by positioning themselves as authentic truth-tellers, challenging corrupt mainstream institutions and fabricated cabals like “The Deep State.”<sup>192</sup> Their lack of traditional medical credentials becomes a source of authority rather than disqualification, as they claim freedom from the financial conflicts and institutional pressures that supposedly compromised conventional healthcare providers.<sup>193</sup> This populist rhetorical strategy proves particularly effective when public trust in institutions is already declining, allowing influencers to present their alternative health advice as more trustworthy than evidence-based medicine.<sup>194</sup> As Dr. Timothy Caulfield explained:

There is a strong correlation between the embrace of “wellness woo” and being susceptible to misinformation. And as conspiracy theories and misinformation become increasingly about ideology, it becomes easier to sell both wellness bunk and conspiracy theories as being “on brand.” In other words, if you are part of our community, this is the cluster of beliefs you must embrace – Big Science is evil, supplements help, you can boost your immune system, vaccines don’t work.<sup>195</sup>

In this connection, one YouTuber:

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<sup>189</sup> Hasell & Chinn, *supra* note 188, at 1.

<sup>190</sup> See, e.g., Eva Wiseman, *The Dark Side of Wellness: The Overlap Between Spiritual Thinking and Far-Right Conspiracy Theories*, GUARDIAN (Oct. 17, 2021, at 5:00 AM ET), <https://www.theguardian.com/lifeandstyle/2021/oct/17/eva-wiseman-conspirituality-the-dark-side-of-wellness-how-it-all-got-so-toxic>; see also Sarah Wilson, *The Wellness Realm Has Fallen into Conspiritualism – I Have a Sense Why*, GUARDIAN (Sept. 14, 2020, at 1:30 PM ET), <https://www.theguardian.com/books/2020/sep/15/the-wellness-realm-has-fallen-into-conspiritualism-i-have-a-sense-why>; Charlotte Ward & David Voas, *The Emergence of Conspirituality*, 26 J. CONTEMP. RELIGION 103, 103 (2011); Adam M. Enders et al., *The Relationship Between Social Media Use and Beliefs in Conspiracy Theories and Misinformation*, 45 POL. BEHAVS. 781, 782 (2021) (contending that “while social media is likely to spread conspiracy theories and some misinformation, such information will be most likely to translate into beliefs for those already attracted to conspiratorial explanations for salient events”).

<sup>191</sup> See Wiseman, *supra* note 190.

<sup>192</sup> Stephanie Alice Baker, *Alt. Health Influencers: How Wellness Culture and Web Culture Have Been Weaponized to Promote Conspiracy Theories and Far-Right Extremism During the COVID-19 Pandemic*, 35 EUR. J. CULTURAL STUD. 3, 4, 10–13 (2022); see also Melissa Zimdars, *Alt-Health Influencers and the Threat of Social Media Deplatforming*, 75 J. ASS’N INFO. SCI. & TECH. 1216, 1217 (2023).

<sup>193</sup> Zimdars, *supra* note 192, at 1221; Baker, *supra* note 192, at 10–15.

<sup>194</sup> Zimdars, *supra* note 192, at 1224; Baker, *supra* note 192, at 10–13.

<sup>195</sup> Wiseman, *supra* note 190.

Jacob Chansley, AKA the “QAnon shaman” – one of the most visible faces of the attack on the U.S. Capitol on . . . January [6,] 2021, thanks to his face paint and horned headgear – is a practitioner of “shamanic arts” who eats natural and organic food, and has more than once been described as an “ecofascist.”<sup>196</sup>

A federal district court judge even granted Chansley’s request for an organic diet while he was incarcerated for his insurrection-related crimes.<sup>197</sup> Chansley’s refusal to eat non-organic prison food went viral on social media, with one Twitter user posting, “It’s a jail, Jacob. It isn’t a Whole Foods.”<sup>198</sup>

The phenomenon of “pastel QAnon” also flourished as wellness influencers began incorporating conspiracy theories into their health and lifestyle content, using aesthetically pleasing social media presentations to make radical ideas seem mainstream and palatable.<sup>199</sup> These influencers skillfully wove together legitimate criticisms of pharmaceutical industry practices with increasingly extreme claims about government control, creating a pathway for followers to move from reasonable skepticism to dangerous conspiracy theories.<sup>200</sup> The ascendance of wellness influencer conspiratoriality and its adverse impacts on public health during the height of the COVID-19 pandemic are the subject of the following section of this Article.

#### IV. THE COVID-19 PANDEMIC: A PERFECT STORM FOR WELLNESS FRAUD

“It is tempting to dismiss the wellness movement as harmless lifestyle branding, but the spread of anti-scientific

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<sup>196</sup> James Ball, ‘Everything You’ve Been Told is a Lie!’ *Inside the Wellness-to-Fascism Pipeline*, GUARDIAN (Aug. 2, 2023, at 9:00 AM ET), <https://www.theguardian.com/lifeandstyle/2023/aug/02/everything-youve-been-told-is-a-lie-inside-the-wellness-to-facism-pipeline>.

<sup>197</sup> Ben Leonard, “QAnon Shaman” Granted Organic Food in Jail After Report of Deteriorating Health, POLITICO (Feb. 3, 2021, at 6:43 PM ET), <https://www.politico.com/news/2021/02/03/qanon-shaman-organic-food-465563>.

<sup>198</sup> The Hoarse Whisperer (@TheRealHoarse), X (formerly TWITTER) (Jan. 11, 2021, at 17:11 ET), <https://x.com/TheRealHoarse/status/1348754476329553928>; Adam Forgie, *Horned Capitol Rioter Goes Viral Again After Mom Says He Won’t Eat Non-Organic Jail Food*, ABC13 NEWS (Jan. 13, 2021, at 9:52 PM ET), <https://wset.com/news/nation-world/horned-capitol-rioter-goes-viral-again-after-mom-says-he-wont-eat-non-organic-jail-food>.

<sup>199</sup> See MAINTENANCE PHASE: *The Wellness to QAnon Pipeline* (Spotify, May 11, 2021); Sirin Kale, *Chakras, Crystals and Conspiracy Theories: How the Wellness Industry Turned its Back on COVID Science*, GUARDIAN (Nov. 11, 2021, at 1:00 AM ET), <https://www.theguardian.com/world/2021/nov/11/injecting-poison-will-never-make-you-healthy-how-the-wellness-industry-turned-its-back-on-covid-science>; E.J. Dickson, ‘Pastel QAnon’ Is Infiltrating the Natural Parenting Community, ROLLING STONE (Dec. 14, 2020), <https://www.rollingstone.com/culture/culture-news/qanon-pastel-antivax-natural-parenting-community-freebirth-1098518/>.

<sup>200</sup> See *The Wellness to QAnon Pipeline*, *supra* note 199; Kale, *supra* note 199; Dickson, *supra* note 199; see also Kaitlyn Tiffany, *The Women Making Conspiracy Theories Beautiful*, ATLANTIC (Aug. 18, 2020), <https://www.theatlantic.com/technology/archive/2020/08/how-instagram-aesthetics-repackage-qanon/615364/>.

misinformation and conspiracy theories and the dismantling of science-based public health infrastructure represent a serious threat.”<sup>201</sup>

The COVID-19 pandemic created unprecedented conditions for wellness fraud to flourish, combining widespread anxiety, social isolation, economic uncertainty, and highly visible public health failures.<sup>202</sup> The pandemic further demonstrated the lure of purported wellness hacks proliferated on the internet by celebrities and social media influencers among a fearful population discouraged by public health messaging.<sup>203</sup> As one report pointed out:

COVID-19 was the first pandemic that unfolded in an information environment transformed by the internet, especially by social media. Informed and well-intentioned efforts to communicate about the threat and appropriate countermeasures (for example, masking and vaccines) were often overwhelmed by dissemination of sensational misinformation and deliberate disinformation. This “infodemic” became a “second pandemic” that harmed how people understood COVID-19 and how they protected themselves from the disease.<sup>204</sup>

The COVID-19 pandemic also exposed the myriad problems associated with unregulated wellness therapeutics and self-help conspiracies promoted on social media that appeal to extreme individualism and endemic distrust in medical expertise.<sup>205</sup>

<sup>201</sup> Henry I. Miller, ‘Wellness’ Grifters’ Snake Oil Imperials Animal and Public Health, AM. COUNCIL ON SCI. & HEALTH (May 13, 2025), <https://www.acsh.org/news/2025/05/13/wellness-grifters-snake-oil-imperils-animal-and-public-health-49465>.

<sup>202</sup> See e.g., *COVID-19 Pandemic Triggers 25% Increase in Prevalence of Anxiety and Depression Worldwide*, WORLD HEALTH ORG. (Mar. 2, 2022), <https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide>; Jay P. Kennedy, Melissa Rorie & Michael L. Benson, *COVID-19 Frauds: An Exploratory Study of Victimization During a Global Crisis*, 20 CRIM. PUB. POL’Y 493, 494 (2021) (“From the very beginnings of the COVID-19 crisis, criminals sought to take advantage of the lack of information available regarding the virus, misinformation coming from official and unofficial sources, and disinformation spread via the Internet and social media channels.”); Mary Ruffolo et al., *Employment Uncertainty and Mental Health During the COVID-19 Pandemic Initial Social Distancing Implementation; A Cross-National Study*, 8 GLOB. SOC. WELFARE 141, 142 (2021).

<sup>203</sup> See, e.g., Justin M. Feldman & Marry Bassett, *US Public Health After COVID-19: Learning from the Failures of the Hollow State and Racial Capitalism*, 384 BMJ, Feb. 2024, at 1 (“describ[ing] how diminished political will to use government powers for service provision hampered the US response to the covid-19 pandemic and what needs to change”); Beatriz C. Dominquez et al., *A Survey of Public Health Failures During COVID-19*, 14 CUREUS, Dec. 2022, at 1 (Dec. 2022) (“analyz[ing] the failures of public health measures in the US and . . . conceptualiz[ing] how to move forward”); Scott C. Ratzan, *Overcoming Cacophony in Public Health Communication After COVID-19*, THINK GLOB. HEALTH (Aug. 24, 2022), <https://www.thinkglobalhealth.org/article/overcoming-cacophony-public-health-communication-after-covid-19> (discussing the “failure of public health communication throughout the pandemic” and explaining that “[t]his failure involved ineffective strategies, inept execution, and the inability to counter disinformation”).

<sup>204</sup> Ratzan, *supra* note 203.

<sup>205</sup> Wiseman, *supra* note 190; *The Wellness to QAnon Pipeline*, *supra* note 199; Kale, *supra* note 199.

### A. Celebrity Wellness Fraud During the Pandemic

High-profile celebrities used their massive social media platforms to promote dubious COVID-19 treatments and conspiracy theories, reaching millions of followers with dangerous misinformation.<sup>206</sup> Gwyneth Paltrow, whose wellness company Goop had already faced criticism for promoting pseudoscientific treatments, leveraged her personal COVID-19 experience to market unproven remedies such as “intuitive fasting” and expensive supplements.<sup>207</sup> Thematically in sync with her earlier promotions of vaginal steaming and vaginal jade egg wellness, Paltrow also sold a candle called “This Smells Like My Vagina” during the pandemic.<sup>208</sup> Her approach exemplified how celebrities transformed personal health struggles into marketing opportunities, using the pandemic as a vehicle to promote their existing wellness products and philosophies.<sup>209</sup>

The United Kingdom’s National Health Service (NHS) specifically condemned Paltrow’s COVID-19 recommendations, with NHS England National Medical Director Stephen Powis stating that Paltrow’s suggestions were “really not the solutions we’d recommend” and emphasizing the need to “take long COVID seriously and apply serious science.”<sup>210</sup> Dr. Powis went on to add that “[a]ll influencers who use social media have a duty of responsibility and a duty of

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<sup>206</sup> See Jen Christensen, *Celebrities May Have Helped Shape Anti-Vaccine Opinions During COVID-19 Pandemic, Study Finds*, CNN (Feb. 24, 2023, at 6:33 AM ET), <https://www.cnn.com/2023/02/24/health/covid-vaccine-celebrity-influence-study/index.html>; E.J. Dickson, ‘A Menace to Public Health’: Doctors Demand Spotify Puts an End to COVID Lies on ‘Joe Rogan Experience,’ ROLLING STONE (Jan. 12, 2022), <https://www.rollingstone.com/culture/culture-news/covid-misinformation-joe-rogan-spotify-petition-1282240/>; Bryan Pietsch & Adela Suliman, *Nicki Minaj Tweets Coronavirus Vaccine Conspiracy Theory, Spotting Struggle Against Misinformation*, WASH. POST (Sept. 14, 2021), <https://www.washingtonpost.com/arts-entertainment/2021/09/14/nicki-minaj-covid-19-vaccine-conspiracy/>; David Robert Grimes, *Medical Disinformation and the Unviable Nature of COVID-19 Conspiracy Theories*, 16 PLOS ONE, Mar. 2021, at 4 (explaining that 5G electromagnetic radiation’s “erroneous link to COVID-19 . . . has been perpetuated by celebrities and has become an extremely enduring claim by fringe groups throughout the course of the pandemic”).

<sup>207</sup> See Editors of Goop, *Gwyneth on Intuitive Fasting*, GOOP (Nov. 14, 2022), <https://goop.com/wellness/health/gwyneth-paltrow-on-intuitive-fasting/>; Ashley P. Taylor, *Gwyneth Paltrow’s Wacky COVID-19 Treatments have no Medical Justification*, LIVESCIENCE (Mar. 1, 2021), <https://www.livescience.com/gwyneth-paltrow-goop-covid-advice-no-evidence.html>; Soo Kim, *Gwyneth Paltrow’s COVID Advice Not Supported by Evidence, Health Experts Warn*, NEWSWEEK (Feb. 26, 2021, at 6:14 AM ET), <https://www.newsweek.com/coronavirus-gwyneth-paltrow-regimen-covid-experts-warning-1572073>; Ashley Welch, *Doctors Warn Against Gwyneth Paltrow’s Advice On Vaginal Jade Eggs*, CBS NEWS (Jan. 23, 2017, at 5:30 PM ET), <https://www.cbsnews.com/news/gwyneth-paltrow-goop-advice-vaginal-jade-eggs-doctors-warning/>.

<sup>208</sup> Hadley Freeman, *Why Is Gwyneth Paltrow Selling a Candle that Smells Like Her Vagina?*, GUARDIAN (Jan. 13, 2020, at 11:24 AM ET), <https://www.theguardian.com/fashion/2020/jan/13/why-is-gwyneth-paltrow-selling-a-candle-that-smells-like-her-vagina-goop>; see also Welch, *supra* note 207.

<sup>209</sup> See, e.g., Christensen, *supra* note 206; Grimes, *supra* note 206, at 4.

<sup>210</sup> Jessica Lee, *Did NHS Warn Against Gwyneth Paltrow’s COVID-19 Advice*, SNOPE (Feb. 25, 2021), <https://www.snopes.com/fact-check/gwyneth-paltrow-goop-covid-advice/>; *Gwyneth Paltrow: NHS Boss Urges Caution over Star’s Long Covid Regime*, BBC (Feb. 24, 2021), <https://www.bbc.com/news/entertainment-arts-56179846>.

care” to take the pandemic and its attendant science soberly.<sup>211</sup> Despite such criticism from medical authorities, Paltrow’s pandemic wellness content generated enormous engagement and sales, demonstrating the power of celebrity influence to override scientific expertise.<sup>212</sup>

Other celebrities joined the social media wellness misinformation ecosystem during the pandemic, with figures like Steve Bannon marketing vitamin “defense packs” with implied COVID-19 prevention claims, and various influencers promoting everything from expensive “immune-boosting” products to unproven supplement regimens.<sup>213</sup> Needless to say, “[t]here [wa]s no evidence that any product or practice—aside from a vaccine—will provide extra or enhanced ‘immune boosting’ protection against COVID-19.”<sup>214</sup> Bannon’s supplement promotion scheme was a favorite object of traditional media ridicule during the pandemic. *Mother Jones* reporter Stephanie Mencimer, for example, described Bannon’s wellness scams as “anti-science mumbo jumbo” and went on to say:

Former Trump adviser and former Breitbart News chief Steve Bannon does not radiate “pinnacle of health.” The portly, cigar-smoking, possibly former alcoholic is not known for his workout ethic. But like many a far-right media figure, including Trump himself (once upon a time), Bannon is now hawking vitamins as a “Wellness Warrior.” People have called Bannon a lot of things over the years. Wellness Warrior is not one of them.<sup>215</sup>

Bannon and Paltrow, however, were not alone. Joe Rogan, for example, told his 13.1 million podcast followers to take ivermectin, a veterinary anti-parasitic drug commonly used for livestock deworming, to fend off COVID infections.<sup>216</sup> The FDA, Centers for Disease Control and Prevention (CDC), and American Medical Association (AMA) repeatedly issued public warnings

<sup>211</sup> Gwyneth Paltrow: *NHS Boss Urges Caution Over Star’s Long Covid Regime*, *supra* note 210.

<sup>212</sup> Mehera Bonner, *Gwyneth Paltrow’s Net Worth Is Enormous Thanks to All Things Goop*, COSMOPOLITAN (Mar. 29, 2023, at 1:20 PM ET), <https://www.cosmopolitan.com/entertainment/celebs/a40967047/gwyneth-paltrow-net-worth/>.

<sup>213</sup> Lynn Stuart Parramore, *What Do Steven Bannon’s Covid Supplements and Gwyneth Paltrow’s Candles Have in Common?*, NBC NEWS (May 21, 2021, at 8:44 PM ET), <https://www.nbcnews.com/think/opinion/what-do-steve-bannon-s-covid-supplements-gwyneth-paltrow-s-ncna1268190> (explaining that “[c]elebrities are using their star power to hawk evidence-free, ridiculous and sometimes even dangerous wellness products”); Stephanie Mencimer, *Steve Bannon: Wellness Warrior?*, MOTHER JONES (Mar. 20, 2021), <https://www.motherjones.com/politics/2021/03/steve-bannon-wellness-warrior/>; Christen Rachul et al., *COVID-19 and “Immune Boosting” on the Internet: A Content Analysis of Google Search Results*, 10 BMJ OPEN, Oct. 2020, at 1–2 (explaining that “celebrities, wellness gurus and supplement companies have been making claims about the need and ways to boost our immune system”); Zaria Gorvett, *Covid-19: Can “Boosting” Your Immune System Protect You?*, BBC (Apr. 9, 2020), <https://www.bbc.com/future/article/20200408-covid-19-can-boosting-your-immune-system-protect-you>.

<sup>214</sup> Rachul et al., *supra* note 213, at 1.

<sup>215</sup> Mencimer, *supra* note 213.

<sup>216</sup> Vanessa Romo, *Joe Rogan Says He Has COVID-19 and Has Taken the Drug Ivermectin*, NPR (Sept. 1, 2021, at 8:28 PM ET), <https://www.npr.org/2021/09/01/1033485152/joe-rogan-covid-ivermectin>.

explaining that ivermectin neither prevents nor treats COVID-19 and can be dangerous when ingested in large doses by humans.<sup>217</sup> They were apparently no match for Rogan and the numerous other influencers who promoted the drug. According to the AMA, “ivermectin dispensing from outpatient retail pharmacies in the U.S. increased from an average of 3,600 prescriptions per week at the pre-pandemic baseline to a peak of 39,000 prescriptions in the week ending Jan. 8, 2021.”<sup>218</sup> By August 2021, more than 88,000 outpatient ivermectin doses had been dispensed at retail pharmacies, a 24-fold increase from the pre-pandemic era.<sup>219</sup>

NFL quarterback Aaron Rodgers, who has been characterized as “a celebrity who transcends the nation’s most popular sport,” “justified his decision to not get vaccinated by speaking out against the highly effective vaccines and spewing a stream of misinformation and junk science” about COVID-19, much to the dismay of infectious disease experts.<sup>220</sup> Numerous other celebrities, including actors Woody Harrelson and John Cusack, and singer MIA, promoted false conspiracy theories that COVID-19 is caused by 5G electromagnetic radiation.<sup>221</sup> Nicki Minaj also joined the fray, famously tweeting that a COVID-19 vaccine caused her unidentified cousin’s unidentified friend to suffer swollen testicles and, consequently, be dumped by his fiancée just weeks before their alleged wedding.<sup>222</sup> The U.S. Department of Justice filed complaints on behalf of the FTC against several companies for deceptive COVID-19 cure advertising, but enforcement actions could not keep pace with the volume of fraudulent claims being promoted through celebrity and influencer channels.<sup>223</sup>

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<sup>217</sup> *Ivermectin and COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 5, 2024), <https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19>; Sara Berg, *Why Ivermectin Should Not Be Used to Prevent or Treat COVID-19*, AM. MED. ASS’N (Sept. 2, 2021), <https://www.ama-assn.org/delivering-care/public-health/why-ivermectin-should-not-be-used-prevent-or-treat-covid-19>; *CDC Alerts Clinicians to Surge in Ivermectin Poisoning During Pandemic*, AM. HOSP. ASS’N (Aug. 27, 2021), <https://www.aha.org/news/headline/2021-08-27-cdc-alerts-clinicians-surge-ivermectin-poisoning-during-pandemic>.

<sup>218</sup> Berg, *supra* note 217.

<sup>219</sup> *Id.*

<sup>220</sup> Ken Belson & Emily Anthes, *Scientists Fight a New Source of Vaccine Misinformation: Aaron Rodgers*, N.Y. TIMES (Nov. 8, 2021), <https://www.nytimes.com/2021/11/08/sports/football/aaron-rodgers-vaccine.html>; see also Theresa Waldrop, *Scientists React to Aaron Rodgers’ Comments on Covid-19 Vaccine and Treatments*, CNN (Nov. 13, 2021, at 1:26 PM ET), <https://www.cnn.com/2021/11/13/us/aaron-rodgers-covid-vaccine-scientists>; Emmanuel Morgan, *Aaron Rodgers Lashes Out About N.F.L.’s Vaccine Requirements*, N.Y. TIMES (Nov. 5, 2021), <https://www.nytimes.com/2021/11/05/sports/football/coronavirus-aaron-rodgers.html>.

<sup>221</sup> See Grimes, *supra* note 206, at 4; Eoin Flaherty, Tristan Sturm & Elizabeth Farries, *The Conspiracy of COVID-19 and 5G: Spatial Analysis Fallacies in the Age of Data Democratization*, 293 SOC. SCI. MED., Jan. 2022, at 1.

<sup>222</sup> See Sarah R. Olutola, *Nicki Minaj’s COVID-19 Vaccine Tweet About Swollen Testicles Signals the Dangers of Celebrity Misinformation and Fandom*, CONVERSATION (Sept. 20, 2021, at 4:25 PM ET), <https://theconversation.com/nicki-minajs-covid-19-vaccine-tweet-about-swollen-testicles-signals-the-dangers-of-celebrity-misinformation-and-fandom-168242>.

<sup>223</sup> See *Coronavirus Response: Enforcement Actions*, FED. TRADE COMM’N, <https://www.ftc.gov/news-events/features/coronavirus/enforcement> (last visited Oct. 16, 2025); *COVID-19 Fraud: Law Enforcement’s Response to Those Exploiting the Pandemic Before the S. J. Comm.*, 116th Cong. (June 9, 2020) (Statement of Calvin A. Shivers, Assistant Director of Criminal

## B. The Disinformation Dozen and Anti-Vaccine Influence

Research by the Center for Countering Digital Hate revealed that just twelve individuals, dubbed the “Disinformation Dozen,” were responsible for 65% of anti-vaccine content shared on Facebook, Instagram, and Twitter during the pandemic.<sup>224</sup> Among this group were prominent wellness figures like Dr. Joseph Mercola, who marketed dietary supplements to his 3.6 million followers while claiming hydrogen peroxide could cure COVID-19, and Sayer Ji, who ran a popular alternative health website and falsely claimed that the Pfizer vaccine killed more elderly people than COVID-19.<sup>225</sup> Robert F. Kennedy, Jr., a long-standing anti-vaxxer and the current Secretary of the U.S. Department of Health and Human Services, was also included in the Disinformation Dozen.<sup>226</sup>

The wellness industry’s existing infrastructure provided an ideal distribution network for pandemic misinformation.<sup>227</sup> Wellness influencers had already cultivated audiences primed to distrust mainstream medicine and seek alternative health solutions, making these communities particularly receptive to anti-vaccine messaging and COVID-19 conspiracy theories.<sup>228</sup> Studies found tight links between wellness-focused social media groups and those spreading COVID-19 misinformation, with content frequently cross-pollinating between health-conscious parenting communities and anti-vaccine networks.<sup>229</sup>

Research also demonstrated the health harms that COVID-19 misinformation caused to children during the pandemic. A 2024 study of the health outcomes associated with youth engagement on TikTok during the pandemic, for example, found that “TikTok can adversely impact mental health through repetitive exposure to mentally distressing content and misleading diagnosis and

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Investigation Division, Fed. Bureau of Investigation); *see also COVID-19 Fraud Enforcement Task Force Releases 2024 Report*, U.S. DEP’T OF JUSTICE (Apr. 9, 2024), <https://www.justice.gov/archives/opa/pr/covid-19-fraud-enforcement-task-force-releases-2024-report> (stating that “[t]he statute of limitations must be extended and the necessary funding and data analytic tools secured for our prosecutors to recover hundreds of millions of dollars more in fraud proceeds, bring remaining offenders to justice, and disrupt criminal networks that continue to victimize our citizens”).

<sup>224</sup> CTR. FOR COUNTERING DIGITAL HATE, *THE DISINFORMATION DOZEN: WHY PLATFORMS MUST ACT ON TWELVE LEADING ONLINE ANTI-VAXXERS* 5–6 (Mar. 24, 2021), <https://counterhate.com/research/the-disinformation-dozen/>.

<sup>225</sup> *Id.* at 12–13, 28–30.

<sup>226</sup> *Id.* at 13–14; *see also* Apoorva Mandavelli, *Kennedy’s New Advisers Promise Closer Scrutiny of Childhood Vaccines*, N.Y. TIMES (June 25, 2025), <https://www.nytimes.com/2025/06/25/health/vaccines-cdc-acip-kennedy.html>.

<sup>227</sup> Rachel E. Moran, Anna L. Swann & Taylor Agajanian, *Vaccine Misinformation for Profit: Conspiratorial Wellness Influencers and the Monetization of Alternative Health*, 18 INT’L J. COMM’N. 1202, 1203 (2024); Abby Vesoulis & Eliana Dockterman, *Pandemic Schemes: How Multilevel Marketing Distributors Are Using the Internet – and the Coronavirus – to Grow Their Businesses*, TIME (July 9, 2020, at 6:29 AM ET), <https://time.com/5864712/multilevel-marketing-schemes-coronavirus/>.

<sup>228</sup> *See, e.g.*, Baker, *supra* note 192; Wiseman, *supra* note 190; Moran et al., *supra* note 227, at 1203.

<sup>229</sup> *See, e.g.*, Dickson, *supra* note 199; Kale, *supra* note 199.

treatment information” and argued that “[r]egulations against harmful content are needed to mitigate these risks and make TikTok safer for youth.”<sup>230</sup>

The effectiveness of wellness-based misinformation during the pandemic stemmed from its integration with authentic-seeming lifestyle content.<sup>231</sup> Wellness influencers did not simply share anti-vaccine posts; instead, they embedded these messages within broader narratives about natural immunity, holistic health, and personal empowerment that resonated with their audiences’ existing beliefs and values.<sup>232</sup> This approach made it difficult for social media platforms to identify and remove harmful content, as the misinformation was interwoven with seemingly legitimate health and wellness advice.<sup>233</sup>

## V. THE MODERN WELLNESS-INDUSTRIAL COMPLEX AND THE DANGERS OF INSTITUTIONAL CAPTURE

“A culture that tolerates and elevates pseudoscience will be at odds with the health of its citizens.”<sup>234</sup>

### A. The Modern Wellness-Industrial Complex and the Dangers of Institutional Capture

Today’s wellness industry represents the culmination of centuries of evolution in health optimization marketing, combining traditional appeals with sophisticated digital marketing techniques and an increasingly complex regulatory environment.<sup>235</sup> The modern wellness-industrial complex encompasses not just

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<sup>230</sup> Roxanne Turuba et al., *Exploring How Youth Use TikTok for Mental Health Information in British Columbia: Semistructured Interview with Youth*, 4 JMIR INFODEMOLOGY, July 2024, at 2.

<sup>231</sup> See, e.g., Moran et al., *supra* note 227, at 1204 (explaining that “influencers deploy microcelebrity practices that forward authenticity, relatability, and accountability and, in doing so, position their informational content as more trustworthy than traditional mainstream media outlets”).

<sup>232</sup> See Moran et al., *supra* note 227, at 1205 (noting that “the orientation of wellness culture to personalized solutions and alternative beliefs makes it a particularly vulnerable space for alternative health influencers to spread misinformation and conspiratorial thinking”); see also Ashley Fetters Maloy & Gerrit De Vynck, *How Wellness Influencers Are Fueling the Anti-Vaccine Movement*, WASH. POST (Sept. 12, 2021), <https://www.washingtonpost.com/technology/2021/09/12/wellness-influencers-vaccine-misinformation/> (contending that “[m]any social media influencers who focus on natural remedies, holistic health and new age spirituality have been sharing posts and videos questioning the wisdom of vaccinating against the coronavirus”).

<sup>233</sup> See Gabrielle O’Brien, Ronith Ganjigunta & Parameer S. Dhillon, *Wellness Influencer Responses to COVID-19 Vaccines on Social Media: A Longitudinal Observational Study*, 26 J. MED. INTERNET RSCH., Nov. 2024, at 1 (concluding that “unregulated wellness influencers have incentives to resist messaging from establishment authorities such as public health agencies”).

<sup>234</sup> JONATHAN N. STEA, *MIND THE SCIENCE: SAVING YOUR MENTAL HEALTH FROM THE WELLNESS INDUSTRY* 22 (2024).

<sup>235</sup> See Kristen R. Klesh, *Navigating FDA and FTC Regulation of Consumer Health & Wellness Devices (Watches, Rings, Masks and More)*, LOEB & LOEB LLP (Nov. 2024), <https://www.loeb.com/en/insights/publications/2024/11/navigating-fda-and-ftc-regulation-of-consumer-health-and-wellness-devices>; Shaun Callaghan et al., *The Trends Defining the \$1.8 Trillion Global Wellness Market in 2024*, MCKINSEY & CO. (Jan. 16, 2024),

supplements and products but entire lifestyle ecosystems that promise comprehensive optimization of physical, mental, and spiritual well-being.<sup>236</sup>

Contemporary wellness entrepreneurs have learned to exploit every loophole in the existing regulatory framework while developing new strategies that push the boundaries of what is permissible.<sup>237</sup> They use carefully crafted language that implies medical benefits without making explicit medical claims.<sup>238</sup> They employ third-party reviews and expert endorsements to lend credibility without taking direct responsibility for specific claims.<sup>239</sup> They position their offerings within broader lifestyle and personal development narratives that make regulatory enforcement more complex.<sup>240</sup> Such tactics have proved particularly fruitful with younger—and more social media reliant—consumers. Today, “[n]early one in five US consumers and one in three US millennials prefer personalized products and services.”<sup>241</sup>

The rise of “biohacking”<sup>242</sup> culture exemplifies modern wellness fraud sophistication.<sup>243</sup> Biohackers position themselves as citizen scientists engaged in self-experimentation and optimization, adopting scientific language and

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<https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/the-trends-defining-the-1-point-8-trillion-dollar-global-wellness-market-in-2024>; Maggie Craig & Kelsey Tavares, *FTC’s Expansive New Advertising Compliance Guidance Covers Marketing of Any Health-Related Product*, DLA PIPER (Jan. 11, 2023), <https://www.dlapiper.com/en-us/insights/publications/2023/01/ftcs-expansive-new-advertising-compliance-guidance-covers-marketing-of-any-health-related-product>.

<sup>236</sup> See Callaghan et al., *supra* note 235.

<sup>237</sup> See, e.g., Leah R. Fowler & Michael R. Ulrich, *Femtechnodystopia*, 75 STAN. L. REV. 1233, 1238–39 (2023); David A. Simon, Carmel Shachar & I. Glenn Cohen, *Skating the Line Between General Wellness Products and Regulated Devices: Strategies and Implications*, 9 J. L. & BIOSCI., July-Dec. 2022, at 1–22.

<sup>238</sup> See Aparajita Lath, *False and Deceptive Health Claims: Buyers Beware*, HARV. L. SCH. PETRIE-FLOM CTR., BILL OF HEALTH (Mar. 13, 2023), <https://petrieflom.law.harvard.edu/2023/03/13/false-and-deceptive-health-claims-buyers-beware/>.

<sup>239</sup> See, e.g., *Whose Endorsement Is Better—Celebrity or Expert?*, ASPIRE, <https://www.aspire.io/blog/celebrity-endorsement-vs-expert-endorsement/> (last visited Oct. 19, 2025); Rhett Power, *Why Third-Party Credibility Is Growing*, FORBES (Apr. 11, 2024, at 10:23 AM ET), <https://www.forbes.com/sites/rhettpower/2024/04/11/why-third-party-credibility-is-growing/>.

<sup>240</sup> See Elizabeth Marglin, *How Do You Know if You Can Trust Wellness Influencers?*, VITACOST.COM (Feb. 11, 2025), <https://www.vitacost.com/blog/trusting-wellness-influencers/>.

<sup>241</sup> Callaghan et al., *supra* note 235; see also Anna Pione et al., *The \$2 Trillion Global Wellness Market Gets a Millennial and Gen Z Glow Up*, MCKINSEY & Co. (May 29, 2025), <https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/future-of-wellness-trends>.

<sup>242</sup> Korin Miller, *Doctors Explain What They Really Think of Biohacking*, PREVENTION (July 30, 2025), <https://www.prevention.com/health/a65428930/what-is-biohacking/> (explaining that “[b]iohacking is essentially DIY biology—making intentional changes to your lifestyle, diet, or environment to optimize health and performance” and “[i]t ranges from simple tweaks like tracking your sleep or trying intermittent fasting, to more extreme practices like implanting microchips”).

<sup>243</sup> See CONFESSIONS OF A MALE GYNECOLOGIST: *Top Ten Biohacking Scams* (Apple Podcasts, Apr. 10, 2025); *Is Biohacking a Scam?*, SLATE (May 15, 2024, at 5:00 AM ET), <https://slate.com/transcripts/TEJOWk5ERVBMbmlhb3JNRDVTeG96MG5zYVNm0hPUzJxbU14bWVGTOU5az0=>; COLE HASTINGS, *The Biohacking Epidemic: A Billion Dollar Scam*, (YouTube, May 4, 2025), <https://www.youtube.com/watch?v=mwQbgUXG-fQ>.

methodology while often lacking any scientific training or oversight.<sup>244</sup> This positioning allows them to make increasingly aggressive claims about their methods and products while maintaining plausible deniability about practicing medicine without a license.<sup>245</sup>

Subscription-based business models have become central to modern wellness fraud, enabling entrepreneurs to generate recurring revenue while making it difficult for consumers to evaluate the total cost of their purchases.<sup>246</sup> These models often begin with low-cost trials or introductory offers that automatically convert to expensive ongoing subscriptions, taking advantage of consumer inertia and the complexity of cancellation processes.<sup>247</sup>

The integration of technology into wellness products has also created new categories of potential fraud. Wearable devices that claim to optimize sleep, meditation, or recovery often make impressive-sounding claims about their capabilities while providing little actual benefit beyond placebo effects.<sup>248</sup> Mobile apps promising to improve mental health, relationships, or productivity through gamified interventions operate in regulatory grey areas while generating detailed data about users' psychological and behavioral patterns.<sup>249</sup>

## B. The RFK Jr. Appointment: Institutional Capture and Public Health Threats

The appointment of Robert F. Kennedy Jr. as Secretary of Health and Human Services (HHS) represents a watershed moment at the intersection of wellness fraud and government policy, demonstrating how anti-vaccine activism and conspiracy theories can achieve institutional legitimacy.<sup>250</sup> Kennedy, who, as mentioned above, made a career out of vaccine skepticism through his organization Children's Health Defense (CHD), brings to the nation's top health position a documented history of promoting debunked theories linking vaccines to autism

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<sup>244</sup> *Top Ten Biohacking Scams*, *supra* note 243.

<sup>245</sup> *See id.*; see also Jancee Dunn, *How to Spot a Wellness Scam*, N.Y. TIMES (May 5, 2023), <https://www.nytimes.com/2023/05/05/well/live/health-wellness-scam.html>.

<sup>246</sup> *See* FED. TRADE COMM'N, BRINGING DARK PATTERNS TO LIGHT 2–3, 12–14, 23 (Sept. 2022), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/P214800%20Dark%20Patterns%20Report%209.14.2022%20-%20FINAL.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/P214800%20Dark%20Patterns%20Report%209.14.2022%20-%20FINAL.pdf).

<sup>247</sup> *See id.*

<sup>248</sup> Natalia Macrynika et al., *The Impact of Mindfulness Apps on Psychological Processes of Change: A Systematic Review*, 3 MENTAL HEALTH RSCH., Mar. 2024, at 2–12.

<sup>249</sup> *See* Fowler & Ulrich, *supra* note 237, at 1238–39; Simon et al., *supra* note 237, at 1–22.

<sup>250</sup> Jennifer D. Oliva, *Government Goes Goop*, 75 EMORY L.J. ONLINE 31, 52–57 (2026); Chantelle Lee, 'Terrifying': Public Health Experts React to Senate's Confirmation of RFK, Jr. to Lead HHS, TIME (Feb. 13, 2025, at 3:38 PM ET), <https://time.com/7222309/rfk-jr-confirmed-hhs-public-health-react/>; Selena Simmons-Duffin, *RFK Jr. Confirmed as Trump's Health Secretary, over Democrat's Loud Objections*, NPR (Feb. 13, 2025, at 11:33 AM ET), <https://www.npr.org/sections/shots-health-news/2025/02/13/nx-s1-5294591/rfk-jr-trump-health-human-services-hhs-vaccines>; Sophia Samantaroy, *Robert F. Kennedy Jr. Confirmed as Health and Human Services Secretary on a 52-48 Vote*, HEALTH POL'Y WATCH (Feb. 13, 2025), <https://healthpolicy-watch.news/robert-f-kennedy-confirmed-as-health-and-human-services-secretary-on-a-52-48-vote/>.

and spreading COVID-19 misinformation.<sup>251</sup> The same day that Kennedy was sworn in as HHS Secretary, the White House issued an executive order to establish a “Make America Health Again” (MAHA) Commission, which invoked well-worn wellness vernacular by calling on the federal health agencies to “‘aggressively combat’ chronic health threats with ‘fresh thinking’ in areas such as nutrition, physical activity, healthy lifestyles, and medication practices, as well as environmental hazards and the quality and safety of foods and drugs.”<sup>252</sup>

Kennedy’s confirmation—despite his lack of medical expertise and well-documented anti-vaccine positions—illustrates the mainstreaming of wellness-based conspiracy theories and the erosion of scientific authority in policymaking.<sup>253</sup> During his confirmation hearings, Kennedy faced intense questioning about his vaccine skepticism but ultimately secured confirmation by vowing not to pursue an “anti-vaccine agenda,” a promise he immediately broke upon taking office.<sup>254</sup> Kennedy’s instantaneous about-face should have been little surprise given that he “consistently downplayed and denied controversial things he has said previously in podcasts, conferences or TV interviews, even though the senators quoted him directly,” including his prior remarks equating the CDC’s childhood vaccine program to Nazi death camps, throughout his hearings.<sup>255</sup>

Within months of his appointment, Kennedy demonstrated the dangers of placing wellness conspiracy theorists in positions of authority within government health agencies.<sup>256</sup> Kennedy halted routine COVID-19 vaccine recommendations

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<sup>251</sup> Shannon Bond, *Inside RFK Jr.’s Nonprofit’s Legal Battles over Vaccines and Public Health*, NPR (Dec. 4, 2024, at 5:00 AM ET), <https://www.npr.org/2024/12/03/nx-s1-5198506/rfk-jr-anti-vaccine-chd-lawsuits>.

<sup>252</sup> Josh Michaud, *What Is (and What is Not) on Trump and Kennedy’s Make America Health Again Public Health Agenda*, KFF (Feb. 19, 2025), <https://www.kff.org/quick-take/what-is-and-what-is-not-on-trump-and-kennedys-make-america-healthy-again-public-health-agenda/>; see Exec. Order No. 14212, 90 Fed. Reg. 9833 (Feb. 19, 2025); *Fact Sheet: President Donald J. Trump Establishes the Make America Healthy Again Commission*, WHITE HOUSE (Feb. 13, 2025), <https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-establishes-the-make-america-healthy-again-commission/>.

<sup>253</sup> BBC Verify Team, *Fact-Checking RFK Jr’s Views on Health Policy*, BBC (Nov. 15, 2024), <https://www.bbc.com/news/articles/c0mzk2y41zvo>.

<sup>254</sup> See Lena H. Sun, Lauren Weber & Rachel Roubein, *How Vaccine Policy, Including for Coronavirus, Has Changed Under RFK Jr.*, WASH. POST (Sept. 19, 2025), <https://www.washingtonpost.com/health/2025/07/24/vaccine-access-recommendations-covid-rfk/>; PBS NEWS, *RFK Jr. Faces Questions over Vaccine Skepticism, Medicaid Reform at Confirmation Hearing*, (Jan. 29, 2025, at 6:50 PM ET), <https://www.pbs.org/newshour/show/rfk-jr-faces-questions-over-vaccine-skepticism-medicare-reform-at-confirmation-hearing>.

<sup>255</sup> Madison Czopek & Samantha Putterman, *Fact Check: RFK Jr’s Statements During Senate Confirmation Hearing*, AL JAZEERA (Jan. 30, 2025), <https://www.aljazeera.com/news/2025/1/30/fact-check-rfk-jrs-statements-during-senate-confirmation-hearing>; see also Ben Jacobs, *A Weird Confirmation Hearing Even for RFK Jr. Boched Answers and Baby Onesies*, NEW YORKER (Jan. 29, 2025), <https://nymag.com/intelligencer/article/robert-f-kennedy-jr-confirmation-hearing-weird.html> (explaining that Kennedy had gone “so far as to say the hazards of being unvaccinated in the U.S. were worse [than] those faced by Anne Frank when hiding from the Nazis”).

<sup>256</sup> See Lisa Blunt Rochester, *Senator: We’re Already Seeing Consequences of RFK Jr’s Vaccine Skepticism*, NEWSWEEK (July 15, 2025, at 9:37 AM ET), <https://www.newsweek.com/senator-were-already-seeing-consequences-rfk-jrs-vaccine-skepticism-opinion-2097373>; Karen Feldcher, *RFK Jr.*

for healthy children and pregnant women, fired the entire seventeen-member Advisory Committee on Immunization Practices (ACIP) that guides U.S. vaccine policy, and replaced career public health officials with vaccine skeptics from his former organization.<sup>257</sup> These actions occurred during a measles outbreak, highlighting the real-world consequences of allowing conspiracy theories to guide public health policy.<sup>258</sup> The American Academy of Pediatrics, the American College of Physicians, and the American Public Health Association were so outraged over Kennedy's anti-scientific COVID-19 vaccine policies that they sued Kennedy, along with the directors of the FDA, National Institutes of Health (NIH), and CDC, in federal district court.<sup>259</sup>

Kennedy's justification for dismantling vaccine advisory committees relied on debunked claims about conflicts of interest and mischaracterized government reports that suggested widespread corruption among public health officials.<sup>260</sup> This approach exemplified the wellness industry's strategy of using legitimate concerns about pharmaceutical industry influence to justify radical positions that endanger public health.<sup>261</sup> Public health experts warned that Kennedy's actions would further erode vaccine confidence and lead to preventable disease outbreaks.<sup>262</sup> As one physician explained, "[v]accination has probably saved more lives and is better researched than most, if not all, aspects of healthcare. RFK Jr. could set this back and be responsible for the death and disability of myriads of people, particularly children."<sup>263</sup>

The Kennedy appointment represents the culmination of decades of efforts by the wellness industry to position alternative health approaches as equivalent to

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*Moves on Vaccines Could Have Broad Ramifications for Public Health, Says Expert*, HARV. T.H. CHAN SCH. OF PUB. HEALTH (June 18, 2025), <https://hsph.harvard.edu/news/rfk-jr-moves-on-vaccines-could-have-broad-ramifications-for-public-health-says-expert/>.

<sup>257</sup> See Will McDuffie & Jade Cobern, *RFK Jr. Appoints Longtime Anti-Vaccine Ally Lyn Redwood to HHS Position*, ABC NEWS (June 25, 2025, at 7:49 PM ET), <https://abcnews.go.com/US/rfk-jr-appoints-longtime-anti-vaccine-ally-lyn/story?id=123213887>; Annika Kim Constantino, *RFK Jr. Removes All Members of CDC Panel Advising U.S. on Vaccines*, CNBC (June 9, 2025, at 4:22 PM ET), <https://www.cnbc.com/2025/06/09/rfk-jr-cdc-panel-vaccines.html>; Stephanie Soucheray, *RFK Jr. Says No COVID Vaccines for Healthy Children, Pregnant Women*, UNIV. MINN. CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (May 27, 2025), <https://www.cidrap.umn.edu/covid-19/rfk-jr-says-no-covid-vaccines-healthy-children-pregnant-women>.

<sup>258</sup> See Lauren Weber, *Unpacking RFK Jr.'s 'Doublespeak' on Vaccines*, WASH. POST (May 11, 2025), <https://www.washingtonpost.com/health/2025/05/11/vaccines-measles-rfk-jr-health/>.

<sup>259</sup> Will Stone, *RFK Jr.'s Vaccine Policy Sparks a Lawsuit from the American Academy of Pediatrics*, NPR (July 8, 2025, at 5:00 AM ET), <https://www.npr.org/sections/shots-health-news/2025/07/08/nx-s1-5459978/rfk-jr-vaccine-pediatrics-public-health-lawsuit>.

<sup>260</sup> Constantino, *supra* note 257; Meredith Wadman, *RFK Jr.'s Purge of CDC Vaccine Advisors Prompts Outrage*, SCIENCE (June 10, 2025, at 3:30 PM ET), <https://www.science.org/content/article/rfk-jr-s-purge-cdc-vaccine-advisers-prompts-outrage>.

<sup>261</sup> See, e.g., Jude Joffe-Block, *Bad Wellness Is All Over Social Media. These Creators Are Pushing Back*, NPR (Feb. 20, 2025, at 5:40 PM ET), <https://www.npr.org/2025/02/20/nx-s1-5277087/wellness-influencers-science-creators-maha-rfk-jr>.

<sup>262</sup> Wadman, *supra* note 260; Sara Moniuszko, *Former Vaccine Panel Ousted by RFK Jr. Says Scientific Rigor Is "Rapidly Eroding,"* CBS NEWS (July 31, 2025, at 12:01 PM ET), <https://www.cbsnews.com/news/acip-vaccine-panel-ousted-by-rfk-jr-speaks-out/>.

<sup>263</sup> *Fact-Checking RFK Jr.'s Views on Health Policy*, *supra* note 253.

evidence-based medicine.<sup>264</sup> By achieving the highest health policy position in the government, the anti-vaccine movement demonstrated how social media-driven conspiracy theories could translate into concrete policy changes with potentially devastating public health consequences.<sup>265</sup> Kennedy's appointment also illustrated how wellness fraud's emphasis on individual choice and distrust of expertise could be weaponized to dismantle the institutional safeguards that protect public health.<sup>266</sup> It is particularly disturbing in light of the inadequate regulatory schemes currently applicable to social media wellness influencers, which is the subject of the following section of this Article.

## VI. REGULATORY INADEQUACIES AND ENFORCEMENT CHALLENGES

“[T]he immense scale, informal culture, and diffuse effects of social media environments present staggering challenges for any entity attempting to enforce regulations effectively.”<sup>267</sup>

The current regulatory framework for wellness fraud in America reflects the accumulated responses to decades of industry evolution, creating a complex patchwork of federal and state authorities, industry self-regulation, and platform policies that often work at cross-purposes.<sup>268</sup> The fundamental challenge is that regulations designed for a world of discrete products sold through traditional retail channels struggle to address an industry increasingly built around content,

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<sup>264</sup> See, e.g., Chelsea Cirruzzo, *The Growing Influence of Vaccine Skeptics Inside HHS*, STAT+ (July 14, 2025), <https://www.statnews.com/2025/07/14/antivaccine-influence-inside-hhs-public-health-experts-alarmed-rfk-jr-hires-vaccine-skeptics/>.

<sup>265</sup> *Id.*

<sup>266</sup> See McFarland, *supra* note 147; Zimdars, *supra* note 192, at 1217; Baker, *supra* note 192, at 10–15.

<sup>267</sup> Rebecca Coyne, *Mitigating the Harms of “Health & Wellness” Influencers*, MICH. J. PUB. AFFS. (Nov. 4, 2024), <https://mjpa.umich.edu/2024/11/04/mitigating-the-harms-of-health-wellness-influencers/>.

<sup>268</sup> See Gilad Mills, *A Contractual Approach to Social Media Governance*, 42 YALE L. & POL'Y REV. 522, 524 (2024) (noting that “[s]ocial media’s impact on individual rights and well-being, social stability, and democratic resilience has bred heated scholarly debate and a hodgepodge of regulatory regimes”); FED. TRADE COMM’N, *supra* note 14; U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES (Sept. 27, 2019), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>; U.S. FOOD & DRUG ADMIN., COMPLEMENTARY AND ALTERNATIVE MEDICINE PRODUCTS AND THEIR REGULATION BY THE FOOD AND DRUG ADMINISTRATION (Feb. 2007), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/complementary-and-alternative-medicine-products-and-their-regulation-food-and-drug-administration>; see also Yvonne Abraham, *Dietary Supplements, Largely Unregulated, Deserve the State’s Skepticism*, BOS. GLOBE (Jan. 29, 2020), <https://www.bostonglobe.com/2020/01/29/metro/dietary-supplements-largely-unregulated-deserve-states-skepticism/>.

communities, and lifestyle narratives.<sup>269</sup> As legal expert Barbara Zabawa recently explained, “from a regulatory perspective, wellness is the wild west.”<sup>270</sup>

The FDA’s authority over dietary supplements remains limited by DSHEA’s framework, which, as explained above, requires the agency to prove harm rather than requiring manufacturers to prove benefit.<sup>271</sup> This burden of proof is particularly challenging given the supplement industry’s size—with over 100,000 products on the market and new ones launching daily—comprehensive safety monitoring is practically impossible with the FDA’s current (and rapidly depleting) resources.<sup>272</sup> Even when the FDA identifies problematic products, the enforcement process is slow and often ineffective, with manufacturers able to reformulate or rebrand products faster than regulators can act.<sup>273</sup> As one law firm recently acknowledged, “[i]nfluencer marketing and self-care messaging have been powerful tools in reaching consumers over social media platforms that were not even contemplated when DSHEA was passed, creating an entirely ‘different marketplace with new, innovative ingredients, claims, marketing tactics, and an environment that evolves in days, not years.’”<sup>274</sup>

The FTC’s authority over wellness advertising and marketing claims provides broader coverage but faces similar resource constraints and enforcement challenges.<sup>275</sup> The FTC’s focus on “material misrepresentations or omissions” that could influence purchasing decisions often struggles with wellness marketing’s increasing sophistication at implying benefits without making explicit claims.<sup>276</sup> The agency’s emphasis on case-by-case enforcement rather than industry-wide standards leads to inconsistent outcomes and allows problematic practices to persist until specific companies are targeted.<sup>277</sup>

State authorities add another layer of complexity, with varying approaches to health claims, professional licensing, telehealth services, and consumer protection.<sup>278</sup> Some states have aggressive enforcement programs targeting

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<sup>269</sup> Kristi Wolff, *Six Key Takeaways on Dietary Supplement Regulation, 30 Years Post-DSHEA*, DAVIS WRIGHT TREMAINE (July 1, 2024), <https://www.dwt.com/insights/2024/07/takeaways-from-dietary-supplement-industry-panel>.

<sup>270</sup> Barbara Zabawa, *No More Wild West: The Need for Wellness Professional Standards*, 50 AM. J.L. & MED. 74, 75 (2024) (explaining that “the FDA doesn’t require premarket approval for nutritional supplements, cosmetics, or wellness devices, which constitute many of the products pushed by wellness practitioners”).

<sup>271</sup> 21 U.S.C. § 342(f) (2025).

<sup>272</sup> Regan L. Bailey, *Current Regulatory Guidelines and Resources to Support Research of Dietary Supplements in the United States*, 60 CRITICAL REV. FOOD SCI. NUTRITION 298, 298–99 (2020).

<sup>273</sup> See, e.g., Starr, *supra* note 88, at 481; Fowler & Ulrich, *supra* note 237, at 1238–39; Simon et al., *supra* note 237, at 4.

<sup>274</sup> Wolff, *supra* note 269.

<sup>275</sup> FED. TRADE COMM’N, *supra* note 14.

<sup>276</sup> *Id.* at 2.

<sup>277</sup> Timothy T. Hughes, *The Federal Trade Commission’s Approach to Regulating Health Claims in Food Advertising*, 3 LOYOLA CONSUMER L. REV. 4, 5–7 (1990).

<sup>278</sup> See *Understanding Legal and Regulatory Requirements for Your Corporate Wellness Startup*, CORP. WELLNESS MAG., <https://www.corporatewellnessmagazine.com/article/understanding-legal-and-regulatory-requirements-for-your-corporate-wellness-startup> (last visited Oct. 28, 2025).

wellness fraud, while others take minimal action.<sup>279</sup> This patchwork creates opportunities for forum shopping, where wellness entrepreneurs can base their operations in permissive jurisdictions while reaching consumers nationwide through digital platforms.

As explained earlier, the rise of social media has created new enforcement challenges that existing regulatory frameworks struggle to address.<sup>280</sup> Traditional regulations assume clear distinctions between advertising and editorial content, between manufacturers and retailers, and between domestic and foreign businesses.<sup>281</sup> Social media wellness fraud often blurs all these distinctions.<sup>282</sup> Influencers promoting products may be simultaneously customers, affiliates, and paid spokespersons.<sup>283</sup> Content may be simultaneously educational, entertaining, and commercial.<sup>284</sup> Business operations may span multiple jurisdictions and platforms with complex revenue-sharing arrangements.<sup>285</sup>

Platform self-regulation has emerged as a significant factor in wellness fraud enforcement with inconsistent results.<sup>286</sup> Social media companies have implemented various policies targeting health misinformation and fraudulent

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<sup>279</sup> See, e.g., Julia B. Strickland, *State Oversight: The Next Frontier for Consumer Protection*, STEPTOE (Apr. 9, 2025), <https://www.steptoec.com/en/news-publications/state-oversight-the-next-frontier-for-consumer-protection.html>.

<sup>280</sup> Zabawa, *supra* note 125; Dickinson, *supra* note 112, at 2461.

<sup>281</sup> See, e.g., FED. TRADE COMM'N, *NATIVE ADVERTISING: A GUIDE FOR BUS.* (Dec. 2015), <https://www.ftc.gov/business-guidance/resources/native-advertising-guide-businesses>.

<sup>282</sup> *Id.*

<sup>283</sup> See, e.g., *What Is Influencer Marketing*, MCKINSEY & CO. (Apr. 10, 2023), <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-influencer-marketing>.

<sup>284</sup> See Jamia Kenan, *Perfecting Your Edutainment Social Media Content Strategy*, SPROUT BLOG (Nov. 20, 2024), <https://sproutsocial.com/insights/edutainment-social-media>.

<sup>285</sup> See William Gasner, *Influencer Compensation Models: A Detailed Guide for Brands and Creators*, STACK INFLUENCE (Apr. 25, 2025), <https://stackinfluence.com/influencer-compensation-models>; Tanya Alain, *Revenue Share in Influencer Marketing*, UPFLUENCE (July 21, 2023), <https://www.upfluence.com/glossary/revenue-share>.

<sup>286</sup> Michael A. Cusumano, Annabelle Gawer & David B. Yoffie, *Can Self-Regulation Save Digital Platforms?*, 30 *INDUST. & CORP. CHANGE* 1259, 1260–61 (2021) (explaining that, “during the past several years, we have seen instances of digital platforms disseminating fake news, distributing fake products, allowing content manipulation for political purposes, and bombarding the public with misinformation on health and other essential matters”); see also *id.* at 1265 (contending that “[p]latform . . . can institute governance rules determining who can and cannot access the platform and access points such as app stores, and influence what users or complementors can do on the platform” and that “governance rules may even put digital platforms in the position as ‘private regulators’ with the ability to shape broad industry architecture as well as the behavior of platform participants”). For an overview of the various content moderation measures that social media platforms advanced to combat COVID-19 misinformation, see Nandita Krishnan et al., *Research Note: Examining How Various Social Media Platforms Have Responded to COVID-19 Misinformation*, 2 *HARV. KENNEDY SCH. MISINFORMATION REV.*, Dec. 2021, at 1–25; *id.* at 2 (explaining that “[r]emedies included soft measures, such as attaching warning labels, and hard measures, such as content removal and account bans” but that “[t]he lack of clarity and transparency from many SMPs regarding their responses to COVID-19 misinformation and systems for applying various remedies makes it difficult for policymakers, researchers, and the general public to determine whether platforms are doing enough to address COVID-19 misinformation”).

marketing, but enforcement is often reactive and inconsistent.<sup>287</sup> Platforms' business models depend on user engagement, creating tensions between comprehensive enforcement and content volume.<sup>288</sup> Algorithmic enforcement systems also struggle with the subtlety of wellness content, often missing sophisticated fraud while incorrectly flagging legitimate health information.<sup>289</sup>

### A. The Psychology of Wellness Fraud Susceptibility

“The frequency with which the Internet is used as a health information source combined with the level of trust people have in this source is troubling given the prevalence of health misinformation online.”<sup>290</sup> Understanding why social media wellness grifting persists despite decades of regulatory effort requires examining the psychological and social factors that make consumers susceptible to dubious health claims.<sup>291</sup> Modern wellness fraud's success reflects not just regulatory failures but deep-seated human psychology that remains essentially unchanged despite centuries of scientific progress.<sup>292</sup>

The fundamental appeal of wellness fraud lies in its promise of agency and control over health outcomes.<sup>293</sup> Traditional medicine, despite its effectiveness, often emphasizes the role of genetics, environment, and random chance in determining health outcomes.<sup>294</sup> Wellness grifting, by contrast, promises that optimal health is achievable through the right choices, products, or practices.<sup>295</sup> This message resonates particularly strongly in American culture, which emphasizes individual responsibility and self-improvement.<sup>296</sup> As one commentator noted, modern wellness fraud “revives mistaken 19th century

<sup>287</sup> See, e.g., MARIA GIOVANNA SESSA, PLATFORMS' POLICIES ON HEALTH MISINFORMATION, EU DISINFO LAB 1–8 (June 2023), [https://www.disinfo.eu/wp-content/uploads/2023/06/20230621\\_HealthFS-1.pdf](https://www.disinfo.eu/wp-content/uploads/2023/06/20230621_HealthFS-1.pdf); Leonardo Madio & Martha Quinn, *Content Moderation and Advertising on Social Media Platforms*, 34 J. ECON. & MANAG. STRATEGY 342, 342 (2024); see also Monica L. Wang, *POV: Health Misinformation Is Rampant on Social Media*, BU TODAY (Feb. 9, 2024), <https://www.bu.edu/articles/2024/health-misinformation-rampant-on-social-media>.

<sup>288</sup> Mills, *supra* note 268, at 585.

<sup>289</sup> See, e.g., Haroon et al., *supra* note 182, at 1–2; Susarla, *supra* note 182; Popken, *supra* note 182.

<sup>290</sup> Xiaoli Nan, Yuan Wang & Kathryn Their, *Health Misinformation*, in THE ROUTLEDGE HANDBOOK OF HEALTH COMMUNICATION 318–332 (Theresa L. Thompson & Nancy Grant Harrison, eds., 3d ed. 2021) (explaining that, in 2019, 72% of Americans used the internet as their first source for health information and that, in 2018, 64% of American adults “reported ‘some’ or ‘a lot’ of trust in the Internet as a health information source”).

<sup>291</sup> See, e.g., Xiaoli Nan, Yuan Wang & Kathryn Their, *Why Do People Believe Health Misinformation and Who Is at Risk? A Systematic Review of Individual Differences in Susceptibility of Health Misinformation*, 314 SOC. SCI. & MED., Dec. 2022, at 1–15.

<sup>292</sup> *Id.*

<sup>293</sup> BAKER, *supra* note 3, at 7 (noting that “[e]xplanations of how and why wellness culture has emerged need to consider the philosophical, religious and political contexts in which individualism has emerged, as well as the economic materialism and consumer culture of late capitalism”); Masa Sasagawa et al., *Positive Correlation Between the Use of Complementary and Alternative Medicine and Internal Locus of Control*, 4 EXPLORE 38, 38–41 (2008).

<sup>294</sup> See, e.g., BAKER, *supra* note 3, at 7; Sasagawa et al., *supra* note 293.

<sup>295</sup> BAKER, *supra* note 3, at 7.

<sup>296</sup> Sasagawa et al., *supra* note 293, at 38–41; MacFarlane et al., *supra* note 108, at 9.

attitudes—that drugs and conventional therapies are useless, and that licensing of health-care providers restricts the public’s freedom of choice.”<sup>297</sup>

The complexity of modern scientific knowledge creates opportunities for wellness entrepreneurs to exploit information asymmetries.<sup>298</sup> While scientific literacy has improved over the decades, the pace of scientific discovery and the technical complexity of modern research make it difficult for consumers to evaluate health claims critically.<sup>299</sup> Wellness entrepreneurs exploit this by using scientific-sounding language and cherry-picked research to support their claims while counting on consumers’ inability to assess the quality of evidence.<sup>300</sup>

Social media has amplified several psychological factors that increase susceptibility to wellness fraud.<sup>301</sup> The platforms’ emphasis on personal narratives and testimonials makes anecdotal evidence seem more compelling than statistical data.<sup>302</sup> The ability to find communities of like-minded individuals reinforces beliefs through social proof and confirmation bias.<sup>303</sup> The algorithmic filtering of information creates echo chambers where dubious health claims are reinforced rather than challenged.<sup>304</sup>

Wellness grifting susceptibility also often coincides with moments of vulnerability or desperation.<sup>305</sup> People facing chronic health conditions, aging concerns, psychological distress, or major life transitions are particularly susceptible to promises of miraculous health transformation or optimization.<sup>306</sup>

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<sup>297</sup> John E. Dodes, *Alternative Therapy: A Historical Perspective on Health Fraud*, QUACKWATCH (Dec. 15, 2019), [https://quackwatch.org/hx/perspective\\_on\\_health\\_fraud/](https://quackwatch.org/hx/perspective_on_health_fraud/).

<sup>298</sup> Nan et al., *supra* note 291, at 13–15.

<sup>299</sup> See Ralph Lewis, *The Appeal of Alternative Medicine*, PSYCH. TODAY (May 15, 2023), <https://www.psychologytoday.com/us/blog/finding-purpose/202305/the-appeal-of-alternative-medicine>.

<sup>300</sup> *See id.*

<sup>301</sup> *See, e.g.*, Novella, *supra* note 119.

<sup>302</sup> *Id.*

<sup>303</sup> *Id.*

<sup>304</sup> *Id.*; MacFarlane et al., *supra* note 108, at 8.

<sup>305</sup> MacFarlane et al., *supra* note 108, at 9.

<sup>306</sup> *See e.g.*, Courtney Rubin, *The Market for Menopause Products is Booming – But There’s An Easy Way to Find What Actually Works*, WOMEN’S HEALTH (Apr. 16, 2025, at 7:00 AM ET), <https://www.womenshealthmag.com/life/a64232891/menopause-market-boom/> (explaining that “[i]n the past, the huge midlife transition into menopause—which is accompanied by massive fluctuations in hormones produced by the ovaries as they shrink, stop releasing eggs, and shift into low gear—was something women just ‘dealt’ with, often in isolation. But . . . ‘menopause influencers’ abound on Instagram, women are comparing hormone therapy regimens with friends, and celebrities like [Gwyneth] Paltrow, Drew Barrymore, Michelle Obama, Naomi Watts, and Serena Williams talk openly about menopause”); *id.* (pointing out that “the massive number of women seeking symptom relief has also allowed misinformation, from menopause influencers and online ads for unregulated products, to spread”); David Harris, *Beware of Ehlers-Danlos Syndrome Scams*, EDS CLINIC (Oct. 2024), <https://www.eds.clinic/articles/common-ehlers-danlos-syndrome-scams> (explaining that “EDS patients are frequently targeted by companies and individuals claiming they have a ‘miracle cure’ for EDS symptoms. These offerings often include expensive supplements, stem cell therapies, or purportedly groundbreaking ‘DNA-based treatments.’”); Lei Yu et al., *Vulnerability of Older Americans to Government Impersonation Scams*, 6 JAMA NETWORK, Sept. 2023, at 2 (“According to a report released by the US Senate Special Committee on Aging, in 2020, older

Wellness entrepreneurs have become sophisticated at identifying and targeting these psychological pressure points through data analytics and targeted advertising.<sup>307</sup>

## B. Toward Effective Regulation: Lessons and Recommendations

The persistence of wellness fraud is not inevitable; it is the predictable consequence of a regulatory framework designed for a different era. Meaningful reform is possible, and the stakes could not be higher. As wellness misinformation increasingly shapes public health decisions—from vaccine hesitancy to the rejection of evidence-based medicine—the costs of continued regulatory failure extend far beyond individual consumer harm to threaten the foundations of public health. Six interconnected reforms—modernizing DSHEA, learning from international regulatory models, reforming platform liability, strengthening FTC enforcement authority, enhancing agency coordination, and balancing consumer protection with innovation—have the potential, if implemented together, to break the cycle of exploitation that has characterized American wellness markets for over a century.

### 1. Modernizing DSHEA

First, DSHEA requires comprehensive modernization to address the realities of a dietary supplement market that has grown from approximately 4,000 products in 1994 to over 100,000 today.<sup>308</sup> The FDA has explicitly called for Congress to authorize mandatory product listing requirements that would require supplement manufacturers to register their products with the agency, including product labels, complete ingredient lists, allergen statements, and all health and

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Americans lost \$100 million to COVID-19–related frauds alone.”); Bryan D. James, Patricia A. Boyle & David A. Bennet, *Correlates of Susceptibility to Scams in Older Adults*, 26 J. ELDER ABUSE NEGL. 107, 114 (2014) (“The oldest old, persons with lower levels of cognitive function, lower psychological well-being, and poorer health and financial literacy appeared to be the most susceptible to scams, independent of level of education and income.”).

<sup>307</sup> See e.g., Natalya Jaime, *Wellness Marketing Strategies to Connect, Engage, and Promote Health-Related Brands*, S. CAL. NEWS GRP. (Feb. 15, 2025), <https://www.socalnewsgroup.com/2025/02/15/wellness-marketing-guide-2025/> (advising that “personalized communication—such as targeted email campaigns, product recommendations based on user behavior, or follow-up after purchase—is essential to creating exclusivity and ensuring customers feel like your brand is speaking directly to their needs” and “[l]everaging data to offer personalized recommendations can increase engagement and foster long-term loyalty. AI, chatbots, or wellness apps that track progress and adapt to users’ preferences are other excellent ways to create a tailored wellness journey for each individual”); Sander van der Linden, *Weapons of Mass Persuasion: Tracing the Story of Psychological Targeting on Social Media*, BEHAV. SCI. (Apr. 10, 2023), <https://behavioralscientist.org/weapons-of-mass-persuasion-tracing-the-story-of-psychological-targeting-on-social-media/>; Joanna Strycharz & Bram Duivenvoede, *The Exploitation of Vulnerability Through Personalised Marketing Communication: Are Consumers Protected?*, 10 INTERNET POL’Y REV., Nov. 2021, at 2.

<sup>308</sup> See Dietary Supplement Listing Act of 2024, S. 4827, 118th Cong. (2024); Press Release, Sen. Dick Durbin, *supra* note 100.

structure/function claims.<sup>309</sup> As the United States Pharmacopeia has observed, the current regulatory framework leaves the FDA without basic visibility into what products are being sold to American consumers, undermining the agency's ability to identify dangerous or illegal products and take appropriate enforcement action.<sup>310</sup>

The Dietary Supplement Listing Act of 2024 represents a promising incremental legislative vehicle for such reform.<sup>311</sup> The Act would require manufacturers to submit product information to the FDA within eighteen months of enactment for existing products and at the time of market introduction for new products, with ongoing obligations to report changes and discontinuations.<sup>312</sup> While industry groups remain divided on the proposal, leading trade associations representing major supplement manufacturers have endorsed mandatory product listing as a necessary first step toward a more transparent marketplace.<sup>313</sup>

Beyond mere listing requirements, effective DSHEA modernization should address the fundamental burden-of-proof problem that plagues current enforcement. The current framework, which requires the FDA to prove that a product is unsafe rather than requiring manufacturers to demonstrate safety and efficacy before marketing, subjects consumers to unnecessary risk while making enforcement prohibitively complex and expensive. A more effective approach would establish tiered evidence requirements based on claim severity: structure/function claims might require less rigorous substantiation than wellness or prevention claims and no claim should reach the market without pre-market documentation demonstrating safety and efficacy.<sup>314</sup>

## 2. Learning from International Regulatory Models

Second, American regulators should examine international approaches that have developed more robust frameworks for addressing wellness influencer

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<sup>309</sup> FOOD & DRUG ADMIN., FY 2025 LEGISLATIVE PROPOSALS 10 (Mar. 2024), <https://www.fda.gov/media/176924/download#:~:text=The%20FY%202025%20budget%20includes,all%20human%20and%20animal%20drugs> (noting that “FDA is seeking to modernize DSHEA to provide for a more transparent marketplace, help facilitate a risk-based regulation of dietary supplements and clarify FDA’s authorities relating to products marketed as ‘dietary supplements’”).

<sup>310</sup> U.S. PHARMACOPEIA, USP GLOBAL PUBLIC POLICY POSITION: REGULATORY REFORM IS NECESSARY TO HELP ENSURE THE QUALITY OF DIETARY SUPPLEMENTS 1–8 (2024), [https://www.usp.org/sites/default/files/usp/document/public-policy/USP\\_Policy%20Position\\_DietarySupplements\\_2024.pdf](https://www.usp.org/sites/default/files/usp/document/public-policy/USP_Policy%20Position_DietarySupplements_2024.pdf).

<sup>311</sup> See S. 4827, *supra* note 308, at § 403D (requiring manufacturers to provide “a copy of the label,” “a list of all ingredients,” “allergen statements,” and “health and structure/function claims”).

<sup>312</sup> See *id.*

<sup>313</sup> See, e.g., Stephen Daniells, *FDA’s 2025 Legislative Wish List Calls for Mandatory Supplement Product Listing*, NUTRADINGREDIENTS-USA (Mar. 12, 2024), <https://www.nutraingredients-usa.com/Article/2024/03/12/FDA-s-2025-legislative-wish-list-calls-for-mandatory-supplement-product-listing/> (quoting Steve Mister, President & CEO, Council for Responsible Nutrition supporting mandatory listing as providing “much needed transparency to the industry”).

<sup>314</sup> FED. TRADE COMM’N, HEALTH PRODUCTS COMPLIANCE GUIDANCE 13 (Dec. 2022), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/Health-Guidance-508.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf) (explaining that “[r]andomized, controlled human clinical trials (RCTs) are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims”).

marketing. Australia's Therapeutic Goods Administration (TGA) provides a particularly instructive model.<sup>315</sup> Under Australia's Therapeutic Goods Advertising Code 2021, paid or incentivized testimonials for therapeutic goods—including complementary medicines equivalent to American dietary supplements—are expressly prohibited.<sup>316</sup> This prohibition extends to social media influencers, brand ambassadors, and anyone who receives “valuable consideration” in exchange for endorsing therapeutic products.<sup>317</sup> Australian law also imposes affirmative obligations on businesses and social media account holders, making them responsible for any content they create, share, or manage—including user-generated content and third-party comments posted on their platforms.<sup>318</sup>

Critically, Australia backs these requirements with meaningful enforcement. Civil penalties for violations can reach AU\$1.65 million per breach for individuals and AU\$16.5 million for corporations, with the possibility of criminal prosecution in serious cases.<sup>319</sup> The TGA actively monitors social media platforms and has authority to require internet service providers to block access to non-compliant websites.<sup>320</sup> In fiscal year 2024-25 alone, the TGA requested removal of over 13,700 unlawful advertisements from digital platforms.<sup>321</sup>

The European Union's Digital Services Act (DSA) offers another model worthy of consideration.<sup>322</sup> The DSA requires “very large online platforms”—those with more than 45 million monthly users in the EU—to identify, analyze, and assess systemic risks arising from the design and operation of their services, explicitly including risks to public health and to users' physical and mental well-

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<sup>315</sup> Aus. Dep't of Health, Disability & Aging Therapeutic Goods Administration, *New Therapeutic Goods Advertising Code 1 January 2022* (Dec. 3, 2021), <https://www.tga.gov.au/news/media-releases/new-therapeutic-goods-advertising-code-1-january-2022>.

<sup>316</sup> Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (Cth) § 24(4) (Austl.) (prohibiting testimonials from persons who have received “valuable consideration” for therapeutic goods), <https://www.legislation.gov.au/F2021L01661/latest/text>.

<sup>317</sup> *See id.* § 24(5) (requiring advertisers to confirm testimonial maker's identity and compliance with Code provisions before use).

<sup>318</sup> Press Release, Therapeutic Goods Admin. (Austl.), *TGA Releases Updated Social Media Advertising Guidance to Support Improved Compliance* (Nov. 5, 2025), <https://www.tga.gov.au/news/media-releases/tga-releases-updated-social-media-advertising-guidance-support-improved-compliance> (explaining that “[b]usinesses and social media account holders, including influencers, are responsible for any content they create, share or manage”).

<sup>319</sup> *See* Therapeutic Goods Act 1989 (Cth) §§ 42DL(12), 42DLB(9) (Austl.) (providing for civil penalties of up to 5,000 penalty units for individuals and 50,000 penalty units for corporations); *see also* Crimes Act 1914 (Cth) s 4AA (Austl.) (setting Commonwealth penalty unit at AU\$330 as of November 2024, yielding maximum penalties of AU\$1.65 million for individuals and AU\$16.5 million for corporations).

<sup>320</sup> Press Release, Therapeutic Goods Admin. (Austl.), *supra* note 318.

<sup>321</sup> *Id.* (noting that “[i]n the 2024-25 financial year, the TGA requested the removal of over 13,700 unlawful advertisements from digital platforms”).

<sup>322</sup> Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act), 2022 O.J. (L 277) 1 [hereinafter Digital Services Act].

being.<sup>323</sup> Platforms must then implement reasonable, proportionate, and effective mitigation measures tailored to those identified risks, which may include adapting content moderation practices, algorithmic recommender systems, and terms of service.<sup>324</sup>

The EU is also developing more targeted regulation through the forthcoming Digital Fairness Act, expected to be proposed by the European Commission in 2026.<sup>325</sup> This legislation will specifically address influencer marketing, including stricter disclosure standards and potential prohibitions on promoting certain categories of high-risk products.<sup>326</sup> France has already enacted comprehensive national legislation regulating influencers under Law No. 2023-451,<sup>327</sup> which defines influencers broadly,<sup>328</sup> and prohibits promotion of specified health-related products, financial products, nicotine products, and cosmetic surgery procedures.<sup>329</sup> American regulators should study these approaches for potentially transferable elements.

### 3. Reforming Platform Liability Under Section 230

Third, effective regulation of social media wellness fraud likely requires targeted reform of Section 230 of the Communications Decency Act. Section 230's broad immunity provision—which protects platforms from liability for content created by third parties<sup>330</sup>—has been interpreted by courts to shield platforms from accountability even when their algorithmic systems actively promote and amplify

<sup>323</sup> See *id.* (76), art. 34(1) (requiring very large online platforms to “identify, analyse and assess . . . any systemic risks” including “any actual or foreseeable negative effects” on “public health” and “serious negative consequences to the person’s physical and mental well-being”).

<sup>324</sup> See *id.* art. 35(1) (requiring platforms to “put in place reasonable, proportionate and effective mitigation measures, tailored to the specific systemic risks identified”).

<sup>325</sup> EUROPEAN COMM’N, DIGITAL FAIRNESS ACT PUBLIC CONSULTATION (July 17–Oct. 24, 2025), <https://digital-strategy.ec.europa.eu/en/consultations/commission-launches-open-consultation-forthcoming-digital-fairness-act>; EUROPEAN COMM’N, COMMISSION STAFF WORKING DOCUMENT: FITNESS CHECK OF EU CONSUMER LAW ON DIGITAL FAIRNESS, (Oct. 3, 2024), [https://commission.europa.eu/document/download/707d7404-78e5-4aef-acfa-82b4cf639f55\\_en?filename=Commission%20Staff%20Working%20Document%20Fitness%20Check%20on%20EU%20consumer%20law%20on%20digital%20fairness.pdf](https://commission.europa.eu/document/download/707d7404-78e5-4aef-acfa-82b4cf639f55_en?filename=Commission%20Staff%20Working%20Document%20Fitness%20Check%20on%20EU%20consumer%20law%20on%20digital%20fairness.pdf).

<sup>326</sup> *Digital Fairness Act Unpacked: Social Media Influencers*, OSBORNE CLARKE (Sept. 9, 2025), <https://www.osborneclarke.com/insights/digital-fairness-act-unpacked-social-media-influencers?utm>.

<sup>327</sup> Loi n° 2023-451 du 9 juin 2023 visant à encadrer l’influence commerciale et à lutter contre les dérives des influenceurs sur les réseaux sociaux [Law No. 2023-451 of June 9, 2023, on Regulating Commercial Influence and Combating the Excesses of Influencers on Social Networks], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], June 10, 2023, No. 2023-451.

<sup>328</sup> See *id.* art. 2 (defining influencers broadly as individuals or entities who use their reputation to communicate content for the purpose of promoting goods, services, or causes in exchange for payment).

<sup>329</sup> See *id.* arts. 4–5 (prohibiting promotion of certain health-related products, financial products, nicotine products, and cosmetic surgery procedures).

<sup>330</sup> 47 U.S.C. § 230(c)(1) (providing that “[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider”).

harmful health misinformation.<sup>331</sup> This immunity creates a structural barrier to effective enforcement that cannot be overcome through agency action alone.

Several legislative proposals offer frameworks for targeted Section 230 reform. The Health Misinformation Act<sup>332</sup> would remove Section 230 immunity for platforms that promote health misinformation through an algorithm during declared public health emergencies.<sup>333</sup> Importantly, the bill would preserve immunity for “neutral” display of content, such as chronological feeds, targeting only the algorithmic amplification that makes health misinformation particularly pernicious.<sup>334</sup> The SAFE TECH Act<sup>335</sup> takes a different approach, proposing to remove Section 230 immunity where a provider or user has accepted payment to make content available.<sup>336</sup> Under this framework, platforms could be held liable for wellness fraud disseminated through paid influencer partnerships and sponsored content—the very mechanisms that drive much contemporary wellness grifting.<sup>337</sup>

A coalition of state attorneys general has also argued that Section 230’s expansive interpretation by courts has improperly displaced state consumer protection authority, preventing states from allocating losses for internet-related wrongs and undermining traditional state authority to protect consumers from fraud.<sup>338</sup> Any Section 230 reform should preserve space for state enforcement while establishing clear federal standards that prevent regulatory arbitrage across jurisdictions.

#### 4. Strengthening FTC Enforcement Authority

Fourth, the FTC requires enhanced authority and resources to address wellness influencer fraud effectively. The Commission’s August 2024 final rule

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<sup>331</sup> See, e.g., Ira Rubinstein & Tomer Kenneth, *Taming Online Public Health Misinformation*, 60 HARV. J. LEGIS. 459, 251–53 (2023).

<sup>332</sup> Health Misinformation Act of 2021, S. 2448, 117th Cong. (2021).

<sup>333</sup> See *id.* § 3(a) (proposing to amend Section 230 to remove immunity for platforms that “promote[] . . . health misinformation through an algorithm used by the provider (or similar software functionality)” during a declared public health emergency).

<sup>334</sup> See *id.* 3(a)(1)(B) (providing that immunity removal “shall not apply if that promotion occurs through a neutral mechanism, such as through the use of chronological functionality”).

<sup>335</sup> Safeguarding Against Fraud, Exploitation, Threats, Extremism, and Consumer Harms Act, S. 560, 118th Cong. (2023).

<sup>336</sup> See *id.* § 2(a)(1)(A)(iii) (proposing to amend 47 U.S.C. § 230(c)(1) to provide that immunity shall not apply “unless the provider or user has accepted payment to make the speech available or, in whole or in part, created or funded the creation of the speech”).

<sup>337</sup> Taylor Hatmaker, *The SAFE TECH Act Offers Section 230 Reform, but the Law’s Defenders Warn of Major Side Effects*, TECHCRUNCH (Feb. 5, 2021, at 2:15 PM ET), <https://techcrunch.com/2021/02/05/safe-tech-act-section-230-warner/> (noting the bill “covers many different types of arrangements that go far beyond paid advertisements” because “[p]latforms accept payments from a wide range of parties during the course of making speech ‘available’ to the public”).

<sup>338</sup> Brief for the States of Tennessee et al. as Amici Curiae Supporting Petitioners 9 (Dec. 7, 2022), *Gonzalez v. Google LLC*, 598 U.S. 617 (2023) (No. 21-1333) (arguing that Section 230’s broad immunity “prevents states from allocating losses for internet-related wrongs”).

banning fake reviews and testimonials represents a significant step forward,<sup>339</sup> prohibiting businesses from creating, buying, or selling fake reviews; suppressing negative reviews; and buying fake followers or engagement metrics to misrepresent social media influence.<sup>340</sup> The rule explicitly allows the agency to seek civil penalties for violations—a crucial enforcement tool that had been uncertain under prior guidance.<sup>341</sup>

Additional reforms should build on this foundation. Current FTC disclosure requirements for influencer endorsements, while improved from earlier iterations, remain inadequate for health-related claims.<sup>342</sup> The Commission has demonstrated willingness to pursue enforcement in this area, sending warning letters to health influencers for inadequate disclosure of material connections,<sup>343</sup> but penalties remain modest relative to the profits generated by wellness fraud. The current maximum civil penalty of \$53,088 per violation may be insufficient to deter well-funded wellness operations, particularly when violations are difficult to detect and enforcement resources are limited.<sup>344</sup>

More robust enforcement should include mandatory disgorgement of profits from fraudulent wellness promotions, as demonstrated in the FTC's action against Teami, LLC, which resulted in the return of over \$930,000 to consumers deceived by influencer-promoted weight loss claims.<sup>345</sup> The FTC should also coordinate more closely with sector-specific regulators like the Financial Industry Regulatory Authority (FINRA), which in 2024 brought its first enforcement actions against broker-dealers for inadequate supervision of financial influencer

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<sup>339</sup> See FED. TRADE COMM'N, *Federal Trade Commission Announces Final Rule Banning Fake Reviews and Testimonials* (Aug. 14, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/08/federal-trade-commission-announces-final-rule-banning-fake-reviews-testimonials> (finalizing rule that prohibits businesses from creating, buying, or selling fake or false reviews and testimonials).

<sup>340</sup> 16 C.F.R. § 465 (2024) (prohibiting, inter alia, fake reviews, suppression of negative reviews, and buying fake followers or views).

<sup>341</sup> Trade Regulation Rule on the Use of Consumer Reviews and Testimonials, 89 Fed. Reg. 68,324, 68,326 (Aug. 22, 2024) (codified at 16 C.F.R. pt. 465) (“The rule authorizes courts to impose civil penalties for knowing violations.”); see also Fed. Trade Comm'n, *The Consumer Reviews and Testimonials Rule: Questions and Answers* (Nov. 2024), <https://www.ftc.gov/business-guidance/resources/consumer-reviews-testimonials-rule-questions-answers>.

<sup>342</sup> See 16 C.F.R. pt. 255 (2023); FED. TRADE COMM'N, DISCLOSURES 101 FOR SOCIAL MEDIA INFLUENCERS (Nov. 2019), <https://www.ftc.gov/business-guidance/resources/disclosures-101-social-media-influencers>.

<sup>343</sup> See, e.g., Press Release, Fed. Trade Comm'n, *FTC Warns Two Trade Associations and a Dozen Influencers About Social Media Posts Promoting Consumption of Aspartame or Sugar* (Nov. 15, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-warns-two-trade-associations-dozen-influencers-about-social-media-posts-promoting-consumption> (sending warning letters to health influencers for inadequate disclosure of material connections).

<sup>344</sup> 16 C.F.R. § 1.98 (2025).

<sup>345</sup> See Press Release, Fed. Trade Comm'n, *FTC Returns More Than \$930,000 to Consumers Who Bought Teami's Deceptively Advertised Teas* (Feb. 22, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-returns-more-930000-consumers-who-bought-teamis-deceptively-advertised-teas>.

campaigns in 2024, and consider whether similar supervisory obligations should apply to companies that engage wellness influencers.<sup>346</sup>

Additionally, Congress should consider whether private rights of action might supplement agency enforcement. Scholars have proposed specific tort liability theories for influencer-caused harms,<sup>347</sup> including duty of care standards tailored to health-related influencer content.<sup>348</sup> While such approaches raise complex questions about speech, liability, and market effects, the inadequacy of current enforcement mechanisms suggests that expanding the universe of potential enforcers may be necessary.<sup>349</sup>

### 5. Enhanced Transparency and Agency Coordination

Fifth, effective regulation requires enhanced transparency mechanisms and improved coordination across regulatory bodies. The EU's Digital Services Act mandates that very large platforms maintain publicly accessible repositories of all advertisements displayed on their services,<sup>350</sup> including information about advertisers, payment sources, and targeting parameters.<sup>351</sup> Similar requirements in the United States would enable regulators, researchers, and the public to identify patterns of wellness fraud and hold platforms accountable for the advertising they host. The current opacity of platform advertising systems makes it virtually impossible to conduct systematic analysis of wellness fraud prevalence or to identify emerging threats before they cause widespread harm.<sup>352</sup>

Agency coordination also requires significant improvement. The current patchwork of federal agencies—FDA, FTC, state attorneys general, and platform-specific policies—creates opportunities for regulatory arbitrage while imposing compliance costs on legitimate businesses that must navigate multiple overlapping

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<sup>346</sup> Press Release, Fin. Indus. Reg. Auth., *FINRA Fines M1 Finance \$850,000 for Violations Regarding Use of Social Media Influencer Program* (Mar. 18, 2024), <https://www.finra.org/media-center/newsreleases/2024/finra-fines-m1-finance-850000-violations-regarding-use-social-media> (announcing first formal FINRA enforcement action against broker-dealer for inadequate supervision of influencer campaigns, finding that influencer posts were “not fair or balanced, or contained exaggerated, unwarranted, promissory or misleading claims”); *see also* Fin. Indus. Reg. Auth., *FINRA Provides Update on Sweep: Social Media Influencers, Customer Acquisition and Related Information Protection* (Feb. 2023), <https://www.finra.org/rules-guidance/guidance/targeted-examination-letters/sweep-update-feb2023> (detailing findings from targeted examination of broker-dealer practices).

<sup>347</sup> *See* Fowler et al., *supra* note 5, at 450–55 (analyzing potential tort liability theories for influencer-caused harms).

<sup>348</sup> *Id.* at 456–60 (proposing specific duty of care standards for health-related influencer content).

<sup>349</sup> *Cf.* In re Fundrise Advisors, LLC, Investment Advisers Act Release No. 6381 (Aug. 22, 2023), <https://www.sec.gov/enforce/ia-6381-s> (imposing \$250,000 civil penalty for failure to ensure proper disclosures in influencer solicitation program involving over 200 content creators paid more than \$8 million).

<sup>350</sup> Digital Services Act, *supra* note 322, art. 39 (requiring very large online platforms to compile and make publicly available repositories containing advertisements displayed on their services).

<sup>351</sup> *Id.* art. 39(2) (requiring repositories to include information about the advertiser, the natural or legal person who paid for the advertisement, and the parameters used to determine the recipients).

<sup>352</sup> *See* Krishnan et al., *supra* note 286, at 3–4 (analyzing platform content moderation responses to COVID-19 misinformation and noting lack of transparency regarding enforcement).

requirements. Formal memoranda of understanding between agencies, unified complaint intake systems, shared enforcement databases, and joint task forces for major wellness fraud investigations would improve both efficiency and effectiveness. Congress should also consider whether consolidating primary jurisdiction in a single agency with appropriate expertise might reduce coordination failures, though such consolidation would need to preserve the distinctive competencies that each agency brings to the problem.

Industry self-regulation and co-regulation may complement governmental efforts. The BBB National Programs' new Institute for Responsible Influence, which provides certification and training for influencers, represents one model, though the effectiveness of voluntary programs depends heavily on industry uptake and meaningful consequences for non-participation.<sup>353</sup> Regulators should consider whether participation in certified self-regulatory programs might provide safe harbor benefits or reduced scrutiny, creating incentives for responsible industry actors while preserving enforcement authority against bad actors.

## 6. Balancing Innovation and Consumer Protection

Sixth and finally, any effective regulatory approach must account for legitimate consumer demand for health-optimization products and services while not driving that demand toward unregulated markets or stifling genuine innovation. This requires establishing clear safe harbors for products and practices that meet defined quality and transparency standards. Products that achieve third-party certification from recognized bodies like the United States Pharmacopeia or NSF International might qualify for streamlined regulatory pathways or reduced enforcement scrutiny, creating market incentives for quality while reserving intensive enforcement resources for health-harming grifters.<sup>354</sup>

Clear regulatory guidance distinguishing permissible lifestyle and general wellness claims from impermissible treatment claims would also reduce uncertainty for legitimate market participants. The current ambiguity about what claims require substantiation and what level of evidence is required creates compliance challenges for responsible companies while providing cover for fraudulent operators who exploit gray areas. Detailed guidance with concrete examples, developed through notice-and-comment rulemaking, would improve compliance while strengthening the evidentiary basis for enforcement against those who cross clearly defined lines.

Consumer education, while insufficient as a standalone strategy, remains a valuable complement to structural reforms. Education efforts should focus less on teaching consumers to identify fraudulent claims—a task that has proven largely futile given the sophistication of modern wellness marketing—and more

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<sup>353</sup> BBB NAT'L PROGRAMS, CTR. FOR INDUS. SELF-REGUL., Inst. for Responsible Influence, <https://industryselfregulation.org/incubator/responsible-influence> (last visited Dec. 29, 2025) (announcing certification and training program for influencers, with full launch planned for spring 2026).

<sup>354</sup> U.S. PHARMACOPEIA, *supra* note 310, at 5–6 (discussing third-party certification programs and quality standards for dietary supplements).

on directing consumers toward reliable information sources and encouraging consultation with qualified healthcare providers. Public awareness campaigns should emphasize the regulatory status of dietary supplements and the meaning (or lack thereof) of various certifications and quality marks.

Together, these six reforms could create a regulatory framework capable of addressing the structural factors that make wellness fraud profitable while preserving space for legitimate innovation and consumer choice. No single reform is sufficient; the challenge of wellness influencer fraud requires coordinated action across multiple dimensions. The question is whether American regulatory institutions can develop the foresight, coordination, and political will necessary to implement such reforms before the next evolution in wellness fraud renders current approaches entirely obsolete.

## VII. CONCLUSION

Snake oil peddlers, con artists, and self-appointed wellness gurus thrive in spaces free from meaningful oversight—where expertise is suspect, institutions are distrusted, and consumer protection is weak. They succeed in chaos, where “truth” is subjective and the influencer’s carefully curated intimacy becomes the only perceived authority.

The story of wellness fraud in America reveals both continuity and adaptation. From 19th-century patent medicines to today’s social media empires, the promise is unchanged: perfect health, optimal performance, freedom from suffering—available for purchase from the right seller. What has changed is the scale and sophistication of the methods. Digital platforms, influencer marketing, and subscription models have exposed the limits of regulatory frameworks built for an earlier marketplace.

The challenge for policymakers is not simply to react to the latest scheme, but to address the structural incentives that make exploitation profitable. Wellness fraud persists because it reflects unmet needs, cultural commitments to individual responsibility, and markets that reward bold claims over careful evidence. Effective regulation must therefore do more than punish deception after the fact; it must strengthen transparency, accountability, and market conditions that favor substantiated innovation over spectacle.

The promise of perfect health will always find eager buyers. Whether American institutions can prevent that promise from continuing to serve as a vehicle for exploitation remains an open question.

# BREAKING THE LEASE, BREAKING THE CYCLE: RESTRUCTURING MISSOURI'S LEASE TERMINATION LAW FOR SURVIVORS OF DOMESTIC VIOLENCE

Ries Freeman\*

## I. INTRODUCTION

Jessica never imagined her life would turn out like this. She lived in a rented apartment with her three children and their father, Joe—a man who initially checked all of her boxes.

Three years into the relationship, everything changed. One night, Joe shoved Jessica against the wall over something trivial. He immediately started crying, apologizing, and swearing it would never happen again. Jessica believed it was a mistake, but it was not. The violence continued to escalate, and without a job, financial independence, any friends or family to turn to, or even her own car (which Joe had sold without telling her), Jessica felt trapped.

When Jessica decided she needed to escape, she was paralyzed—not just by fear of Joe, but by the overwhelming legal and financial barriers standing in her way. The lease they signed together became one of her biggest obstacles. Her name was legally tied to Joe's by the lease, leaving her afraid that she could be sued, faced with unpredictable termination fees, or dragged into court. Even contacting their landlord risked alerting Joe, potentially giving him a reason to retaliate. She felt stuck, forced to choose between enduring abuse or risking homelessness for herself and her children.

Jessica began researching a way out. After browsing website after website for an answer, she came across the possibility of breaking her lease early. But the more she read, the more confused she became. Joe still had access to the apartment, which raised concerns about whether that might count against her, as current Missouri law was not on her side.<sup>1</sup> She did not know whether her landlord would demand proof, or what kind.<sup>2</sup> The process seemed unclear, with no timeline for how long it might take. Even the term “reasonable termination fee” was vague and

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<sup>1</sup> See generally MO. REV. STAT. § 441.920.2(1) (2024) (Provision of Missouri tenant law protecting victims of, *inter alia*, domestic violence does not apply if “[t]he applicant, tenant, or lessee allowed the person named in any documentation listed in subsection 4 of this section into the premises[.]”); *Missouri Housing Laws*, WOMENSLAW.ORG, <https://www.womenslaw.org/laws/mo/housing-laws> (last visited Oct. 2, 2025).

<sup>2</sup> See MO. REV. STAT. § 441.920.4 (2024) (Lease termination applicant may be required to provide, e.g., a signed document from a victim services provider; documentation from medical or mental health provider who treated the applicant for injuries related to domestic or sexual violence or stalking; or a police report); WOMENSLAW.ORG, *supra* note 1.

open-ended.<sup>3</sup> Jessica had no money of her own and was not sure what rights she had—but it seemed she might have to defend herself just to invoke them.

Jessica initially felt relief when she stumbled upon these tenant protections; they were supposed to help people like her. That relief quickly faded. Instead of feeling protected, she felt defeated by the thought of navigating a legal maze, knowing she could not afford an attorney, let alone obtain one without Joe knowing. She did not know how much risk she could take—legally, financially, emotionally, or physically. With three children depending on her, she clicked out of the browser and stepped away, uncertain whether pursuing this path would bring safety or more harm.

Jessica’s story is entirely fictional, but it reflects the experiences of many domestic violence survivors.<sup>4</sup> In fact, one in four women,<sup>5</sup> one in seven men,<sup>6</sup> and one in two transgender individuals in the United States will experience domestic violence in their lifetime.<sup>7</sup> Fifty-seven percent of women experiencing homelessness report domestic violence as the predominant cause,<sup>8</sup> and nearly half of survivors admit they remained in abusive relationships because they lacked alternative housing.<sup>9</sup> In other words, housing insecurity is both a cause and a consequence of abuse.<sup>10</sup>

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<sup>3</sup> See MO. REV. STAT. § 441.920.6 (2024); WOMENSLAW.ORG, *supra* note 1.

<sup>4</sup> See, e.g., Interviews by Melissa Davey, *The Most Dangerous Time*, GUARDIAN, <https://www.theguardian.com/society/ng-interactive/2015/jun/02/domestic-violence-five-women-tell-their-stories-of-leaving-the-most-dangerous-time> (last visited Oct. 6, 2025) (providing personal stories women shared during interviews about their experiences leaving an abusive relationship and that informed the fictional account of Jessica’s story).

<sup>5</sup> See, e.g., Alanna Vagianos, *30 Shocking Domestic Violence Statistics that Remind Us It’s an Epidemic*, HUFFPOST, [https://www.huffpost.com/entry/domestic-violence-statistics\\_n\\_5959776](https://www.huffpost.com/entry/domestic-violence-statistics_n_5959776) (last updated Apr. 21, 2025).

<sup>6</sup> *Id.*

<sup>7</sup> Sarah Peitzmeir et al., *Intimate Partner Violence in Transgender Populations: Systematic Review and Meta-Analysis of Prevalence and Correlates*, 110 AM. J. PUB. HEALTH e1 (2020) (systemic review of intimate partner violence prevalence in transgender populations finds significantly higher rates of intimate partner violence compared to cisgender individuals, and cites data from the 2015 U.S. Transgender Survey, where 54% of respondents reported experiencing some sort of intimate partner violence).

<sup>8</sup> Sara Behmerwohld, *Domestic Violence and Homelessness*, HUM. OPTIONS (Nov. 9, 2023), <https://humanoptions.org/domestic-violence-and-homelessness/>.

<sup>9</sup> *Domestic Violence and Homelessness*, NAT’L COAL. FOR THE HOMELESS, <https://nationalhomeless.org/domestic-violence/> (last visited Oct. 6, 2025) (“45% of all domestic violence survivors had previously stayed with an abusive partner as a result of not having an alternative place to go.”).

<sup>10</sup> E.g., Robbie Sequeira, *Survivors of Domestic and Sexual Violence Can Break Their Leases Early in Some States*, STATELINE (May 10, 2024, 5:00 AM), <https://stateline.org/2024/05/10/survivors-of-domestic-and-sexual-violence-can-break-their-lease-early-in-some-states/> (quoting Kate Walz, associate director of litigation at the National Housing Law Project: “Gender-based violence is both the cause and consequence of housing instability. Housing instability increases your risk of it, and housing instability comes as a result of it.”).

Despite these statistics, survivors like Jessica often find that legal protections and available resources fall short of providing a safe and practical way out.<sup>11</sup>

Early lease termination laws can be a vital tool for survivors of domestic violence seeking to break free from abuse and secure housing<sup>12</sup>—but only if those laws are accessible, understandable, and enforceable.<sup>13</sup> Missouri statute Section 441.920 falls short in fulfilling this protective function because it operates as an affirmative defense rather than a proactive right.<sup>14</sup> The current structure leaves survivors to navigate legal and financial uncertainty at a time when clarity and safety are most critical.<sup>15</sup>

In response, this Comment (1) analyzes how early lease termination laws can better support survivors of domestic violence and (2) proposes specific suggestions for legislative reform. Part II introduces the dynamics of domestic violence, including definitions, data, and its intersection with housing instability. It also discusses federal protections, their limitations, and the role of state legislation in addressing the housing needs of survivors. Then, Part III discusses domestic violence in Missouri, highlighting the state's current protections. Next, Part IV analyzes Section 441.920 of the Missouri Revised Statutes and explains how this protection is inadequate to safeguard survivors. Part V then provides the distinction between affirmative defense statutes, like Missouri's, and more proactive statutes used by a majority of states. In Part VI, this Comment proposes

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<sup>11</sup> Malore Dusenbery & Susan Nembhard, *Nine Ways Policymakers Can Improve Domestic Violence Response*, URB. INST. (Oct. 25, 2024), <https://www.urban.org/urban-wire/nine-ways-policymakers-can-improve-domestic-violence-response> (“[T]he systems designed to provide safety and justice [for survivors of domestic violence]—from traditional legal processes to restorative justice programs, community-based support, and victim services—often fall short.”). See generally *The Sobering Reality of Domestic Violence and Homelessness*, VISION HOUSE (Jan. 20, 2025), <https://visionhouse.org/news/the-sobering-reality-of-domestic-violence-and-homelessness> (discussing how limited access to resources, legal barriers, and systemic inequities lead to ineffective legal protections, hindering a survivor's ability to secure and maintain safe housing); Stephanie Agnew, *Barriers to Justice: Identifying the Hidden Ways Survivors are Punished in Domestic Violence Court*, CHI. APPLESEED (Sept. 9, 2021), <https://www.chicagoappleseed.org/2021/09/08/identifying-hidden-barriers-in-dv-court/> (noting concerns that orders of protection are often the only remedy courts can offer survivors, even when they are insufficient, and quoting an advocate who described an order of protection as “‘a piece of paper that says you can't be abusive to me anymore.’”).

<sup>12</sup> See Sequeira, *supra* note 10.

<sup>13</sup> See generally Dusenbery & Nembhard, *supra* note 11 (“Communication and transparency involves sharing information with survivors clearly, frequently, and consistently throughout the justice process. . . . Policies and practices that assign [sic] staff to set expectations with and update survivors, make legal processes more transparent, and break down bureaucratic barriers could reduce isolation and increase support for survivors.”).

<sup>14</sup> The statute functions as an affirmative defense, meaning that instead of denying a landlord's claim outright, a survivor must introduce domestic violence as a new fact to excuse noncompliance with lease obligations after enforcement has begun. This distinction is significant because it requires survivors to invoke the statute protection defensively in response to landlord action, rather than granting an independent, self-executing right to terminate a lease. See discussion *infra* Part V; see generally MO. REV. STAT. § 441.920 (2024).

<sup>15</sup> See Rebecca Lynn, *Re-Victimization by the Court System*, BREAK SILENCE AGAINST DOMESTIC VIOLENCE BLOG, <https://breakthesilencedv.org/?p=9769> (last visited Dec. 29, 2025).

recommendations Missouri should consider for reform. Finally, Part VII concludes by addressing potential landlord concerns and outlines how the proposed reforms can balance the interests of both survivors and property owners.

## II. UNDERSTANDING DOMESTIC VIOLENCE: SOCIAL, HOUSING, AND LEGAL DIMENSIONS

### A. What is Domestic Violence?: Definitions and Statistics

Domestic violence—also referred to as intimate partner violence, domestic abuse, dating abuse, gender-based violence, or relationship abuse—is defined as “a pattern of behaviors used by one partner to maintain power and control over another partner in an intimate relationship.”<sup>16</sup> While often associated with physical harm, domestic violence can also include sexual, emotional, economic, psychological, and technological abuse.<sup>17</sup> Medical literature recognizes that all forms of abuse can result in severe, recurrent, and escalating harm, with poor long-term outcomes if left unaddressed.<sup>18</sup>

Domestic violence affects individuals of all genders, sexual orientations, and relationship types;<sup>19</sup> anyone can be a victim or a perpetrator of abuse.<sup>20</sup> Domestic violence can occur between married or unmarried partners, in both opposite-sex and same-sex relationships, and between co-parents.<sup>21</sup> Although the term “domestic violence” tends to hold a stereotype of physical harm within a heterosexual marriage,<sup>22</sup> abuse takes many forms and occurs across many relationships.<sup>23</sup> As such, some advocates prefer the term “intimate partner violence,” which more inclusively reflects these dynamics.<sup>24</sup>

A helpful framework for understanding the nature of abuse is the Power and Control Wheel, developed by the Domestic Abuse Intervention Project.<sup>25</sup> The Power and Control Wheel illustrates how abusers use tactics such as emotional

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<sup>16</sup> *Understand Relationship Abuse, We’re All Affected by the Issue of Domestic Violence*, NAT’L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/identify-abuse/understand-relationship-abuse/> (last visited Oct. 6, 2025) [hereinafter *Understand Relationship Abuse*].

<sup>17</sup> *Domestic Violence*, U.S. DEP’T JUST.: OFF. ON VIOLENCE AGAINST WOMEN (last updated Jan. 22, 2025), <https://www.justice.gov/ovw/domestic-violence>.

<sup>18</sup> See, e.g., Martin R. Huecker et al., *Domestic Violence*, in STATPEARLS (StatPearls Publ’g, Apr. 9, 2023), <https://www.ncbi.nlm.nih.gov/books/NBK499891/> (without proper social service and mental health intervention, all forms of abuse may be recurrent and escalating, with a poor prognosis for recovery).

<sup>19</sup> See Jill Filipovic, *14 Misconceptions About Domestic Violence*, DOMESTICSHELTERS.ORG (Jan. 29, 2018), <https://www.domesticshelters.org/articles/domestic-violence-op-ed-column/14-misconceptions-about-domestic-violence>.

<sup>20</sup> *Understand Relationship Abuse*, *supra* note 16.

<sup>21</sup> See U.S. DEP’T JUST.: OFF. ON VIOLENCE AGAINST WOMEN, *supra* note 17.

<sup>22</sup> See Hannah Craig, *You Ask, We Answer: Domestic Violence FAQs*, DOMESTICSHELTERS.ORG (July 18, 2022), <https://www.domesticshelters.org/articles/faq/domestic-violence-faq-you-ask-we-answer>.

<sup>23</sup> See *id.*

<sup>24</sup> See *id.*

<sup>25</sup> *Understanding the Power and Control Wheel*, DOMESTIC ABUSE INTERVENTION PROGRAMS, <https://www.theduluthmodel.org/wheels/faqs-about-the-wheels/> (last visited Dec. 28, 2025).

manipulation, economic control, isolation, and intimidation to maintain dominance over their partner.<sup>26</sup> These behaviors are not isolated or impulsive<sup>27</sup>—they are deliberate strategies rooted in entitlement and designed to dismantle equality in the relationship.<sup>28</sup>

Understanding the dynamics of domestic violence is crucial to crafting responsive legal protections.<sup>29</sup> Abuse is never acceptable. It is a learned, intentional pattern of behavior designed to exert control.<sup>30</sup> Survivors face extreme challenges in reclaiming control over their lives,<sup>31</sup> yet traditional responses fail to account for the complexity of these dynamics.<sup>32</sup>

The numbers are startling. Approximately 5.3 million incidents of domestic violence occur each year against women in the United States, resulting in nearly 1,300 deaths and 2 million injuries.<sup>33</sup> Eighty-five percent of domestic violence survivors are women.<sup>34</sup> In 2023, over one-third of female homicide victims were killed by an intimate partner.<sup>35</sup> Yet most incidents of intimate partner violence go unreported to police,<sup>36</sup> which can leave survivors without access to protection or resources. The overwhelming prevalence and long-lasting consequences of domestic violence underscore the urgent need for stronger legal protections, sustained advocacy, and policy reform at structural and systemic levels.<sup>37</sup>

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<sup>26</sup> See *id.*; *Power and Control Wheel*, DOMESTIC ABUSE INTERVENTION PROGRAMS (Mar. 2017) <https://www.theduluthmodel.org/wp-content/uploads/2017/03/PowerandControl.pdf>.

<sup>27</sup> See Filipovic, *supra* note 19; Vagianos, *supra* note 5 (“Domestic violence is not a singular incident, it’s an insidious problem deeply rooted in our culture[.]”).

<sup>28</sup> See, e.g., *Why People Abuse, Abuse is Never Okay. Learn Why People Abuse.*, NAT’L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/identify-abuse/why-do-people-abuse/> (last visited Jan. 4, 2026).

<sup>29</sup> See generally Dusenbery & Nembhard, *supra* note 11 (“Understanding and addressing . . . trauma is crucial in aiding survivors on their journey to recovery and empowerment.”).

<sup>30</sup> See NAT’L DOMESTIC VIOLENCE HOTLINE, *supra* note 28.

<sup>31</sup> See, e.g., *Why People Stay, It’s Not as Easy as Simply Walking Away.*, NAT’L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/support-others/why-people-stay-in-an-abusive-relationship/> (last visited Dec. 29, 2025).

<sup>32</sup> See Jessica Resnick, *To End Domestic Violence, We Need a Holistic Approach*, CTR. FOR JUST. INNOVATION (Oct. 29, 2024), <https://www.innovatingjustice.org/updates/end-domestic-violence/> (“Despite the devastating impacts of intimate partner violence on communities across the country, traditional responses to it often fall short of what survivors and the people most impacted really need.”).

<sup>33</sup> *Domestic Violence/Intimate Partner Violence Facts*, EMORY UNIV. SCH. MED.: DEP’T PSYCHIATRY & BEHAV. SCIS., [https://med.emory.edu/departments/psychiatry/nia/resources/domestic\\_violence.html](https://med.emory.edu/departments/psychiatry/nia/resources/domestic_violence.html) (last visited Mar. 19, 2025).

<sup>34</sup> *Id.*

<sup>35</sup> See Lizabeth Remrey, *Homicide Victimization in the United States, 2023*, BUREAU JUST. STAT. (May 2025), <https://bjs.ojp.gov/document/hvus23.pdf>.

<sup>36</sup> See EMORY UNIV. SCH. MED.: DEP’T PSYCHIATRY & BEHAV. SCIS., *supra* note 33.

<sup>37</sup> See generally Evelyn Rose, Charlotte Mertens & Jennifer Balint, *Structural Problems Demand Structural Solutions: Addressing Domestic and Family Violence*, 30 VIOLENCE AGAINST WOMEN 3633 (2024), <https://journals.sagepub.com/doi/epub/10.1177/10778012231179212> (arguing that many current responses to domestic violence fail to address the structural inequalities that produce and sustain violence, and calling for legal and policy frameworks that more meaningfully consider and combat the root causes of domestic and family violence); see, e.g., VISION HOUSE, *supra* note 11.

Leaving an abusive relationship tends to be the most dangerous time for a survivor.<sup>38</sup> A woman is seventy times more likely to be murdered in the few weeks after separation than at any other time throughout the relationship.<sup>39</sup> In fact, “women are more likely to be killed by an intimate partner . . . than by anyone else.”<sup>40</sup> These challenges help explain why it takes a survivor an average of seven attempts to leave before they do so successfully.<sup>41</sup> These realities reinforce the importance of legal frameworks that support—not complicate—escape.<sup>42</sup> When a lease, housing policy, or statute becomes another source of control or confusion for survivors, it can deter them from leaving.<sup>43</sup>

### B. The Intersection of Domestic Violence and Housing

There is a substantial nexus between domestic violence and housing.<sup>44</sup> A study by the U.S. Department of Justice found that 77% of domestic violence incidents “occur[] at or near the survivor’s home.”<sup>45</sup> Abuse often takes place behind closed doors—where survivors are the most vulnerable, and abusers feel the most powerful.<sup>46</sup> “While many . . . see [their] home as a place of relaxation and

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<sup>38</sup> See 50 *Obstacles to Leaving*, NAT’L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/resources/get-help-50-obstacles-to-leaving/> (last visited June 6, 2025).

<sup>39</sup> Vagianos, *supra* note 5.

<sup>40</sup> *The Scope of the Problem: Intimate Partner Homicide Statistics*, VAWNET: AN ONLINE RES. LIBR. ON DOMESTIC & SEXUAL VIOLENCE, <https://vawnet.org/sc/scope-problem-intimate-partner-homicide-statistics> (last visited Jan. 4, 2026).

<sup>41</sup> See NAT’L DOMESTIC VIOLENCE HOTLINE, *supra* note 38.

<sup>42</sup> See generally VISION HOUSE, *supra* note 11 (discusses the barriers to housing for survivors and suggests “[t]he intersection of domestic violence and homelessness underscores the critical need for comprehensive solutions that address both immediate safety concerns and long-term stability”).

<sup>43</sup> Maeve Walsh, *Ohio Bill Grants Sexual, Domestic Violence Victims’ a Right To End Lease Unscathed*, NBC COLUMBUS NEWS (Apr. 17, 2023, 5:30 AM), <https://www.nbc4i.com/news/local-news/columbus/ohio-bill-grants-sexual-domestic-violence-victims-a-right-to-end-lease-unscathed/> (“But given the few housing protections afforded to victims and survivors in Ohio, being bound to a lease agreement could mean the difference between staying with and leaving an abusive partner, according to attorney Melissa Benson, who leads the Columbus Legal Aid Society’s housing team. ‘Many times survivors of domestic violence struggle to leave their abusers just in general, but there is an extra barrier of, ‘What happens with my lease? Do I still owe this landlord money? Do I have to move? Can I move?’” Benson said. ‘And then for some people, there’s, ‘If I move, is my partner going to find me?’”).

<sup>44</sup> See, e.g., Behmerwohld, *supra* note 8.

<sup>45</sup> JENNIFER L. TRUMAN & RACHEL E. MORGAN, SPECIAL REPORT: NONFATAL DOMESTIC VIOLENCE, 2003-2012, U.S. DEP’T OF JUST.: BUREAU OF JUST. STAT. NCJ 244697 (Apr. 2014), <https://bjs.ojp.gov/content/pub/pdf/ndv0312.pdf>.

<sup>46</sup> See *Domestic Violence Is a Housing Problem*, VERSO (Feb. 6, 2025), <https://www.versobooks.com/blogs/news/domestic-violence-is-a-housing-problem> (excerpting Alva Gotby’s book *FEELING AT HOME: TRANSFORMING THE POLITICS OF HOUSING* (2025) in a blog post: “Domestic abuse is thus a housing issue not only in the sense of being a leading cause of women’s homelessness, but also because the design of private homes creates shelter for harmful behaviour. The very thing that is supposed to protect people from violence – the private domestic space – becomes a source of violence and a condition for its continuation.”).

peace,” those subjected to intimate partner violence may “see it as a place of terror and stress.”<sup>47</sup>

For survivors considering leaving, obtaining and maintaining safe housing can be one of the greatest barriers.<sup>48</sup> Fear of homelessness,<sup>49</sup> financial difficulties,<sup>50</sup> the affordable housing crisis,<sup>51</sup> and limited shelter space<sup>52</sup> can make escape seem impossible. Some survivors may avoid emergency shelters altogether because of stigma,<sup>53</sup> fear of retaliation, the risk of further victimization, or the very real possibility of being turned away.<sup>54</sup>

Domestic violence can lead to long-term housing instability.<sup>55</sup> Survivors may face eviction based on nuisance complaints, property damage caused by their abuser, or police involvement related to the abuse.<sup>56</sup> Housing instability can be

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<sup>47</sup> See generally *When Home Isn't Safe*, FAM. CRISIS CTRS. (Nov. 6, 2023), <https://www.familycrisiscenters.org/when-home-isnt-safe/> (“While many of us see our home as a place of relaxation and peace, many others see it as a place of terror and stress.”).

<sup>48</sup> See VISION HOUSE, *supra* note 11.

<sup>49</sup> See Behmerwohld, *supra* note 8.

<sup>50</sup> See Susan Johnston Taylor, *5 Financial Challenges Facing Survivors of Domestic Abuse*, U.S. NEWS & WORLD REP. (Oct. 26, 2016, 10:24 AM), <https://money.usnews.com/money/personal-finance/articles/2016-10-26/5-financial-challenges-facing-survivors-of-domestic-abuse> (discussing the following financial challenges survivors face: housing, limited access to money, employment, tax issues, and coerced debt).

<sup>51</sup> See Behmerwohld, *supra* note 8.

<sup>52</sup> See, e.g., Monica McLaughlin & Debbie Fox, *Housing Needs of Survivors of Domestic Violence, Dating Violence, and Stalking*, NAT'L LOW INCOME HOUS. COAL.: 2024 ADVOCs.' GUIDE 6-8, 6-9 (2024), [https://nlhc.org/sites/default/files/AG-2024/6-2\\_Housing-Needs-of-Survivors-of-Domestic-Violence-Dating-Violence-and-Stalking.pdf](https://nlhc.org/sites/default/files/AG-2024/6-2_Housing-Needs-of-Survivors-of-Domestic-Violence-Dating-Violence-and-Stalking.pdf) (discussing the intersection between domestic violence and homelessness and providing statistics for unmet needs due to limited resources and full shelters: “The National Network to End Domestic Violence’s 17th Annual Domestic Violence Counts Report found that in just one 24-hour period in 2022, almost 12,692 nationwide requests for shelter and housing went unmet[.]”).

<sup>53</sup> See generally, e.g., Allison Crowe & Christine E. Murray, *Stigma from Professional Helpers Toward Survivors of Intimate Partner Violence*, 6 PARTNER ABUSE 157 (2015) (study of intimate partner violence reveals feelings of stigma in employment. In education systems within sample).

<sup>54</sup> E.g., NAT'L DOMESTIC VIOLENCE HOTLINE, *supra* note 38; Kaitlyn Short, *Domestic Violence Against Women in the United States*, BALLARD BRIEF (Apr. 2020), <https://ballardbrief.byu.edu/issue-briefs/domestic-violence-against-women-in-the-united-states> (explaining that even though there have been efforts to further support survivors, “many state-funded solutions to domestic violence are inaccessible or ineffective to all IPV victims, and many are turned away from resources that do exist.”).

<sup>55</sup> See, e.g., Behmerwohld, *supra* note 8.

<sup>56</sup> See *Fair Housing and Domestic Violence*, NAT'L HOUS. L. PROJECT, <https://www.nhlp.org/initiatives/fair-housing-housing-for-people-with-disabilities/fair-housing-and-domestic-violence/> (last visited Jan. 3, 2026) (explaining that survivors may be evicted or denied housing due to the violence committed against them, including under nuisance ordinances or property damage caused by the abuser).

exacerbated by economic abuse,<sup>57</sup> such as destroyed credit,<sup>58</sup> coerced debt,<sup>59</sup> or lost access to income and financial accounts.<sup>60</sup> These finance-related harms can make it considerably more difficult for survivors to secure independent housing once they decide to flee.<sup>61</sup> As a result, survivors often face housing insecurity not due to personal choice, but because abuse-driven legal and financial consequences restrict their housing options.

### C. Federal Protections and Challenges

Congress passed the Violence Against Women Act (VAWA) in 1994 in response to growing concerns about rising crime rates, particularly against women.<sup>62</sup> The legislation marked the first comprehensive federal effort to address domestic violence by expanding protections, funding shelters and legal aid, supporting advocacy efforts, and enhancing law enforcement and judicial training.<sup>63</sup> It also established federal penalties for certain domestic violence-related

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<sup>57</sup> See generally On Point with Meghna Chakrabarti, *'He Wanted to Destroy Me Financially': The Economic Abuse of Domestic Violence Survivors*, WBUR, at 08:25 (Jan. 27, 2025), <https://www.wbur.org/onpoint/2025/01/27/economic-abuse-domestic-violence-survivors> (statement of Adrienne Adams, a professor in the Department of Psychology at Michigan State University, during a podcast discussion) (“Economic abuse is a specific and unique form of domestic violence. It involves using abusive behavior to control a person's access to and their use of economic resources. And economic resources can be things like income, cash, credit.”); see also Vagianos, *supra* note 5 (providing that 98% of domestic violence cases involve economic abuse).

<sup>58</sup> See, e.g., *Safe, Accessible Housing for Survivors: The Low-Barrier Approach*, DIST. ALL. FOR SAFE HOUS. (2012), [https://ncdvtmh.org/wp-content/uploads/2022/10/Safe-Accessible-Housing-for-Survivors\\_The-Low-Barrier-Approach.pdf](https://ncdvtmh.org/wp-content/uploads/2022/10/Safe-Accessible-Housing-for-Survivors_The-Low-Barrier-Approach.pdf) (“Women suffer physical injuries that can take years to heal, and many experience homelessness or housing instability as a direct result of *the havoc their abusers have wreaked on their credit*, rental and employment histories as a means of exerting power and control.”) (emphasis added).

<sup>59</sup> See, e.g., On Point, *supra* note 57, at 15:14; Katie Herchenroeder, *She Escaped Her Abuser. But Not Before He Buried Her in Debt*, MOTHER JONES (May 16, 2025), <https://www.motherjones.com/politics/2025/05/she-left-her-abuser-not-before-he-buried-her-in-debt/> (details a survivor’s experience with coerced debt, and illustrates how it can accompany other forms of abuse but remain hidden, often leaving survivors with lasting financial damage and making it much harder to leave the relationship).

<sup>60</sup> See, e.g., On Point, *supra* note 57 (statement of Kiesha Preston, a survivor featured on the podcast to share her experience with economic abuse) (“I woke up the next morning [after calling the police and taking out a protective order], and our bank account had been completely wiped out. Every single dime that was in it, he had removed, put it into an account that I couldn’t access. So, I quite literally had zero dollars, three kids, and no job, and I had to figure out, what am I gonna do next?”).

<sup>61</sup> See Sherri Gordon, *How to Identify Financial Abuse in a Relationship*, VERYWELLMIND, <https://www.verywellmind.com/financial-abuse-4155224> (last updated July 14, 2024) (“[I]f an abuser is particularly violent and the victim needs to leave to stay safe, this is difficult without money or a credit card. And if they need to leave the relationship permanently, finding safe and affordable housing is challenging.”).

<sup>62</sup> See Nathan Kemper & Lisa N. Sacco, *The Violence Against Women Act (VAWA): Historical Overview, Funding, and Reauthorization*, CONG. RSCH. SERV. (Apr. 23, 2019), <https://www.congress.gov/crs-product/R45410>.

<sup>63</sup> See generally *August 2023: The Long History of Domestic Violence and the Development of DVSN*, DOMESTIC VIOLENCE SERVS. NETWORK, INC. (Aug. 21, 2023), <https://www.dvsn.org/august-2023-the-long-history-of-domestic-violence-and-the-development-of-dvsn/>.

offenses.<sup>64</sup> Senator and Chairman of the Committee on the Judiciary at the time, Joe Biden, stated in a Senate Hearing on June 20, 1990, three broad goals of the bill: “The first goal is to try and make streets a little bit safer for women; the second goal is to make their homes a little bit safer; and, the third goal is to protect their civil rights.”<sup>65</sup> He admitted at the time that the bill was only a “positive step in changing people’s attitudes”—not a complete solution—but has continued to call VAWA his “proudest legislative achievement.”<sup>66</sup>

Since its enactment, Congress has reauthorized VAWA multiple times: in 2005 to expand its protections to victims of dating violence and stalking;<sup>67</sup> in 2013 to include LGBTQ individuals, Native Americans, and immigrants;<sup>68</sup> and in 2022 to narrow the “boyfriend loophole,” which restricted firearm access for abusive partners.<sup>69</sup>

Although these developments represent progress in protecting survivors, ongoing legal reform remains essential to ensure comprehensive and equitable protections across the United States.<sup>70</sup> Courts have declined to recognize a fundamental constitutional right to be free from private acts of violence, significantly limiting justice for survivors.<sup>71</sup> At the same time, courts and lawmakers have acknowledged, as a matter of policy rather than constitutional mandate, that protecting individuals from domestic violence is a core

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<sup>64</sup> See Kemper & Sacco, *supra* note 62 (explains that VAWA impacted federal investigations and prosecutions of violence against women by establishing new offenses and penalties for interstate violations of protection orders and stalking, mandating restitution for federal sex offenses, and creating civil remedies for victims).

<sup>65</sup> See *Legislation to Reduce the Growing Problem of Violent Crime Against Women: Hearing Before the S. Comm. On the Judiciary*, 101st Cong., S. Hrg. 101-939, pt. 1 (1990) (statement of Sen. Biden, Chairman, Sen. Comm. on the Judiciary).

<sup>66</sup> See *id.*; see also Darlene Superville & Colleen Long, *Watch: Biden Delivers Remarks on 30th Anniversary of Violence Against Women Act*, PBS NEWS, <https://www.pbs.org/newshour/politics/watch-live-biden-delivers-remarks-30th-anniversary-of-violence-against-women-act> (last updated Sept. 12, 2024).

<sup>67</sup> See DOMESTIC VIOLENCE SERVS. NETWORK, INC., *supra* note 63.

<sup>68</sup> See *US: Violence Against Women Act Renewed, Lessons from Renewal Process Should Spur Further Reforms*, HUM. RTS. WATCH (Feb. 28, 2013, 2:48 PM), <https://www.hrw.org/news/2013/02/28/us-violence-against-women-act-renewed>.

<sup>69</sup> See DOMESTIC VIOLENCE SERVS. NETWORK, INC., *supra* note 63 (“VAWA’s next reauthorization passed the House of Representatives in 2019 but stalled in the Senate over language closing the ‘boyfriend loophole’ by prohibiting those convicted of abusing, assaulting, or stalking a current or former dating partner (not just a spouse, cohabitant, or coparent) from owning a firearm.”).

<sup>70</sup> See generally *Violence Against Women in the United States and the State’s Obligation to Protect*, BATTERED WOMEN’S JUST. PROJECT (Jan. 21, 2011), <https://bwjp.org/site-resources/violence-against-women-in-the-united-states-and-the-states-obligation-to-protect/>.

<sup>71</sup> See *Deshaney v. Winnebago Cnty. Dep’t of Soc. Servs.*, 489 U.S. 189, 203 (1989) (holding that the Due Process Clause of the Fourteenth Amendment does not require the state to protect individuals from private acts of violence, even where the state was aware that a child faced severe abuse by a parent).

governmental responsibility.<sup>72</sup> Still, legal protections remain uneven and incomplete.<sup>73</sup>

As of 2013, VAWA provides specific housing protections, including prohibitions on evicting or denying housing based solely on a tenant's status as a victim of domestic violence, dating violence, sexual assault, or stalking.<sup>74</sup> Further, tenants residing in housing covered by VAWA can request an emergency transfer out of their residence.<sup>75</sup> This provision creates a way for survivors to be transferred to another unit if they (1) request a transfer and (2) believe they are in imminent danger of further violence if they remain in the unit, or were a victim of sexual assault on the premises within the previous ninety days.<sup>76</sup> However, because VAWA only applies to federally subsidized housing, tenants in the private rental market remain outside its coverage.<sup>77</sup> This leaves a substantial portion of survivors (many of whom do qualify for federal housing assistance, but do not receive it) vulnerable to eviction, discrimination, or coercion by private landlords, who are not subject to VAWA's housing protections.<sup>78</sup> The resulting gap in coverage is considerable, given that 90% of renters in the United States rely on private housing.<sup>79</sup>

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<sup>72</sup> *Nicholson v. Williams*, 203 F. Supp. 2d 153, 269 (E.D.N.Y. 2002) (distinguishing *DeShaney* and observing that, as a matter of policy, the government has a responsibility to protect victims of domestic violence from abusive partners: "Just as the government has a responsibility to protect children from an abusive parent, so too does the government have a responsibility to protect a victim of domestic violence from her partner[.]").

<sup>73</sup> See generally BATTERED WOMEN'S JUST. PROJECT, *supra* note 70; Resnick, *supra* note 32.

<sup>74</sup> See Kemper & Sacco, *supra* note 62.

<sup>75</sup> 24 C.F.R. § 5.2005 (2000).

<sup>76</sup> See *id.*

<sup>77</sup> See generally *VAWA Housing Protections*, WOMENSLAW.ORG, <https://www.womenslaw.org/laws/federal/vawa-housing-protections/basic-information/how-does-vawa-protect-housing-rights-victims> (last visited Dec. 29, 2025) (only tenants in federally subsidized housing—such as public housing, Section 8 vouchers, or units receiving federal housing assistance—are eligible for VAWA housing protections, leaving private-market tenants unprotected because private landlords do not have to follow the protections).

<sup>78</sup> See generally *Federal Rental Assistance Fact Sheets*, CTR. ON BUDGET & POL'Y PRIORITIES, <https://www.cbpp.org/research/housing/federal-rental-assistance-fact-sheets#US> (last updated Jan. 23, 2025) ("[B]ut 4 in 10 low-income people in the United States are experiencing homelessness or pay over half their income for rent. Most don't receive federal assistance due to limited funding."); *77% of Low-Income Renters Needing Federal Rental Assistance Don't Receive It*, CTR. ON BUDGET & POL'Y PRIORITIES, <https://www.cbpp.org/77-of-low-income-renters-needing-federal-rental-assistance-dont-receive-it> (last visited Jan. 4, 2026) ("Out of 22.9 million households needing assistance, 17.6 million did not receive it."); *Lost Housing, Lost Safety: Survivors of Domestic Violence Experience Housing Denials and Evictions Across the Country*, NAT'L L. CTR. ON HOMELESSNESS & POVERTY (Feb. 2007), <https://homelesslaw.org/wp-content/uploads/2018/10/Lost-Housing-Lost-Safety.pdf> (documenting that victims of domestic violence are frequently denied housing because of the abuse itself, including denials in both federally subsidized and private housing markets).

<sup>79</sup> Cf. *How Many Subsidized Housing Units Are Available in the United States?*, USAFACTS, <https://usafacts.org/answers/how-many-subsidized-housing-units-are-available/country/united-states/> (last visited Dec. 29, 2025) (In 2022, there were approximately 45 million rental units nationwide. Subsidized housing units only accounted for about 4.5 million of those units. Therefore, only about 10% of the 45 million renter households live in federally subsidized housing in the United States).

Even where VAWA applies, enforcement gaps persist.<sup>80</sup> Landlords may exploit procedural complexities or legal loopholes, hindering the purpose of VAWA even more.<sup>81</sup> Some landlords have evicted survivors by using pretexes like nuisance violations or damage caused by abusers.<sup>82</sup> In other instances, landlords have denied survivors housing altogether or evicted them due to concerns about potential disturbances or their status as victims.<sup>83</sup>

VAWA has improved housing stability for some survivors of intimate partner violence, but it is not a comprehensive housing solution.<sup>84</sup> VAWA's scope is limited, its application is uneven, and it is still vulnerable to loopholes.<sup>85</sup> To mitigate these shortcomings, both state and federal governments must prioritize policies that promote survivor safety and reduce barriers to escape, because housing instability is one of the most common reasons for remaining in or returning to an abusive relationship.<sup>86</sup> A proper solution includes not only strengthening existing protections but also creating new laws that address the realities survivors face.<sup>87</sup>

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<sup>80</sup> See generally Members of the National VAWA Housing Working Group, *Re-authorization of Violence Against Women Act, Testimony for the Record*, ACLU 1, 8 (Mar. 7, 2019), submitted to the Subcommittee on Crime, Terrorism, and Homeland Security, [https://www.aclu.org/sites/default/files/field\\_document/vawa\\_housing\\_working\\_group\\_-\\_vawa\\_2019\\_testimony\\_final\\_3.13.19.pdf](https://www.aclu.org/sites/default/files/field_document/vawa_housing_working_group_-_vawa_2019_testimony_final_3.13.19.pdf) (“Many of the protections enshrined in VAWA are inconsistently implemented at best, and at worst, ignored.”).

<sup>81</sup> See, e.g., *Gorsuch Homes, Inc. v. LeMasters*, 2016 Ohio App. LEXIS 2033\* (Ohio Ct. App. May 31, 2016) (upholding an eviction based on a claim that the tenant allowed a trespasser onto the property, despite the tenant being a victim of domestic violence; the dissent argued that such eviction notices exploit loopholes by lacking clear details and fail to protect victims of domestic violence).

<sup>82</sup> See *EHOC, ACLU Urge 6 St. Louis County Municipalities to Drop Laws That Punish Domestic Violence Victims*, ACLU Mo. (Jan. 24, 2019, 11:30 AM), <https://www.aclu-mo.org/en/news/ehoc-aclu-urge-6-st-louis-county-municipalities-drop-laws-punish-domestic-violence-victims> (describing how Rosetta Watson, a domestic violence survivor, was evicted and banned from living in Maplewood, Missouri, for 6 months after calling the police multiple times for help under the city's nuisance ordinance); NAT'L HOUS. L. PROJECT, *supra* note 56.

<sup>83</sup> NAT'L L. CTR. ON HOMELESSNESS & POVERTY, *supra* note 78, at 10 (“In an example from Texas, a woman was denied admission to public housing explicitly because she was a domestic violence victim. She was told ‘not to bother applying’ because the housing authority did not want people with ‘that kind of history’ living in Public Housing. Two other Texas women were denied public housing admission because of previous property damage or wrongful arrest resulting from domestic violence against them.”).

<sup>84</sup> See, e.g., *How NYCHA Puts the Lives of Gender-Based Violence Survivors at Risk by Delaying Emergency Transfers*, LEGAL SERVS. NYC (2024), <https://www.legalservicesnyc.org/wp-content/uploads/2024/12/LSNYCs-Trapped-in-Danger-Report-2024.pdf> (despite having the legal right to emergency transfers under VAWA, nearly 2,000 survivors remained on waitlists as of September 2024).

<sup>85</sup> See generally Members of the National VAWA Housing Working Group, *supra* note 80.

<sup>86</sup> See generally *Learn About Policies and Legislation for a Future Free of Abuse.*, NAT'L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/stakeholders/policies/> (last visited Aug. 5, 2025); VISION HOUSE, *supra* note 11.

<sup>87</sup> See generally *Recommended Legal Reforms for Inclusion in the U.S. National Action Plan on Gender-Based Violence*, ABA COMM. ON DOMESTIC & SEXUAL VIOLENCE (2021), [https://www.americanbar.org/content/dam/aba/publications/domestic-violence/aba\\_nap-gbv\\_report.pdf](https://www.americanbar.org/content/dam/aba/publications/domestic-violence/aba_nap-gbv_report.pdf).

#### D. State Legislation and the Role of Property Law

At the state level, there have been growing efforts to address the housing needs of domestic violence survivors.<sup>88</sup> Recognizing that VAWA protections do not extend to tenants in housing with private landlords, many state legislators have enacted statutes to fill this gap.<sup>89</sup> Most important for this discussion are early lease termination laws which remove penalties for ending a lease early when one is a victim or in imminent danger of becoming a victim of domestic violence, sexual assault, or stalking.<sup>90</sup> These laws are designed to reduce the risk of further harm, alleviate financial burden, and promote housing stability at a pivotal moment in a survivor's life.<sup>91</sup>

While not legally equivalent, VAWA's emergency transfer provisions and state early lease termination statutes serve similar purposes.<sup>92</sup> Unlike VAWA's relatively uniform federal framework, state early lease termination statutes vary widely in structure, clarity, accessibility, and effectiveness.<sup>93</sup> Both are designed to help survivors escape danger and secure safer housing without facing traditional legal or financial ramifications.<sup>94</sup> As a result, differences in notice periods, documentation requirements, remaining obligations, and general scope can either facilitate a safe exit or function as another barrier.<sup>95</sup>

The legal structure of American federalism contributes, in part, to this inconsistency and variation.<sup>96</sup> Under the Tenth Amendment, states have broad

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<sup>88</sup> See, e.g., Sequeira, *supra* note 10.

<sup>89</sup> See generally *id.* (discussing pre-and-contemporaneous COVID-19 related changes to VAWA requirements) (“More than a dozen states have passed measures in the past five years bolstering rental protections for survivors by allowing them to break their leases if they provide evidence of stalking, sexual assault or an abusive domestic relationship.”).

<sup>90</sup> See generally *Housing Rights of Domestic Violence and Sexual Assault Survivors: A State and Local Law Compendium*, NAT'L HOUS. L. PROJECT (Feb. 2024), <https://www.nhlp.org/wp-content/uploads/2024-NHLP-Compendium-of-Housing-Rights-for-DVS.pdf>.

<sup>91</sup> See generally Sequeira, *supra* note 10 (lease termination laws empower survivors to leave abusive situations, alleviate financial burdens, and improve housing security; quoting advocates discussing how retraumatization and instability result when survivors are not given viable options or support to escape).

<sup>92</sup> Compare WOMENSLAW.ORG, *supra* note 77 (explaining how emergency housing transfers due to abuse work under VAWA), with *Washington Housing Laws*, WOMENSLAW.ORG, <https://www.womenslaw.org/laws/wa/housing-laws> (last visited Aug. 5, 2025) (describing Washington's early lease termination protections for domestic violence survivors).

<sup>93</sup> See generally NAT'L HOUS. L. PROJECT, *supra* note 90.

<sup>94</sup> See generally McLaughlin & Fox, *supra* note 52, at 6-9 (VAWA's emergency transfer provisions are meant to protect victims who face continued threats or violence by enabling them to move to safer housing without losing assistance or facing eviction—highlighting how the policy helps survivors transition “from crisis to stability” through emergency transfers and transitional housing support); Sequeira, *supra* note 10.

<sup>95</sup> See generally *id.* (compiling current state and local housing protections for domestic violence survivors as of September 2023).

<sup>96</sup> See generally Noah M. Kazis, *The Failed Federalism of Affordable Housing: Why States Don't Use Housing Vouchers*, 121 MICH. L. REV. 221, 226 (2022) (arguing that the US federal structure leaves individual's dependent on state-level policy design, and that “the participation of states and cities has generated little variation, experimentation, or contestation despite the real need for these federalism values.”).

police powers to regulate public health, safety, and general welfare, which traditionally include property law and landlord-tenant relationships.<sup>97</sup> Thus, property law and landlord-tenant relationships are governed primarily by state law.<sup>98</sup> States have broad discretion to enact laws that are transformative for survivors or laws that are ineffective, unclear, or entirely absent.<sup>99</sup> While this decentralized structure allows states to be experimental and tailor their laws to local needs, it also gives rise to a fragmented system.<sup>100</sup> Consequently, a survivor's ability to terminate a lease—and the process required to do so—depends on the state in which they reside.<sup>101</sup>

### III. MISSOURI'S LEGAL LANDSCAPE FOR DOMESTIC VIOLENCE SURVIVORS

#### A. The Scope of Housing Insecurity Among Survivors in Missouri

Domestic violence remains a leading cause of homelessness among women and families,<sup>102</sup> and Missouri is no exception. In 2012, there were 41,494 domestic violence-related incidents reported in Missouri, with 9,354 involving cohabitants.<sup>103</sup> In 2023, the Missouri Coalition Against Domestic and Sexual Violence (MOCADSV) recorded 43,078 crisis intervention contacts, reflecting the high demand for emergency services, advocacy, and guidance.<sup>104</sup> Current resources fall far short of demand: while 3,745 adults received shelter, 19,901 others had their requests unmet.<sup>105</sup> The pervasiveness of domestic violence,

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<sup>97</sup> See U.S. CONST. amend. X.

<sup>98</sup> See generally *id.*

<sup>99</sup> See Charlotte Gerchick, *Where is Home? The Challenge of Finding Safe Housing Via Early Lease Termination for Victims of Domestic Violence*, 26 WASH. & LEE J. CIV. RTS. & SOC. JUST. 279, 317 (2019).

<sup>100</sup> See Randy E. Barnett, *Article I, Sec. 8: Federalism and the Overall Scope of Federal Power: Why Federalism Matters*, NAT'L CONST. CTR., <https://constitutioncenter.org/the-constitution/articles/article-i/section/8712> (last visited Dec. 29, 2025).

<sup>101</sup> See *id.*; see generally NAT'L HOUS. L. PROJECT, *supra* note 90 (resource dedicated to disseminating state specific details for housing protections of survivors suggests the varying differences in laws across states).

<sup>102</sup> See e.g., Behmerwohld, *supra* note 8; NAT'L COAL. FOR THE HOMELESS, *supra* note 9; VISION HOUSE, *supra* note 11.

<sup>103</sup> *Crime in Missouri 2012*, MO. STAT. ANALYSIS CTR.: MO. STATE HIGHWAY PATROL RSCH. & DEV. DIV. (2012), <https://www.mshp.dps.missouri.gov/MSHPWeb/SAC/pdf/2012CrimeInMO.pdf>.

<sup>104</sup> 2023 MOCADSV Member Agencies' Domestic Violence Statewide Statistics, MO. COAL. AGAINST DOMESTIC & SEXUAL VIOLENCE, [https://mocadsv.coalitionmanager.org/resourcemanager/resourcefile/details/1234?&page\\_y=577.3984375](https://mocadsv.coalitionmanager.org/resourcemanager/resourcefile/details/1234?&page_y=577.3984375) (last visited Dec. 28, 2025).

<sup>105</sup> *Id.*

intersection with homelessness, shortage of resources, and broader societal impact demonstrate the urgent need for stronger legal protections.<sup>106</sup>

### B. Missouri's Statutory Tools for Domestic Violence Survivors

Missouri has enacted various laws designed to protect domestic violence survivors, particularly in securing immediate safety.<sup>107</sup> One of the primary legal remedies available to survivors in Missouri is the order of protection under Section 455.050<sup>108</sup> of the Missouri Revised Statutes. These orders may prohibit contact, remove abusers from shared residences, or offer temporary relief concerning finances, housing, or child custody.<sup>109</sup> If an Order of Protection is granted, it may also include tailored provisions requiring the abuser to relinquish firearms, undergo a substance abuse evaluation, or attend an intervention program.<sup>110</sup> Survivors can seek these Orders without an attorney and at no cost,<sup>111</sup> and violations of such Orders can carry criminal penalties.<sup>112</sup> However, many Protective Orders are temporary<sup>113</sup> and may still be defied by abusers.<sup>114</sup>

Missouri's criminal code includes four degrees of domestic violence, allowing prosecutors to respond to varying levels of abuse.<sup>115</sup> The fourth degree, added in 2017, broadened domestic violence protection by expanding criminal liability to include non-physical or non-life-threatening incidents.<sup>116</sup> Additionally, law enforcement officers are required to inform victims of available resources and are supposed to provide or arrange transportation for the abused party to shelters

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<sup>106</sup> See VISION HOUSE, *supra* note 11.

<sup>107</sup> See, e.g., MO. REV. STAT. §§ 455.010, .050, .080 (2024).

<sup>108</sup> MO. REV. STAT. § 455.050 (2024).

<sup>109</sup> See generally *Missouri Restraining Orders*, WOMENSLAW.ORG, <https://www.womenslaw.org/laws/mo/restraining-orders> (last visited Dec. 28, 2025).

<sup>110</sup> See, e.g., *File for an Order of Protection*, ST. LOUIS CNTY. CTS., <https://stlcountycourts.com/forms/file-for-an-order-of-protection/> (last visited Dec. 28, 2025).

<sup>111</sup> See generally WOMENSLAW.ORG, *supra* note 109.

<sup>112</sup> See generally *id.*

<sup>113</sup> See *Orders of Protection-Adult, Information for Both Parties*, MO. CTS. (Nov. 2021), <https://www.courts.mo.gov/file.jsp?id=69655> (Under Missouri law, there are two types of protective orders. An *ex parte* order of protection may be issued by a judge without notice to the abuser. It remains effective until a full hearing can be held, typically within fifteen days. At the hearing, a judge can issue a full order of protection, which generally lasts between 180 days and one year. The court has discretion to impose a longer order, lasting up to ten years. These longer orders are rare because they require specific written findings and the abuser must be given notice and provided the opportunity to be heard).

<sup>114</sup> See, e.g., Laura Bauer, *Woman's Calls to KC Police Failed to Stop Domestic Violence. Can That Change Now?*, KAN. CITY STAR, <https://www.kansascity.com/news/local/article308868465.html> (last updated July 9, 2025, 12:48 PM) (providing a survivor's story where she had an order of protection against her shooter, but a shooting still occurred).

<sup>115</sup> *Missouri Domestic Violence Laws—6 Things You Need to Know*, ROSE LEGAL SERVS. (Dec. 15, 2020), <https://www.roselegalservices.com/missouri-domestic-violence-laws-6-things-you-need-to-know/>.

<sup>116</sup> MO. REV. STAT. § 565.076(1)(6) (2024) (extends DV protections significantly: "The person knowingly attempts to cause or causes the isolation of such domestic victim by unreasonably and substantially restricting or limiting his or her access to other persons, telecommunication devices or transportation for the purpose of isolation.").

or hospitals.<sup>117</sup> However, Missouri does not have a mandatory arrest law, and enforcement practices vary by jurisdiction, limiting the consistency and reliability of protections across the state.<sup>118</sup>

Despite these mechanisms, Missouri provides limited protections at the intersection of domestic violence and housing. Some housing-related relief is available through court orders, such as restraining an abuser from a dwelling, requiring an abuser to make rent or mortgage payments, or prohibiting the abuser from taking actions regarding joint property.<sup>119</sup> However, these remedies are discretionary, short-term, and rarely provide lasting housing security.

Even when survivors obtain legal protections, they often remain tied to their abusers—whether legally, financially, or through ongoing threats, control, or fear.<sup>120</sup> Protective orders often prohibit an abuser from returning to the home, but violations are common.<sup>121</sup> Abusers still know the survivor’s location unless the survivor was able to relocate.<sup>122</sup> When law enforcement fails to respond, protections expire, or shelters are full, survivors can be left without safe or sustainable options to relocate or feel protected in their home if they must remain.<sup>123</sup>

#### IV. MO. REV. STAT. § 441.920 – TENANT PROTECTIONS FOR SURVIVORS OF DOMESTIC VIOLENCE

In 2019, Missouri enacted Section 441.920 (Tenancy of victim or potential victim of domestic violence, sexual assault, or stalking—Affirmative defenses—Documentation), which establishes certain housing rights for survivors of domestic

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<sup>117</sup> MO. REV. STAT. §§ 455.080(4), (5) (2024).

<sup>118</sup> ROSE LEGAL SERVS., *supra* note 115 (explaining that in other jurisdictions, if law enforcement is sought for a domestic violence incident, an arrest must be made).

<sup>119</sup> *See* MO. REV. STAT. §§ 455.045, .050 (2024).

<sup>120</sup> *See, e.g., Humansville Man Faces Multiple Felonies in Violent Domestic Case Involving Arson Attempt*, EL DORADO SPRINGS SUN (Mar. 26, 2025), <https://eldoradospringsmo.com/front-page/humansville-man-faces-multiple-felonies-in-violent-domestic-case-involving-arson-attempt/> (highlighting an instance when a survivor had an active court order barring the abuser from contact, but he returned to the survivor’s home and “repeatedly pressured her to drop the order.”).

<sup>121</sup> *See, e.g., Jackie Rehwald, ‘I Took My Life Back’: Domestic Violence Survivor Shares Her Story*, SPRINGFIELD NEWS LEADER, <https://www.news-leader.com/story/news/local/ozarks/2021/01/15/missouri-domestic-violence-survivor-story-lifetime-protection-bill-victim/4140329001/> (last updated Jan. 15, 2021, 1:09 PM) (“Saylor left her ex-husband in June 2011 and divorced him in 2012. But that didn’t end the domestic violence. Saylor’s ex continued to stalk and harass her. He’s violated orders of protection multiple times, resulting in seven probation violations.”).

<sup>122</sup> *See generally Safety Planning: In a Confidential Address*, WOMENSLAW.ORG, <https://www.womenslaw.org/safety-planning/safety-confidential-address> (last updated May 23, 2019) (provides steps that a survivor can take to remain safe in their home and ways to keep an address confidential after relocating).

<sup>123</sup> *See, e.g., These Women Survived Domestic Violence. Now They’re Taking a Stand to Help Others*, AMNESTY INT’L (Oct. 24, 2019), <https://www.amnesty.org/en/latest/news/2019/10/gun-violence-report/> (sharing five survivor stories from Louisiana, including one that highlights the consequences of an expired protective order “Even with the protective order in place, he stalked and harassed me. I was still too scared to call the police. He barged into my house and threatened to kill himself, to kill other people. I had entered a new relationship and that made things 10 times worse. Those few years after leaving were hell. I was unaware that I could renew my protective order, so it expired.”).

violence.<sup>124</sup> The statute contains several provisions intended to prevent discrimination and offer an affirmative defense for lease termination.

The following sections are relevant.

Section 2 of the statute prohibits housing discrimination against tenants or applicants based on their status as a victim or potential victim of domestic violence.<sup>125</sup> However, exceptions allow landlords to act if the tenant voluntarily allowed the abuser onto the premises or if the landlord reasonably believes the abuser poses a threat to the property.<sup>126</sup>

Section 3 provides that a survivor may raise an affirmative defense to avoid liability for rent after vacating the premises due to domestic violence.<sup>127</sup> To assert this defense, the tenant must show they were a victim or in imminent danger of becoming a victim of domestic violence, notify the landlord, and provide any requested documentation.<sup>128</sup>

Section 4 of the statute outlines the documentation requirements.<sup>129</sup> If a landlord requests proof, the tenant must provide either (1) a signed statement from a victim service provider, health care professional, or mental health professional, attesting that the tenant has experienced domestic violence,<sup>130</sup> or (2) documentation from a law enforcement agency (including a police report), court, or administrative agency.<sup>131</sup>

Section 6 permits landlords to charge a “reasonable termination fee,” but the statute does not define what qualifies as reasonable.<sup>132</sup>

### A. Statute Inadequacy — Gaps in Legal Protections for Survivors

Early lease termination can provide a critical pathway to safety, empower survivors to relocate, manage their legal obligations, and regain control over their circumstances. While Missouri’s current statute reflects a legislative intent to support survivors, it is not structured to fully meet their needs.<sup>133</sup> Rather than establishing a proactive right, the statute offers an affirmative defense—an approach that can discourage survivors from seeking protection at all.<sup>134</sup> The

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<sup>124</sup> MO. REV. STAT. § 441.920 (2024).

<sup>125</sup> MO. REV. STAT. § 441.920.2 (2024).

<sup>126</sup> MO. REV. STAT. § 441.920.2(1), (2) (2024).

<sup>127</sup> MO. REV. STAT. § 441.920.3 (2024).

<sup>128</sup> *Id.*

<sup>129</sup> MO. REV. STAT. § 441.920.4 (2024).

<sup>130</sup> *Id.* § 441.920.4(1) (2024).

<sup>131</sup> MO. REV. STAT. § 441.920.4(2) (2024).

<sup>132</sup> MO. REV. STAT. § 441.920.6 (2024).

<sup>133</sup> *See generally* MO. REV. STAT. § 441.920 (2024) (provides only an affirmative defense, not automatic relief; conditioning protection on third-party documentation and permitting a landlord-imposed termination fee).

<sup>134</sup> *See, e.g.,* Lynn, *supra* note 15 (survivors are often deterred from seeking help due to fear of retraumatization, lack of control in the courtroom, and a legal system that can feel biased, disbelieving, or abusive).

statute's structural limitations and procedural ambiguities undermine its effectiveness as a legal tool for several reasons.

First, the statute is puzzling to understand and raises accessibility concerns. Its legal language is complex, the procedural steps are unclear, and the process is unpredictable. By contrast, principles of procedural justice in domestic cases emphasize the use of plain language in protective legal mechanisms.<sup>135</sup> Survivors already facing trauma may therefore find the statute inaccessible or intimidating, leading to a sense of overwhelm.<sup>136</sup>

Landlord discretion further weakens the statute's effectiveness. Section 2 allows landlords to deny protections if they "reasonably believe[] that a person named in any documentation listed in subsection 4 of this section poses a threat to the safety of the other occupants or the property[,] and that reasonable landlord standard introduces inconsistency into the survivor's path to a safer home."<sup>137</sup> The standard can enable personal bias, misunderstanding of domestic violence, or the motivations of a landlord to influence outcomes for survivors.<sup>138</sup> Whether documentation is required is left entirely to the landlord's discretion.<sup>139</sup> The statute provides no clear standards or timelines for such requests, creating uncertainty for tenants.<sup>140</sup> In emergencies, the absence of documentation requests may facilitate quicker escapes, but may also hurt survivors later in court when they do not have sufficient proof. Conversely, when landlords do decide to request documentation, the delays in termination and repeated interactions expose survivors to additional stress, potential retaliation, and continued risk.

The statute also fails to clarify when lease termination takes effect.<sup>141</sup> Without a defined timeline, survivors are left uncertain about when their rent liability ends. This ambiguity is particularly harmful in emergencies, for those with financial concerns, or mental health.<sup>142</sup> Survivors who want to avoid court

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<sup>135</sup> See generally Danielle Malangone, *Integrating Procedural Justice in Domestic Violence Cases*, CTR. FOR CT. INNOVATION (Nov. 2016), [https://www.innovatingjustice.org/wp-content/uploads/2016/10/DVFactSheet\\_November2016\\_IntegratingPJinDVCases.pdf](https://www.innovatingjustice.org/wp-content/uploads/2016/10/DVFactSheet_November2016_IntegratingPJinDVCases.pdf) (complex legal language and unclear procedures undermine procedural justice in domestic violence cases, particularly for trauma-impacted litigants, and recommending the use of plain language to improve accessibility and understanding).

<sup>136</sup> See, e.g., VISION HOUSE, *supra* note 11 ("[N]avigating complex . . . systems can be overwhelming, especially for those dealing with trauma.").

<sup>137</sup> MO. REV. STAT. § 441.920.2 (2024).

<sup>138</sup> See *E.M. v. Conifer LLC*, 208 N.Y.S.3d 815 (City Ct. 2024) (finding a landlord violated state and federal domestic violence housing protections by imposing lease termination policies that delayed a survivor's relocation, where the delay stemmed from the landlord's own policies, showing how personal judgment and motivations can impact a survivor's safety) (Note: Though this is a New York case, the reasoning is applicable in understanding the limits and frustrations of the Missouri statute).

<sup>139</sup> MO. REV. STAT. § 441.920.4 (2024).

<sup>140</sup> See, e.g., *id.* (Demonstrating that Missouri's statute provides for no time specifications once a request is submitted).

<sup>141</sup> See generally MO. REV. STAT. § 441.920 (2024).

<sup>142</sup> See generally Michael G. Wessells & Kathleen Kostelny, *The Psychosocial Impacts of Intimate Partner Violence Against Women in LMIC Contexts: Toward a Holistic Approach*, 19 INT'L J. ENV'T RSCH. & PUB. HEALTH 1 (2022); Yvette Howard, *The Impact of Domestic Violence on Mental Health*, BRIGHTER TOMORROW (Feb. 21, 2023), <https://brightertomorrowtherapy.com/the-impact-of-domestic-violence-on-mental-health/>.

processes, fear uncertainty, or cannot afford representation are burdened by this shortfall.<sup>143</sup>

Additional barriers arise from the documentation requirements. While the statute allows for various forms of proof, it lacks clarity regarding what is sufficient.<sup>144</sup> Survivors in rural or underserved areas may struggle to access qualifying professionals, while others face logistical obstacles such as transportation, childcare, or communication tools.<sup>145</sup> Even where survivor advocates exist, understaffing and overwhelming demand make can make accessing resources onerous or unrealistic.<sup>146</sup> The alternative—relying on law enforcement records—can be equally problematic. Many survivors fear police involvement, distrust the system, or worry about retaliation.<sup>147</sup>

Finally, Section 6 permits landlords to impose a “reasonable” termination fee without defining what reasonable means.<sup>148</sup> This vagueness in the statute is especially harmful given the financial strain many survivors bear and the high prevalence of economic abuse.<sup>149</sup> Granting landlords such broad discretion over fees risks exploitation of survivors and may deter them from seeking protection under the statute. Landlords are financially motivated to recover losses, and without clear limits, they may impose burdensome costs on survivors.<sup>150</sup>

## V. AFFIRMATIVE DEFENSE STATUTES UNDERMINE THE PURPOSE OF EARLY LEASE TERMINATION

The structure of early lease termination statutes impacts their accessibility and effectiveness.<sup>151</sup> A majority of states provide a survivor with a procedural right to terminate their lease, but Missouri’s statute functions as an affirmative defense.<sup>152</sup> Missouri’s framework leaves serious consequences for survivors.

Under Missouri law, an affirmative defense must be asserted in a legal answer and include a “short and plain statement of the facts showing that the

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<sup>143</sup> See generally *id.*

<sup>144</sup> See MO. REV. STAT. § 441.920.4 (2024).

<sup>145</sup> See generally Rose et al., *supra* note 37; Mary K. Wolfe et al., *Transportation Barriers to Health Care in the United States: Findings From the National Health Interview Survey, 1997-2017*, 110 AM. J. PUB. HEALTH 815 (2020).

<sup>146</sup> See generally MO. COAL. AGAINST DOMESTIC & SEXUAL VIOLENCE, *supra* note 104 (In 2023 there were 19,901 adults who requested shelter, but their needs were unmet due to lacking resources).

<sup>147</sup> See generally Malangone, *supra* note 135 (“Many domestic violence litigants may have little faith in the justice system and may perceive the system to be biased or corrupt.”).

<sup>148</sup> MO. REV. STAT. § 441.920.6 (2024).

<sup>149</sup> Chakrabarti, *supra* note 57; see also Vagianos, *supra* note 5.

<sup>150</sup> See Walsh, *supra* note 43 (“Based on our experience with campus landlords, some would oppose allowing a victim to terminate their lease early because it would hurt their bottom line,” Hegarty said in an email. “That said, we have had landlords who have been willing to allow a victim out of a lease early without penalty. But, they are the exception rather than the rule.”).

<sup>151</sup> See Gerchick, *supra* note 99, at 317.

<sup>152</sup> See generally NAT’L HOUS. L. PROJECT, *supra* note 90; compare NEV. REV. STAT. § 118A.345 (“Notwithstanding any provision in a rental agreement to the contrary, if a tenant, cotenant or household member is the victim of domestic violence, harassment, sexual assault or stalking, the

pleader is entitled to relief.”<sup>153</sup> It is used by a defendant to avoid liability, even if the plaintiff’s claims are proven.<sup>154</sup> This means tenants cannot confidently end their lease by following a clearly defined process. Instead, they must be prepared to defend their decision to leave in court if sued for breach, unpaid rent, or damages.<sup>155</sup> This reactive model undermines the law’s protective intent, increases a survivor’s chance of litigation, and deters them from seeking safety.

By contrast, a proactive statutory right allows the lease to terminate by operation of law once the tenant abides by specific requirements.<sup>156</sup> The procedure typically includes giving notice, providing documentation, and vacating the unit.<sup>157</sup> Litigation can still occur, but the burden shifts: Instead of a survivor proving abuse, a landlord must prove noncompliance. This shift empowers survivors to act promptly, rather than waiting for judicial approval or fearing legal retaliation.

Missouri’s statute leaves too much uncertainty.<sup>158</sup> A tenant must prove by a preponderance of the evidence that: (1) they were a victim (or in imminent danger of becoming a victim) of domestic violence, sexual assault, or stalking, (2) they notified their landlord, and (3) they provided documentation if requested.<sup>159</sup> Even then, the statute allows landlords to impose a reasonable termination fee—undefined and discretionary—creating additional risk.<sup>160</sup>

This legal ambiguity created by the statute is not just technical. Many survivors fear retaliation, lack legal representation, or are confused by the process.<sup>161</sup> Landlord-tenant disputes often involve power imbalances: Landlords are far more likely to be represented by counsel, while tenants—who are disproportionately low-income women and people of color—often are not.<sup>162</sup>

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tenant or any cotenant may terminate the rental agreement by giving the landlord written notice of termination effective at the end of the current rental period or 30 days after the notice is provided to the landlord, whichever occurs sooner.”), with MO. REV. STAT. § 441.920.3 (“In any action brought by a landlord against a tenant . . . a tenant shall have an *affirmative defense* . . .”) (emphasis added).

<sup>153</sup> Patel v. Pate, 128 S.W.3d 873, 876 (Mo. Ct. App. 2004).

<sup>154</sup> *Id.*

<sup>155</sup> See MO. REV. STAT. § 441.920(3); WOMENSLAW.ORG, *supra* note 1.

<sup>156</sup> See, e.g., NEV. REV. STAT. § 118A.345 (2017), <https://www.leg.state.nv.us/nrs/nrs-118a.html#NRS118ASec345>; ARIZ. REV. STAT. § 33-1318(A), <https://www.azleg.gov/ars/33/01318.htm>; GA. CODE ANN. § 44-7-23 (2025).

<sup>157</sup> See generally NEV. REV. STAT. § 118A.345 (2017), <https://www.leg.state.nv.us/nrs/nrs-118a.html#NRS118ASec345>; ARIZ. REV. STAT. § 33-1318(A), <https://www.azleg.gov/ars/33/01318.htm>; GA. CODE ANN. § 44-7-23 (2025).

<sup>158</sup> See generally MO. REV. STAT. § 441.920.3 (2024).

<sup>159</sup> *Id.*

<sup>160</sup> See *id.* § 441.920.6.

<sup>161</sup> Resnick, *supra* note 32 (“Many domestic violence litigants are self-represented and lack information about the court process, how to present their case, or what information is admissible. It is not uncommon for those without counsel to leave court without understanding how to access resources to ensure their safety — such as obtaining a protective order — or, for litigants, what is expected of them to ensure compliance with a court order.”).

<sup>162</sup> Russell Engler, *Connecting Self-Representation to Civil Gideon: What Existing Data Reveal About When Counsel Is Most Needed*, 37 FORDHAM URB. L. J. 37, 47 (2010) (“Tenants rarely are represented by counsel, while the representation rate of landlords varies from low rates in some courts, to highs of 85-90% in others; 44 where landlord representation is high, the typical case pits a represented landlord against an unrepresented tenant. The demographics of the tenants reveal a

In most other states, early lease termination is structured as a procedural right: when tenants follow the statutory steps, the lease ends.<sup>163</sup> If a landlord believes the tenant failed to comply, they may still challenge it—but the dispute centers on procedure, not the survivor's abuse. This model does not eliminate landlord rights; it provides clarity and predictability for both parties.<sup>164</sup>

Missouri uses this proactive approach in section 41.944 of the Missouri Revised Statutes (Certain military service, termination of lease), which grants active-duty service members the right to terminate a lease upon compliance.<sup>165</sup> The procedural requirements include providing written notice to their landlord and supplying a copy of the official orders or a signed letter confirming the orders from a commanding officer.<sup>166</sup> The statute specifies how much notice must be provided (at least 15 days), the required documentation, and when payment and return of the security deposit must occur.<sup>167</sup> It imposes no requirement for court approval or litigation, and it does not condition the tenant's release from the lease on prevailing in a legal dispute.<sup>168</sup> This model—clear, administrative, and self-executing—respects the service member's need to relocate quickly and without financial penalty.<sup>169</sup>

Survivors of domestic violence also face similarly urgent circumstances and deserve the same clarity.<sup>170</sup> Missouri's current model—like those in Illinois, Kansas, and Wyoming—leaves survivors legally exposed.<sup>171</sup> To fulfill its protective purpose, section 441.920 should be restructured as a self-executing right.

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vulnerable group of litigants, typically poor, often women, and disproportionately racial and ethnic minorities.”)

<sup>163</sup> See generally WASH. REV. CODE ANN. § 59.18.575 (2022), <https://app.leg.wa.gov/rcw/default.aspx?cite=59.18.575>; see also *Application Assistant Lease Termination Process and Law*, ADDRESS CONFIDENTIALITY PROGRAM (May 2022), <https://dcs.colorado.gov/sites/dcs/files/Lease%20Termination%20Process%20%26%20Law.pdf>; NEB. REV. STAT. ANN. § 76-1431.01 (LexisNexis 2025).

<sup>164</sup> See, e.g., Gerchick, *supra* note 99, at 319-20.

<sup>165</sup> MO. REV. STAT. § 41.944 (1991).

<sup>166</sup> See generally *id.*

<sup>167</sup> *Id.*

<sup>168</sup> See generally *id.*

<sup>169</sup> See generally *id.* (describes the specific and definitive directives for service members ending their lease).

<sup>170</sup> See, e.g., *Legal Center*, WOMEN AGAINST ABUSE, <https://www.womenagainstabuse.org/services/legal-center> (last visited Dec. 29, 2025) (presents testimonials of grateful survivors that demonstrate the hole that organizations and attorneys must fill in order for DV victims to obtain the same protections as presented for military personnel).

<sup>171</sup> Compare MO. REV. STAT. § 441.920 (2019), with 735 ILL. COMP. STAT. ANN. 5/9-106.2 (2025), and KAN. STAT. ANN. § 58-25-137, and WYO. STAT. ANN. § 1-21-1303 (2025).

## VI. RECOMMENDATIONS FOR MISSOURI REFORM: A VICTIM-CENTERED APPROACH

### A. Proposed Statutory Changes to Missouri's Statute

Survivors in private housing—those unprotected by the federal Violence Against Women Act—remain at risk of being legally and financially bound to abusive households unless Missouri's statute offers clear, usable protections.<sup>172</sup> To better protect tenant survivors, the Missouri legislature should reform section 441.920 in two key ways: (1) restructure the statute to create a proactive right to terminate a lease, rather than an affirmative defense; and (2) adopt specific revisions to clarify, standardize, and strengthen the statute's procedural and substantive protections. The recommendations below—drawn from statutes in other states and original analysis—are proposed to improve the statute.

#### 1. Restructure the Statute as a Proactive Right

As argued in Part IV, *supra*, section 441.920 should function as a self-executing right, not an affirmative defense. If a tenant complies with the statute's notice and documentation requirements, the lease should terminate by law—without court intervention or exposure to rent liability.

#### 2. Define Timing Requirements

Missouri's current statute lacks defined timing requirements,<sup>173</sup> creating uncertainty for tenants and inconsistency in judicial interpretation. When early lease termination is framed as a proactive right, clearly established timelines are essential to ensure predictability, structure, and fairness for both landlords and tenants.

Most states include a timeframe within which a qualifying incident must have occurred prior to giving notice.<sup>174</sup> For example, Arizona, Maine, Oklahoma, and South Dakota require the qualifying incident to occur within thirty days.<sup>175</sup> At the other end of the spectrum, California allows a window of 180 days.<sup>176</sup> States

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<sup>172</sup> See, e.g., Walsh, *supra* note 43 (provides a survivor's thoughts on whether an early lease termination statute could have benefitted her if Ohio had one at the time: "Lauren said she 'would love to see something like' the Safe Homes Act in place. Had it been when she terminated her lease, it may have saved her the stress of financial or other backlash."). This account illustrates the real-world consequences that can occur in the absence of clear statutory protections and underscores the need for states like Missouri to adopt clear, usable early lease termination mechanisms.

<sup>173</sup> MO. REV. STAT. § 441.920.3 (2019); see also Agnew, *supra* note 11.

<sup>174</sup> See generally NAT'L HOUS. L. PROJECT, *supra* note 90 (compiles current state and local housing protections for domestic violence survivors as of September 2023).

<sup>175</sup> ARIZ. REV. STAT. § 33-1318(A), <https://www.azleg.gov/ars/33/01318.htm>; ME. REV. STAT. tit. 14, § 6001 (2025); OKLA. STAT. tit. 41, § 111 (2025); S.D. CODIFIED LAWS § 43-32-19.1 (2025).

<sup>176</sup> CAL. CIV. CODE § 1946.7(a) (West 2025).

like Massachusetts and Nevada use a ninety-day timeline, striking a reasonable balance between urgency and practicality.<sup>177</sup>

Missouri should adopt a similar standard of allowing tenants to terminate a lease within ninety days of the most recent incident of domestic violence, sexual assault, or stalking. This approach strikes a middle ground between other statutory frameworks (such as states requiring notice within thirty days of the incident and those permitting termination up to 180 days later) while accommodating the realities of delayed reporting, safety planning, and seeking support.

In addition to setting a window for when the incident must occur, the statute should also state how much notice a tenant must give a landlord before termination takes effect. This element can directly affect landlords and varies across states.<sup>178</sup> The majority require a thirty-day notice period between written notice and the lease's termination.<sup>179</sup> Some states, like Kentucky and North Carolina, require the termination to occur at least thirty days after the landlord receives notice.<sup>180</sup> Other states, like Arizona, Louisiana, and Tennessee, allow the parties to mutually agree on an earlier release date within thirty days of notice.<sup>181</sup> Some states even have different timelines depending on the lease type.<sup>182</sup> Washington's ninety-day notice period<sup>183</sup> is unusually burdensome for tenants, especially in emergency situations. Illinois, Kansas, and Wyoming include some sort of notice requirements even though their statutes operate as affirmative defenses; Missouri is the only affirmative defense statute without clarity on notice.<sup>184</sup>

Missouri should require a thirty-day notice period while allowing flexibility for an earlier termination if both parties agree. This structure protects landlords by guaranteeing a unit re-rent window, while also respecting the urgency survivors may face. It strikes a fair balance between safety and predictability.

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<sup>177</sup> MASS. GEN. LAWS ch. 186, § 24; NEV. REV. STAT. § 118A.345.

<sup>178</sup> See generally NAT'L HOUS. L. PROJECT, *supra* note 90.

<sup>179</sup> See generally *id.*

<sup>180</sup> KY. REV. STAT. § 383.300 (2025); N.C. GEN. STAT. § 42-45.1 (2025) ("Any protected tenant may terminate his or her rental agreement for a dwelling unit by providing the landlord with a written notice of termination to be effective on a date stated in the notice that is at least 30 days after the landlord's receipt of the notice.").

<sup>181</sup> ARIZ. REV. STAT. § 33-1318(A), <https://www.azleg.gov/ars/33/01318.htm>; LA. REV. STAT. § 9:3261.1; TENN. CODE ANN. § 66-7-112 (provides that once a tenant provides their landlord with the correct notice, they can agree on a time that the lease terminates, or it will terminate thirty days from the notice).

<sup>182</sup> See, e.g., ME. REV. STAT. tit. 14, § 6001(6)(D) (2025) ("A victim may terminate a lease early due to an incident or threat of domestic violence, sexual assault or stalking by providing: (1) *Seven days'* written notice and documentation required pursuant to paragraph H, in the case of a lease of *less than one year*; or (2) *Thirty days'* written notice and documentation required pursuant to paragraph H, in the case of a lease with a term of *one year or more.*") (emphasis added).

<sup>183</sup> WASH. REV. CODE ANN. § 59.18.575(1)(b).

<sup>184</sup> Compare MO. REV. STAT. § 441.920 (2019), with 735 ILL. COMP. STAT. ANN. 5/9-106.2 (2025), and KAN. STAT. ANN. § 58-25-137, and WYO. STAT. ANN. § 1-21-1303 (2025).

### 3. Documentation Requirements

Under the current statute, tenants must provide “any requested documentation” to the landlord—a vague and discretionary standard that grants landlords excessive control and introduces uncertainty into the process.<sup>185</sup> This discretion is especially dangerous, as it can deter survivors from seeking protection or result in arbitrary rejections.<sup>186</sup>

States vary widely in their approach to documentation.<sup>187</sup> Some require strict forms of proof, typically limited to protective orders, police reports, or court documentation.<sup>188</sup> Others have adopted more flexible models that allow for documentation from mental health professionals, advocates, or even attorneys.<sup>189</sup> Uniquely, North Carolina permits a broad range of certifiers but requires a safety plan and a written recommendation that the tenant should be relocated when using more flexible proof.<sup>190</sup> Vermont is among the most lenient, allowing self-certification by the tenant.<sup>191</sup>

Although Missouri’s current statute appears flexible regarding documentation, this flexibility is undermined by its structure as an affirmative defense.<sup>192</sup> In practice, the evidentiary weight of different forms of documentation—such as “a document signed by . . . [a] mental health professional”—may be subject to judicial bias or skepticism, especially when compared to police reports or court orders.<sup>193</sup> This may discourage tenants from relying on less “official” forms of proof, even if they are legitimate and safer to obtain.

Missouri should adopt a structured but flexible documentation framework. Indiana provides a strong model as the state permits multiple forms of documentation while establishing clear criteria to ensure good-faith use of the statute.<sup>194</sup> Flexibility is key to accessibility, but it must be paired with procedural clarity to support a truly self-executing right.<sup>195</sup> Survivors should not have to guess what is “good enough” to break free from abuse safely and lawfully.

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<sup>185</sup> MO. REV. STAT. § 441.920.3 (2019).

<sup>186</sup> See, e.g., Walsh, *supra* note 43; Gerchick, *supra* note 99 (explains how tenants may struggle to escape domestic violence situations due to subjective landlord discretion, discriminatory practices, and penalties, which can discourage survivors from attempting to use protections that may otherwise be available to them).

<sup>187</sup> See generally NAT’L HOUS. L. PROJECT, *supra* note 90.

<sup>188</sup> See ARIZ. REV. STAT. § 33-1318(A), <https://www.azleg.gov/ars/33/01318.html>; GA. CODE ANN. § 44-7-23 (2025); KY. REV. STAT. § 383.300 (2025).

<sup>189</sup> See, e.g., HRS § 521-80(a).

<sup>190</sup> N.C. GEN. STAT. § 42-45.1 (2025).

<sup>191</sup> VT. STAT. ANN. tit. 9, § 4472 (2025).

<sup>192</sup> See generally MO. REV. STAT. § 441.920 (2024).

<sup>193</sup> *Id.*

<sup>194</sup> BURNS IND. CODE ANN. § 32-31-9-12 (2025).

<sup>195</sup> See, e.g., Dusenbery & Nembhard, *supra* note 11.

#### 4. Tenant Obligations Upon Termination

Missouri's current statute appears to release tenants from future rent liability if they satisfy the statutory requirements and successfully raise the defense in court.<sup>196</sup> However, it also permits landlords to "impose a reasonable termination fee," a vague and discretionary clause that reintroduces financial uncertainty and undermines the statute's protective purpose.<sup>197</sup>

For survivors, who are statistically more likely to face financial hardship, this ambiguity can be a significant deterrent to seeking relief.<sup>198</sup> To offer meaningful protection, Missouri must clarify the tenant's obligations upon lease termination. This is especially critical if the statute is reconstructed as a proactive right.

States that treat early lease termination as a proactive right vary in their approach to tenant liability: Utah allows a defined termination fee equal "the equivalent of one month of rent," with clear payment timing;<sup>199</sup> California holds tenants responsible for only fourteen days of rent after notice;<sup>200</sup> Georgia, Hawaii, Indiana, and Louisiana, require tenants to pay a prorated amount of rent through the termination date;<sup>201</sup> Colorado holds tenants liable for a month of rent following notice;<sup>202</sup> and many other states waive all future rent and penalties once termination occurs under the statute.<sup>203</sup> These models reflect a range of approaches, but the most survivor-friendly statutes eliminate ambiguity and discretionary fees entirely, ensuring tenants know exactly what they owe and when.<sup>204</sup>

Missouri should eliminate the vague "reasonable termination fee" language and adopt a clear, prorated rent liability model in regard to tenant obligations. Specifically: (1) tenants should provide thirty days written notice to their landlord, (2) the lease should end either on a mutually agreed upon date, or thirty days after notice, and (3) tenants should be liable only for rent owed through the termination date (up to one full month's rent). This process assumes that the tenant provided the required documentation. Missouri should also consider including a clause similar to California's stating that liability should be reduced or eliminated if the landlord relets the unit before the lease ends.<sup>205</sup>

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<sup>196</sup> See generally MO. REV. STAT. § 441.920(3) (2024).

<sup>197</sup> See generally MO. REV. STAT. § 441.920(6) (2024).

<sup>198</sup> See Anne C. Johnson, *From House to Home: Creating a Right to Early Lease Termination for Domestic Violence Victims*, 90 MINN. L. REV. 1859, 1866 (2006) ("Once victims make the difficult decision to leave their abusers, those who occupy rental housing face the challenge of avoiding fees related to early lease termination.").

<sup>199</sup> UTAH CODE § 57-22-5.1.

<sup>200</sup> CAL. CIV. CODE § 1946.7(a) (West 2025).

<sup>201</sup> GA. ANN. CODE § 44-7-23 (2025); HAW. REV. STAT. § 521-80(a) (2025); BURNS IND. CODE ANN. § 32-31-9-12 (2025); LA. REV. STAT. § 9:3261.1 (2025).

<sup>202</sup> COLO. REV. STAT. § 38-12-402(1).

<sup>203</sup> See, e.g., NAT'L HOUS. L. PROJECT, *supra* note 90.

<sup>204</sup> See Johnson, *supra* note 198.

<sup>205</sup> CAL. CIV. CODE § 1946.7(e) (West 2025) (providing that a survivor's rent obligation is reduced or eliminated if the landlord relets the unit before the lease term ends, preventing continued financial liability after early termination and aligning landlord mitigation of damages with survivor protection).

This approach promotes fairness and transparency while still protecting a landlord's interest in rent continuity and mitigating financial loss. By removing financial ambiguity, the statute would become more accessible and practical for survivors, supporting safety without imposing an unpredictable burden.<sup>206</sup>

## 5. Treatment of Prepaid Rent and Security Deposits

Missouri's current statute is silent on how to treat prepaid rent and security deposits when a tenant terminates a lease under the domestic violence protection provision.<sup>207</sup> This lack of guidance creates confusion, invites disputes, and can lead to survivors being penalized.<sup>208</sup> To promote clarity, reduce litigation, and protect survivors from financial harm, Missouri should adopt clear statutory rules regarding the allocation of these funds.

### a. Security Deposits

Most states apply their general landlord-tenant laws to early lease terminations but add clarifying provisions to prevent abuse or ambiguity.<sup>209</sup> The majority of states explicitly prohibit landlords from withholding a deposit solely because a tenant lawfully terminated their lease due to domestic violence.<sup>210</sup> For example: Nevada permits standard deductions but prohibits withholding the deposit for early termination if the tenant complied with the statute;<sup>211</sup> New York explicitly states that landlord's "shall not withhold any part of the security deposit due to the tenant's exercise of rights under this section";<sup>212</sup> and, Arizona allows landlords to withhold the deposit only if the tenant fails to meet the statute's requirements.<sup>213</sup> Minnesota is an outlier, stating that the tenant "forfeits all claims for the return of the security deposit," a provision that undermines the protective purpose of the statute.<sup>214</sup> Some states, like Hawaii and Colorado, allow landlords to retain the deposit temporarily until certain obligations—such as paying a final month's rent—are fulfilled.<sup>215</sup>

Missouri should clarify that tenants who properly comply with the statute are entitled to the return of their security deposit, subject only to standard deductions under Missouri law (unpaid rent, damages beyond normal wear and

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<sup>206</sup> See, e.g., Dusenbery & Nembhard, *supra* note 11.

<sup>207</sup> See generally MO. REV. STAT. § 441.920 (2025).

<sup>208</sup> See, e.g., WOMEN AGAINST ABUSE, *supra* note 170 ("Lack of understanding of the criminal and legal systems can become significant barriers to victims of domestic violence in establishing safety. Legal advocacy is often the deciding factor in whether a victim will successfully leave an abusive relationship.").

<sup>209</sup> See generally NAT'L HOUS. L. PROJECT, *supra* note 90.

<sup>210</sup> See generally *id.*

<sup>211</sup> NEV. REV. STAT. § 118A.345 (2025) ("Except as otherwise provided in NRS 118A.242, if the tenant or cotenant has paid a security deposit, the deposit must not be withheld for the early termination of the rental agreement if the rental agreement is terminated pursuant to this section.").

<sup>212</sup> N.Y. REAL PROP. LAW § 227-c (McKinney 2025).

<sup>213</sup> ARIZ. REV. STAT. ANN. § 33-1318(A) (2025).

<sup>214</sup> MINN. STAT. § 504B.206 (2025).

<sup>215</sup> HAW. REV. STAT. § 521-80(a) (2025); COLO. REV. STAT. § 38-12-402(1) (2025).

tear, etc.). The statute should also allow tenants to apply their deposit toward any prorated rent owed through the termination date. Language similar to California's could be instructive: "Notwithstanding any law, a landlord shall not, due to the termination, require a tenant who terminates a lease or rental agreement pursuant to this section to forfeit any security deposit money or advance rent paid."<sup>216</sup> If any portion of the deposit is withheld, the tenant should receive a full and specific written statement of the deductions.<sup>217</sup> Survivors who comply with the statute should not fear hidden costs, face financial uncertainty, or be penalized for using the protection.

### **b. Prepaid Rent**

If a tenant has prepaid rent that extends beyond the termination date, that amount should be credited toward any remaining rent due.<sup>218</sup> Any overpayment should be refunded once the tenant has vacated the premises and complied with the statute.<sup>219</sup>

Missouri should expressly provide that: (1) prepaid rent must be applied to any remaining rent due through the termination date; (2) any excess must be refunded to the tenant; and (3) refunds need not be returned until the property is vacated and statutory requirements are met.

Clear rules regarding both prepaid rent and security deposits are particularly critical given that many survivors face severe financial hardship and rely on these funds to secure safe housing after leaving.<sup>220</sup>

The core reforms outlined above—establishing a proactive right, clarifying timing, requiring documentation, defining tenant obligations, and providing guidance on security deposit and prepaid rent—are proposed to make Missouri's statute more accessible, predictable, and survivor-centered.

## **B. Additional Considerations for Implementation into Missouri's Statute**

In addition to the reforms previously discussed, Missouri should also consider exploring the following considerations. These additional considerations,

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<sup>216</sup> CAL. CIV. CODE § 1946.7(e) (2025); *see also* N.Y. REAL PROP. LAW § 227-c (McKinney 2025) ("The tenant terminating the lease shall be entitled to a refund for any prepaid rent or other payments covering the period after the effective date of the lease termination, as long as the tenant has vacated the premises.").

<sup>217</sup> *See, e.g.*, MASS. GEN. LAWS ch. 186, § 24 (2025).

<sup>218</sup> *See, e.g.*, CAL. CIV. CODE § 1946.7 (West 2025).

<sup>219</sup> *See, e.g., id.*

<sup>220</sup> *See, e.g.*, Jennifer Luu, *Her Abuser Knows Her Address, but She Can't Move. The 'Impossible Choice' Some Renters Face*, SBS NEWS (last updated May 8, 2025, 5:50 AM), <https://www.sbs.com.au/news/the-feed/article/her-abuser-knows-her-address-but-she-cant-move-away-the-impossible-choice-victims-face/1021pcnu0> ("Phoebe [the survivor] said she was too nervous to give notice and break the lease before she was able to secure a new rental.").

while not currently strictly necessary to implement a functioning framework, offer further guidance and suggestions to strengthen the statute overall:

1. Notice Template: Missouri could include a sample notice form or a list of required elements, following the example of states like California and Louisiana.<sup>221</sup> A standard template promotes compliance and reduces technical disputes, especially for tenants wishing to use the protection without representation or guidance.

2. Abuser Liability Provision: To balance landlord and tenant interests, Missouri should consider adopting language that would allow landlords to pursue the abuser for economic losses resulting from early lease termination. This is an effective way to relieve the tenant of liability but provide an avenue for the landlord to be compensated. This approach, used in Arizona, for example, frames the abuser as having interfered with the rental contract and shifts financial accountability appropriately.<sup>222</sup>

3. Impact on Co-Tenants: Missouri's statute could provide more clarity if it included guidance on how early termination by one tenant affects others on the lease. Some states release all co-tenants,<sup>223</sup> while others preserve the landlord's rights by holding the remaining co-tenants responsible for ongoing obligations.<sup>224</sup>

4. Landlord Obligations and Confidentiality: To protect survivor privacy, Missouri should prohibit landlord disclosure of the tenant's reason for terminating, unless required by law or authorized by the tenant.<sup>225</sup>

5. Provision For Landlord Failure to Comply: Some states have included provisions in their statutes that discuss ways that landlords can be held liable for a failure to abide by the statute.<sup>226</sup>

All of the recommendations discussed should be seriously considered, but it is equally important to address how these reforms, if implemented, would impact landlords. Part VI acknowledges the concerns that may arise from expanding tenant protections.

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<sup>221</sup> CAL. CIV. CODE § 1946.7 (West 2025); LA. STAT. ANN. § 9:3261.1 (2025).

<sup>222</sup> ARIZ. REV. STAT. ANN. § 33-1318(I) (2025) (“A person named in an order of protection or a departmental report pursuant to subsection A of this section who provokes an early lease termination under this section is deemed to have interfered with the residential rental agreement between the landlord and tenant regardless of whether the person named in an order of protection or a departmental report pursuant to subsection A of this section is a party to the rental agreement, and the person named in an order of protection or a departmental report pursuant to subsection A of this section may be civilly liable for all economic losses incurred by a landlord for the domestic violence or sexual assault early lease termination. This civil liability includes unpaid rent, early lease termination fees, costs to repair damage to the premises and any reductions or waivers of rent previously granted to the tenant who was the victim of domestic violence or sexual assault.”); *see also* COLO. REV. STAT. § 38-12-402(1) (2025); KY. REV. STAT. ANN. § 383.300 (West 2025); ME. REV. STAT. tit. 14, § 6001 (2025).

<sup>223</sup> *See, e.g.*, N.J. REV. STAT. § 46:8-9.7 (2025).

<sup>224</sup> *See, e.g.*, VA. CODE ANN. § 55.1-1236 (2025).

<sup>225</sup> *See, e.g.*, COLO. REV. STAT. § 38-12-402(4)(a) (“If a tenant to a residential rental agreement or lease agreement notifies the landlord that the tenant is a victim of unlawful sexual behavior, stalking, domestic violence, or domestic abuse, the landlord shall not disclose such fact to any person except with the consent of the victim or as the landlord may be required to do so by law.”).

<sup>226</sup> *See, e.g.*, CAL. CIV. CODE § 1946.7(k) (West 2025).

## VII. ADDRESSING POTENTIAL LANDLORD CONCERNS

While Missouri should strengthen tenant protections, reforms must also consider landlords' interests. To reiterate, survivors who lack access to safe housing are more likely to remain in or return to an abusive environment.<sup>227</sup> Yet, landlords have shown resistance towards further protections for survivors.<sup>228</sup>

There are practical ways to address landlord concerns without compromising survivor safety. For example, allowing landlords to pursue the abuser for damages, treating them as having interfered with the lease.<sup>229</sup> The Arizona statute permits landlords to recover unpaid rent, termination-related costs, and property damage from the abuser, shifting liability away from the survivor while preserving the landlord's financial interests.<sup>230</sup> At the end of the day, the abuser is the one who should be held accountable.

Other states have implemented provisions that further protect landlords. Louisiana limits the statute's applicability to landlords owning six or more units.<sup>231</sup> Utah disqualifies tenants who have previously received eviction notices from using the early lease termination right.<sup>232</sup> California imposes stricter documentation rules for proof that is not court-certified, requiring it to have a letterhead.<sup>233</sup> These provisions offer policymakers options to balance survivor safety with landlord protection.

Concerns about false reporting, while often cited, regularly reflect assumptions and bias that result in heightened proof requirements and barriers for survivors.<sup>234</sup> Domestic violence is significantly underreported, and therefore, misuse of early termination seems rare.<sup>235</sup> Survivors do not report for many reasons, but some of them include retaliation, lack of understanding of available resources, being judged, and fear of not being believed.<sup>236</sup> That fear is relevant in the landlord-tenant context, where a landlord's willingness to believe and act on a survivor's account can determine whether the law offers real protection.<sup>237</sup> Missouri's statute has existed since 2019 with little to no litigation, suggesting that survivors rarely invoke it.<sup>238</sup>

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<sup>227</sup> See generally NAT'L DOMESTIC VIOLENCE HOTLINE, *supra* note 86; VISION HOUSE, *supra* note 11.

<sup>228</sup> See, e.g., SENATE COM. COMM., H.B. 261 (2023), [https://gc.nh.gov/bill\\_status/legacy/bs2016/HearingReport.aspx?id=4874&sy=2024](https://gc.nh.gov/bill_status/legacy/bs2016/HearingReport.aspx?id=4874&sy=2024).

<sup>229</sup> See ME. REV. STAT. tit. 14, § 6001 (2025); LA. REV. STAT. § 9:3261.1 (2025).

<sup>230</sup> ARIZ. REV. STAT. § 33-1318(I) (2025).

<sup>231</sup> LA. REV. STAT. § 9:3261.1(A) ("This Section shall apply only to a lease agreement for a residential dwelling within a building or structure consisting of six or more separate residential dwellings.").

<sup>232</sup> See UTAH CODE ANN. § 57-22-5.1(7).

<sup>233</sup> CAL. CIV. CODE § 1946.7(b)(3)(C).

<sup>234</sup> See Sequeira, *supra* note 10 (argues that fears of false reporting drive documentation requirements that disproportionately burden survivors, particularly given the underreporting of domestic violence and the risks associated with seeking third-party proof).

<sup>235</sup> *Id.*; see also Lynn, *supra* note 15.

<sup>236</sup> See generally "Why Didn't You Say Anything?," NAT'L DOMESTIC VIOLENCE HOTLINE, <https://www.thehotline.org/resources/why-didnt-you-say-anything/> (last visited Aug. 5, 2025).

<sup>237</sup> See Sequeira, *supra* note 10.

<sup>238</sup> See generally *Who Pays for Damages?*, DOMESTICSHELTERS.ORG (June 21, 2017),

If Missouri seeks further assurance for landlords, it could consider a landlord relief fund to offset economic losses in cases of early termination<sup>239</sup>—recognizing that domestic violence is a societal problem that requires shared responsibility.<sup>240</sup> Ultimately, landlords’ rights are not absolute.<sup>241</sup> Strengthening protections for survivors does not unduly impair those rights; it ensures that tenants can escape violence without facing impossible legal or financial barriers.<sup>242</sup>

## VIII. CONCLUSION

Jessica’s story is fictional, but it reflects the reality facing survivors across Missouri. Housing insecurity remains one of the most significant barriers facing survivors of domestic violence, and Missouri’s current affirmative defense model leaves too many survivors vulnerable. Like Jessica, tenants may discover that the very laws meant to protect them are ambiguous, dependent on landlord discretion, and come with too much uncertainty to rely on. The statute’s current structure undermines its purpose and forces survivors to navigate systems that can retraumatize and delay safe exit from abuse. In a moment when safety depends on strategic, careful action, the law should remove obstacles, not add them.

Transforming section 441.920 into a proactive, self-executing right would provide survivors with a clear, accessible path to safety. A well-defined procedure benefits both tenants and landlords by offering predictability, reducing litigation, and ensuring fair outcomes. This model respects survivor autonomy, reduces financial entrapment, preserves limited shelter resources, allows survivors to plan their path to freedom, and promotes housing stability for children and families.

As Sue Webeck, the Domestic Violence Crisis Service chief executive, said: “No-one should be forced to stay in a violent and unsafe situation because they can’t afford the cost of breaking their lease.”<sup>243</sup> Missouri has the opportunity

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<https://www.domesticshelters.org/articles/housing/who-pays-for-damages> (“They don’t result in reported cases, so there’s no body of law developed,” Wider says. “Decisions are being made all the time that touch on this issue, but they’re not being reported.”).

<sup>239</sup> See, e.g., Walsh, *supra* note 43 (reasoning for establishing landlord relief: “Both Grim and former state Rep. Lisa Sobecki, now a Lucas County Commissioner and one of the original authors of HB 134, said the Safe Homes Act provides ample protection to landlords and property managers. Like those who have experienced sexual or domestic violence, Sobecki said landlords ‘didn’t ask for these things either when they rent out their property.’ The measure sets aside a \$200 nonrefundable tax credit that’s able to be renewed if a landlord or property manager suddenly is left without a rent-paying tenant.”).

<sup>240</sup> *Domestic Violence Quotes*, NAT’L CTR. FOR DOMESTIC VIOLENCE, <https://www.ncdv.org.uk/domestic-abuse-quotes/> (“This [domestic abuse] is not something that simply takes place behind closed doors and that others can ignore; it is something that affects us all. It affects our economy, it affects our society, and it affects our young people as they are growing up.”).

<sup>241</sup> See, e.g., Charlotte Gerchick, *supra* note 99, at 317-18 (2019).

<sup>242</sup> Walsh, *supra* note 43 (“This [talking about the early lease termination protections] is going to be one less barrier for survivors of domestic violence and sexual assault to be able to find a safe place to rest their head.”).

<sup>243</sup> *Laws Allowing Domestic Violence Victims to More Easily Break a Rental Lease Take Effect in the ACT*, ABC PREMIUM NEWS (Dec. 9, 2024), <https://www.abc.net.au/news/2024-12-10/act-domestic-violence-lease-legislation-takes-effect/104704082>.

to lead with a statute that reflects the urgency of survivor safety, closes gaps left by federal law, fulfills the protective purpose of early lease termination, and ensures that tenants like Jessica can flee danger without facing new threats from the very system designed to protect them.

# VISUAL ARTS ARE THE ONLY ARTS WITH MORALS: GENERATIVE AI AND AURAL ARTS

Megan Pilege\*

## I. INTRODUCTION

“[E]verybody who creates for a living should be in code red.”<sup>1</sup> In early April 2023, TikTok user Ghostwriter977 posted a piece titled “*Heart on My Sleeve*” (stylized in lowercase) that seemed to be sung by Drake and The Weeknd.<sup>2</sup> However, as the song gained massive popularity, Drake and The Weeknd’s recording label released a chilling statement: the voices in the song, which had convinced millions of listeners, were, in fact, *not* Drake or The Weeknd, but an artificially generated imitation made from recordings of Drake and The Weeknd’s songs.<sup>3</sup>

Artificial intelligence (“AI”) has been steadily growing in the art market, rising from \$0.62 billion to \$0.88 billion from 2025 to 2026, with an annual growth rate (CAGR) of 42.1%.<sup>4</sup> The trend of AI art has grown exponentially alongside Generative AI’s public accessibility and development,<sup>5</sup> especially with its ability to mimic human intelligence, enabling AI programs to learn and develop without human intervention.<sup>6</sup> This form of Generative AI is a machine learning model that learns to generate content similar to the data it was trained on.<sup>7</sup> Generative AI can be used in a myriad of ways, including generating art based on an artist’s style, creations, or techniques.<sup>8</sup> It can also be used to “create” compositions and realistically reproduce an artist’s voice by studying millions of inputted music or

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<sup>1</sup> Kyle Chayka, *Is A.I. Art Stealing from Artists?*, *NEW YORKER* (Feb. 10, 2023), <https://www.newyorker.com/culture/infinite-scroll/is-ai-art-stealing-from-artists>.

<sup>2</sup> See Ikram Ali Mohammed, *Eliminating Ghostwriters: How a Federal Right of Publicity Can Save the Music Industry from Generative Artificial Intelligence*, 31 *J. INTELL. PROP. L.* 212, 218 (2024).

<sup>3</sup> See Joseph Grasser et al., *Ghostwriter in the Machine: Copyright Implications for AI-generated Imitations*, *NAT’L L. REV.: GLOB. IP & TECH. L. BLOG* (May 17, 2023), <https://natlawreview.com/article/ghostwriter-machine-copyright-implications-ai-generated-imitations>.

<sup>4</sup> BUS. RSCH. CO., *GENERATIVE ARTIFICIAL INTELLIGENCE (AI) IN ART GLOBAL MARKET REPORT* (2026), <https://www.thebusinessresearchcompany.com/report/generative-artificial-intelligence-ai-in-art-global-market-report>.

<sup>5</sup> See Sachin Waikar, *When AI-generated Art Enters the Market, Consumers Win – and Artists Lose*, *GRADUATE SCH. OF STAN. BUS.* (May 20, 2025), <https://www.gsb.stanford.edu/insights/when-ai-generated-art-enters-market-consumers-win-artists-lose>.

<sup>6</sup> See *Artificial Imagination: The Rise of Generative AI*, *UC BERKELEY EXEC. EDUC.*, <https://executive.berkeley.edu/thought-leadership/blog/artificial-imagination-rise-generative-ai> (“Generative AI operates at the intersection of advanced algorithms and intricate data patterns. At its foundation lies the concept of neural networks, inspired by the human brain’s structure. These networks consist of layers of interconnected nodes or ‘neurons’ that process and transmit information.”).

<sup>7</sup> See Chayka, *supra* note 1.

<sup>8</sup> See Ihor Tsyvina, *What Is the AI Art Generator & Why the Art Industry Is About to Die*, *RETROSTYLE GAMES* (Apr. 12, 2024), <https://retrostylegames.com/blog/what-is-ai-art-generator/>.

analyzing various recordings.<sup>9</sup> Vocalists have caught their voices being used to promote a program's work, celebrities have found lookalikes in commercials, and musicians have discovered songs in their name that they did not actually create. It has even gone further than nature itself: creators on TikTok used AI to generate the likeness of child victims to narrate the details of the crimes that killed them.<sup>10</sup> One mother was forced to relive one of her biggest regrets as an AI version of her child said he would still be alive had she only looked right.<sup>11</sup>

Copyright law itself offers little guidance and has been mostly silent on how AI will mesh within the copyright world.<sup>12</sup> Artists have filed lawsuits, but, following the law's lead, courts have yet to provide a clear answer about AI's use of copyrighted works in the aural arts.<sup>13</sup> Commentators have argued both for and against AI art and proposed numerous opinions on whether AI "art" is truly art.<sup>14</sup> Artists have noticed AI-generated art encroaching on their space and have voiced their fears of being replaced by AI's cheaper, faster programming.<sup>15</sup>

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<sup>9</sup> See Mark T. Goracke, *The Summer of "Deep Drakes": How Generative AI Is Creating New Music and Copyright Issues*, HOLLAND & KNIGHT (May 2, 2023), <http://hklaw.com/en/insights/publications/2023/05/the-summer-of-deep-drakes-how-generative-ai-is-creating-new-music>.

<sup>10</sup> Jennifer Hassan, *AI Is Being Used to Give Dead, Missing Kids a Voice They Didn't Ask For*, WASH. POST (Aug. 9, 2023), <https://www.washingtonpost.com/technology/2023/08/09/ai-dead-children-tiktok-videos/>.

<sup>11</sup> Eleanor Liang, *AI Is Working as a New Voice for Missing Children, Though Disapproved by Victims' Parents*, J. BY LETTERLY (Aug. 23, 2023), <https://journal.letterly.io/blog/articles/ai-working-as-a-new-voice-for-missing-children-though-disapproved-by-victims-parents/#> ("If my mom turned right, I could have been alive today. Unfortunately, she turned left,' the childlike voice says . . .").

<sup>12</sup> See generally Lisa T. Ortiz & D. Sean West, *Human Authorship Requirement Continues To Pose Difficulties for AI-generated Works*, PERKINS COIE (Feb. 29, 2024), <https://perkinscoie.com/insights/article/human-authorship-requirement-continues-pose-difficulties-ai-generated-works> ("While leaving open the possibility that some AI-generated works might be protectable, the guidance did not provide any examples of what sufficient human authorship might be and clearly stated that works generated by AI systems solely in response to user prompts are uncopyrightable.").

<sup>13</sup> See *UMG Recordings, Inc. v. Suno, Inc.*, 1:24-cv-11611, (Mass. Dist. Ct. filed June 4, 2024) (CourtListener); see also *Aural*, WEBSTER'S NEW WORLD COLL. DICTIONARY (4th ed. 2004) ("[O]f or received through the ear or the sense of hearing"); see also *Sound Art*, AVANTE ARTE, <https://avantarte.com/glossary/sound-art> (last visited Aug. 5, 2025) ("Sound art is a form of artistic expression where sound serves as the central medium and material. . . . [M]ore of an aural experience than visual art, but visual elements can coexist with sound.").

<sup>14</sup> See generally Mackenzie Caldwell, *What Is an "Author"?—Copyright Authorship of AI Art Through a Philosophical Lens*, 61 HOUS. L. REV. 411 (2023); Benjamin Schafer, *What's so Fair About AI Art Generators? A Fair Use Analysis of Generative AI*, 23 FLA. ST. U. BUS. REV. 129 (2024); Andrew Ahrenstein, *AI Generated Art and the Gap in Copyright Law*, 15 AM. U. INTELL. PROP. BRIEF 23 (2024).

<sup>15</sup> See Nathan Seth Lowell, *AI Create: The Brave New World and Copyright Implications of AI-generated Artwork*, 28 VA. J.L. & TECH. 1, 44 (2024); see also Eleni Polymenopoulou, *Rembrandt's Missing Piece: AI Art and the Fallacies of Copyright Law*, 19 WASH. J.L. TECH. & ARTS 64, 79 (2024); Evan Sommer, *Real Concerns for an Artificial Threat: Artists, AI, and the Battle to Script Hollywood's Future*, 25 NEV. L.J. 449, 452-53 (2025).

Copyright law originated to encourage artistic creation for the public good and has expanded as technology in the art world and society overall advanced.<sup>16</sup> The rapid evolution of AI, however, has not triggered a mirroring expansion in copyright law, allowing the threat of AI to run rampant in the aural art world. Aural artists face Generative AI without guaranteed legal backup, worried they are already a dataset because AI “artists” do not ask permission before using copyrighted art to generate their works.<sup>17</sup> Human artists are then in less demand, diminishing the creative pool of aural art and causing art to lose the “spark” only humans can incite.<sup>18</sup>

Moral rights had been introduced prior to AI’s explosion, providing limited protections to visual artists through the Visual Artists Rights Act (“VARA”). VARA’s moral rights are a step in the right direction to protect artists from AI, particularly the right of integrity, which prevents the “distortion, mutilation, or other modification” of a visual work.<sup>19</sup> VARA is exclusive to visual works, however, and the Act’s many limitations and narrow scope of applicability currently leave aural artists stranded.

Those in favor of AI argue it is a tool to assist creativity, that artists have been afraid of change before and found those changes only allowed for more creativity and methods of expression,<sup>20</sup> that the generated piece is a different song entirely from the original,<sup>21</sup> or that the music industry is and has always been built on “mimicking” existing music.<sup>22</sup> There is, however, a difference between taking inspiration from art and using an exact piece in a dataset to generate similar-sounding art. Though some protections, such as the right of publicity, have previously defended celebrity voices against human infringement,<sup>23</sup> that these are

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<sup>16</sup> *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 430 (1984) (“From its beginning, the law of copyright has developed in response to significant changes in technology.”); see also Kevin Liftig, *The Evolution of Copyright Law in the Arts*, 113 UCONN HONORS SCHOLAR THESES 1, 1 (2009).

<sup>17</sup> See discussion *infra* Section III.D.

<sup>18</sup> See discussion *infra* Section III.E.

<sup>19</sup> Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5128.

<sup>20</sup> See Arts at MIT, *Panel Discussion: How is Generative AI Transforming Art and Design?*, YOUTUBE (Nov. 15, 2023), <https://www.youtube.com/watch?v=GpOrpiLHhIM> (explaining that when photography was first developed, many painters feared photography would render painting useless, but it actually allowed painters to focus on abstractionism and impressionism rather than realism, which photography was able to represent).

<sup>21</sup> See Rachel Reed, *AI Created a Song Mimicking the Work of Drake and The Weeknd. What Does That Mean for Copyright Law?*, HARV. L. TODAY (May 2, 2023), <https://hls.harvard.edu/today/ai-created-a-song-mimicking-the-work-of-drake-and-the-weeknd-what-does-that-mean-for-copyright-law/> (“If I, as a person, listen to a whole bunch of Drake music and write my own song, having been inspired by him, but I don’t use the same lyrics or the same music, everybody would agree that’s not a copy. Why wouldn’t the same standard apply to an AI?”).

<sup>22</sup> See Sky Stack, *Why All Music Is Unoriginal*, MEDIUM (May 15, 2017), <https://medium.com/@skykstack/why-all-music-is-unoriginal-e154d524e7a2>; see also Klaus Frieler & Frank Riedemann, *Is Independent Creation Likely to Happen in Pop Music?*, 15 MUSICAE SCIENTIAE 17, 26-27 (2011) (analyzing a study of average people given small sections of pop songs and asked to invent melodies, finding that the resulting melodies were “comparable in complexity and construction to some of the hit songs included in this study.”).

<sup>23</sup> See *Main Sequence, Ltd. v. Dudesy, LLC*, 2:24-cv-00711, (C.D. Cal. filed Jan. 25, 2024) (CourtListener); see also *Waits v. Frito-Lay, Inc.*, 978 F.2d 1093, 1098-1099 (9th Cir. 1992).

state-mandated and not federal protections, the availability of First Amendment defenses to creative works,<sup>24</sup> and the narrow scope of these protections are all indicators that these existing protections fall well short of sufficiently protecting all human creators and their creations.

Action must come from Congress in the form of new copyright protections that include moral rights for aural artists to balance the encouragement of creativity with AI's use of copyrighted art as a dataset. A moral rights act for aural art would protect human artists from potential revenue and streaming losses, even as AI technology continues to improve, thereby increasing creativity in the arts as human and artificial creators find space for each other.

This Comment will first discuss the history and advancement of copyright law and VARA's moral rights. Then, this Comment will delve into AI's background and its integration of dataset models using existing music used in data training to generate new aural art. Next, this Comment will discuss artists' and consumers' responses to AI's rapid growth in the art world. This Comment will then consider the existing protections for aural art and artists, and the limitations to those protections. Then, this Comment will examine the ethical implications of using AI in the art world without moral rights limiting what AI can do. Finally, this Comment will propose new legislation to strike a balance using VARA, allowing room for AI-generated music without displacing human creators.

## II. THE ORIGINS OF COPYRIGHT LAW AND AI-GENERATED ART

The importance of artistic works has been recognized since the founding of the U.S. and the drafting of our Constitution, leading to the creation of copyright law to protect artistic expression and further underscoring the value of artworks. Since its inception, copyright law has been ever-expanding alongside technological advances in the arts. One such expansion introduces and protects moral rights, though only to a very limited extent. As AI technology advances in the art world, copyright law has yet to account for the rise of AI in the aural arts, leaving aural artists alone and largely unprotected.

### A. Copyright Law

The power to enact copyright law was granted to Congress in the United States Constitution, with the goal of encouraging the continued production of art for the public good.<sup>25</sup> Congress chose to grant artists several rights to control how

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<sup>24</sup> See J. THOMAS MCCARTHY & ROGER E. SCHECHTER, *RIGHTS OF PUBLICITY AND PRIVACY* § 8:23 (2d ed. 2025) (explaining that the First Amendment provides another set of limitations to the right of publicity). (The right of publicity and the First Amendment is a topic in need of further discussion but is not the focus of this paper).

<sup>25</sup> U.S. CONST. art. I, § 8, cl. 8 (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . .”); see also *Copyright Basics*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/ip-policy/copyright-policy/copyright-basics> (last visited May 31, 2025) (“The primary purpose behind copyright law is to foster the creation and dissemination of works for the benefit of the public.

their works are used or sold as an economic incentive to fulfill copyright law's goal.<sup>26</sup> The incentive works by ensuring artists personally benefit from creating, enabling them to profit from or financially support themselves through their art and continue creating art in the future.<sup>27</sup> Through copyright law, art became a viable career and livelihood, providing significant value to American culture and the economy, and later was considered a passion and a pivotal expression of national and cultural heritage.<sup>28</sup>

The first foray into copyright law came from the Copyright Act of 1790, which established the general structure of copyright and extended protections solely to books, maps, and charts.<sup>29</sup> Artists were given rights over their works for a fourteen-year period, allowing them to exclusively choose where, when, and how to publish their works until the protection—or the additional fourteen-year renewal period, if artists so chose—would expire, with limited exceptions.<sup>30</sup> This gave artists of books, maps, and charts the ability to exclusively control and benefit from their works.<sup>31</sup> Courts repeatedly emphasized the economic importance of copyright protections and rejected natural rights arguments.<sup>32</sup> Demographics over the ten years following the Act demonstrate how the economic focus affected copyrighting works: of the few printed works that were registered for a copyright, fewer still were artistic and creative works such as poetry, and the number of

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By granting authors the exclusive right to authorize certain uses of their works, copyright provides economic incentives to create new works and to make them available in the marketplace.”); *see also* *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975) (“The immediate effect of our copyright law is to secure a fair return for an ‘author’s’ creative labor. But the ultimate aim is, by this incentive, to stimulate artistic creativity for the general public good.”).

<sup>26</sup> *See* *Goldstein v. California*, 412 U.S. 546, 555 (1973) (“[T]o encourage people to devote themselves to intellectual and artistic creation, Congress may guarantee to authors and inventors a reward in the form of control over the sale or commercial use of copies of their works.”).

<sup>27</sup> *See* *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“The economic philosophy empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and the useful Arts.’”); *see also* Matthew J. Sag, *Beyond Abstraction: The Law and Economics of Copyright Scope and Doctrinal Efficiency*, 81 TUL. L. REV. 187, 193-94 (2006) (“[F]aced with the choice between creating and copying, it makes more sense to copy. . . . [I]n a competitive market, the market price will be that of the lowest cost producer, which the author will never be. As such, without some mechanism to appropriate the benefits of their investments, authors and publishers will under-invest in the production of information products.”).

<sup>28</sup> *See* 135 Cong. Rec. H12607–08 (daily ed. June 5, 1990) (statement of Rep. Robert Kastenmeier) (“Society is the ultimate loser when these works are modified or destroyed. They should be preserved in the way the artist intended, and as the important part of our cultural heritage that they are.”).

<sup>29</sup> Copyright Act, ch. 80, 1 Stat. 124 (1790) (codified as amended at 17 U.S.C. §§ 101-1511).

<sup>30</sup> *Id.*

<sup>31</sup> *See* *A Beginner’s Guide to Copyright Law in the United States*, INSIDE OUT LEGAL, <https://inoutlaw.com/a-beginners-guide-to-copyright-law-in-the-united-states/> (last visited Aug. 5, 2025); *see also* *Copyright Basics*, UNIV. MINN. LIBRS., <https://www.lib.umn.edu/services/copyright/basics> (last visited Aug. 5, 2025).

<sup>32</sup> Yvette Joy Liebesman, *Redefining the Intended Copyright Infringer*, 50 AKRON L. REV. 765, 781-782 (2016).

publishers or printers requesting copyright swiftly grew to rival the number of authors registering copyrights.<sup>33</sup>

Over the next 200 years, Congress added to and revised copyright law, expanding the types of art that can be copyrighted from solely printed, fact-based works to include a broader range of creative fields, such as musical compositions, photographs, and drawings.<sup>34</sup> As copyright law expanded, it continued to focus on economic goals when protecting the creative arts; while some methods of creation, such as photographs, were added because they did not exist in 1790, others were added as they gained more commercial value.<sup>35</sup> Sheet music and music written in books had been acceptable as “prints” from the 1790 Act, but it was not until 1831 that musical compositions, regardless of print status, were included.<sup>36</sup> Even as musical compositions were recognized as a type of work worthy of copyright protection, they remained limited by the economic perspective.<sup>37</sup> Congress did not find sound recordings eligible for federal copyright protection until 1971, and still excluded sound recordings made before 1972 until the Music Modernization Act of 2018.<sup>38</sup> Courts applied this expansion when reviewing cases, such as by interpreting what constitutes pirating of a copyrighted work.<sup>39</sup>

### B. Moral Rights and the Visual Artists Rights Act

As the push for creation persevered, the economic lens seemed to take a back seat to artists’ rights, creating space for moral rights to emerge as a new form of protection for them.<sup>40</sup> With its emphasis on the cultural losses if the arts and

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<sup>33</sup> See Oren Bracha, *Commentary on the U.S. Copyright Act 1790*, COPYRIGHT HISTORY: PRIMARY SOURCES ON COPYRIGHT (2008), [https://www.copyrighthistory.org/cam/tools/request/showRecord.php?id=commentary\\_us\\_1790#\\_ednref24](https://www.copyrighthistory.org/cam/tools/request/showRecord.php?id=commentary_us_1790#_ednref24).

<sup>34</sup> See Act of Mar. 4, 1909, ch. 320, 35 Stat. 1075, 1076-77.

<sup>35</sup> See J. Michael Keyes, *Musical Musings: The Case for Rethinking Music Copyright Protection*, 10 MICH. TELECOMM. TECH. L. REV. 407, 412 (2004) (“[T]he music ‘industry’ functioned much like other industries that were providing works of authorship to the public: printing copies and selling those hard copies to the public through retail outlets and roving salesman. Because music had similar commercial qualities to books, it made conceptual sense that Congress and the courts would treat music just like any other work protected by copyright.”).

<sup>36</sup> Punit Motiwala, *World Music Day 2024: The History of Music and Copyright*, COPYRIGHT ALL. (June 20, 2024), <https://copyrightalliance.org/history-music-copyright/>.

<sup>37</sup> See *Arnstein v. Porter*, 154 F.2d 464, 473 (2d Cir. 1946) (“The plaintiff’s legally protected interest is not, as such, his reputation as a musician but his interest in the potential financial returns from his compositions . . . .”); see also *White-Smith Music Pub. Co. v. Apollo Co.*, 209 U.S. 1, 11 (1908) (“[W]hile it is true that copyright statutes are intended to reward mental creations or conceptions, that the extent of this protection is a matter of statutory law, and that it has been extended only to the tangible results of mental conception, and that only the tangible thing is dealt with by the law, and its multiplication or reproduction is all that is protected by the statute.”).

<sup>38</sup> See *How Does Copyright Work for Sound Recordings*, LIBR. OF CONG. (last updated Sept. 8, 2020), <https://ask.loc.gov/recorded-sound/faq/313179>.

<sup>39</sup> See *Folsom v. Marsh*, 9 F. Cas. 342, 348 (Mass. Dist. Ct. 1841) (holding that an invasion of copyright occurs when the “value of the original is sensibly diminished, or the labors of the original author are substantially to an injurious extent appropriate by another.”).

<sup>40</sup> See Brandon J. Pakkebie, *Form Over Function: Remediating VARA’s Exclusion of Visual Art with Functional Qualities*, 103 IOWA L. REV. 1329, 1332 (2018) (“Moral rights also protect artists’

artistic expressions disappeared, copyright law in the United States has deep roots in moral issues, though it was initially addressed in economic terms. The U.S.'s concept of moral rights originated in the French concept of moral rights, or *le droit moral*, which considers art to be an "extension of the artist's personality," meaning that anything that negatively impacts the work also harms the artist.<sup>41</sup> These rights were eventually included in copyright statutes across Continental Europe as fundamental, inclusive rights for the individual artist.<sup>42</sup>

The United States adopted a limited variation of Continental moral rights through VARA in the Judicial Improvements Act of 1990, providing copyright law with much-needed additions.<sup>43</sup> VARA filled a gap in copyright law by shifting the focus from economic rights to non-economic moral rights.<sup>44</sup> The United States mimicked existing moral rights protections, though the French's "personhood" view of moral rights exceeded that of the United States's.<sup>45</sup> Personhood, according to philosophers Georg William Friedrich Hegel and Immanuel Kant, theorizes that artists are so deeply intertwined with their works that they treat their creations as they would treat themselves.<sup>46</sup> Therefore, copyright law granting moral rights provides artists with the legal control to match their internal control.<sup>47</sup> The "personhood" concept can be seen in VARA not only in the rights granted, but also through the passing of rights: these moral rights cannot be transferred, but the artist can choose to waive the rights at any time, emphasizing the artist's choice to do

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creativity. One law professor writes that "[i]f artists feel more secure about the treatment they as creators and their creations will receive, they are more likely to create. Recognizing moral rights is one way a society can encourage artists to create."").

<sup>41</sup> See Jill R. Applebaum, *The Visual Artists Rights Act of 1990: An Analysis Based on the French Droit Moral*, 8 AM. U. INT'L L. REV., 183, 187 (1992) ("It is designed to protect the author's right to maintain respect for his or her name and work. Since the primary justification for the right is the idea that art is an extension of the artist's personality, and that to mistreat the work is to harm the artist, the right attaches to the artist who creates work, and not to the work itself.").

<sup>42</sup> See Elizabeth Schéré, *Where Is the Morality? Moral Rights in International Intellectual Property and Trade Law*, 41 FORDHAM INT'L L.J. 773, 775-76 (2018); see also Ritik Agrawal, *Critical Comparison Between the Moral Rights Framework in the US and European Copyright Law*, JUS SCRIPTUM (Jan. 15, 2025), <https://www.juscriptumlaw.com/post/critical-comparison-between-the-moral-rights-framework-in-the-us-and-european-copyright-law>.

<sup>43</sup> See Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5128.

<sup>44</sup> See Sonya G. Bonneau, *Honor and Destruction: The Conflicted Object in Moral Rights Law*, 87 ST. JOHN'S L. REV. 47, 95 (2013); see also Ana-Victoria Moreno, *VARA Turns Thirty-One: How Amending the Visual Artists Rights Act of 1990 to Add Guiding Language Can Further Advance the Act's Purpose*, 8 TEX. A&M J. PROP. L. 103, 113 (2022) ("It is clear that U.S. copyright law focuses on the economic interest and commercialism of works because the law places emphasis on the commercial exploitation of information.").

<sup>45</sup> See Paul Edward Geller, *Toward an Overriding Norm in Copyright: Sign Wealth*, 159 REVUE INT'L DU DROIT D'AUTEUR 3, 28-29 (1994) ("In the United States, the initial owners of rights are authors, often natural persons that independently create works, but also enterprises that employ creators and direct their work. . . . French law . . . treats moral rights as 'inalienable' since they are 'attached' to the very 'person' of the author.").

<sup>46</sup> Christopher S. Yoo, *Rethinking Copyright and Personhood*, 2019 U. ILL. L. REV. 1039, 1041 ("[A]uthors have such deep connections with their creations that respect for their sense of self requires giving them a degree of ongoing control over those works.").

<sup>47</sup> See *id.*

with the creation as the artist pleases.<sup>48</sup> Unlike its French counterpart, VARA's moral rights continue to aid in preserving American culture through preserving American art.<sup>49</sup>

### 1. The Right of Attribution

The right of attribution allows artists to claim authorship, establishing they are the creator of the work(s) and preventing a work of art from being credited to anyone other than the original artist or from putting the artist's name on another's work.<sup>50</sup> This right also allows artists to disclaim or repudiate authorship, meaning an artist can refuse to put their name on a work of art and reject any association or connection with the piece.<sup>51</sup> Repudiating authorship additionally bars using the artist's name on "distorted," "mutilated," or "modified" variations of the artist's work when the changes harm the artist's reputation, even if the original was theirs.<sup>52</sup>

### 2. The Right of Integrity

VARA grants artists the exclusive right of integrity in two ways, the first by allowing the artist to prevent the intentional "distortion, mutilation, or other modification of that work which would be prejudicial to [the artist's] honor or reputation."<sup>53</sup> Again, this emphasizes the moral, non-economic issues of copyright infringement by affording artists protection when their reputation or honor is harmed through subjective assessments of damage.

Once a sufficient change to the work is proven, the artist must then prove prejudicial damage to their honor or reputation.<sup>54</sup> Although the bill lists them as primary triggers, it does not define honor, reputation, or prejudice, leaving those terms for the courts to define.<sup>55</sup> The district court in *Carter v. Helmsley-Spear, Inc.*, a leading VARA case, consulted a dictionary to define honor as "commonly

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<sup>48</sup> See 17 U.S.C. §106A(e).

<sup>49</sup> See 136 CONG. REC. H36947-48 (daily ed. Oct. 27, 1990) (statement of Rep. Hamilton Fish) ("By creating a right of integrity, it protects society against the mutilation and destruction of those works of visual art that make up an important part of our cultural heritage, and gives individual artists the legal right to prevent distorting changes in their work."); see also 133 CONG. REC. S22800-85 (daily ed. Aug. 6, 1987) (statement of Sen. Ted Kennedy) ("[VARA] will . . . faithfully reflect our commitment to the creative arts as an essential part of our heritage.").

<sup>50</sup> Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089.

<sup>51</sup> *Id.*; see also *Carter v. Helmsley-Spear, Inc.*, 71 F.3d 77, 81 (2d Cir. 1995); see generally *Arnold Herstand & Co. v. Gallery: Gertrude Stein, Inc.*, 211 A.D.2d 77, 81 (N.Y. App. Div. 1995) (explaining Courts have recognized when artists wish to disclaim their works outside of the moral rights context); Simon Stern, *Copyright as a Property Right? Authorial Perspectives in Eighteenth-Century England*, 9 U.C. IRVINE L. REV. 461, 475 (2019).

<sup>52</sup> See *Carter*, 71 F.3d at 81.

<sup>53</sup> Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5128.

<sup>54</sup> *Kerson v. Vt. L. Sch., Inc.*, 79 F.4th 257, 269 (2d Cir. 2023).

<sup>55</sup> *Carter v. Helmsley-Spear, Inc.*, 861 F. Supp. 303, 323 (S.D.N.Y. 1994) ("VARA, however, does not define the terms 'prejudicial,' 'honor,' or 'reputation.' Thus, the Court must construe these terms.").

understood to mean ‘good name or public esteem.’”<sup>56</sup> The Second Circuit later quoted a House Report referring to “artistic worth” and “honor” in the same breath, writing that both “encourage[] the author in the arduous act of creation.”<sup>57</sup> Reputation, on the other hand, is typically “the condition of being regarded as worthy or meritorious.”<sup>58</sup> Courts after *Carter* have still had difficulty explaining what honor and reputation are, and instead rely on “readily understood meanings,” determining them on a case-by-case basis.<sup>59</sup> VARA commentators refer to honor as what the artist thinks of and feels about the piece, while reputation is typically defined as what others think and feel about the piece.<sup>60</sup>

Once the artists show a distortion, modification, or mutilation of their work and how their honor or reputation has been impacted, the next step is to prove that the damage was prejudicial. Also lacking a definition in the bill, *Massachusetts Museum of Contemporary Art Foundation, Inc. v. Buchel* used the recommendation from a 1990 House Report to find evidence of prejudice based on how the modifications and changes to the original piece affect the artist’s reputation or honor.<sup>61</sup> *Carter* found prejudice to be “injury or damage due to some judgment of another.”<sup>62</sup> Legislative history insinuates that prejudice toward an artist’s reputation occurs when a work of recognized stature is modified, distorted, or mutilated.<sup>63</sup> This suggests an automatic infringement of the right of integrity if the work is of recognized stature, while works that are not recognized would need to prove prejudice.

The second part to the right of integrity allows the artist to prevent the intentional and negligent destruction of artworks of “recognized stature.”<sup>64</sup> A clear definition of “recognized stature” is also excluded from VARA, which Judge Edelstein, in *Carter*, calls a “gate-keeping mechanism.”<sup>65</sup> Indeed, when VARA has been applied in a lawsuit over the destruction of an artwork, many artists lose their claim because the court does not consider their artwork a work of “recognized

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<sup>56</sup> *Id.*

<sup>57</sup> *Carter v. Helmsley-Spear, Inc.*, 71 F.3d 77, 83 (2d Cir. 1995).

<sup>58</sup> *Carter*, 861 F. Supp. at 323.

<sup>59</sup> See Marko Iglendza, *Moral Rights Protection Under the Visual Artists Rights Act of 1990: The Judicial Interpretation in Carter v. Helmsley-Spear*, 5 DEPAUL J. ART TECH. & INTEL. PROP. L. 187, 205 (1995); see also *Leveille v. Upchurch*, No. 3:19-cv-908-J-39MCR, 2020 U.S. Dist. LEXIS 256443, at \*205 (M.D. Fla. 2020) (“Though the allegations of damage are conclusory, it can be reasonably inferred from the facts alleged that Plaintiff’s reputation would be harmed by Defendant’s alterations to the Works.”).

<sup>60</sup> See William M. Landes, *What Has the Visual Arts Rights Act of 1990 Accomplished?* (Univ. of Chi. L. Sch., Working Paper No. 123, 2020).

<sup>61</sup> *Mass. Museum of Contemp. Art Found., Inc. v. Buchel*, 593 F.3d 38, 54 (1st Cir. 2010).

<sup>62</sup> *Carter v. Helmsley-Spear, Inc.*, 861 F. Supp. 303, 323 (S.D.N.Y. Aug. 31, 1994).

<sup>63</sup> See 135 CONG. REC. H12596–98 (daily ed. June 20, 1989) (statement of Rep. Robert Kastenmeier) (“The second is a right of integrity, to prevent and seek redress for destruction, distortion, mutilation, or other modification that is prejudicial to the author’s honor or reputation. If the work is one of recognized stature, the bill presumes prejudice to the author’s honor or reputation.”).

<sup>64</sup> Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5129.

<sup>65</sup> *Carter*, 861 F. Supp. at 325 (“[P]rotection is afforded only to those works of art that art experts, the art community, or society in general views as possessing stature.”).

stature.”<sup>66</sup> In case law, VARA-triggering destruction of art found reputational harm to be “damage to [the artist’s] good name, public esteem, or reputation in the artistic community” as it relates to the piece of art rather than the artist’s general standing in the art world.<sup>67</sup> *Carter* held that for VARA protections to apply to the destruction of art, artists must show that the art is “meritorious,”<sup>68</sup> referencing the prior definition of reputation, and that those with a strong presence in the arts recognize the work as such.<sup>69</sup>

### 3. VARA’s Limitations

Yet, while VARA expands moral rights for artists, it is also highly limiting.<sup>70</sup> A “Work of Visual Art” protected by VARA is a “painting, drawing, print, or sculpture” with “200 copies or fewer.”<sup>71</sup> VARA specifically excludes art such as motion pictures, audiovisual works, books, any work “made for hire,” and merchandising items or ads.<sup>72</sup>

VARA includes several additional exceptions that offer protection when the piece is destroyed or modified without fault by anyone, such as the “passage of time” or non-negligent changes to the piece for presentation or conservation purposes.<sup>73</sup> Works of Visual Art that are part of a building and cannot be removed without altering the work also do not violate VARA if the artist gave permission to incorporate the work into the building, or if the building’s owner made a good-faith effort to inform the artist of any changes to the building.<sup>74</sup> These exceptions suggest that moral rights can be exempted because of natural causes or when artists fail to monitor their rights.

VARA’s guidelines are strict and exclude even some forms of visual art.<sup>75</sup> In the 25 years since VARA was enacted, there is still a significant hole in

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<sup>66</sup> See Laura Flahive Wu, *Massachusetts Museum of Contemporary Art v. Buchel: Construing Artists’ Rights in the Context of Institutional Commissions*, 32 COLUM. J.L. & ARTS 151, 159 (2008) (“[C]ourts avoid construing the extent of VARA protection by finding that works do not meet the threshold requirements for ‘visual art’ protected by VARA.”); see also *Scott v. Dixon*, 309 F. Supp. 2d 395, 400-01 (E.D.N.Y. 2004); *Pollara v. Seymour*, 344 F.3d 265, 271 (2d Cir. 2003) (Gleeson, J., concurring) (explaining that while the majority found the banner unprotected because it was not a “work of visual art,” it was also unprotected because it was not a work of recognized stature).

<sup>67</sup> *Mass. Museum of Contemp. Art Found., Inc. v. Buchel*, 593 F.3d 38, 54 (1st Cir. 2010).

<sup>68</sup> *Meritorious*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/meritorious> (last visited July 2, 2025) (“[D]eserving of honor or esteem”); see also *Carter v. Helmsley-Spear, Inc.*, 861 F. Supp. 303, 325 (S.D.N.Y. 1994).

<sup>69</sup> *Carter*, 861 F. Supp. at 325 (“[A] plaintiff must make a two-tiered showing: (1) that the visual art in question has ‘stature,’ *i.e.* is viewed as meritorious, and (2) that this stature is ‘recognized’ by art experts, other members of the artistic community, or by some cross-section of society.”).

<sup>70</sup> See Pakkebie, *supra* note 40, at 1335-40 (discussing VARA’s exceptions and the “narrow scope” of VARA’s applicability).

<sup>71</sup> Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5128-33.

<sup>72</sup> *Id.*

<sup>73</sup> 17 U.S.C. §106A(c).

<sup>74</sup> 17 U.S.C. §113(d).

<sup>75</sup> See *Pollara v. Seymour*, 344 F.3d 265, 269 (2d Cir. 2003) (“Congress explicitly limited VARA’s protection to works ‘intended for exhibition use only,’ as opposed to works intended for use in a publication or the photographer’s photo album.”).

copyright law where similar protections for anyone other than VARA's specific visual artists should be—voice actors and musicians, for example, are some of the unlucky artists who continue to lack moral rights in the United States.<sup>76</sup>

### C. Finding and Removing Copyright Infringement

When a right has been infringed through the unauthorized copyright of a work, it is up to the artist to discover and address copyright infringement.<sup>77</sup> The artist could retain a lawyer and resolve the issue either by an alternative method, such as mediation, or turn to the courts.<sup>78</sup> Using mediation and other methods that avoid the court process is typically more straightforward, but can be challenging to obtain a favorable judgment at times, and does not provide the same remedies as litigation.<sup>79</sup> If the litigation route is chosen, the artist can either file an injunction to prevent the defendant from using the artist's work or sue for damages for infringing the artist's rights.<sup>80</sup> Litigation, however, has many issues, one of which is the cost—a report from the American Intellectual Property Law Association found that the average cost of a copyright infringement case is \$278,000.<sup>81</sup> Using the courts to handle copyright infringement issues also takes time and has a stunningly complex system.<sup>82</sup> Smaller artists, therefore, likely lack the time and

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<sup>76</sup> See generally 17 U.S.C. § 101 (VARA provides protections specifically to artists who create “works of visual art.” According to this definition, a “work of visual art” includes “(1) a painting, drawing, print, or sculpture existing in a single copy or in a limited edition of 200 copies or fewer that are signed and consecutively numbered by the author, or, in the case of a sculpture, in multiple cast, carved, or fabricated sculptures of 200 or fewer that are consecutively numbered by the author and bear the signature or other identifying mark of the author; or (2) a still photographic image produced for exhibition purposes only, existing in a single copy or in a limited edition of 200 copies or fewer that are signed and consecutively numbered by the author.” However, VARA does not extend protections to all forms of art or artists. Excluded from the definition of “works of visual art” are items such as posters, maps, globes, technical drawings, diagrams, applied art, motion pictures, audiovisual works, books, magazines, newspapers, and advertising or promotional materials, indicating voice actors and musicians are among those artists who continue to lack moral rights in the United States).

<sup>77</sup> See William M. Landes & Richard A. Posner, *An Economic Analysis of Copyright Law*, 18 J. LEG. STUD. 325, 345 (1989) (“No effort is made by the Copyright Office to search copyrighted works before issuing a copyright, so copyright is not issued but is simply asserted by the author . . .”).

<sup>78</sup> See *How Are Most Copyright Disputes Settled?*, MYERS L. GRP., <https://www.themyerslg.com/blog/how-copyright-disputes-settle/> (last visited Mar. 26, 2026).

<sup>79</sup> See Anthony Ciolli, *Lowering the Stakes: Toward a Model of Effective Copyright Dispute Resolution*, 110 W. VA. L. REV. 999, 1017 (2008).

<sup>80</sup> See *Mass. Museum of Contemp. Art Found., Inc. v. Buchel*, 565 F. Supp. 2d 245, 247 (D. Mass. 2008) (artist Buchel countersued under VARA claiming the museum violated his rights by covering his unfinished work with tarpaulins, thereby distorting his piece, and allowing museum visitors to pass the covered work, claiming this was a form of exhibition).

<sup>81</sup> Terrica Carrington, *A Small Claims Court Is on the Horizon for Creators*, COPYRIGHT ALL. (Oct. 4, 2017), <https://copyrightalliance.org/small-claims-court-on-the-horizon/>.

<sup>82</sup> See Ciolli, *supra* note 79, at 1001-1002 (“[B]ecause of the ‘backlog in the federal courts and the fact that federal courts are obligated to resolve criminal matters before civil matters where doing so is reasonable,’ it often takes longer to obtain a civil trial on the merits in federal court than in state court.”).

funds to navigate the complex, expensive process and hope for a judgment in their favor.<sup>83</sup>

To address these issues, the Copyright Claims Board (“CCB”) was established in late 2020 for small claims, meaning artists pursuing damages of less than \$30,000.<sup>84</sup> Artists can petition the Board with copyright infringement claims and be heard by three officers who schedule meetings and hearings, like standard litigation cases, but on an expedited scale.<sup>85</sup> The CCB additionally has the power to dismiss claims it feels are “unsuitable for determination,” which the CCB has used to its advantage ever since it began taking claims in 2022.<sup>86</sup> The CCB released statistics from 2022 to 2026 and stated that of the 1920 total claims filed, 787 were dismissed during initial review.<sup>87</sup> Not only have about 40% of claims been dismissed, but large claims such as Universal Music Group’s (“UMG”) in *UMG v. Suno* will not be eligible for review by the CCB, as UMG requested “\$150,000 per work infringed” and therefore fell outside the CCB’s cap.<sup>88</sup>

Copyright infringement claims have been brought many times concerning musical pieces as musicians catch familiar melodies, beats, or lyrics in another musician’s songs.<sup>89</sup> As technology evolved to the point where much of music listening occurs via streaming on online, third-party websites, a method for removing the copyrighted piece from an online third-party site was born.<sup>90</sup> When the “copy” is uploaded to an online website, the artist may send a takedown notice to the host website requesting removal of the “copy” due to the Digital Millennium Copyright Act (“DMCA”).<sup>91</sup> The DMCA will issue a takedown and require an online host to remove infringing material if the copyright holder can show a “good-faith belief” the online work is using unauthorized material.<sup>92</sup> Furthermore, a

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<sup>83</sup> See *id.* at 1002-08.

<sup>84</sup> See 17 U.S.C. §1501-1511.

<sup>85</sup> See 17 U.S.C. §1502; see also 17 U.S.C. §1503(a)(1)(E).

<sup>86</sup> 17 U.S.C. §1506(f)(3); see also *Key Statistics*, COPYRIGHT CLAIMS BD., <https://ccb.gov/CCB-Statistics-and-FAQs-April-2025.pdf> (last visited Mar. 26, 2026).

<sup>87</sup> *Key Statistics*, COPYRIGHT CLAIMS BD., <https://ccb.gov/CCB-Statistics-and-FAQs.pdf> (last visited Apr. 9, 2026).

<sup>88</sup> See *id.*; see also *UMG Recordings, Inc. v. Suno, Inc.*, No. 1:24-cv-11611 (Mass. Dist. Ct. filed June 24, 2024) (CourtListener).

<sup>89</sup> See Peter Burditt, “*Ice Ice Baby*” and the David Bowie-Queen Legal Battle That Tainted Vanilla Ice’s Career, AM. SONGWRITER (Aug. 20, 2024, 10:09 AM), <https://americansongwriter.com/ice-ice-baby-and-the-david-bowie-queen-legal-battle-that-tainted-vanilla-ices-career/> (discussing how Bowie and Queen’s legal teams threatened to file a lawsuit after Vanilla Ice used the base line from Bowie and Queen’s song “Under Pressure” before settling); *Williams v. Bridgeport Music, Inc.*, 2015 U.S. Dist. LEXIS 97262 (C.D. Cal. 2015); *Skidmore v. Led Zeppelin*, 952 F.3d 1051 (9th Cir. 2020).

<sup>90</sup> See Will Brewster, *The History of the First Music Streaming Service*, MIXDOWN (Nov. 11, 2024), <https://mixdownmag.com.au/features/the-history-of-music-streaming/>; see also R. Polk Wagner, *Reconsidering the DMCA*, 42 HOUS. L. REV. 1107, 1108 (2005) (claiming that the Digital Millennium Copyright Act was passed as “an industry-backed response to the radical advances in digital technology . . .”).

<sup>91</sup> See *A&M Records v. Napster, Inc.*, 239 F.3d 1004, 1027 (9th Cir. 2001) (“[W]e place the burden on plaintiffs to provide notice to Napster of copyrighted works and files containing such works available on the Napster system before Napster has the duty to disable access to the offending content.”).

<sup>92</sup> 17 U.S.C. §512(c)(3)(A).

DMCA takedown only works on pieces that infringe a copyrighted work—even having a trademark is insufficient to issue a takedown.<sup>93</sup> If the piece is not removed swiftly enough, the site owners could be liable for copyright infringement.<sup>94</sup> The difficulty with AI-generated art trained on copyrighted work is that it is still undecided in the law whether the use is infringing the copyrighted piece(s) and who owns the generated output.<sup>95</sup> Because of the unknowns still floating around copyright law, a takedown may or may not work on an AI-generated piece.<sup>96</sup> Despite new measures to aid in resolving copyright infringement disputes, a challenge persists and has been growing due to the rise in AI-generated works and the lack of a legal framework and protections.<sup>97</sup> More AI-generated music leads to more of what artists see as copyright infringement, but, unfortunately for human artists, the law has yet to see Generative AI in the same way.

#### D. AI's Generated Origin Story

Although AI discussions have become more prominent in recent years, AI is not a brand-new technology. Interest in AI grew in the 1960s and 1970s with the creation of neural networks woven into machine learning, which, in recent years, has led to the production of better, more sophisticated generated artworks.<sup>98</sup> Machine learning is the process of training a computer system without human

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<sup>93</sup> See 17 U.S.C. § 512(c)(3)(A) (“[A] notification of claimed infringement must be a written communication provided to the designated agent of a service provider that includes substantially the following: . . . [I]dentification of the copyrighted work claimed to have been infringed.”); see also *When Social Media Takedown Notices Aren't Enough*, JABURG WILK L. FIRM, <https://www.jaburgwilk.com/news-publications/when-social-media-takedown-notices-arent-enough> (last visited July 12, 2025) (“For trademark infringing content, there is no statutory equivalent of the DMCA’s takedown process.”).

<sup>94</sup> See *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005) (“One infringes contributorily by intentionally inducing or encouraging direct infringement, and infringes variously by profiting from direct infringement while declining to exercise the right to stop or limit it.”); see also *How Long Does a DMCA Takedown Take? When Can I Expect Results?*, DMCA AUTH., <https://dmcaauthority.com/how-long-does-dmca-takedown-take/> (last visited June 19, 2025) (explaining that DMCA takedowns could occur from 24 hours up to 6 months).

<sup>95</sup> Bao Tran, *How DMCA Affects AI-generated Music Platforms*, PATENTPC (Mar. 25, 2026), <https://patentpc.com/blog/how-dmca-affects-ai-generated-music-platforms>.

<sup>96</sup> See Bao Tran, *DMCA and AI Content Creation are Copyrighted Works Off-Limits?*, PATENTPC (Mar. 27, 2026), <https://patentpc.com/blog/dmca-and-ai-content-creation-are-copyrighted-works-off-limits> (“When AI is trained using copyrighted works, there’s an inherent risk of infringement. Even if the AI does not directly reproduce the copyrighted work, it could generate content that is too similar to the original material. In this case, the creator or user of the AI tool could potentially face a DMCA takedown notice or even a lawsuit for copyright infringement.”).

<sup>97</sup> See Muhammad Hamza Zakir et al., *Navigating the Legal Labyrinth: Establishing Copyright Frameworks for AI-generated Content*, 9 REMITTANCES REV. 2515, 2522 (Jan. 2024) (“As AI technologies advance, producing everything from artwork to literature and music, traditional copyright principles centered on human creativity are being tested, leading to a mosaic of legal battles across jurisdictions.”).

<sup>98</sup> Myk Eff, *The History and Evolution of AI-generated Art*, MEDIUM (June 3, 2023), <https://medium.com/p/e5cca5a8e83>; see also Larry Hardesty, *Explained: Neural Networks*, MASS. INST. TECH. (Apr. 14, 2017), <https://news.mit.edu/2017/explained-neural-networks-deep-learning-0414>.

intervention to learn and refine its performance on a task using “training data” provided to it for study.<sup>99</sup>

The human brain contains neurons that form networks through synaptic connections.<sup>100</sup> Artificial neural networks are comprised of layered, interconnected neurons that mimic the human learning process.<sup>101</sup> “Deep learning” adds layers to neural networks, enabling Generative AI models to analyze provided samples and generate new, structurally similar content.<sup>102</sup> There are several types of neural networks and methods for deep learning to train AI models.<sup>103</sup> The most common variant is supervised learning, where a program is given datasets of images separated into specific categories.<sup>104</sup> The program is fed an image, generates a corresponding output of scores representing the new data’s similarity to the original,<sup>105</sup> and the machine adjusts its internal parameters, called “weights,” until the resulting scores are close to the original.<sup>106</sup> Unfortunately, this process does not accept large amounts of data that are not yet separated into categories.<sup>107</sup> AI image generation at this stage required uncategorized data sets as the training data; therefore, supervised learning would not be sufficient.<sup>108</sup> In 2014, researchers solved the problem through unsupervised learning, in which machines examine

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<sup>99</sup> 15 U.S.C. § 9401(11).

<sup>100</sup> See Mary B. Kennedy, *Synaptic Signaling in Learning and Memory*, COLD SPRING HARBOR PERSPS. BIOLOGY (Dec. 30, 2013), <https://cshperspectives.cshlp.org/content/8/2/a016824.full.pdf+html> (“Excitatory neurons . . . each receive thousands of synaptic inputs and, in turn, make thousands of synaptic connections onto other neurons.”)

<sup>101</sup> See CHARU C. AGGARWAL, *NEURAL NETWORKS AND DEEP LEARNING* 1 (2d ed. 2023) (“This biological mechanism is simulated in artificial neural networks, which contain computation units that are referred to as neurons. . . . The computational units are connected to one another through weights, which serve the same role as the strengths of synaptic connections in biological organisms.”)

<sup>102</sup> See Hardesty, *supra* note 98; see also Elena Canorea, *Generative AI Beyond: How it Works and Real Use Cases*, PLAIN CONCEPTS, <https://www.plainconcepts.com/generative-ai-guide/> (last visited Mar. 27, 2026).

<sup>103</sup> See Yann LeCun et al., *Deep Learning*, 521 NATURE 436, 436 (2015).

<sup>104</sup> *Id.*

<sup>105</sup> See Gustavo E.A.P.A. Batista et al., *A Study of the Behavior of Several Methods for Balancing Machine Learning Training Data*, 6 ACM SIGKDD EXPLS. NEWSL. 20, 22 (2004) (“Some classifiers . . . yield a score that represents the degree to which an example is a member of a class. Such ranking can be used to produce several classifiers, by varying the threshold of an example pertaining to a class.”).

<sup>106</sup> LeCun et al., *supra* note 103; see also Rene Y. Choi et al., *Introduction to Machine Learning, Neural Networks, and Deep Learning*, 9 TRANSLATIONAL VISION SCI. & TECH. (SPECIAL ISSUE) 2, 2 (2020) (“The basic steps of supervised machine learning are (1) acquire a dataset and split it into separate training, validation, and test datasets; (2) use the training and validation datasets to inform a model of the relationship between features and target; and (3) evaluate the model via the test dataset. . . . In each iteration, the performance of the algorithm on the training data is compared with the performance on the validation dataset. In this way, the algorithm is tuned by the validation set.”).

<sup>107</sup> See Batta Mahesh, *Machine Learning Algorithms – A Review*, 9 INT’L J. SCI. & RSCH. 381, 386 (2020) (“If you have lesser amount of data and clearly labelled data for training, opt for Supervised Learning. Unsupervised Learning would generally give better performance and results for large data sets.”).

<sup>108</sup> See Stephanie Kirmer, *A Critical Look at AI Image Generation*, MEDIUM (Oct. 17, 2024), <https://medium.com/data-science/a-critical-look-at-ai-image-generation-45001f410147> (“[Image generator models are] created by taking giant datasets of images . . .”).

uncategorized, readily available raw data to learn how to categorize it.<sup>109</sup> Unsupervised learning teaches AI programs through generative adversarial networks (“GANs”) using generative neural networks.<sup>110</sup> There are many other methods of using AI to generate content, though GANs are among the more popular methods for generating multimedia.<sup>111</sup>

GANs pit two neural networks against each other: a generator that generates samples based on original samples provided by a data model, and a discriminator that distinguishes between the original samples and the generated fake samples.<sup>112</sup> Consider the generator as the “artist” and the discriminator as the “art critic”—the generator is tasked with producing a brown horse with blue eyes and a blonde mane, which the discriminator then reviews along with the training data to determine which images are fake and which are real.<sup>113</sup> The process alternates between the networks until the discriminator cannot distinguish between the original and the generated fakes.<sup>114</sup> GANs have since been continuously improved and now have a wide range of applications, including generating or modifying naturalistic images, creating data for training other models, and even transforming existing data.<sup>115</sup> However, these programs require input data to generate new images. The data models provided as input come from various online sources, legally downloaded or otherwise.<sup>116</sup> To quickly and efficiently gather data, programs were created to “scrape” or “mine” the Internet, compiling as much data as possible so the machine has plenty of data to learn from.<sup>117</sup>

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<sup>109</sup> See Anne-Sofie Maerten & Derya Soydaner, *From Paintbrush to Pixel: A Review of Deep Neural Networks in AI-generated Art*, ARXIV, <https://arxiv.org/pdf/2302.10913> (last updated Oct. 6, 2025); see also Will Knight, *Where the AI Art Boom Came From—and Where It’s Going*, WIRED (Jan. 12, 2023, 7:00 AM), <https://www.wired.com/gallery/where-the-ai-art-boom-came-from-and-where-its-going/>.

<sup>110</sup> See Maerten & Soydaner, *supra* note 109, at 4; see also Knight, *supra* note 109.

<sup>111</sup> See George Lawton, *GANs vs. VAEs: What Is the Best Generative AI Approach?*, TECH TARGET (Mar. 10, 2025), <https://www.techtartget.com/searchenterpriseai/feature/GANs-vs-VAEs-What-is-the-best-generative-AI-approach>.

<sup>112</sup> Knight, *supra* note 109; see also Ian Goodfellow et al., *Generative Adversarial Networks*, 63 COMM’NS ACM 139, 140-41 (2020).

<sup>113</sup> Sylvain Combettes, *A Basic Intro to GANs (Generative Adversarial Networks)*, TOWARDS DATA SCI. (Oct. 26, 2020), <https://towardsdatascience.com/a-basic-intro-to-gans-generative-adversarial-networks-c62acbcefff3/>.

<sup>114</sup> Maerten & Soydaner, *supra* note 109, at 4.

<sup>115</sup> See Knight, *supra* note 109; see also Goodfellow et al., *supra* note 112, at 144 (“[A]fter studying a collection of photos of zebras and a collection of photos of horses, GANs can turn a photo of a horse into a photo of a zebra.”).

<sup>116</sup> U.S. COPYRIGHT OFF., COPYRIGHT AND ARTIFICIAL INTELLIGENCE PART 3: GENERATIVE AI TRAINING 13-14 (forthcoming 2025) (“Training data can be acquired in various ways from a variety of sources. One common practice is downloading ‘publicly available’ data from the internet. This can mean . . . ‘scrap[ing]’ data from online sources, such as deploying stream-ripping software to download millions of video or subtitle files from YouTube. Or it can mean downloading pre-existing databases, such as an entire copy of Wikipedia using one of the regularly provided backups offered by the site.”).

<sup>117</sup> See Moaiad Ahmad Khder, *Web Scraping or Web Crawling: State of Art, Techniques, Approaches and Application*, 13 INT’L J. ADVANCES SOFT COMPUTING & APPLICATIONS 145 (2021) (“Web scraping or web crawling . . . can be used to gather and compile data from across thousands, or over millions, of pages for processing and drawing information from.”).

The explosion of AI-generated visual art began in 2022, when powerful programs such as DALL-E, Midjourney, and Stability AI became widely available.<sup>118</sup> These programs surpass previous Generative AI systems by being open to public use and generating even higher-quality, highly realistic images using diffusion models rather than GANs.<sup>119</sup> Diffusion models add visual “noise” to training data, or “irrelevant or additional data” that is added to help the machine “determine what [it is] looking at, even when the original image itself isn’t clear.”<sup>120</sup> By adding noise, the system learns to reverse the addition, allowing for better, faster image generation, as the system can now predict what noise needs to be removed from new data samples when generating images.<sup>121</sup> DALL-E was the first to program detailed image generation from a user’s text prompt.<sup>122</sup> Midjourney’s eruption was similar, starting as a bot on the popular communication platform Discord, where users only needed to type the command “/imagine” for prompts to quickly and easily generate images.<sup>123</sup> The public’s access to AI-generation programs has caused interest in AI-generated works to skyrocket.<sup>124</sup> As people had the opportunity to generate any and all art, companies like Microsoft and Meta began to follow the trend of text-to-image AI programs.<sup>125</sup>

Backlash and lawsuits against AI-training web scrapers recently surfaced regarding the unauthorized download of data for AI-training,<sup>126</sup> even though web scraping has been commonly used in search engines like Google for years.<sup>127</sup> Those

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<sup>118</sup> See Knight, *supra* note 109.

<sup>119</sup> See Maerten & Soydaner, *supra* note 109, at 5-6.

<sup>120</sup> Nanobaly, “Noise” in AI: How to Add Noise to Images to Optimize Model Training, INNOVATIANA (Aug. 9, 2024), <https://www.innovatiana.com/en/post/add-noise-in-ai> (defining noise as “irrelevant or additional data” which can be added during machine learning to help the machine “determine what [it is] looking at, even when the original image itself isn’t clear”).

<sup>121</sup> See Dave Bergmann & Cole Stryker, *What Are Diffusion Models?*, IBM, <https://www.ibm.com/think/topics/diffusion-models> (last visited Mar. 27, 2026); see also Kemal Erdem, *Step by Step Visual Introduction to Diffusion Models.*, ERDEM (Nov. 1, 2023), <https://erdem.pl/2023/11/step-by-step-visual-introduction-to-diffusion-models> (providing diagrams to aid visualizing the process); see also Sergios Karagiannakos & Nikolas Adaloglou, *How Diffusion Models Work: The Math from Scratch*, AI SUMMER (Sept. 29, 2022), <https://theaisummer.com/diffusion-models/>.

<sup>122</sup> See Kate Vass, *History of AI – the New Tools: DALL-E and Midjourney*, KATE VASS GALERIE (May 8, 2025), <https://www.katevassgalerie.com/blog/history-of-ai-dalle-midjourney>.

<sup>123</sup> Ugo Peter, *How Midjourney Became a Billion-Dollar AI Art Startup in Less Than a Year*, MEDIUM (Aug. 2, 2023), <https://medium.com/@oluigbopeter/how-midjourney-became-a-billion-dollar-ai-art-startup-in-less-than-a-year-416663997f77>.

<sup>124</sup> See Will Knight, *DALL-E Mini Is the Internet’s Favorite AI Meme Machine*, WIRED (June 27, 2022, 7:00 AM), <https://www.wired.com/story/dalle-ai-meme-machine/>.

<sup>125</sup> See *Top Generative AI and AI Art News from 2022*, ODSC (Dec. 13, 2022), <https://opendatascience.com/top-generative-ai-and-ai-art-news-from-2022/>.

<sup>126</sup> See Catherine Thorbecke, *Google Hit with Lawsuit Alleging It Stole Data from Millions of Users to Train Its AI Tools*, CNN (July 12, 2023, 8:48 AM), <https://www.cnn.com/2023/07/11/tech/google-ai-lawsuit/index.html>; see also Paul DelSignore, *The Growing Revolt Against AI Data Scraping*, MEDIUM (Aug. 15, 2023), <https://medium.com/the-generator/the-growing-revolt-against-ai-data-scraping-505d1a7ee1d2>.

<sup>127</sup> See *In-depth Guide to How Google Search Works*, GOOGLE, <https://developers.google.com/search/docs/fundamentals/how-search-works> (last updated Dec. 18,

opposed to web scraping argue that data mining impinges on privacy and that access to the scraped data requires consent.<sup>128</sup> Even Thomson Reuters, the owner of the popular legal research site Westlaw, brought a copyright infringement claim concerning data taken for AI training by the competing legal research site Ross.<sup>129</sup>

AI training concerns have been so prevalent that the United States Copyright Office launched an Artificial Intelligence initiative in March 2023 to “examine the copyright law and policy issues raised by [AI] . . . including the use of copyrighted materials in AI training.”<sup>130</sup> Through this initiative, the Copyright Office recently published some guidelines on Generative AI training, acknowledging that some training may be prima facie copyright infringement.<sup>131</sup> However, the report also includes a defense for data scraping, and no solution is given to artists fighting against AI programs that gather collections of long and arduous creative work only to easily generate similar art pieces.<sup>132</sup>

### E. AI’s Interference in the Visual Arts—and the Roaring Backlash

AI-generated art has been hit by controversies and public backlash, no matter what media it is shared across. AI-generated art shared on social media has drawn a multitude of negative comments, ranging from criticism of the ethics of AI art to cruel comments and bullying that have even extended to work that was not AI-made.<sup>133</sup> Outcry spread as AI generation grew, and the public made it clear it did not appreciate AI taking the place of human art.

The first AI-generated piece to be sold at the renowned New York auction house Christie’s, “*Edmond de Belamy*,” was sold for \$432,000 in 2018.<sup>134</sup> However, controversies over generated art mainly spread after an AI-generated piece won the Colorado State Fair’s digital art competition in 2022. Using

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2025) (“Once Google discovers a page’s URL, it may visit (or ‘crawl’) the page to find out what’s on it. We use a huge set of computers to crawl billions of pages on the web.”).

<sup>128</sup> See Vlad Krotov et al., *Legality and Ethics of Web Scraping*, 47 COMM’NS ASS’N FOR INFO. SYS. 555, 561-65 (Jan. 2020).

<sup>129</sup> Thomson Reuters Enter. Ctr. GmbH v. ROSS Intel. Inc., 765 F. Supp. 3d 382, 390-91 (D. Del. Feb. 11, 2025) (Ross trained its AI using “Bulk Memos,” which was a compilation of legal questions that included Westlaw headnotes Ross did not have permission to use).

<sup>130</sup> *Copyright Office Launches New Artificial Intelligence Initiative*, U.S. COPYRIGHT OFF. (Mar. 16, 2023), <https://www.copyright.gov/newsnet/2023/1004.html>.

<sup>131</sup> See U.S. COPYRIGHT OFF., *supra* note 116, at 26-31.

<sup>132</sup> See *id.*

<sup>133</sup> See generally Suyash Sahay, “*AI Slop*”: Fans React to LEGO GTA 6 Trailer 2 AI Remake, SPORTSKEEDA (May 23, 2025, 20:24 GMT), <https://www.sportskeeda.com/gta/ai-slop-fans-react-lego-gta-6-trailer-2-ai-remake> (discussing the comments received such as “Ai = lazy” and “BOOOOOO AI GENERATED IMAGREY SUCKS” when a user posted a LEGO remake of a GTA 6 trailer made by AI); see also SamDoesArts, *Artist Bullied off X/Twitter for “Using AI Art,”* YOUTUBE (Jan. 18, 2025), <https://www.youtube.com/watch?v=5xkSQMQy42g> (discussing how an X/Twitter slammed an artist’s piece for being AI-generated, causing other users to bully the artist until the account was deleted); see also @zentric101, X (Jan. 10, 2025, 9:23 PM), [https://x.com/zentric101/status/1877919340080632123?t=Qhyc9F-\\_koCn1Mw03cEDSg&s=19](https://x.com/zentric101/status/1877919340080632123?t=Qhyc9F-_koCn1Mw03cEDSg&s=19).

<sup>134</sup> Jonathan Jones, *A Portrait Created by AI Just Sold for \$432,000. But Is It Really Art?*, GUARDIAN (Oct. 26, 2018, 11:36 EDT), <https://www.theguardian.com/artanddesign/shortcuts/2018/oct/26/call-that-art-can-a-computer-be-a-painter>.

Midjourney, Jason Allen created “*Théâtre D’opéra Spatial*” by generating more than 900 images from various words and prompts.<sup>135</sup> After the outcry, the Colorado State Fair changed its art competition to allow AI-generated art but required artists to declare if they had used AI programs.<sup>136</sup>

Since the 2022 competition, controversies about AI use have not abated in the art world. In 2023, the Hague’s Mauritshuis museum held an open call titled “*My Girl with a Pearl*,” asking artists to create temporary substitutes for Johannes Vermeer’s famous painting *Girl with a Pearl Earring* while it was on loan to another museum.<sup>137</sup> The museum selected 170 submissions to display on its website, while the top five selections were printed and placed on the wall where the original painting hung.<sup>138</sup> However, Julian van Dieken, one winner and artist of *A Girl With Glowing Earrings*, revealed that his creation was an AI-generated image, and the online backlash was immediate.<sup>139</sup> Freelance art curator Elif Nadir theorizes that this uproar was caused because the original painting carried “such a deep national symbolism that its replacement by a random piece of computational art without historical dimension felt like an act of national betrayal.”<sup>140</sup>

Artist Hollie Mengert found a published Stable Diffusion model that enabled others to recreate AI-generated pieces in her distinct style, featuring light colors and joyful cartoon characters.<sup>141</sup> The model was linked to her name, and the pieces it produced mimicked her illustrations typically used for Disney and Nickelodeon commissions.<sup>142</sup> Mengert raised complaints online, but all that changed was that the model’s publisher, Ogbogu Kalu, updated the model with a file to inform downloaders that “Hollie [Mengert] is not affiliated with this.”<sup>143</sup>

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<sup>135</sup> See *Controversial AI-created Artwork That Won First Place, Sparks Changes at Colorado State Fair*, KOAA NEWS5, <https://www.koaa.com/news/covering-colorado/controversial-ai-created-artwork-that-won-first-place-sparks-changes-at-colorado-state-fair> (last updated July 19, 2023, 6:27 AM).

<sup>136</sup> *Id.*

<sup>137</sup> See *My Girl with a Pearl*, MAURITSHUIS, <https://www.mauritshuis.nl/en/what-s-on/mauritshuis-at-home/mygirlwithapearl> (last visited May 31, 2025).

<sup>138</sup> Taylor Dafoe, *After Sending ‘Girl With a Pearl Earring’ Out on Loan, the Mauritshuis Has Hung an A.I. Facsimile in Its Place. Fans Are Not Happy*, ARTNET (Feb. 28, 2023), <https://news.artnet.com/art-world/mauritshuis-museum-girl-with-a-pearl-earring-ai-facsimile-2263100>.

<sup>139</sup> *See id.*

<sup>140</sup> Elif Nadir, “*AI-Girl with a Pearl Earring*” – *Ethics & Arts or the Art of Ethics*, HOUSE OF ETHICS (Apr. 24, 2023), <https://www.houseofethics.lu/2023/04/24/the-ai-girl-with-a-pearl-earring-ethics-arts-or-the-art-of-ethics/>.

<sup>141</sup> See Andy Baio, *Invasive Diffusion: How One Unwilling Illustrator Found Herself Turned into an AI Model*, WAXY (Nov. 1, 2022), <https://waxy.org/2022/11/invasive-diffusion-how-one-unwilling-illustrator-found-herself-turned-into-an-ai-model/>.

<sup>142</sup> *Id.*; see generally Hollie Mengert, HOLLIE MENGERT: ABOUT ME, <https://holliemengert.com/aboutme> (last visited Aug. 4, 2025).

<sup>143</sup> Baio, *supra* note 141.

### III. CHAOS IN THE AURAL ARTS

“A voice is as distinctive and personal as a face. The human voice is one of the most palpable ways identity is manifested,” Judge Noonan wrote.<sup>144</sup> AI can—and has—been used without penalty to modify, distort, and mutilate music without crediting the original authors. Musicians face more issues than just stolen music, including lost profits, the threat of declining creativity, and unanswered questions about consent, because AI has been allowed to run rampant in its generation. The many artists who do not meet VARA’s standards are easy targets for AI, leading to a multitude of ethical problems even without addressing AI’s internal biases.<sup>145</sup>

#### A. Current Aural Protections

The law recognizes aural art protections under the “musical works . . . [and] sound recordings” categories.<sup>146</sup> Due to these different categories, a song could have multiple copyright holders, as the composer would hold the rights to the song as a musical work, and any musician who records the piece would hold the rights to the recording as a sound recording.<sup>147</sup>

Aural arts are granted the standard copyright protections of reproduction, allowances for derivative works, distribution, and the additional ability for artists of musical works to perform publicly.<sup>148</sup> Along with copyright protections, the law includes methods for other artists to use copyrighted works with the original creator’s permission; music, for example, requires two licenses to use a copyrighted song: a sync license to use the music with visual material, and a master-use license for the piece itself.<sup>149</sup> Before Generative AI entered the aural arts, people intending to use a song would need to obtain permission from the original artist and provide some compensation for the use, as an incentive to be granted permission and to acknowledge and respect the artist.<sup>150</sup> Despite the

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<sup>144</sup> *Midler v. Ford Motor Co.*, 849 F.2d 460, 463 (9th Cir. 1988).

<sup>145</sup> See Zachary Small, *Black Artists Say A.I. Shows Bias, With Algorithms Erasing Their History*, N.Y. TIMES (July 4, 2023), <https://www.nytimes.com/2023/07/04/arts/design/black-artists-bias-ai.html> (explaining how many artists found racial bias toward Black people, history and culture when using AI to generate images); see also Leonardo Nicoletti & Dina Bass, *Humans Are Biased. Generative AI Is Even Worse*, BLOOMBERG (June 9, 2023), <https://www.bloomberg.com/graphics/2023-generative-ai-bias/> (finding how most generated images of people in higher-paying jobs were men with light skin tones).

<sup>146</sup> 17 U.S.C. §102.

<sup>147</sup> See Hope Juzon, *Fake Drake? AI Music Generation Implicates Copyright and the Right of Publicity*, 99 WASH. L. REV. 987, 993 (2024).

<sup>148</sup> See 17 U.S.C. §106.

<sup>149</sup> See *Leadsinger, Inc. v. BMG Music Publ’g*, 512 F.3d 522, 527 (9th Cir. 2008) (“A synchronization license is required if a copyrighted musical composition is to be used in . . . synchronization with an audiovisual work.”) (quoting *ABKCO Music, Inc. v. Stellar Records, Inc.*, 96 F.3d 60, 62 n.4 (2d Cir. 1996)); see also *Agee v. Paramount Commc’ns, Inc.* 59 F.3d 317, 324 (2d Cir. 1995) (holding that defendant infringed plaintiff’s copyright because defendant failed to get a master use license to reproduce plaintiff’s soundtrack).

<sup>150</sup> See *How to Get Permission to Use a Song: The Ultimate Guide*, DOODOOC (Dec. 18, 2024), <https://blog.doodooc.com/how-to-get-permission-to-use-a-song/>.

requirement for permission, AI “artists” have been able to use music and other aural recordings without consent, prompting human artists to question why the law fails to apply to artificial artists.

What copyright law is missing is protection against using copyrighted material as training data. AI users and companies have recognized and exploited the gap as justification for using copyrighted art in data training.<sup>151</sup> Without access to copyrighted material, AI generators would have difficulty producing new pieces. Visual artists have the untested ability to sue for infringement because AI’s output is a modified, distorted variation of the input dataset, which the moral right of integrity protects against through VARA.<sup>152</sup> Preserving only specific visual artists’ integrity allows AI users and companies to continue exploiting a loophole in copyright protection where rights are extended to some, rather than all.

Individual voices have their own form of protection, even though the protections are not through copyright law. A sound recording requires the recording to be “fixed in any tangible medium,” which, according to the Ninth Circuit in *Midler v. Ford Motor Company*, does not cover the sound of the voice itself because sounds are not “fixed” expressions.<sup>153</sup> While a voice cannot be copyrighted, the right of publicity was established to protect against the “commercial use of one’s identity.”<sup>154</sup> One’s identity is used by “name, likeness, or other recognizable aspects of one’s persona,” including photographs of the individual and their voice.<sup>155</sup> The use must also be commercial to succeed in a right of publicity claim, which J. Thomas McCarthy argues “artistic works” do not fall under without “any form of exploitation that is done with the goal of making money.”<sup>156</sup>

Right of publicity has been successfully invoked in case law concerning a celebrity’s voice versus an AI mimic, but while a voice is protected, compositions and musical works are not protected by the right of publicity, even though they are created using voices.<sup>157</sup> This means the musician performing a piece is protected,

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<sup>151</sup> See Dan Milmo, ‘Impossible’ to Create AI Tools like ChatGPT Without Copyrighted Material, *OpenAI Says*, GUARDIAN (Jan. 8, 2024, 8:40 EST), <https://www.theguardian.com/technology/2024/jan/08/ai-tools-chatgpt-copyrighted-material-openai> (“OpenAI said it believed that ‘legally, copyright law does not forbid training’.”).

<sup>152</sup> See Enrico Bonadio & Siri-Helen Egeland, *Street and Graffiti Art Between Augmented Reality and Artificial Intelligence: A Copyright Perspective*, 18 U. ST. THOMAS L.J. 528, 541 (2022) (“Digital augmentation, distortion, and transformation triggered by . . . AI may also irritate practitioners of these forms of art and, in principle, amount to a violation of their integrity rights.”) (footnote omitted).

<sup>153</sup> *Midler v. Ford Motor Co.*, 849 F.2d 460, 462 (9th Cir. 1988) (“Copyright protects ‘original works of authorship fixed in any tangible medium of expression.’ A voice is not copyrightable. The sounds are not ‘fixed.’”) (quoting 17 U.S.C. §102(a)).

<sup>154</sup> See Jonathan Faber, *A Brief History of Right of Publicity (NIL)*, RIGHT OF PUBLICITY, <https://rightofpublicity.com/brief-history-of-rop> (last visited Aug. 3, 2025).

<sup>155</sup> See *Publicity*, CORNELL L. SCH., <https://www.law.cornell.edu/wex/publicity> (last visited Aug. 6, 2025).

<sup>156</sup> MCCARTHY & SCHECHTER, *supra* note 24, at § 3.4 (“The use must be ‘commercial’ in nature. . . . The antithesis of commercial use is the use of the plaintiff’s name or image in connection with news reporting, commentary or artistic works.”).

<sup>157</sup> See *Main Sequence, Ltd. v. Dudesy, LLC*, 2:24-cv-00711, (C.D. Cal. filed Jan. 25, 2024) (Court

but the song itself is not covered through this right. Right of publicity may have worked to sue Ghostwriter977 for “*Heart on My Sleeve*,” as the AI production used Drake and The Weeknd’s voices, but it would be a long process: UMG, Drake’s label, would need to discover who Ghostwriter977 was, and, if such information could be found, the fight would go to the court system without an end date in sight. Even if UMG were to emerge victorious, there would be no judgment ordering online sites like Spotify and YouTube to remove “*Heart on My Sleeve*,” because the right of publicity is not federally recognized and can only give a “trademark-like” interest.<sup>158</sup> The right of publicity may allow artists to sue or seek an injunction to combat publicly available AI programs, but there is no way to remove online, user-published AI-generated work without a clear indication that the AI work is reproducing copyrighted material.<sup>159</sup>

The right of publicity is also limited by its availability because it is not federally recognized.<sup>160</sup> Instead, this right is acknowledged in most—but not all—states, and the forms of protection vary considerably.<sup>161</sup> Though commonly used by celebrities, the right of publicity is supposedly available for all who live in certain states and believe their identity has been misused.<sup>162</sup> Despite this premise, several states that recognize the right of publicity require the individual’s “identity” to have economic value, which is easy for celebrities to demonstrate but difficult for non-celebrities.<sup>163</sup> A federal Nurture Originals, Foster Art and Keep

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Listener) (granting an injunction barring AI-generating defendants from “uploading, posting or broadcasting” media using plaintiff’s “image, voice or likeness” without express approval from plaintiffs); see also *Right of Publicity*, INT’L TRADEMARK ASS’N, <https://www.inta.org/topics/right-of-publicity/> (last visited Aug. 3, 2025).

<sup>158</sup> See *Lehrman v. Lovo, Inc.*, 790 F. Supp. 3d 348, 365 (S.D.N.Y. July 10, 2025) (quoting *Jackson v. Odenat*, 9 F. Supp. 3d 342, 355 (S.D.N.Y. 2014)); *Right of Publicity*, *supra* note 157.

<sup>159</sup> See Mr. DMCA Helper, *Steps to Take Down Copyright Infringing Content Using DMCA Notice*, DMCA, <https://www.dmca.com/FAQ/How-can-I-file-a-DMCA-Takedown-Notice> (last updated Nov. 22, 2023) (explaining the DMCA process to remove an online work requires proof of copyright ownership); see also *The DMCA Notice and Takedown Process*, COPYRIGHT ALL., <https://copyrightalliance.org/education/copyright-law-explained/the-digital-millennium-copyright-act-dmca/dmca-notice-takedown-process/> (last visited July 12, 2025) (“The DMCA notice and takedown process is a tool for copyright holders to get user-uploaded material that infringes their copyrights taken down off of websites and other internet sites.”).

<sup>160</sup> *Right of Publicity*, *supra* note 157; see *Main Sequence, Ltd. v. Dudesy*, 2:24-cv-00711 (C.D. Cal. filed Jan. 25, 2024) (CourtListener).

<sup>161</sup> See Jennifer Rothman, *Rothman’s Roadmap to the Right of Publicity*, RIGHT OF PUBLICITY ROADMAP, <http://rightofpublicityroadmap.com/> (last visited Aug. 8, 2025) (providing a state-by-state map of the United States that provide any chosen state’s information on the right of publicity); see also Samuel Cohen, *Closer to a Federal Right of Publicity – Senate Introduces NO FAKES Act*, SHEPPARD (Aug. 14, 2024), <https://www.mygamecounsel.com/2024/08/articles/artificial-intelligence/closer-to-a-federal-right-of-publicity-senate-introduces-no-fakes-act/>.

<sup>162</sup> Cristina Fernandez, *The Right of Publicity on the Internet*, 8 MARQ. SPORTS L. REV. 289, 291 (1998).

<sup>163</sup> See Jennifer L. Carpenter, *Internet Publication: The Case for an Expanded Right of Publicity for Non-Celebrities*, 6 VA. J.L. & TECH 3, 5-6 (“Whereas celebrities regularly prevail in litigation challenging the appropriation of their identities, non-celebrities have much more difficulty showing that the commercial value of their identity has been exploited.”); see also *Sarver v. Chartier*, 813 F.3d 891, 903 (9th Cir. 2016) (“California’s right of publicity law ‘prohibit[s] any other person from using

Entertainment Safe (“NO FAKES”) Act had been reintroduced to the House of Representatives and Senate in 2024.<sup>164</sup> The Acts were meant to mimic the right of publicity and provide federal protection for the identity and voice of all individuals.<sup>165</sup> Unfortunately, there has been no action on either bill, even as another version was presented to the House of Representatives in 2025.<sup>166</sup>

Unless the bill passes and is enacted, several states across the United States will continue to lack right-of-publicity protections, meaning lesser-known, smaller aural artists in those states are missing yet another right that could have, if used artfully, protected their art.<sup>167</sup>

### B. Stunningly Unprepared for AI and the Aural Arts

The copyright world was unprepared when AI-generated art began circulating in the arts, and because of the lack of protection, it has fallen to judges to decide what is and what is not allowed.<sup>168</sup> Congress has not presented a conclusive decision, and AI-generated auditory works continue to spread, taking advantage of the legal uncertainty and claiming that the voices and aural works by professionals, celebrities, and ordinary individuals seem to be fair game.<sup>169</sup>

“*Heart on My Sleeve*” went wildly viral in just a few days, and without any protections against AI’s terrifying power, Drake’s label had to dig deep to combat the generated piece, eventually using a small detail at the beginning.<sup>170</sup> While the AI song contained Ghostwriter977’s original lyrics, because the AI was trained on Drake’s copyrighted songs, the label was able to spot a “producer tag”—a watermark producers include to detect copying. UMG fought to have the song removed by issuing a DMCA takedown, and because the producer tag was part of the piece, showing direct copying of the original Drake song, the song was taken

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a celebrity’s name, voice, signature, photograph, or likeness for commercial purposes without the [celebrity’s] consent.”) (quoting *Comedy III Prods., Inc. v. Gary Saderup, Inc.*, 25 Cal. 4th 387, 391 (Cal. 2001)).

<sup>164</sup> NO FAKES Act of 2024, S. 4875, 118th Cong. (2024); NO FAKES Act of 2024, H.R. 9551, 118th Cong. (2024).

<sup>165</sup> See *SAG-AFTRA Applauds Introduction of NO FAKES Act in the House*, SAG AFTRA (Sept. 12, 2024), <https://www.sagaftra.org/sag-aftra-applauds-introduction-no-fakes-act-house>.

<sup>166</sup> See NO FAKES Act of 2025, H.R. 2794, 119th Cong. (2025); see also NO FAKES Act of 2024, S. 4875, 118th Cong. (2024); NO FAKES Act of 2024, H.R. 9551, 118th Cong. (2024).

<sup>167</sup> See Rothman, *supra* note 161.

<sup>168</sup> See Diane Hong, *Legal Frontiers in Copyright: The Case of AI-generated Artwork*, SYRACUSE J. INT’L L. & COM. BLOG (Feb. 5, 2024), <https://jilc.syr.edu/2024/02/05/legal-frontiers-in-copyright-the-case-of-ai-generated-artwork/> (“[T]he emergence of AI-generative platforms has broadened the role of a judge, intensifying the legal challenges regarding appropriation art. Such legal disputes often bear unsatisfactory conclusions since they bestow an art critic’s role to the judge and the judges are being asked to rule on the very nature of art.”).

<sup>169</sup> See Matt Reynolds, *AI-generated Music is Everywhere; is Any of it Legal?*, ABA J. (Jan. 18, 2024, 3:50 PM), <https://www.abajournal.com/web/article/ai-generated-music-is-everywhere-is-any-of-it-legal>.

<sup>170</sup> See Nilay Patel, *AI Drake Just Set an Impossible Legal Trap for Google*, VERGE (Apr. 19, 2023, 1:11 PM), <https://www.theverge.com/2023/4/19/23689879/ai-drake-song-google-youtube-fair-use> (“‘We removed the video after receiving a valid copyright notification for a sample included in the video,’ is what YouTube spokesperson Jack Malon said about the situation.”).

down.<sup>171</sup> However, UMG and those looking for the producer tag were likely the only ones who could identify that this was copyrighted.<sup>172</sup> Without the tags, it would be much more difficult for a label to tell if the piece is copyrighted, and even more challenging to prove enough evidence to justify a takedown, because an artist's *style* is currently fair game.<sup>173</sup>

Drake has not just been a victim of AI in music but also a contributor to the problem. Drake released a diss track in April 2024, using AI to generate the voices of rappers Snoop Dogg and the late Tupac Shakur (“2Pac”) to antagonize fellow rapper Kendrick Lamar during their feud.<sup>174</sup> Despite not intending to profit from the song, Drake had to pull the song from all platforms when 2Pac’s estate threatened to sue.<sup>175</sup> While Drake’s diss track was more obvious about its AI-generated cameos, as 2Pac had unfortunately passed in 1996,<sup>176</sup> it did not stop the public from flooding Snoop Dogg with questions and concerns about the piece.<sup>177</sup> Neither 2Pac’s estate nor Snoop Dogg had permitted Drake to use their voices or status to participate in his feud, nor had they approved of the message their voices had said on the track.

AI began to transition to vocal recordings when James Earl Jones retired as the voice of Darth Vader, but allowed Disney to keep and utilize existing data files of his voice.<sup>178</sup> Disney turned to the company Respeecher to create new, AI-made dialogue based on the existing archival recordings.<sup>179</sup> The recordings were then trained into Respeecher’s system and layered over another actor who read the requested lines.<sup>180</sup> The company did the same for Hungary’s late Darth Vader voice

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<sup>171</sup> Steve Kramarsky & Jack Millson, *Non-Functional by Design?—Court Considers the Applicability of Copyright Act to ‘Look and Feel’ of a Website*, N.Y.L.J. ONLINE (May 15, 2023); see also Patel, *supra* note 170 (“UMG has followed up by issuing individual URL-by-URL takedowns to YouTube as copies of the song pop up, all based on the Metro Boomin tag . . .”).

<sup>172</sup> Grasser et al., *supra* note 3.

<sup>173</sup> See *id.*; Patel, *supra* note 170 (“[I]f Ghostwriter977 simply uploads ‘Heart on [M]y Sleeve’ without that Metro Boomin tag, they will kick off a copyright war that pits the future of Google against the future of YouTube in a potentially zero-sum way.”).

<sup>174</sup> Matthew Strauss, *Drake Taunts Kendrick Lamar Again on Diss Song with AI 2Pac and Snoop Dogg Verses*, PITCHFORK (Apr. 20, 2024), <https://pitchfork.com/news/drake-taunts-kendrick-lamar-again-on-diss-song-with-ai-2pac-and-snoop-dogg-verses/>.

<sup>175</sup> See Silvia Tine, *Snoop Dogg Reacts to Drake’s AI Diss Track Aimed at Kendrick Lamar*, DILEMA RADIO (Apr. 20, 2024), <https://dilemaradio.com/snoop-dogg-reacts-to-drakes-ai-diss-track-aimed-at-kendrick-lamar/> (noting that Drake did not make the track available on streaming platforms); see also Maya Chung, *Why Drake Had to Take Down His Song That Featured AI-Tupac Vocals*, TIME MAG. (Apr. 26, 2024, 5:00 PM), <https://time.com/6971720/drake-tupac-ai/> (Howard King, attorney for 2Pac’s estate, called the use of the deceased rapper’s voice a “flagrant violation” and “blatant abuse” of 2Pac’s legacy).

<sup>176</sup> *Tupac Shakur Dies*, HISTORY.COM, <https://www.history.com/this-day-in-history/september-13/tupac-shakur-dies> (last updated May 27, 2025).

<sup>177</sup> See Tine, *supra* note 175.

<sup>178</sup> See Sarah Parvini, *James Earl Jones’ Darth Vader Voice Lives on Through AI. Voice Actors See Promise and Peril in That*, AP NEWS (Sept. 10, 2024, 11:59 PM), <https://apnews.com/article/james-earl-jones-darth-vader-artificial-intelligence-10643d1a4b5b13575d4a7b457f0d858e>.

<sup>179</sup> Tim Lammers, *James Earl Jones Signed Over Rights for AI to Recreate Darth Vader’s Voice*, FORBES, <https://www.forbes.com/sites/timlammers/2024/09/09/james-earl-jones-signed-over-rights-for-ai-to-recreate-darth-vaders-voice/> (last updated Sept. 9, 2024, 11:55 PM).

<sup>180</sup> *Voice Cloning F.A.Q.*, RESPEECHER, <https://www.respeecher.com/faq> (last visited May 23, 2025).

actor, completing the voice model in only two weeks, which, the company writes, was longer than it had hoped.<sup>181</sup> The recreated Darth Vader sound is now used in new shows and movies released after Jones's vocal retirement from Darth Vader, and can even be heard in video games like *Fortnite*.<sup>182</sup> While Jones's decision to allow the use of his voice makes sense for a character as iconic as Darth Vader with an equally iconic voice,<sup>183</sup> the fact that AI now offers the same possibilities to all types of voice roles raises new concerns for voice actors: that studios would prefer a quicker, easier, artificial "actor" to fill their shoes.<sup>184</sup>

Even without moral rights protections, some individuals whose voices had been "copied" sought other means to protect themselves. Sony Music Group, UMG, and Warner Music Group sued AI music companies Suno and Udio for using copyrighted songs in their AI's training data.<sup>185</sup> The lawsuit was filed in June 2024, but the trial has yet to be scheduled.<sup>186</sup> Bette Midler refused Ford's request to sing in its commercial, prompting Ford to hire a "sound-alike," which led to a right of publicity lawsuit against Ford and its advertising agency, resulting in a \$400,000 judgment for Midler at a jury trial.<sup>187</sup> Rachel Reed, when commenting on the Drake and The Weeknd "song" from 2023, recommends bypassing a copyright protection argument completely, instead citing the Midler case and the right of publicity.<sup>188</sup> This recommendation means Reed believes that copyright law is not sufficient to protect a copyrightable work—in this case, music—from infringement.<sup>189</sup> Scarlett Johansson claimed the AI personal assistant released by OpenAI in May 2024 used a voice actress who copied Johansson's voice to the

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<sup>181</sup> *Reviving the Hungarian Voice of Darth Vader with AI Voice Cloning Technology*, RESPEECHER, <https://www.respeecher.com/case-studies/reviving-the-hungarian-voice-of-darth-vader> (last visited July 2, 2025).

<sup>182</sup> John-Anthony Disotto, *Forget the Force, AI Brings the Late James Earl Jones' Iconic Darth Vader Voice to Fortnite*, TECHRADAR (May 16, 2025), <http://techradar.com/computing/artificial-intelligence/forget-the-force-ai-brings-the-late-james-earl-jones-iconic-darth-vader-voice-to-fortnite>.

<sup>183</sup> See Carlos Morales, *James Earl Jones' Voice Is the Only Reason the Most Iconic Villain in Movie History Exists*, IGN, <https://www.ign.com/articles/james-earl-jones-voice-acting-darth-vader-mufasa> (last updated Sept. 11, 2024, 5:11 PM) ("To this day, Vader remains one of the most prominent voice roles in film history . . ."); see also David Garcia-Gonzalez, *The Iconic Darth Vader Voice*, GOLOCALISE (Apr. 26, 2023), <https://glocalise.com/blog/the-iconic-darth-vader-voice/> ("The voice of Darth Vader is one of the most iconic and recognizable voices in popular culture. It's a deep and menacing voice that has become synonymous with the character himself.").

<sup>184</sup> See Jeremy Engle, *Are You Worried About A.I. Taking Human Jobs?*, N.Y. TIMES (Feb. 7, 2025), <https://www.nytimes.com/2025/02/07/learning/are-you-worried-about-ai-taking-human-jobs.html> (voice actor Hank Azaria finds it a little worrisome and "plain wrong" that artificial intelligence could soon recreate the voices he had created for the show "The Simpsons.>").

<sup>185</sup> See *Record Companies Bring Landmark Cases for Responsible AI Against Suno and Udio in Boston and New York Federal Courts, Respectively*, RECORDING INDUS. ASS'N AM. (June 24, 2024), <https://www.riaa.com/record-companies-bring-landmark-cases-for-responsible-ai-against-suno-and-udio-in-boston-and-new-york-federal-courts-respectively/>.

<sup>186</sup> See *UMG Recordings, Inc. v. Suno, Inc.*, No. 1:24-cv-11611 (Mass. Dist. Ct. filed June 24, 2024) (CourtListener).

<sup>187</sup> *Midler v. Young & Rubicam, Inc.*, Nos. 90-55027, 90-55028, 1991 U.S. App. LEXIS 22641, at \*2 (9th Cir. Sept. 20, 1991).

<sup>188</sup> Reed, *supra* note 21.

<sup>189</sup> See *id.*

point where close friends could not discern the AI voice as someone else, according to the actress.<sup>190</sup> Johansson went public with the dispute and retained legal counsel, to which OpenAI responded by removing the personal assistant.<sup>191</sup> While legal action has yet to be filed after OpenAI removed the personal assistant voice similar to Johansson's, some believe the actress still has a claim under the right of publicity.<sup>192</sup> To draw attention to the problem and the dislike of AI and its "predatory" nature, musicians across multiple genres and levels of popularity have begun signing an open letter warning against AI to defend the music industry, though there is no clear indication that this attempt has worked.<sup>193</sup>

The open letter renouncing AI's hand in musical compositions shows these musicians understand the potential disasters of AI's impact in their field: creators like Ghostwriter977 will not stop producing "original" pieces like "*Heart on My Sleeve*." Instead, AI creators will find a way around producer tags so labels cannot issue a takedown next time. "[I]'m just getting started," Ghostwriter977 posted, urging listeners to drop their phone numbers to send individuals the AI song with a "new link if they take it down" to get around the takedown.<sup>194</sup> All that was learned from Ghostwriter977's attempt was how not to use a celebrity as clickbait. "[AI generators] have data that doesn't belong to them," artist Karla Ortiz says, "That data is my artwork, that's my life. It feels like my identity."<sup>195</sup> In just a few words, Ortiz summarizes the concept that illustrates the entire reason for the existence of moral rights.

The more AI develops, the more convincing it becomes, to the point where listeners struggle to tell apart authentic voices from fake, generated voices.<sup>196</sup> While it may be a fun thought at first, perhaps to trick friends or make personalized Batman quotes,<sup>197</sup> AI and its uses in aural creations become concerning when used

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<sup>190</sup> Bobby Allyn, *Scarlett Johansson Says She Is 'Shocked, Angered' over New ChatGPT Voice*, NPR (May 20, 2024, 7:16 PM), <https://www.npr.org/2024/05/20/1252495087/openai-pulls-ai-voice-that-was-compared-to-scarlett-johansson-in-the-movie-her>.

<sup>191</sup> Dan Milmo, *Scarlett Johansson's OpenAI Clash Is Just the Start of Legal Wrangles over Artificial Intelligence*, GUARDIAN (May 27, 2024, 9:33 EDT), <https://www.theguardian.com/technology/article/2024/may/27/scarlett-johansson-openai-legal-artificial-intelligence-chatgpt>.

<sup>192</sup> *Id.*

<sup>193</sup> See Cheyenne DeVon, *Billie Eilish, Nicki Minaj, Jon Bon Jovi and over 200 Artists Call for Protections Against "Predatory Use of AI"*, CNBC (Apr. 5, 2024, 2:35 PM), <https://www.cnbc.com/2024/04/05/billie-eilish-nicki-minaj-200-artists-sign-letter-against-ai-music.html>.

<sup>194</sup> Daysia Tolentino, *Viral AI-powered Drake and The Weeknd Song Is Removed from Streaming Services*, NBC News (Apr. 18, 2023, 2:04 PM), <https://www.nbcnews.com/pop-culture/viral-ai-powered-drake-weeknd-song-removed-streaming-services-rcna80098>.

<sup>195</sup> Kashmir Hill, *This Tool Could Protect Artists from A.I.-Generated Art That Steals Their Style*, N.Y. TIMES (Feb. 13, 2023), <https://www.nytimes.com/2023/02/13/technology/ai-art-generator-lensa-stable-diffusion.html>.

<sup>196</sup> See Simon Bland, *"Unsuspecting Listeners Couldn't Tell the Difference Between AI Renderings and the Real Thing"*, NAT'L MUSEUMS LIVERPOOL, <https://www.liverpoolmuseums.org.uk/stories/unsuspecting-listeners-couldnt-tell-difference-between-ai-renderings-and-real-thing> (last visited July 4, 2025).

<sup>197</sup> See *Batman AI Voice Generator – the Dark Knight Hero*, NICEVOICE, <https://nicevoice.org/ai-voice-generator/batman/> (last visited Mar. 23, 2026).

for nefarious purposes.<sup>198</sup> Though AI technology is nothing new, it continues to uncover new areas to expand into, much to the chagrin of musicians who find their art unprotected against this new wave of technology.

### C. Losses Musicians Face

Artists can earn money for their creations through various ways, such as selling their art, crowdfunding, or commissions.<sup>199</sup> Musicians, for example, earn royalties from two separate copyrights when their song is played: composition—lyrics and melodies used in the song—and sound recording, the actual audio recording of the song.<sup>200</sup> The increase in AI scraping artists' work and livelihoods means artists currently have to choose between two evils: either letting others scrape, generate, and sell art based on the artist's own works, or pulling their art from websites, which means losing clients, fame, and commissions.<sup>201</sup> Because of AI, artists are now competing with an artificial, faster, and cheaper version of themselves.<sup>202</sup> "I think artists should be more afraid because I could see the music industry saying, 'We don't really need you anymore. We have your vocal profile,'" says SIXFOOT5, a songwriter who uses AI to change the voice of his songs into that of famous singer-songwriter Adele.<sup>203</sup> After "*Heart on My Sleeve*" was released, Spotify CEO Daniel Ek praised AI and its ability to convincingly generate music, claiming it would benefit the music industry because it would "lead to more music . . . [and] also benefit[] Spotify, because the more creators we

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<sup>198</sup> See Sebastian Starcevic, *AI 'Tom Cruise' Joins Fake News Barrage Targeting Olympics*, POLITICO (Nov. 10, 2023, 9:25 AM), <https://www.politico.eu/article/ioc-says-it-was-hit-by-fake-news-campaign-and-ai-tom-cruise/> (discussing when Tom Hanks was involved in a documentary bashing the Olympics, only to find the actor was AI-generated); see also Carson Blackwelder, *Tom Hanks Warns Followers About AI-generated Ads Using His Name, Likeness and Voice*, ABC NEWS (Aug. 30, 2024, 10:33 AM), <https://abcnews.go.com/GMA/Culture/tom-hanks-warns-followers-ai-generated-ads/story?id=113272901>; Carrie Pallardy, *How Big of a Threat is AI Voice Cloning to the Enterprise?*, INFO. WEEK (Mar. 13, 2025), <https://www.informationweek.com/machine-learning-ai/how-big-of-a-threat-is-ai-voice-cloning-> (YouTube's CEO sent content creators private videos that turned out to be AI to "steal credentials and install malware.").

<sup>199</sup> Amanda Myers, *How Digital Artists Can Monetize Their Art*, SPREADSHOP (Mar. 1, 2024), <https://www.spreadshop.com/blog/2024/03/01/how-digital-artists-can-monetize-their-artwork-in-2024/>.

<sup>200</sup> Amy X. Wang, *How Musicians Make Money – or Don't at All – In 2018*, ROLLINGSTONE (Aug. 8, 2018), <https://www.rollingstone.com/pro/features/how-musicians-make-money-or-dont-at-all-in-2018-706745/>.

<sup>201</sup> See Claudia Sofia Quiñones Vilá, *A Brave New World: Maneuvering the Post-Digital Art Market*, 12 ARTS 240 (Nov. 16, 2023), <https://www.mdpi.com/2076-0752/12/6/240> ("[A]rtists can remove their artwork from websites or only upload low-resolution images, but this negatively impacts their ability to obtain new commissions and make a living.").

<sup>202</sup> See Baio, *supra* note 141 ("[AI] directly uses the work of the artists themselves to replace them."); see also Oren Bracha, *Generating Derivatives: AI and Copyright's Most Troublesome Right*, 25 N.C.J.L. & TECH. 345, 353 (Apr. 2024) ("[T]echnology can supply consumer demand at low cost and on an impressive level of customization and quality.").

<sup>203</sup> Nathan Rousseau Smith, Emily Lippiello & Ivan Pereira, *AI Songs That Mimic Popular Artists Raising Alarms in the Music Industry*, ABC NEWS (Nov. 3, 2023, 1:44 PM), <https://abcnews.go.com/US/ai-songs-mimic-popular-artists-raising-alarms-music/story?id=104569841>.

have on our service the better it is and the more opportunity we have to grow engagement and revenue.”<sup>204</sup>

AI and its music generation ability could grow Spotify, but at a significant cost to the original artists—Michael Smith is currently facing charges for using AI bots to stream his AI-generated songs billions of times, stealing “millions in royalties that should have been paid to musicians, songwriters, and other rights holders whose songs were legitimately streamed.”<sup>205</sup> A popular music streaming platform, Deezer, reported in April 2025 that 18% of daily uploads are AI-generated, a massive jump from 10% in January 2025.<sup>206</sup> Spotify has even created playlists made solely of AI-generated, “generic ambient tracks by artists that don’t actually exist.”<sup>207</sup> The commercial acceptance of AI-generated works has caused human artists to lose well-earned commissions in the name of “creation.”<sup>208</sup>

Though artists and their creations are the backbone of AI-generated art, some music creators globally will see 24% of their revenues at risk of loss by 2028.<sup>209</sup> By that time, AI music is projected to comprise 20% of music streaming platform revenues and nearly 60% of music library revenues.<sup>210</sup> Musicians take home, on average, close to 12% of national industry revenues, partly because streaming services pay ridiculously low royalties.<sup>211</sup> Artists already struggle to earn a living from their art’s revenue, most resorting to collaboration deals with

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<sup>204</sup> Elizabeth Dilts Marshall, *Spotify’s Daniel Ek Praises AI’s Potential to Boost Music Creation – and the Company’s Bottom Line*, BILLBOARD (Apr. 25, 2023), <https://www.billboard.com/pro/spotify-ceo-daniel-ek-praises-artificial-intelligence/>.

<sup>205</sup> Liv McMahon, *Man Accused of Using Bots and AI to Earn Streaming Revenue*, BBC (Sept. 6, 2024), <https://www.bbc.com/news/articles/cly3ld9wy3eo>; see also *North Carolina Musician Charged with Music Streaming Fraud Aided by Artificial Intelligence*, U.S. ATT’Y’S OFF. S.D.N.Y. (Sept. 4, 2024), <https://www.justice.gov/usao-sdny/pr/north-carolina-musician-charged-music-streaming-fraud-aided-artificial-intelligence>; see also *United States v. Smith*, No. 1:24-cr-00504, (S.D.N.Y. filed Aug. 26, 2024) (CourtListener).

<sup>206</sup> *Deezer Reveals 18% of All New Music Uploaded to Streaming is Fully AI-generated*, DEEZER NEWSROOM (Apr. 16, 2025), <https://newsroom-deezer.com/2025/04/deezer-reveals-18-of-all-new-music-uploaded-to-streaming-is-fully-ai-generated/>.

<sup>207</sup> LIZ PELLY, MOOD MACHINE: THE RISE OF SPOTIFY AND THE COSTS OF THE PERFECT PLAYLIST 52 (2025).

<sup>208</sup> See Matt Corral, *The Harm & Hypocrisy of AI Art*, CORRAL DESIGN, <https://www.corralldesign.com/writing/ai-harm-hypocrisy> (last visited July 29, 2025) (“Now, the companies who would have previously hired artists can turn to a cheap, mechanical equivalent, and as long as this option is available some won’t be able to resist. AI images may be inferior in the details, but they’re incredibly cost efficient and near instantaneous.”).

<sup>209</sup> *Global Economic Study Shows Human Creators’ Future at Risk from Generative AI*, CISAC (Dec. 2, 2024), <https://www.cisac.org/Newsroom/news-releases/global-economic-study-shows-human-creators-future-risk-generative-ai>.

<sup>210</sup> *Id.*

<sup>211</sup> Amy X. Wang, *Musicians Get Only 12 Percent of the Money the Music Industry Makes*, ROLLINGSTONE (Aug. 7, 2018), <https://www.rollingstone.com/pro/news/music-artists-make-12-percent-from-music-sales-706746/> (reporting how total music revenues per year is around \$43 billion, while artists are paid \$5 billion, or close to twelve percent); see also Lia Faenza, *Playing for Pennies: How Streaming Royalties Leave Independent Artists Struggling*, WASH (Dec. 6, 2024), <https://thewash.org/2024/12/06/playing-for-pennies-how-streaming-royalties-leave-independent-artists-struggling/> (commenting on the amount streaming giants pay, with Apple Music paying \$0.0075 in royalties and Spotify paying \$0.003).

major companies like Apple or clothing stores, and introducing AI-generated music that both copies a musician and detracts from their streaming revenue is an added hardship musicians were not prepared to face.<sup>212</sup> Professor Ben Zhao believes artists are “afraid of posting new art,” because of a “fear of feeding this monster that becomes more and more like them.”<sup>213</sup> “For a band that doesn’t even really exist to then get all that social media traction, it’s so discouraging,” says newer musician Tilly Louise, commenting on the viral rise of AI-generated band “The Velvet Sundown.”<sup>214</sup> Though the music industry has always been a competitive field, what was once artist versus artist has now become artists versus a machine that could displace any and all of them.<sup>215</sup>

On the other hand, the U.S. Bureau of Labor Statistics’ (“BLS”) Occupational Outlook Handbook predicts no significant changes in employment rates in the Arts and Design industry from 2024 to 2034 and even a slight growth of 2%-3% in employment during that time.<sup>216</sup> Additionally, companies like YouTube and Deezer have developed technology to flag uploaded pieces that contain “synthetic audio.”<sup>217</sup> This way, Deezer says, the site “maintain[s] transparency within its platform while recognizing the contributions of human artists.”<sup>218</sup> Even AI rights management sites Vermillio and Musical AI are working on technology that extends YouTube’s ability to tag pieces made from synthetic audio automatically.<sup>219</sup>

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<sup>212</sup> See Dave Edwards, *The Music Industry Is Built on Artists, but Shuns Creators*, FUTURE (Oct. 5, 2021), <https://future.com/music-copyright-ugc/> (“One of the primary reasons most musicians—not just the top .01 percent—need to make money outside of recorded music is because the economics of streaming make it incredibly difficult to make a living, much less generate wealth, off listening alone.”).

<sup>213</sup> Hill, *supra* note 195.

<sup>214</sup> Dylan Butts, *AI-generated Music Is Going Viral. Should the Music Industry be Worried?*, CNBC (July 17, 2025, 1:27 AM), <https://www.cnbc.com/2025/07/17/ai-generated-music-is-going-viral-should-the-music-industry-worry.html>.

<sup>215</sup> See Adam Clair, *What AI in Music Can – and Can’t – Do*, VOX (Aug. 5, 2024, 8:00 AM), <https://www.vox.com/the-highlight/358201/how-does-ai-music-work-benefits-creativity-production-spotify> (“Whereas musicians may have seen each other as competition just a couple of years ago . . . AI poses a threat to the field as a whole that may not benefit even the luckiest among them.”).

<sup>216</sup> *Entertainment and Sports Occupations*, U.S. BUREAU LAB. STAT. (Aug. 28, 2025), <https://www.bls.gov/ooh/entertainment-and-sports/home.htm>; see also *Arts and Design Occupations*, U.S. BUREAU LAB. STAT. (Apr. 18, 2025), <https://www.bls.gov/ooh/arts-and-design/home.htm>; see also *Music Directors and Composers*, U.S. BUREAU LAB. STAT. (Aug. 28, 2025), <https://www.bls.gov/ooh/entertainment-and-sports/music-directors-and-composers.htm>; see also *Musicians and Singers*, U.S. BUREAU LAB. STAT. (Sept. 16, 2025), <https://www.bls.gov/ooh/entertainment-and-sports/musicians-and-singers.htm>.

<sup>217</sup> Jack Buehrer, *The Music Industry Is Building the Tech to Hunt Down AI Songs*, VERGE (June 21, 2025, 7:00 AM), <https://www.theverge.com/ai-artificial-intelligence/686767/music-industry-ai-song-detection-tracking-licensing>; see also *Deezer Reports 18 Percent of Daily Music Uploads Are AI-generated*, VMP (Apr. 18, 2025), <https://web.archive.org/web/20250526173711/https://www.vinylmeplease.com/blogs/music-industry-news/deezer-reports-18-percent-of-daily-music-uploads-are-ai-generated#section4>.

<sup>218</sup> *Deezer Reports 18 Percent of Daily Music Uploads are AI-generated*, *supra* note 217.

<sup>219</sup> See Buehrer, *supra* note 217.

But as Comic Lab podcast co-host Brad Guigar says, “I think much like automation in factories where a robot can’t build the whole car, but a robot could build 40% to 60% of the car, you’re going to have a lot of uses for AI art.”<sup>220</sup> While employment rates are not expected to decrease, the BLS figures likely include music produced by AI creators, who could be employed for a majority of projects due to the cheaper, faster results they deliver. Furthermore, few music streaming giants, especially the popular beasts Spotify and Apple Music, are flagging AI-generated music; on the contrary, Spotify actively promotes and encourages AI-generated tracks.<sup>221</sup> At the very least, allowing AI generators to use existing pieces haphazardly in any manner they choose lowers the value of all art.<sup>222</sup>

#### D. Does No Consent Equal Theft?

Leaving out aural art from the VARA protections does not mean there are no attribution or integrity concerns in the aural arts. AI programs, as the creators lack sync licenses and master-use licenses, are not legally using the scraped songs.<sup>223</sup> Allowing AI to bypass copyright protections illegally seems to stray from the preservation of moral values in the arts, thereby defeating VARA’s primary purpose.<sup>224</sup>

AI artists have argued that artists throughout history—including, maybe even especially musicians—have also “stolen” from other creators to create something new.<sup>225</sup> But the difference is that human creators take inspiration from

<sup>220</sup> *Have We Become the People We Fought?*, COMIC LAB, at 20:55 (Sept. 1, 2022), <https://pocketcasts.com/podcasts/ebf6dd20-d33c-0135-9e60-5bb073f92b78/16d9c50a-81b2-4739-b429-e429090659fb>.

<sup>221</sup> See PELLY, *supra* note 207, at 125-26 (discussing how Spotify temporarily removed 7% of Generative AI company Boomy’s tracks solely because the AI-generated songs were streamed by AI listeners, not because Boomy’s 14.5 million songs were AI-generated); see also Graham Barlow, *Apple and Spotify are Sleepwalking into an AI Music Crisis – and The Velvet Sundown Mess Shows They Need to Act Fast*, TECHRADAR (July 3, 2025), <https://www.techradar.com/computing/artificial-intelligence/apple-and-spotify-are-sleepwalking-into-an-ai-music-crisis-and-the-velvet-sundown-mess-shows-they-need-to-act-fast>.

<sup>222</sup> See Kelly LeBlanc, *Art Under Fire: How AI Challenges Artistic Authenticity and Integrity*, INFORMATION TODAY (May 2024), <https://www.infoday.com/it/may24/LeBlanc--How-AI-Challenges-Artistic-Authenticity-and-Integrity.shtml> (“AI tools have a negative effect on professional opportunities for contemporary artists, craftspeople, and creators. . . . [AI] reduces work and contracts, lowers the monetary value of art in our modern world, and even undermines the creativity and skills required to be an artist.”).

<sup>223</sup> See *Leadsinger, Inc. v. BMG Music Publ’g*, 512 F.3d 522, 527 (9th Cir. 2008) (“A synchronization license is required if a copyrighted musical composition is to be used in . . . synchronization with an audiovisual work.”) (quoting *ABKCO Music, Inc. v. Stellar Records, Inc.*, 96 F.3d 60, 63 n.4 (2d Cir. 1996)); see also *Agee v. Paramount Communs., Inc.* 59 F.3d 317, 324 (2d Cir. 1995) (holding that defendant infringed plaintiff’s copyright because defendant failed to get a master use license to reproduce plaintiff’s soundtrack).

<sup>224</sup> See Bonneau, *supra* note 44, at 65 (“[VARA] is specifically predicated on the ‘preservation model’ of moral rights, whereby the destruction of works of art not only affects an artist’s reputation, but also ‘represents a loss to society.’”).

<sup>225</sup> See Mike Loukides, *Creativity Isn’t Just Remixing*, O’REILLY (Nov. 14, 2023), <https://www.oreilly.com/radar/creativity-isnt-just-remixing/> (“It’s naïve to say that creativity isn’t

others, sometimes even lifting direct sounds, with the end result building on that inspiration and using human emotion and experience to create something new.<sup>226</sup> Furthermore, artists have been largely aware that their work may serve as the backbone inspiration for other creations, but are usually unaware that they are the subject of or included in an AI-generating model's training data.<sup>227</sup> The lack of awareness of AI scraping contributes to the perception of using AI to generate music as unethical, because the generated pieces draw on human inspiration to create less-than-human work that is often difficult to identify as AI-generated.<sup>228</sup> And while some human musicians have also taken it too far, toeing the line between inspiration and direct copying, copyright law exists to allow the original creator to defend their work, unlike the few and highly limited defenses against AI's use.<sup>229</sup> And in AI's involvement, the human aspect is missing, turning the creative process into a mechanical one and sidelining human compositions in favor of something "new."<sup>230</sup>

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partly based on the work of predecessors. You wouldn't get Beethoven without the works of Haydn and Mozart. . . . Of all the arts, music has historically been the most amenable to borrowing, stealing, or whatever you want to call it. The history of Thelonious Monk's 'Rhythm-a-Ning' stretches back to George Gershwin's 'I Got Rhythm' and Duke Ellington's 'Ducky Wucky,' and forward (or is it sideways) to songs as unlikely as the theme song for *The Flintstones*."); see David Boles, *AI Art Is Real Art and Not Stolen*, BOLES BLOGS (May 6, 2023), <https://bolesblogs.com/2023/05/06/ai-art-is-real-art-and-not-stolen/>.

<sup>226</sup> Beverly Regino, *AI: Artistic Infringement*, MIRROR (Mar. 3, 2023), <https://vnhsmirror.com/219832/uncategorized/ai-artistic-infringement/> ("When it comes to the phrase 'great artists steal,' it's not about literally taking someone else's work. It's about finding inspiration from the artists that inspire you and blending it with your own unique perspective and experiences to create something new.").

<sup>227</sup> Trystan S. Goetze, *AI Art Is Theft: Labour, Extraction, and Exploitation: Or, on the Dangers of Stochastic Pollocks*, ARXIV (June 5, 2024), <https://arxiv.org/pdf/2401.06178> ("Artists know that sharing their work will in part serve to inspire others in developing their own artistic projects, and this is generally considered good. But until recently, most artists were unaware that data brokers had also been gathering the work that they had shared for the purpose of training AI models. While both uses of shared art lead to the production of new, potentially aesthetically pleasing images, this narrowly consequentialist analysis of the good of art sharing overlooks that the intermediary process is different.").

<sup>228</sup> See Sophia Omarji, *The Psychology of AI-generated Music: How We Perceive and Respond to Machine-Made Melodies*, MEDIUM (June 28, 2024), <https://medium.com/illumination/the-psychology-of-ai-generated-music-how-we-perceive-and-respond-to-machine-made-melodies-3b323519a796> ("Whilst AI can mimic existing patterns to create something new, human creativity is unique in the sense it is driven by emotional depth, personal experience and intention. Here, AI replicates the *process* of creativity, but the authenticity of human artistic expression remains distinct.").

<sup>229</sup> See *Goldstein v. California*, 412 U.S. 546, 555 (1973).

<sup>230</sup> See generally Ted Chiang, *Why A.I. Isn't Going to Make Art*, NEW YORKER (Aug. 31, 2024), <https://www.newyorker.com/culture/the-weekend-essay/why-ai-isnt-going-to-make-art> (arguing that creating art requires the artist to make many conscious and unconscious decisions, but only few are made when using generative AI to program a creation).

### E. The Fading of Aural Art Creativity

AI has grown so much that now, AI models analyze and copy “virtually all the music ever made” to generate “new” songs.<sup>231</sup> But how can it be “new” when it is merely a blend of songs already written? Performer and composer Yosvany Terry comments that while AI does the work musicians used to do by composing music for film and television, AI music lacks the human depth that emotion in music brings out.<sup>232</sup> “[M]usicians are connectors, not just songwriters. They’re connecting people around stories and feelings. This is the magic power of a song and what the most successful tunes do: they connect. Humans. Around stories,” writes Tommy Darker.<sup>233</sup> Human-made art includes elements of humanity, while AI’s algorithm lacks the capacity to generate that human element.<sup>234</sup> And with AI becoming the standard baseline to “create” new works, it sets the requirement for a “good,” popular piece to be also based on AI technology.<sup>235</sup> For example, when computers first came out with programs like Adobe, people initially feared the new technology, but eventually realized it was just a tool.<sup>236</sup> Since then, the art world has seen an increase in digitally created art.<sup>237</sup> However, what Natalia Ilyin found was that while computers were used as tools, the software they provided had become so common and expected that artists who did not use such features found it challenging to break into the art industry.<sup>238</sup> While it may be the easier way to “create” art, the art’s creativity is missing.<sup>239</sup> AI can produce an output, but lacks the capacity to incorporate facets of an artist’s personality and thought process into it, showing how creativity is impossible for AI.<sup>240</sup> The courts have ruled on technological “creativity” on a few occasions, such

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<sup>231</sup> *Five Years Later: The Music Modernization Act: Hearing Before Subcomm. on Cts., Intell. Prop., and the Internet of the Comm. on the Judiciary U.S. H.R.*, 118th Cong. 20 (2023) (statement of David Porter, Artist).

<sup>232</sup> See Liz Mineo, *If It Wasn’t Created by a Human Artist, Is It Still Art?*, HARV. GAZETTE (Aug. 15, 2023), <https://news.harvard.edu/gazette/story/2023/08/is-art-generated-by-artificial-intelligence-real-art/>.

<sup>233</sup> Tommy Darker, *Why Musicians Can’t Thrive in the Modern Ecosystem*, MEDIUM (July 23, 2014), <https://medium.com/the-musicpreneur/why-musicians-cant-thrive-in-the-modern-ecosystem-7cdc1d49e6ef>.

<sup>234</sup> See Sarah Andersen, *The Alt-Right Manipulated My Comic. Then A.I. Claimed It.; Guest Essay*, N.Y. TIMES (Dec. 31, 2022), <https://www.nytimes.com/2022/12/31/opinion/sarah-andersen-how-algorithm-took-my-work.html>.

<sup>235</sup> See Natalia Ilyin, “*AI Is Just a Tool*” – and Other Fictions, COMMON EDGE (Feb. 18, 2025), <https://commonedge.org/ai-is-just-a-tool-and-other-fictions/>.

<sup>236</sup> See *id.*

<sup>237</sup> See Mariam Samake, *The Digital Wave: The Shift from Traditional to Digital Mediums in Art*, SCI. SURV. (July 20, 2023), <https://thesciencesurvey.com/arts-entertainment/2023/07/20/the-digital-wave-the-shift-from-traditional-to-digital-mediums-in-art/>.

<sup>238</sup> See Ilyin, *supra* note 235.

<sup>239</sup> See Chiang, *supra* note 230 (“[A]ny writing that deserves your attention as a reader is the result of effort expended by the person who wrote it. Effort during the writing process doesn’t guarantee the end product is worth reading, but worthwhile work cannot be made without it.”).

<sup>240</sup> See Anna Shtefan, *Creativity and Artificial Intelligence: A View from the Perspective of Copyright*, 16(7) J. INTELL. PROP. L. & PRAC. 720, 721 (2021) (“[T]he definitions of creativity are

as in *Thaler v. Perlmutter*, where the D.C. Circuit Court of Appeals, in a three-judge panel, unanimously affirmed that works of art must be created by a human to be copyrightable, and that AI alone lacks the required element.<sup>241</sup> In *Feist Publications, Inc. v. Rural Telephone Service Co., Inc.*, the Supreme Court held that “independent creation plus a modicum of creativity” is required for a work to be copyrightable and creativity “cannot be so mechanical or routine as to require no creativity whatsoever.”<sup>242</sup> The Copyright Office used this standard to determine the images in comic book *Zarya of the Dawn* was not copyrightable, because the author’s “guidance” of generating the art through Midjourney was not enough to constitute authorship.<sup>243</sup>

As AI usage increases, so does artist backlash, including by way of strikes, uploading lower-resolution artworks, and downloading software to try to block AI scraping.<sup>244</sup> But these solutions force artists to produce fewer or lower-quality works. Creativity does not just fade when AI users generate work by compiling existing art but also fades when artists stop creating. In May 2023, the Writers Guild of America went on strike, representing Hollywood screenwriters who demanded protection against the threat of AI and refused to return to work until a new contract was signed almost five months later.<sup>245</sup> The Screen Actors Guild-American Federation of Television and Radio Artists also went on strike in July 2023, demanding protection from the threat of being replaced by AI.<sup>246</sup> The strikes led to cuts or cancellations in film and television, and highly anticipated films like *Mission: Impossible – Dead Reckoning Part Two*, *Dune: Part Two*, *The Lord of*

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developed from . . . four main aspects: the process, the result, the set of necessary conditions, and the personality of the creator. . . . [I]n terms of the authors’ personalities, the emphasis here is on their inner state, motivation, and the desire to express themselves through creativity. It is also the ability to set new challenges, a certain level of courage to step into the unknown and do something they have never done before.”); see also Mark A. Runco, *AI Can Only Produce Artificial Creativity*, 33 J. CREATIVITY 1, 2 (2023) (“Authenticity is impossible for AI, but is also an important part of human creativity.”).

<sup>241</sup> See Dan Mangan, *Art Created Autonomously by AI Cannot be Copyrighted*, *Federal Appeals Court Rules*, CNBC (Mar. 19, 2025, 11:42 AM), <https://www.cnbc.com/2025/03/19/ai-art-cannot-be-copyrighted-appeals-court-rules.html>.

<sup>242</sup> *Feist Publ’ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 346, 362 (1991).

<sup>243</sup> *Zarya of the Dawn Letter*, U.S. COPYRIGHT OFF. 1, 3, 9 (2023), <https://www.copyright.gov/docs/zarya-of-the-dawn.pdf>, (“As the Supreme Court has explained, the ‘author’ of a copyrighted work is the one ‘who has actually formed the picture,’ the one who acts as ‘the inventive or master mind.’ *Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 52, 61 (1884). A person who provides text prompts to Midjourney does not ‘actually form’ the generated images and is not the ‘master mind’ behind them.”).

<sup>244</sup> See Melissa Heikkilä, *Four Ways to Protect Your Art from AI*, MIT TECH. REV. (Nov. 21, 2024), <https://www.technologyreview.com/2024/11/21/1107108/four-ways-to-protect-your-art-from-ai/>.

<sup>245</sup> Jake Coyle, *In Hollywood Writers’ Battle Against AI, Humans Win (for Now)*, AP NEWS (Sept. 27, 2023, 4:35 PM), <https://apnews.com/article/hollywood-ai-strike-wga-artificial-intelligence-39ab72582c3a15f77510c9c30a45ffc8>.

<sup>246</sup> Molly Kinder, *Hollywood Writers Went on Strike to Protect Their Livelihoods from Generative AI. Their Remarkable Victory Matters for all Workers*, BROOKINGS (Apr. 12, 2024), <https://www.brookings.edu/articles/hollywood-writers-went-on-strike-to-protect-their-livelihoods-from-generative-ai-their-remarkable-victory-matters-for-all-workers/> (“On July 13, the Screen Actors Guild-American Federation of Television and Radio Artists (SAG-AFTRA) announced their own strike—the first time that writers and actors had simultaneously gone on strike since 1960.”).

*the Rings: The War of the Rohirrim*, or *Spider-Man: Beyond the Spider-Verse* were delayed by months or even years.<sup>247</sup> Here, creativity was not stopped; it was just delayed. However, several TV shows suffered a different fate; despite positive reviews and new seasons promised by the producers, multiple shows were unfortunately cancelled.<sup>248</sup> Similarly, AI-generated art and its practice of secretly appropriating copyrighted material pose a significant threat to artists' livelihoods and to the spread of creativity in aural arts.

#### IV. A BALANCE FOR CREATIVITY AND COPYRIGHT

Without moral rights protections, music and other aural arts are left vulnerable to Generative AI. Consumers also stand to suffer from AI-generated works, tricked into believing new tunes are the product of one's favorite artist, or paying for a mimic rather than what was supposed to be a professional's work. I propose a three-part solution to the fight between aural artists' rights and AI technology: providing musicians with the rights of attribution and integrity through a new Aural Artists Rights Act ("AARA"), ensuring AI-generated music comes with warning labels and credit to the music used in AI training, and encouraging musicians to accept AI-generated pieces.

Copyright law needs yet another Act from Congress that expands its provision of moral rights—but this time, to more than just a handful of visual artists. Some states have attempted to pass moral rights legislation, but what one state can pass is different from what another can, leading to uneven protection depending on where the musician is located.<sup>249</sup> While Generative AI likely cannot be stopped, added protections will allow the ever-expanding technology to run alongside the creativity of real human artists. This addition to copyright law will allow Generative AI to "create" once the AI user receives permission from the original artists, while ensuring that permission is necessary and encouraged.

##### A. An Act for Moral Rights

AARA should draw inspiration from VARA rather than amend or copy it. Using VARA directly would include inapplicable exceptions, such as the exception for artworks integrated with a building,<sup>250</sup> and protection against the destruction of a work of recognized stature.<sup>251</sup> These exceptions are unnecessary for an aural work, as sound arts are not tangible and therefore cannot be

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<sup>247</sup> Sonaiya Kelley, *All the Major Movies and TV Shows Delayed by the Strikes*, L.A. TIMES, <https://www.latimes.com/entertainment-arts/business/story/2023-09-19/tv-shows-movies-delayed-list-writers-strike-sag-aftra> (last updated Oct. 23, 2023, 4:46 PM).

<sup>248</sup> See Kayla Laguerre-Lewis, *11 TV Shows Canceled During the 2023 Strikes*, SCREEN RANT (Nov. 16, 2023, 8:30 AM), <https://screenrant.com/tv-shows-canceled-2023-writers-actors-strikes/>.

<sup>249</sup> See H.B. 2091, 113th Gen. Assemb. (Tenn. 2023) (enacted); see also Ensuring Likeness, Voice and Image Security (ELVIS) Act of 2025, MS H.B. 768 (describing Mississippi's suggested version of the ELVIS Act, which died in committee).

<sup>250</sup> See 17 U.S.C. §113(d).

<sup>251</sup> See Judicial Improvements Act of 1990, Pub. L. No. 101-650, 104 Stat. 5089, 5129.

“destroyed” in the way VARA protects against.<sup>252</sup> The aural Act, however, should grant the right of attribution, and, most importantly in the fight against AI, the right of integrity to prevent modifications and distortions of aural work. Additionally, the new moral rights act should include the ability to waive protected rights—so aural artists can choose whether and when to allow another person to use their piece. Like requesting a license, Generative AI users would request permission by reaching out to the artist, who would decide whether to grant permission and waive their rights to integrity in that situation.<sup>253</sup>

Unfortunately, providing moral rights would not completely solve the problem. Artists would still be forced to play “whack-a-mole,” diligently scrolling through streaming sites for any evidence of copyright infringement. However, that is how copyright law generally works; it is up to the artist to identify the use of copyrighted material in a different work and then pursue legal remedies for infringement concerns—it has always been the artist’s responsibility to identify infringement.<sup>254</sup> Therefore, a new Act granting moral rights to aural artists would not change the existing copyright law procedures.

This solution, while not perfect, slots between the problem of AI training and the currently unprotected aural artworks in a place no other existing law can fill. While some artists can—and have—gotten away with asserting the right of publicity, once an AI-generated piece is uploaded to a website, asserting the right of publicity does not allow for immediate takedown as with the DMCA. Furthermore, the high cost of litigation in right-of-publicity cases is a significant concern for artists who earn lower revenues. UMG could afford a drawn-out, complicated legal battle, but solo artists and small labels might not find any eventual judgment to be worth the costs. If an artist were to deem the right of publicity worth using, their rights may be limited by the state in which the claim is made, because many state Right of Publicity statutes fail to extend protection to everyone, especially non-celebrities and lesser-known artists.<sup>255</sup> As for pro-AI arguments for fair use, eyes are currently on the courts in cases like *UMG v. Suno* to see what they decide.<sup>256</sup> With other methods of protecting aural arts applicable only to a few, an addition to copyright law that grants moral rights to the aural arts provides protection to all.

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<sup>252</sup> See *Philosophy of Art*, BRITANNICA, <https://www.britannica.com/topic/philosophy-of-art/The-mediums-of-art> (last updated Oct. 4, 2022) (“It might at first be thought that the medium of music consists of the musical score on which the composer writes the notes, but the written notes are not music; they are a set of visual cues for the production of the tones to be emitted by the various instruments. . . . [T]he medium of music consists of the physical sound waves by means of which the sound sensations enter the consciousness of the listener.”).

<sup>253</sup> See DOODOC, *supra* note 150.

<sup>254</sup> See Landes & Posner, *supra* note 77.

<sup>255</sup> See *Dora v. Frontline Video, Inc.*, 15 Cal. App. 4th 536, 542 n.2 (Cal. Ct. App. 1993) (“[T]here is a split of opinion among jurisdictions as to whether a ‘non-celebrity’ should have the right to sue for the commercial value of unpermitted use of personal identity . . .”).

<sup>256</sup> See Corral, *supra* note 208 (“Only because this has never happened at such scale and speed before, has the law been slow to respond, and the AI companies so far have got away with it. Much like Uber, it seems they knew that if they moved fast and broke things, they could make their money and be established before the law caught up with them - whilst claiming to disrupt and innovate for the common good.”).

### B. Citing the Original as a Homage and a Table of Contents

To allow technology to be a tool in the growth of art and music, as has been the case since music was invented, human and AI artists should be allowed to create. AI should not, however, be given free rein to use copyrighted works. Training data should be limited to aural art available for public use and art that the original artist has legally permitted to be used for AI generation. The final output should include warning labels and ways for listeners to understand that the piece was created with AI. Technologies like YouTube's and Deezer's that add warning labels to each AI track keep the audience informed and aware of which band or aural art they are listening to. If streaming websites also include names of the original pieces or musicians used in the dataset, the AI creator pays homage to artists who created through longer methods than a simple typed command. When listening to a song on Spotify, for example, the user can view the lyrics, artist, and credits of the piece currently playing, which means credit to the input artists can be added to an easily accessible location.<sup>257</sup> Including links or recommendations to the scraped pieces would direct listeners to the original artists, allowing those musicians to earn some of the revenue the AI piece would have taken from them. Especially with the anti-AI art bias currently circulating through the art community, if listeners were aware of what, rather than who, created the piece, they might follow the trail back to the original artist rather than staying with the AI-generated piece.<sup>258</sup> Requiring AI creators to be honest and transparent about what they are scraping would ensure that the proper channels of accessing copyrighted works are followed.<sup>259</sup> While not a complete solution to the potential decline in revenue for human aural creators, sending listeners to the original pieces allows the human artists to also profit from the AI.

### C. Aural Artists Have the Right to Choose AI

When proper protection is in place and credit is given, musicians can feel more at ease granting permission to use their songs or styles as training data or making them publicly available for AI use.<sup>260</sup> Aural artists could continue earning revenue by allowing AI to use their pieces if the AI artist compensates the original artist—with this Act, it is up to the copyright holder to decide what they feel their

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<sup>257</sup> See *Clickable Song Credits on Spotify*, SPOTIFY SUPPORT, <https://support.spotify.com/us/artists/article/song-credits/> (last visited Aug. 8, 2025).

<sup>258</sup> See Lucas Bellaiche et al., *Human Versus AI: Whether and Why We Prefer Human-Created Compared to AI-Created Artwork*, 8 SPRINGEROPEN 1, 3 (2023) (“[P]articipants tended to prefer the painting that was labelled ‘human-created’ relative to the painting labelled ‘AI-created’ . . . [S]everal recent studies have reported similar anti-AI findings in music . . .”).

<sup>259</sup> See Lanre Bakare, *An AI-generated Band Got 1m Plays on Spotify. Now Music Insiders Say Listeners Should be Warned*, GUARDIAN (July 14, 2025, 2:00 EDT), <https://www.theguardian.com/technology/2025/jul/14/an-ai-generated-band-got-1m-plays-on-spotify-now-music-insiders-say-listeners-should-be-warned> (quoting the British Phonographic Industry’s chief strategy officer as she proposed “transparency obligations for AI companies so that music rights can be licensed and enforced . . .”).

<sup>260</sup> See DeVon, *supra* note 193.

piece is worth before allowing another to use it. One artist allows AI to use her voice as long as she is paid half of the resulting royalties, which is an ingenious way to encourage all forms of creation without forcing artists to suffer.<sup>261</sup> With artists no longer too concerned with the rapid growth of AI technology and how it may affect their careers, they are likely to be more open and willing to create, thereby going full circle back to the original goal of copyright law. Users who create AI-generated pieces are then only stopped by consent, and the creativity of human artists would no longer be affected by AI-generated content. Music has been built on the backs of previous musicians, all inspiring one another,<sup>262</sup> and it is best for the music industry to allow that process to continue without requiring advanced technological tools or resorting to illegal or unethical means.

## V. CONCLUSION

Copyright law, despite protecting moral rights for specific art forms, has yet to account for AI-generated works and AI's rapid growth in the art community. Copyright law was created to encourage the production of art for the public good, so this continued oversight in protections strays far from its original purpose. Because aural art is not provided the necessary protections, AI "creators" have gone wild with the freedom to use copyrighted aural pieces even as musicians and other artists fight back and speak out against AI. This divide in the art community negatively affects the "public good" and needs to be corrected to return to a space where artists have the freedom and incentives to create.

Widespread federal protection is therefore needed to protect all aural artists, which can likely be achieved using an imitation of VARA's version of moral rights because of the right of integrity. The right of integrity reaffirms aural artists' right to control their works as they please and re-establishes the need for consent when using another's art directly. This addition to copyright law is desperately needed to protect all artists, including Drake and The Weeknd, from losing revenues, rights guaranteed through fundamental copyright law, and the spark to continue creating.

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<sup>261</sup> Antonio Pequeño IV, *Grimes Helps Artists Distribute Songs Using Her AI Voice—If They Split Royalties. Here's How It Works.*, FORBES (June 12, 2023, 5:41 PM), <https://www.forbes.com/sites/antoniopequenoiv/2023/06/12/grimes-helps-artists-distribute-songs-using-her-ai-voice--if-they-pay-royalties-heres-how-it-works/>.

<sup>262</sup> See Regino, *supra* note 226.