BUYER BE WELL

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Abstract: As cutting-edge consumer wellness products and services increasingly assume the functions of healthcare, courts may be quietly replacing the complex legal protections of health law with contract law's logic of buyer beware. Analysis of case law reveals how courts uncritically enforce terms in wellness contracts that could be deemed impermissible in traditional healthcare settings. The result is a potential blind spot where courts fail to directly account for the qualities that warrant health's special legal treatment. Companies can thus mimic healthcare's aesthetics and replicate its risks without assuming its obligations. By centering contract law in the governance of a subset of health-affecting consumer transactions, this Article challenges the myth that wellness is always meaningfully distinct from healthcare. It argues that as care migrates from public to private ordering, contract law not only facilitates the erosion of health protections but also holds underused tools that courts can leverage to restore them. It proposes a factor-based test to determine when wellness products functionally substitute for care. Ultimately, it warns that wellness is becoming a deregulatory tool, calling on courts to respond with modest doctrinal interventions that protect consumers and preserve some of the safeguards afforded to contracts in healthcare.

INTRODUCTION

What we once understood as healthcare—a domain of primarily public ordering mediated by professional regulation—is blurring into wellness, a domain of private ordering, governed primarily by contract.[1] Companies like

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[1] Barbara J. Zabawa, *Defining the Field of Wellness Law*, 53 HOFSTRA L. REV. 491, 497, 519–20 (2025); *see infra* notes 63–68 (defining wellness).

Amazon,[2] Apple,[3] and billionaire-backed technology startups[4] now deliver increasingly sophisticated and occasionally healthcare-like products that bypass many, or even all, of the protections typically present in healthcare. Consumers can buy subscription-based toilets that analyze their waste for health risks,[5] or talk to an artificial intelligence (AI) chatbot about their mental health in place of a licensed therapist.[6] In these ways and others, certain corners of the wellness industry are beginning to resemble medicine and healthcare.[7] And, if we allow these elements of wellness and the contract law that governs them to stand entirely outside the normative commitments of healthcare, we risk exporting healthcare to the marketplace without importing any of the legal protections that accompany it.

We have traditionally viewed healthcare and wellness as categorically distinct. This traditional understanding assumes that healthcare involves diagnosing and treating disease.[8] It is involuntary, sought out of necessity and not out of desire.[9] Economically, health is understood as different from other goods.[10] It is marked by uncertainty, information asymmetry, and a heightened need for trust.[11] Its value depends on its customization to the individual's specific circum-

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[2] *See* Prakash Bulusu & Andrew Diamond, *Amazon Launches Health AI Agent on Amazon Website and App with Free 24/7 Access to Virtual Care for Prime Members*, AMAZON NEWS (Mar. 10, 2026), https://www.aboutamazon.com/news/retail/amazon-health-ai-agent-one-medical [perma.cc/4DF3-MZ99]; *Amazon One Medical*, AMAZON, https://health.amazon.com/onemedical [perma.cc/NDY8-RF73] (describing various medical treatments offered through Amazon's One Medical service).

[3] *See, e.g.*, Ben Court, *Your Apple Watch May Know More About Your Health Than Your Doctor*, MEN'S HEALTH (Dec. 27, 2024), https://www.menshealth.com/health/a63273934/apple-watch-10-health-fitness-evolution/ [perma.cc/8DY2-UPMH]; *see also* DocWire News Editors, *Doctor Credits Apple Watch for Detecting Heart Irregularity, Saving His Life*, CARDIO CARE TODAY (Sep. 11, 2023), https://www.cardiocaretoday.com/post/apple-watch-saves-doctors-life-detects-underlying-condition [perma.cc/2JU4-3KDT] (describing the first-generation Apple Watch's ability to take an electrocardiogram for the user).

[4] *See, e.g.*, Bennett M. Sherman, *Biohackers Convene in Honduras for Unregulated Gene Therapy Trials Without FDA Oversight*, NAD+ AGING SCI. (Feb. 23, 2024), https://www.nad.com/news/biohackers-convene-in-honduras-for-unregulated-gene-therapy-trials-without-fda-oversight?ref=thenerdreich.com [perma.cc/MS7E-HAEP] (reporting on a biotech startup, backed by prominent technology investors, conducting human gene-therapy trials outside FDA oversight under a regulatory regime designed to attract medical experimentation).

[5] *See, e.g.*, *TrueLoo*: *The AI-Powered Toilet Seat for Seniors*, TOI LABS, toilabs.com/trueloo/ [perma.cc/MEC2-DVQL].

[6] *See, e.g.*, *Woebot Health Terms of Service*, WOEBOT HEALTH, https://woebothealth.com/terms-webview/ [perma.cc/3X32-K7YS] (describing an AI chatbot offering mental-health self-help interactions while expressly disclaiming provision of therapy or any clinician-patient relationship).

[7] *See* Zabawa, *supra* note 1, at 521–22 (identifying multiple areas in which modern understanding of health and wellness overlap).

[8] *Id.* at 519.

[9] *Id.*

[10] Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 948 (1963).

[11] *Id.* at 964–66.

stances.[12] It is remarkably inelastic, meaning consumers cannot easily defer or substitute care when needs arise.[13] Health also has a different moral valence.[14] The stakes are physical, occasionally irreversible, and often life-altering.[15] These features of healthcare render ordinary market assumptions inadequate.[16]

Where the market mechanisms are a poor fit, the law must impose limits. To that end, we have developed numerous laws recognizing that health is exceptional and, consequently, that regulation is necessary.[17] Healthcare is one of the most heavily regulated areas of the economy.[18] Robust professional and ethical commitments govern healthcare; courts treat medical relationships and transactions differently from ordinary commercial and consumer relationships and transactions precisely because of the interests they implicate.[19] Health law rests on the foundational premise that healthcare is special and should be treated accordingly.

Wellness is different than health. Wellness entails reaching above and beyond an otherwise acceptable health baseline, rather than returning to a normal state of functioning.[20] It is an elective choice consumers may make because they want to, not because they have to.[21] Wellness products and services can

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[12] Deborah A. Stone, *The Struggle for the Soul of Health Insurance*, 18 J. HEALTH POL. POL'Y & L. 287, 291 (1993).

[13] Arrow, *supra* note 10, at 957.

[14] Lois Shepherd, *Assuming Responsibility*, 41 WAKE FOREST L. REV. 445, 455 (2006); Raymond Tallis, Commentary, *Do We Need a New Word for Patients? Leave Well Alone*, 318 BRIT. MED. J. 1756, 1757 (1999).

[15] *See infra* Part I.

[16] *See infra* Part I.

[17] *See, e.g.*, 42 U.S.C. § 18091(2) (recognizing the health insurance market as uniquely subject to federal regulation and situating the Affordable Care Act (ACA) within a broader lineage of health legislation); 21 U.S.C. § 393(a)–(b) (establishing federal oversight of drugs and medical devices in recognition that health products require regulatory intervention beyond ordinary market mechanisms); *see also* TIMOTHY STOLTZFUS JOST, HEALTH CARE AT RISK: A CRITIQUE OF THE CONSUMER-DRIVEN MOVEMENT 50–53 (2007) (documenting the historical failure of consumer-directed healthcare and the structural inadequacy of market mechanisms to distribute medical costs equitably). The Committee on the Costs of Medical Care, privately convened, represented an early coordinated effort to identify the need for collective intervention in healthcare financing. *Id.*

[18] *See* HEALTH LAW AS PRIVATE LAW 1–2 (I. Glenn Cohen et al. eds., 2025).

[19] *See* Maxwell J. Mehlman, *Why Physicians Are Fiduciaries for Patients*, 12 IND. HEALTH L. REV. 1, 3 nn.5–6 (2015) (citing five pages of cases and articles in support of the proposition that physicians are fiduciaries to their patients).

[20] *See* Zabawa, *supra* note 1, at 491 (distinguishing "wellness" from treatment of imminent disease). Zabawa explains that the core problems common to wellness law are "two-fold":

> First, whether an imminent disease or illness is at issue when the consumer seeks to improve their wellbeing. If so, then it is not wellness the consumer seeks, but health care. Second, whether the individual's choice to engage in wellness activities is undermined by an intervening authority or situational circumstance. If so, then it is not wellness.

Id.

[21] *Id.*

also be mass-produced and mass-consumed.[22] American consumers—eighty-two percent of whom view wellness as a top priority—can choose wellness products and services based solely on their tastes and preferences.[23] Therefore, wellness, some argue, is appropriately a product of and subject to the free market, which is governed primarily by consumer contracts.[24] Nevertheless, as the $480 billion wellness economy expands at nearly ten percent per year,[25] its most advanced offerings increasingly resemble healthcare in form and function, and are consumed as such.

The rise in popularity and sophistication of wellness is happening in concert with a broader institutional retreat from public health governance.[26] In some ways, this is a longstanding trend. The Food and Drug Administration (FDA) already exercises enforcement discretion over low-risk general wellness products,[27] which fall within its statutory authority to regulate devices.[28] Products intended to "maintain[] or encourage[e] a healthy lifestyle" escape FDA regulation entirely.[29] This regulatory arbitrage has permitted the modern wellness economy to flourish.[30] In other ways, this trend is new. The U.S. Supreme

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[22] *See* KATHERINE JOHNSTON, GLOBAL WELLNESS ECONOMY MONITOR 2025, at 19–20 (2025), https://globalwellnessinstitute.org/wp-content/uploads/2025/11/2025-GWI-WE-Monitor_DIGITAL-FINAL.pdf [perma.cc/4XN4-WU3C] (reporting substantial consumer spending driving growth in the wellness industry, indicating widespread production and consumption of wellness products and services).

[23] *What Is the Future of Wellness?*, MCKINSEY & CO., 2 (Nov. 20, 2024), https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-the-future-of-wellness [perma.cc/4KL3-A6A4].

[24] *See infra* notes 171–172 and accompanying text (discussing limited Food and Drug Administration (FDA) and Federal Trade Commission (FTC) involvement in regulating wellness).

[25] *What Is the Future of Wellness?*, *supra* note 23, at 2.

[26] *See* JOHNSTON, *supra* note 22, at vi (finding that "[t]he global wellness economy grew by 7.9% from 2023–2024" and "has doubled in size since 2013"); *see also* Stephen Olaide Aremu et al., *The United States Withdrawal from the World Health Organization (WHO), Its Implications for Global Health Governance*, 21 GLOBALIZATION & HEALTH 1, 4 (2025) (reviewing recent institutional retrenchment and diminished coordination in global public health governance).

[27] U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2026) [hereinafter U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS POLICY FOR LOW RISK DEVICES]. The FDA defines a general wellness product as having "(1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions . . . ." *Id.* at 3.

[28] *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393 (establishing the FDA's authority to regulate "devices intended for human use").

[29] 21st Century Cures Act, Pub. L. No. 114-255, § 3060(a), 130 Stat. 1033, 1130–32 (2016) (codified at 21 U.S.C. § 360j(o)). Section 3060(a) of the 21st Century Cures Act amended section 520 of the Federal Food, Drug, and Cosmetic Act (FDCA) to remove certain software functions from the FDCA definition of a device, including those that "maintain[] or encourag[e] a healthy lifestyle . . . ." *Id.*; 21 U.S.C. § 360j(o). Other functions that were removed include: (1) to provide "administrative support [for] a health care facility"; (2) to "serve as electronic patient records"; and (3) to transfer, store, or display data, or to convert data formats. *Id.*

[30] *See* David A. Simon, Carmel Shachar & I. Glenn Cohen, *Skating the Line Between General Wellness Products and Regulated Devices: Strategies and Implications*, 9 J.L. & BIOSCIENCES 1, 4

Court and executive branch have accelerated a deliberate reduction of agency authority, with far-reaching implications for the federal government's role in health.[31] Federal disinvestment in public healthcare, medical education, and scientific research, including recent moves to constrain National Institutes of Health (NIH) funding, shifts the locus of health innovation toward private actors with financial interests in developing wellness products for the private market.[32] At the same time, political figures have begun to treat wellness not merely as a consumer preference but as a civic obligation.[33] Recent calls by executive branch officials to require wearable device adoption by 2029,[34] deny public benefits to those with "unhealthy" lifestyles,[35] or to treat diabetes with

(2022) (describing how firms strategically introduce products as "wellness" goods outside FDA jurisdiction before later marketing them as regulated medical devices).

[31] *See* Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412–13 (2024) (overturning longstanding precedent—the *Chevron* doctrine—requiring federal courts to defer to reasonable agency decisions); Kaye Pestaina, Michelle Long & Justin Lo, *Supreme Court Decision Limiting the Authority of Federal Agencies Could Have Far-Reaching Impacts for Health Policy*, KAISER FAM. FOUND. (July 1, 2024), https://www.kff.org/private-insurance/issue-brief/supreme-court-decision-limiting-the-authority-of-federal-agencies-could-have-far-reaching-impacts-for-health-policy/ [perma.cc/R5SF-MGYL] (reviewing implications of *Loper Bright* for health policy); *see also* Exec. Order No. 14219, 90 Fed. Reg. 10583, 10583 (Feb. 19, 2025) ("It is the policy of [the Trump] Administration . . . to commence the deconstruction of the overbearing and burdensome administrative state.").

[32] *See* OFF. OF DIR., NAT'L INSTS. OF HEALTH, SUPPLEMENTAL GUIDANCE TO THE 2024 NIH GRANTS POLICY STATEMENT: INDIRECT COST RATES, NOTICE NO. NOT-OD-25-068, at 1 (2025), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-068.html [perma.cc/DRF4-X4DS] (imposing a uniform fifteen percent cap on indirect cost rates for NIH research grants); Lydia DePillis & Christine Zhang, *How Health Care Remade the U.S. Economy*, N.Y. TIMES (July 3, 2025), https://www.nytimes.com/interactive/2025/07/03/business/economy/healthcare-jobs.html [perma.cc/6G8B-QWKT] (describing the adverse effects of proposed Trump Administration changes on health insurance, access, expenses, medical education, and research); *see also* 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 [perma.cc/3XWJ-PKZF] ("American science, long a source of national power and pride, is increasingly becoming a private enterprise.").

[33] *See* Joseph Choi, *Trump Swears in Mehmet Oz as CMS Administrator*, THE HILL (Apr. 18, 2025), https://thehill.com/homenews/5255977-trump-swears-in-mehmet-oz-as-cms-administrator/ [perma.cc/8BWF-P25R] (quoting Dr. Oz as saying that "healthy people don't consume health care resources," and that "[t]he best way to reduce drug spending is to use less drugs, because you don't need them, because you're healthy, and it feels a lot better").

[34] Puyaan 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/ [perma.cc/68BH-FJTS].

[35] *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/ [perma.cc/7BU8-NSFH] (quoting Secretary of the U.S. Department of Health and Human Services (HHS) Robert F. Kennedy Jr. as saying that "[i]f you're smoking three packs of cigarettes a day, should you expect society to pay when you get sick? . . . The best answer to that is to realign our incentives so that the economic incentives, the individuals and the industry align with the public health outcomes that we desire").

cooking classes instead of providing access to insulin[36] reflect a national ideological shift that casts health as a test of individual virtue rather than a matter of collective concern.[37] If these ideas come to fruition, wellness interventions once considered optional may become mandatory, and their functions will continue to drift toward healthcare. Thus, this characterization of wellness as purely elective, low-risk, and unconcerned with disease is increasingly unsustainable, as are the rationales employed to justify its laissez-faire treatment.[38]

As wellness complements—and may someday even replace—healthcare, it imports a legal regime that may facilitate the displacement of health law's substantive protections with contract law's emphasis on private rights and freedom.[39] Courts routinely treat consumer products with obvious health implications—biometric monitors, direct-to-consumer genomics, personalized nutrition platforms—as nothing more than ordinary consumer transactions, without critically engaging their health-related functions.[40] Wellness tools that can function nearly indistinguishably from drugs, devices, diagnostics, or treatment disclaim efficacy, waive liability, and seamlessly route disputes into arbitration.[41] Although courts invalidate unfair terms in clinical settings,[42] today's health tech companies largely avoid such scrutiny by framing themselves as part of the wellness or lifestyle space.[43] In the rare cases in which courts explicitly consider the fuzzy distinction between healthcare and wellness in contract disputes, the mere presence of a physician-patient relationship appears

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[36] Katie Hawkinson, *Trump's FDA Chief Suggests Diabetics Should Take Cooking Classes Under MAHA Agenda,* THE INDEPENDENT (May 29, 2025), https://www.the-independent.com/news/world/americas/us-politics/fda-maha-diabetes-cooking-b2757678.html [perma.cc/4D3D-EFZA].

[37] *See, e.g.*, EXEC. OFF. OF THE PRESIDENT, THE MAKE AMERICA HEALTHY AGAIN (MAHA) REPORT: MAKE OUR CHILDREN HEALTHY AGAIN 16, 72 (2025), https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf [perma.cc/DV32-GUT9] (framing contemporary health problems as rooted in lifestyle choices and calling for behavioral and lifestyle interventions).

[38] *See infra* Part I.B.

[39] *See infra* Part II.A–B. (comparing legal protections associated with healthcare versus wellness).

[40] For example, courts have treated wearable and diagnostic technologies with health implications as standard consumer products, emphasizing consumers' assent to clickwrap agreements within private contracts rather than applying public-law frameworks. *See* Toth v. Everly Well, Inc., 118 F.4th 403, 409–10 (1st Cir. 2024) (holding that a consumer assented to an arbitration agreement in clickwrap contract associated with an at-home food-sensitivity blood test); Houtchens v. Google LLC, 649 F. Supp. 3d 933, 938–39 (N.D. Cal. 2023) (finding that consumers assented to an arbitration clause governing use of Fitbit smartwatches); McLellan v. Fitbit, Inc., No. 3:16-cv-00036, 2017 WL 4551484, at *2 (N.D. Cal. Oct. 11, 2017) (same).

[41] *See, e.g.*, Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1020–21 (9th Cir. 2016) (upholding arbitration provisions and liability disclaimers for services marketed as wellness tools despite delivering results with medical implications).

[42] *See, e.g.*, Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 442 (Cal. 1963) (invalidating a hospital liability waiver on public policy grounds because the transaction implicated essential public interests in medical care); *see infra* Part II.A.

[43] *See infra* Part II.B.

to be dispositive.[44] What first appears to be an age-old story of quackery and technological disruption is, ultimately, one of legal transformation that raises urgent questions about wellness as a tool of healthcare deregulation.

Scholars have examined the privatization of traditional healthcare,[45] the limits of regulatory oversight in the wellness economy,[46] and the role of contract law in healthcare payments.[47] Meanwhile, most legal critiques of consumer health technologies remain focused on privacy,[48] data ownership,[49] or rectifying information asymmetries.[50] This Article shifts the focus to contract law's role in the wellness economy and the burgeoning field of "wellness

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[44] *See* Curmode v. Alsbrooks, 880 S.E.2d 320, 322 (Ga. Ct. App. 2022) (enforcing exculpatory clause for massage-therapy services provided at a wellness spa because, unlike medical malpractice claims, the statutory duty of care depends on a physician-patient relationship, and the massage therapist was not a physician).

[45] *See* Erin C. Fuse Brown & Mark A. Hall, *Private Equity and the Corporatization of Health Care*, 76 STAN. L. REV. 527, 535 (2024) (examining private equity's expansion into hospitals, nursing facilities, and physician practices as part of broader trends toward the "corporatization, financialization, and commercialization" of health care—market-oriented shifts that can be understood as dimensions of healthcare privatization); JOST, *supra* note 17, at 13–22 (detailing the neoliberal shift toward privatized, consumer-driven care); HEALTH LAW AS PRIVATE LAW, *supra* note 18, at 1–2; Daniel G. Aaron, *The Crisis in U.S. Cancer Care: Law, Markets, and Privatization*, 110 MINN. L. REV. 1325, 1325, 1331–33 (2026) (theorizing privatization as a shift from "community-centered approaches to approaches centered on individuals and firms," and applying that framework to cancer care to show how "patent law, healthcare law, and innovation law, and [FDA] law" have shifted cancer governance toward private markets, corporate control, and individualized medical interventions).

[46] *See* Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1217–23 (2014) (arguing that FDA oversight of digital health technologies has historically "relied on nonbinding guidance documents" and "case-by-case enforcement" rather than firm regulatory rules); Sarah Duranske, *This Article Makes You Smarter! (Or, Regulating Health and Wellness Claims)*, 43 AM. J.L. & MED. 7, 19–20 (2017) (examining potential consumer harms arising from false claims by health and wellness products, including economic, psychological, and physical risks); Leah R. Fowler & Michael R. Ulrich, *Femtechnodystopia*, 75 STAN. L. REV. 1233, 1238 (2023) (exploring these issues in the context of the femtech market).

[47] Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 667–88 (2008) (describing the role of courts and contract law in protecting patients); Wendy K. Mariner, *Standards of Care and Standard Form Contracts: Distinguishing Patient Rights and Consumer Rights in Managed Care,* 15 J. CONTEMP. HEALTH L. & POL'Y 1, 25 (1998).

[48] *See* Leah R. Fowler, Jim Hawkins & Jessica L. Roberts, *Uncertain Terms*, 97 NOTRE DAME L. REV. 1, 6–7 (2021) (analyzing privacy concerns in digital health technologies, including consumers' reliance on companies' promises to protect health data); Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 143, 154–55 (2017) (analyzing competing models of health data protection and the central role of privacy frameworks in regulating health information); Nicolas P. Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65, 67–68 (2014) (critiquing the HIPAA-centered model of U.S. health privacy regulation and its limits in protecting health data).

[49] *See* Jessica L. Roberts, *Progressive Genetic Ownership*, 93 NOTRE DAME L. REV. 1105, 1111 (2018) (examining competing property frameworks for genetic data and debates over ownership of personal genetic information).

[50] *See* Leah R. Fowler, *Health App Lemons*, 74 ALA. L. REV. 65, 69 (2022) (examining consumer confusion and information asymmetries in digital health app markets).

law."[51] It shows how existing doctrines that allow courts to treat consumer rights in health-affecting transactions as ordinary and waivable can be reframed to provide targeted, restrained solutions to a dynamic problem that has thus far resisted broader regulatory reform.

Part I dismantles the myths that sustain the presumed health-wellness divide.[52] It argues that this conventional framing is at odds with market realities, as the wellness industry offers products and services that mirror traditional healthcare in both form and function. Through wellness, moral and legal responsibility for health begins to shift from the state to the individual, and from public governance to private ordering. As a result, this Part reveals that wellness can take on many of the same characteristics that once justified healthcare's special treatment. Yet this Part also shows that law continues to maintain the formal distinction between the two, and it argues that courts' refusal to engage with wellness in a nuanced way ultimately enables its deregulatory potential.

Part II analyzes contract doctrine as the primary governance mechanism for health-affecting transactions in both healthcare and wellness.[53] It compares how courts have treated contract terms—including waivers, consent, and arbitration clauses—in healthcare agreements with how they enforce analogous provisions in wellness agreements. In healthcare, these terms are scrutinized against a backdrop of public policy and patient protection; in wellness, they are typically enforced as ordinary consumer bargains. This comparison reveals a pattern: in wellness, courts prioritize formal assent over functional stakes, formal disclaimers over product functions, and formal descriptions over actual intent. As the once-sharp distinction we assumed existed between healthcare and wellness continues to fade, the asymmetry in the legal treatment of contracts in these domains becomes increasingly difficult to justify.

Finally, Part III advances and defends the proposition that contract law can and should account for the riskiest subset of wellness transactions that involve heightened physical, psychological, and financial stakes.[54] It proposes a five-factor test to help courts identify when wellness products functionally substitute for healthcare and therefore warrant heightened scrutiny.[55] Building on that framework, this Part demonstrates how existing contract doctrines—such as public policy, unconscionability, warranties, and good faith—can begin

[51] *See* Zabawa, *supra* note 1, at 493–94 (surveying statutes, regulations, and case law to articulate a definition of wellness law). Ultimately, Zabawa proposes to define "wellness law" as "[a] field of legal study and practice involving self-determined individuals seeking to reach optimal levels of functioning in life's various dimensions and the legal tools that can assist the wellness consumer's ability to achieve their goals effectively and equitably." *Id.* at 543.

[52] *See infra* notes 56–198 and accompanying text.

[53] *See infra* notes 201–350 and accompanying text.

[54] *See infra* notes 351–459 and accompanying text.

[55] *See infra* Part III.A.

to address the risks posed by these transactions, but only if courts first identify the stakes. Rather than expanding courts' institutional role, the proposed approach leverages their existing authority to interpret contracts and mediate private power, ensuring that wellness grows without eroding the protections historically associated with health.

I. DEBUNKING THE MYTH OF THE WELLNESS-HEALTHCARE DIVIDE

Since the country's founding, health libertarianism, grounded in economic freedom and freedom of therapeutic choice, conscience, religion, and inquiry, has shaped and limited approaches to the law and regulation of healthcare.[56] Today, that ethos finds renewed expression in the wellness economy.[57] The rise of increasingly sophisticated consumer wellness products, the ease of self-monitoring and self-experimentation, and a digital ecosystem in which expertise is diffuse have transformed an age-old American tradition of health self-determination into a powerful industry with significant stakeholders.[58] Now, the line between wellness and healthcare is steadily blurring, creating a conceptual disconnect with potentially significant legal consequences.

Section A of this Part defines wellness and healthcare and explains the longstanding legal exceptionalism attached to healthcare, establishing the doctrinal baseline against which wellness is contrasted.[59] Section B identifies and challenges two core assumptions that sustain the perceived divide between healthcare and wellness: first, that wellness does not implicate the diagnosis or treatment of disease, and second, that wellness is purely an elective lifestyle choice.[60] Section C considers how law continues to treat healthcare and wellness as categorically distinct despite this conceptual instability.[61] Using tax law as an illustrative domain, it shows that some areas of law probe the boundary between the two more carefully than others, even as the formal distinction persists.[62]

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[56] *See* Lewis A. Grossman, *The Origins of American Health Libertarianism*, 13 YALE J. HEALTH POL'Y L. & ETHICS 76, 96–97 (2013) (explaining that American health-libertarian arguments for freedom of therapeutic choice date to the nation's early years and challenged medical-licensing regimes by invoking not only bodily autonomy, but also economic freedom, freedom of inquiry, and freedom of conscience and religion).

[57] *See* Anna Kirkland, *What Is Wellness Now?*, 39 J. HEALTH POL. POL'Y & L. 957, 959–64 (2014) (giving a historical perspective of wellness since Halbert L. Dunn first introduced the term in a 1959 article called "High-Level Wellness for Man and Society").

[58] *See What Is the Future of Wellness?*, *supra* note 23, at 3–4 (identifying drivers of growth in wellness); JOHNSTON, *supra* note 22, at 13 (same); *see also* Shan Feng, Matti Mäntymäki, Amandeep Dhir & Hannu Salmela, *How Self-Tracking and the Quantified Self Promote Health and Well-Being: Systematic Review*, 23 J. MED. INTERNET RSCH. 120, 121 (2021) (analyzing rapid proliferation of self-tracking in people's daily lives and health care).

[59] *See infra* notes 63–82 and accompanying text.

[60] *See infra* notes 83–146 and accompanying text.

[61] *See infra* notes 147–198 and accompanying text.

[62] *See infra* notes 173–198 and accompanying text.

A. Defining Wellness and Healthcare

Defining wellness is a harder task than it first appears. As a buzzword, wellness means many things to many people, promising everything and nothing at once.[63] The National Wellness Institute captures this amorphous nature, for example, by vaguely defining wellness as "functioning optimally within your current environment."[64] In some ways, it is easier to define wellness by what it is not. By official accounts, it is not healthcare, because healthcare implies medical necessity.[65] According to this logic, individual consumers using wellness products are not vulnerable patients.[66] They engage in wellness because they want to, not because they have to in order to diagnose, treat, or prevent a disease.[67] It is a discretionary lifestyle choice that empowered consumers make only if they want to.[68] The framing of wellness as elective, low-risk, and personal underwrites its cultural narratives and legal classifications.

This loose definition positions wellness in contrast to healthcare, which *is* intended to diagnose, treat, or prevent disease, and is something vulnerable people engage in only out of necessity. Health law has long rested on the prem-

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[63] *See* Kirkland, *supra* note 57, at 957–58 (noting that "in typical buzzword fashion, the appeal of the term ['wellness'] comes from its ability to float above thorny and contested details and to mean different things to different stakeholders so that it becomes viewed as an uncontroverted good").

[64] *See Wellness Defined*, WELLNESS ALL., https://www.wellnessalliance.org/resources-and-tools/wellness-defined [perma.cc/PQA5-6YE7] (noting that "[w]ellness is a conscious, self-directed, and evolving process of achieving one's full potential[;] encompasses lifestyle, mental and spiritual well-being, and the environment[;] is positive, affirming, and contributes to living a long and healthy life[; and] is multicultural and holistic, involving multiple dimensions"); *see also* Bill Hettler, *Wellness: Encouraging a Lifetime Pursuit of Excellence*, 8 HEALTH VALUES 13, 13 (1984) (defining wellness "as an active process through which individuals become aware of and make choices toward a more successful existence"). Alternatively, the Global Wellness Institute defines wellness as "the active pursuit of activities, choices, and lifestyles that lead to a state of holistic health." JOHNSTON, *supra* note 22, at i.

[65] Zabawa, *supra* note 1, at 520.

[66] *Id.*

[67] Simon, Shachar & Cohen, *supra* note 30, at 6; *see infra* notes 167–171 and accompanying text (explaining intended use and 21st Century Cures Act carveouts). As Professor Zabawa explains:

> [W]ellness prioritizes self-management and aims to achieve something beyond a baseline healthy state. Another way to look at the difference between medical care (or health care) and wellness is the consumer's state of being when using health care or wellness. When a consumer uses health care, they are doing so because of an imminent disease or other medical threat.

Zabawa, *supra* note 1, at 519.

[68] *See* DEBORAH LUPTON, THE QUANTIFIED SELF: A SOCIOLOGY OF SELF-TRACKING 47 (2016) (describing wellness practices as discretionary acts of self-invention undertaken for personal health and wellbeing). *But see* Kirkland, *supra* note 57, at 964 (arguing that wellness programs have also been criticized as "(1) promot[ing] a conservative, individualistic health ideology, thereby undercutting communal, structural, redistributive, and sympathetic approaches to health; (2) promot[ing] workplace discrimination in programs as actually implemented within firms and organizations; and (3) promot[ing] homogeneity and prescrib[ing] one specific way of life for everyone, thus creating a problematic trend in a diverse democratic society").

ise that medical care is exceptional in form, stakes, and meaning.[69] As a result, healthcare is entitled to special protections that other areas of the economy—like wellness—are not.[70] This is not simply because it is always high-risk or high-tech.[71] Instead, this exceptionalism arises because healthcare involves relationships, decisions, products, and services that carry unique economic, moral, physical, and social consequences.

The economic and moral justifications for this healthcare exceptionalism are well established. In his foundational work on uncertainty and welfare economics, Kenneth Arrow noted that healthcare markets cannot function like typical markets due to structural information asymmetries and the unpredictability of health needs.[72] Consumers often lack the expertise to assess quality or outcomes, and the need for care is often both urgent and non-deferrable, making competitive choice illusory.[73] Healthcare's value comes from whether the specific person can benefit from the medical intervention, not simply their "tastes and preferences."[74] These features undermine the assumptions of rational choice theory and justify regulatory intervention to correct market failures[75]

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[69] *See* Mark A. Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO. L.J. 583, 591–94 (2008) (explaining how "U.S. law regards medical service differently than . . . commercial transactions"). In health law, "special rules . . . arise directly from the fiduciary attributes of the doctor-patient relationship, such as the laws of medical confidentiality, informed consent, and professional liability." *Id.* at 584.

[70] *Id.* at 584, 591–94.

[71] Many medical interactions within the healthcare system are little more than conversations. *See* Zabawa, *supra* note 1, at 510 ("Importantly, the annual wellness visit is not intended to diagnose, treat, cure, or mitigate an injury; during an annual wellness visit, the portion of the visit dedicated to treating the medical condition is billed separately using different billing codes.").

[72] Arrow, *supra* note 10, at 951. *But see* JOST, *supra* note 17, at 75–76 (describing responses to Arrow's article and the consensus in certain economic circles by the 1970s that "need for medical care did not exist independently of consumer demand, and consumer demand was driven by the presence of health insurance"). Scholars often credit Kenneth Arrow's seminal article as the foundation of healthcare exceptionalism in health economics. *See* Amitabh Chandra, Amy Finkelstein, Adam Sacarny & Chad Syverson, *Health Care Exceptionalism? Performance and Allocation in the US Health Care Sector*, 106 AM. ECON. REV. 2110, 2111 (2016) (noting that Arrow's article "started the modern field of health economics by emphasizing key features of the health care industry that distinguish it from most other[s]").

[73] Arrow, *supra* note 10, at 957, 966; *see also* JOST, *supra* note 17, at 74–76, 94–97 (explaining why health care markets deviate from classical economic models due: to uncertainty, information asymmetry, and the moral stakes of care, following Kenneth Arrow's foundational analysis); Nancy Tomes, *Merchants of Health: Medicine and Consumer Culture in the United States, 1900–1940*, 88 J. AM. HIST. 519, 525 (2001) (explaining that illness is often unexpected and patients lack the expertise to evaluate medical care, limiting meaningful consumer choice).

[74] Stone, *supra* note 12, at 291.

[75] *See Market Failure in Economics: Types and Causes Explained*, INVESTOPEDIA (Jan. 23, 2026), https://www.investopedia.com/terms/m/marketfailure.asp [perma.cc/9J5R-CQU7] ("A market failure is an adverse outcome in a free market system in which the forces of supply and demand fail to ensure the efficient distribution of goods and services.").

that we have come to expect in the healthcare industry.[76] The economic argument for regulating healthcare extends beyond the benefit to the individual. It is also good for society. Put simply, healthy people are more productive and require less social support over time.

Though these characteristics exist in varying degrees in other potentially exploitative transactions, such as consumer credit,[77] healthcare consumers are uniquely vulnerable. Beyond economic justifications, healthcare raises distinct moral and ethical concerns: decisions about it directly implicate bodily integrity, human dignity, and life-or-death matters.[78] When goods become commodified, their availability primarily depends on consumers' willingness and capacity to pay, and market logic governs their distribution rather than moral obligation or social need.[79] Certain "goods," such as human organs and babies, should therefore be shielded from pure market exchange, lest commodification degrade their social meaning or facilitate coercion.[80] In other words, in some cases, such as healthcare, it is wrong to allocate resources purely on the basis of ability to pay, in part because people are inherently valuable and worthy of dignity.[81] Such a system is both ripe for exploitation and creates situations in which the poor are regularly left to die on an even more upsetting scale than we currently tolerate.[82] This creates an ethical imperative to intervene in ways that do not exist in most other areas of the economy.

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[76] *See* Arrow, *supra* note 10, at 945, 957 (documenting market failures and explaining that collective intervention may be necessary to approximate optimality); JOST, *supra* note 17, at 94–95 (demonstrating that cognitive biases and irrational decision-making under uncertainty systematically undermine consumer welfare in health markets, justifying regulatory correction). *But see* Chandra et al., *supra* note 72, at 2110 (arguing that health care has "more in common with 'traditional' sectors subject to market forces than often assumed").

[77] *See, e.g.*, Will Dobbie & Paige Marta Skiba, *Information Asymmetries in Consumer Credit Markets: Evidence from Payday Lending*, 5 AM. ECON. J.: APPLIED ECON. 256, 262 (2013) (explaining how information asymmetry in payday lending markets creates borrower vulnerability and default risk).

[78] *See* Shepherd, *supra* note 14, at 450 ("[The patient is] sick, sometimes desperate, sometimes dying, seeking care, comfort, direction, and (sometimes life-saving) aid from others with the resources, special skills and knowledge to help."); Tallis, *supra* note 14, at 1757 (distinguishing healthcare patients from customers in commercial transactions). Patients are "often vulnerable, certainly worried, sometimes uncomfortable, and frequently frightened. [The term c]ustomer . . . erases something that lies at the heart of medicine: compassion and a relationship of trust." *Id.*

[79] M. Cathleen Kaveny, *Commodifying the Polyvalent Good of Health Care*, 24 J. MED. & PHIL. 207, 211 (1999).

[80] Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1849, 1854–55 (1987).

[81] *See* Matt McManus, *Kant's Theory of Human Dignity*, PHIL. NOW (2022), https://philosophynow.org/issues/150/Kants_Theory_of_Human_Dignity [perma.cc/N8V9-E6SJ] (explaining Immanuel Kant's view that human dignity places human life "above all price"). A full exploration of philosophical and religious arguments for and against the inherent value of people is beyond the scope of this article.

[82] *See* Stone, *supra* note 12, at 291 (observing that market allocation of medical care ties access to ability to pay rather than medical need).

B. Wellness as Distinct from Healthcare: Reexamining the Assumed Divide

Wellness is treated as unexceptional because we assume it is categorically different than health. This Section interrogates two core assumptions that sustain that perceived divide. Subpart 1 examines the assumption that wellness does not implicate the treatment or diagnosis of physical disease or illness.[83] Subpart 2 considers the related assumption that wellness activities are no more than voluntary or elective lifestyle choices.[84] Nevertheless, these assumptions break down upon closer inspection.

1. The Assumption That Wellness Does Not Implicate Diagnosis or Treatment

A core narrative in defining wellness concerns its relationship with physical health. As discussed above, healthcare involves diagnosing and treating things that are wrong with the body and mind; those that deviate *below* what we consider normal functioning.[85] By contrast, wellness is about augmenting health, leading to "enrichment of one's quality of life."[86] It's not about being healthy per se, but about living your best life, above and beyond an otherwise acceptable health baseline.[87]

Wellness, of course, does encompass many things that simply enhance one's physical, emotional, and spiritual well-being without deviating into anything resembling medicine. By some views, it is yoga, meditation, massages, and getting at least 10,000 steps per day. But wellness is so much more than that, and it is never entirely independent of health. The distinction between curing a disease and improving well-being is arbitrary, and what we consider a disease or impairment is contextual and subject to change over time.[88] Further, many major wellness models incorporate physical health,[89] and any serious discussion of wellness inevitably bleeds into questions of physical health.

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[83] Zabawa, *supra* note 1, at 491; *see infra* notes 85–110 and accompanying text.

[84] Zabawa, *supra* note 1, at 491; *see infra* notes 111–146 and accompanying text.

[85] *See supra* Part I.A.

[86] Michael D. Oliver, Debora R. Baldwin & Subimal Datta, *Health to Wellness: A Review of Wellness Models and Transitioning Back to Health*, 9 INT'L J. HEALTH WELLNESS & SOC'Y 41, 41 (2018).

[87] Zabawa, *supra* note 1, at 498; *see also* Kirkland, *supra* note 57, at 959 ("Wellness captures the sense that the era of combating diseases has given way to a more complex problem of success in modernity: living well, since so many more of us live long lives, entirely avoiding the diseases and accidents that killed our ancestors.").

[88] *See* Leigh Z. Osofsky, *Wellness and the Tax Law*, 59 GA. L. REV. 443, 446–47 (2025) (describing how what we consider to be disease—like mental health—and how we think about treating it—like concepts of preventive care—change over time).

[89] *See* Oliver et al., *supra* note 86, at 44–48 (describing the major wellness models over the last sixty years).

Wellness also takes the form of things that increasingly resemble, in varying degrees, core modalities of medicine, such as drugs, devices, diagnostics, and treatments. Nütrops supplements promise enhanced cognition and mood.[90] Wearable rings and wristbands track blood oxygen and heart rate variability,[91] and neurostimulation headsets are marketed for focus, recovery, or aesthetic benefits.[92] Direct-to-consumer companies offer an expansive array of blood tests,[93] personalized genetic tests,[94] hormone panels,[95] sleep apnea screening,[96] and smartphone-based hearing tests for consumers to use in the comfort of home.[97] AI chatbots[98] and uncredentialed social media influencers dispense health support through alternative framing, such as wellness "coaching."[99]

The impact of these wellness technologies and services is often neutral or even beneficial, and they fill important unmet needs. Empirical research shines light on how people interact with these products. Studies reveal that people adopt consumer wellness technologies for a variety of pragmatic, psychological, and social reasons, often shaped by their relationship with the healthcare system, their identities, and the barriers they face. For many, these tools offer easy, convenient resources that the healthcare system does not, including personalized data, early warnings of potential health issues, and disease prevention.[100] For historically underserved communities, wearable technology, well-

[90] *See, e.g.*, *Nütrops Daily Gummies*, NÜTROPS, https://nutrops.co/products/nutrops-daily-gummies [perma.cc/9FAW-P6PK] (purporting to support "comprehensive brain health—both short-term cognition and long-term brain health benefits. Benefits include cognition, energy, brain health, mood, sleep, and gut health").

[91] *See, e.g.*, OURA, https://ouraring.com/ [perma.cc/S2ND-UU3S] ("Oura Ring . . . collect[s] deeply personal health metrics and insights.").

[92] *See, e.g.*, LIFTID, https://www.getliftid.com/ [perma.cc/KPR2-LXY3] ("A new hi-tech consumer product, powered by Transcranial Direct Current Stimulation (tDCS), that will dramatically change the way we live.").

[93] *See, e.g.*, FUNCTION HEALTH, https://www.functionhealth.com/ [perma.cc/AW82-AHVB] (offering membership that includes more than 160 annual lab tests spanning heart health, hormones, kidneys, livers, and thyroid, without a doctor's referral or insurance).

[94] *See, e.g.*, 23ANDME, https://www.23andme.com/ [perma.cc/YBN3-M7XJ] (advertising at-home genetic testing for consumers to learn about their "health, ancestry, and traits").

[95] FUNCTION HEALTH, *supra* note 93.

[96] *See, e.g.*, LOFTA, https://lofta.com/ [perma.cc/9QTD-GGY3] ("Test for sleep apnea in the comfort of your own home.").

[97] *See, e.g.*, JABRA ENHANCE, https://www.jabraenhance.com/how-it-works [perma.cc/T944-BRSN] (offering an "online hearing test" for hearing aids).

[98] *See, e.g.*, EARKICK, https://earkick.com/ [perma.cc/FQ8B-AJCY] (advertising a "[p]ersonal AI [chatbot] for [m]ental [w]ellness" to "[t]rack and improve your mental health in real time").

[99] *See, e.g.*, Hailee (@hailee.fiercee), LINKTREE, https://linktr.ee/haileee_fierceee [perma.cc/M6P8-7P8F].

[100] *See* Simon Trinh, Devin Skoll & Leslie Ann Saxon, *Health Care 2025: How Consumer-Facing Devices Change Health Management and Delivery*, 27 J. MED. INTERNET RSCH. 1, 5 (2025) (showing that wearable wellness technology enables early detection across a range of conditions and provides personalized health insights and preventative capabilities that traditional healthcare systems have not historically offered at scale); Shaojing Fan, Ramesh C. Jain & Mohan Kankanhalli, *A Com-*

ness apps, and other direct-to-consumer wellness products are perceived as offering more equitable and accessible alternatives to traditional healthcare.[101] These products also make enticing implicit and explicit promises that appeal across demographics: to live longer,[102] improve health outcomes,[103] and navigate one's own body on one's own terms.[104]

Despite its harmless reputation, wellness is not without many of the risks more readily associated with healthcare. Those who rely on consumer health and wellness products can likewise experience economic, psychological, and indirect physical harm.[105] Failure to identify a serious problem due to misplaced reliance on wellness data can result in missed opportunities for diagnosis and treatment. Physical harm can also be more direct. Imagine traditional psychotherapy, delivered by a licensed professional and regulated as healthcare. Because it is high-risk and in the healthcare domain, it is subject to considerable oversight, including fiduciary duties, standards of care, mandatory reporting, and privacy, among others.[106] Now, imagine an AI-powered mental health

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prehensive Picture of Factors Affecting User Willingness to Use Mobile Health Applications, 5 ACM TRANS. COMPUT. HEALTHC. 1, 12–13 (2024) (finding that users across eight countries, including the United States, cite "personal health monitoring & disease prevention" as a primary motivation for using mobile health applications); TRUSTED FUTURE, SURVEY DATA: CONNECTED HEALTHCARE 1 (2022), https://trustedfuture.org/survey-data-connected-healthcare/ [perma.cc/KX6G-68L8] (finding that 41% of Americans use smartwatches or wearable devices to monitor their health, 30% use apps to proactively detect conditions and receive alerts as a form of preventive care, and 49% use health apps to set and reach fitness and wellness goals—all without a clinical visit).

[101] *See, e.g.*, Monique White et al., *Examining Motivation Factors for African American Students' Use of Consumer Wearables*, 9 DIGIT. HEALTH 1, 11 (2023) (illustrating how wearables can be "particularly effective in at-risk communities" where health disparities have persisted). For example, the study emphasized the value of wearables for individuals to monitor and reduce risk factors in Mississippi, where African Americans experience the nation's highest rates of cardiovascular disease. *Id.*; *see* TRUSTED FUTURE, *supra* note 100, at 3 (finding that 64% of Americans believe affordable, high-quality care should be available to everyone regardless of where they live, and that respondents viewed "connected health technologies" as a means of reducing barriers and achieving more equitable outcomes); *see also* Ranganathan Chandrasekaran, Muhammed Sadiq T & Evangelos Moustakas, *Usage Trends and Data Sharing Practices of Healthcare Wearable Devices Among US Adults: Cross-Sectional Study*, 27 J. MED. INTERNET RSCH. 1, 13 (2025) ("Challenges in obtaining health resources and general distrust in health care infrastructure and systems have also motivated Hispanic individuals to look at wearable devices to better monitor their health care.").

[102] *See, e.g.*, Yeyang Su, Heidi C. Howard & Pascal Borry, *Users' Motivations to Purchase Direct-to-Consumer Genome-Wide Testing: An Exploratory Study of Personal Stories*, 2 J. CMTY. GENETICS 135, 138 (2011) (finding that one of the individuals' primary motivating factors for using direct-to-consumer genetic testing is to learn genetic risk information to "live a longer life").

[103] Trinh et al., *supra* note 100, at 5.

[104] *See* TRUSTED FUTURE, *supra* note 100, at 2, 4 (finding that 49% of Americans believe connected health technologies allow people more control over their health, and framing wearables and apps as enabling a new generation of patients to take ownership of their health beyond the doctor's office).

[105] Duranske, *supra* note 46, at 19–20.

[106] *See, e.g.*, Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U.C. DAVIS L. REV. 1577, 1587–90 (2007) (describing licensure, professional discipline, credentialing,

chatbot offering mood tracking and cognitive reframing.[107] A consumer using it to manage their depression has shockingly few of the protections a similarly situated psychotherapy patient enjoys.[108] These services involve similar risks, including suicide,[109] yet the law treats them differently because one is healthcare and the other is not.

We may wish to believe that wellness is not about diagnosing or treating diseases or conditions, but the divide was already blurry and is only becoming blurrier.[110] This can create a disconnect between how wellness is labeled and how it functions, in which assumptions about what wellness is supposed to do override careful consideration of what wellness products actually do and the realities in which people use them.

2. The Assumption That Wellness Is a Purely Voluntary Lifestyle Choice

As wellness products are becoming more sophisticated in terms of functionality, we are simultaneously witnessing a broader cultural shift in how we talk about the role of wellness in our lives. Recall that the second factor that distinguishes wellness from healthcare is that wellness is an optional component of a healthy lifestyle.[111] This narrative of voluntariness, however, collapses under the weight of economic precarity, institutional failure, and ideological pressure. When there are few alternatives and the dominant cultural narrative frames every aspect of health as a personal responsibility, distinguishing between lifestyle choices and obligations becomes increasingly challenging.

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peer review, and malpractice law as legal mechanisms for regulating healthcare quality and enforcing minimum standards of care); Rebecca Weintraub Brendel, Marlynn H. Wei, Ronald Schouten & Judith G. Edersheim, *An Approach to Selected Legal Issues: Confidentiality, Mandatory Reporting, Abuse and Neglect, Informed Consent, Capacity Decisions, Boundary Issues, and Malpractice Claims*, 94 MED. CLIN. N. AM. 1229, 1230–33, 1237 (2010) (surveying legal obligations in medical practice, including confidentiality, mandatory reporting, informed consent, and malpractice standards).

[107] *See, e.g.*, *Woebot Health Terms of Service*, *supra* note 6.

[108] *See, e.g.*, Teddy Rosenbluth, *Seeking a Sounding Board? Beware the Eager-to-Please Chatbot*, N.Y. TIMES (Mar. 26, 2026), https://www.nytimes.com/2026/03/26/well/mind/ai-chatbots-relationships.html [perma.cc/4DSS-R5T3] (finding that leading AI models "were highly sycophantic, taking the users' side . . . even when the user described situations in which they broke the law, hurt someone or lied").

[109] Rob Kuznia, Allison Gordon & Ed Lavandera, *'You're Not Rushing. You're Just Ready.' Parents Say ChatGPT Encouraged Son to Kill Himself*, CNN (Nov. 20, 2025), https://www.cnn.com/2025/11/06/us/openai-chatgpt-suicide-lawsuit-invs-vis [perma.cc/M9BU-YMCH]; *see also* Mary Cunningham, *ChatGPT Served as "Suicide Coach" in Man's Death, Lawsuit Alleges,* CBS NEWS (Jan. 15, 2026), https://www.cbsnews.com/news/chatgpt-lawsuit-colordo-man-suicide-openai-sam-altman/ [perma.cc/LKM2-DFV6] (reporting that a man died by suicide after using ChatGPT as a therapy substitute, with the chatbot allegedly encouraging self-harm rather than directing him to professional care).

[110] *See* Simon et al., *supra* note 30, at 3 (distinguishing between exempt and non-exempt "general wellness products" under the 21st Century Cures Act).

[111] Zabawa, *supra* note 1, at 491.

The shifting role of wellness in American life is influenced by many factors. From one direction, we see a growing—and often justified—dissatisfaction and distrust of the medical establishment. Traditional healthcare systems, burdened by administrative overhead, insurance hurdles, and staffing shortages, often deliver impersonal, inaccessible, and slow care.[112] For many, particularly in stigmatized domains like mental and reproductive health, the system's formal structures reinforce alienation rather than trust.[113] Frustration with private insurance leaves many desperate for alternatives.[114] Trust in medical and scientific expertise is waning.[115] Public health agencies, marred by political interference and inconsistent messaging, have undermined their own authority.[116] Wellness offers a personalized and convenient alternative to broken systems.

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[112] *See* JESSICA BUCHTER, JENNY CORDINA & JILLIAN ECKROATE, CONSUMERS RULE: DRIVING HEALTHCARE GROWTH WITH A CONSUMER-LED STRATEGY 2–3 (2024), https://www.mckinsey.com/industries/healthcare/our-insights/consumers-rule-driving-healthcare-growth-with-a-consumer-led-strategy [perma.cc/B5WM-9Z5S] (observing that many consumers are not satisfied with their health care experiences and want more innovation).

[113] *See* Meghan A. Bohren et al., *Strategies to Reduce Stigma and Discrimination in Sexual and Reproductive Healthcare Settings: A Mixed-Methods Systematic Review*, PLOS GLOB. PUB. HEALTH, June 15, 2022, at 3 (showing that structural stigma and discrimination in reproductive healthcare lead to mistreatment, delayed or foregone care, and diminished trust); Supriya Misra et al., *Systematic Review of Cultural Aspects of Stigma and Mental Illness Among Racial and Ethnic Minority Groups in the United States: Implications for Interventions*, 68 AM. J. CMTY. PSYCH. 486, 486–87 (2021) (finding that mental-illness stigma among racial and ethnic minority groups includes structural stigma in the form of service barriers, lower-quality care experiences, provider discrimination, lack of culturally responsive services, and distrust of mental-health providers and treatment).

[114] *See* Charlie M. Wray, Lenny Lopez, Meena Khare & Salomeh Keyhani, *Cost-Related Access Barriers, Medical Debt, and Dissatisfaction with Care Among Privately Insured Americans*, 38 J. GEN. INTERNAL MED. 938, 938–39 (2022) (finding that "cost-related access barriers, medical debt, and dissatisfaction with care" were common among privately insured Americans, especially those in fair or poor health); *see, e.g.*, José A. Pagán & Mark V. Pauly, *Access to Conventional Medical Care and the Use of Complementary and Alternative Medicine*, 24 HEALTH AFFS. 255, 259–61 (2005) (finding that adults who delayed or forwent needed medical care due to costs were more likely to use complementary and alternative medicine).

[115] *See* Jake Johnson, *Major Survey Finds 100 Million Americans See US Healthcare System as 'Expensive' or 'Broken,'* W. HEALTH (Dec. 14, 2021), https://westhealth.org/news/major-survey-finds-100-million-americans-see-us-healthcare-system-as-expensive-or-broken [perma.cc/8LA5-F675] (finding perceptions of the healthcare system worse after the Covid-19 pandemic than before); Roy H. Perlis et al., *Trust in Physicians and Hospitals During the COVID-19 Pandemic in a 50-State Survey of US Adults*, 7 JAMA NETWORK OPEN 1, 4 (2024) (finding declining trust in physicians and hospitals, with lower trust associated with reduced likelihood of pursuing vaccination); Brian Kennedy & Alec Tyson, *Americans' Trust in Scientists, Positive Views of Science Continue to Decline*, PEW RSCH. CTR. (Nov. 14, 2023), https://www.pewresearch.org/science/2023/11/14/americans-trust-in-scientists-positive-views-of-science-continue-to-decline [perma.cc/E9YK-USR8] (finding declining public confidence in science as serving the public interest); *see also* Alec Tyson & Brian Kennedy, *Public Trust in Scientists and Views on Their Role in Policymaking*, PEW RSCH. CTR. (Nov. 14, 2024), https://www.pewresearch.org/science/2024/11/14/public-trust-in-scientists-and-views-on-their-role-in-policymaking/ [perma.cc/6PYU-PNXF] (noting a small increase in public trust in scientists since 2023, but an overall downward trend since the pandemic).

[116] *See* Selena Simmons-Duffin, *Poll Finds Public Health Has a Trust Problem,* NPR (May 13, 2021), https://www.npr.org/2021/05/13/996331692/poll-finds-public-health-has-a-trust-problem [perma.

The growing preference for a digital-first approach to health—driven, in part, by the wellness economy—reflects deeper frustrations with using and navigating the healthcare system.[117] Consider consumer apps and wearables, which grow in popularity every year.[118] Most Americans own at least one device and "track at least one health metric digitally."[119] Nevertheless, patterns of uptake reveal persistent demographic and structural trends. Younger adults, particularly Gen Z and Millennials, are the most enthusiastic adopters of wearables.[120] Perhaps relatedly, this younger cohort is also the least likely to say they "completely trust" health information from a healthcare provider,[121] and many feel they lack guidance on preventive care.[122] Ease of use[123] and peer adoption[124] thus position wellness as both a workaround and a tool to empower consumers, especially when they ultimately interact with the healthcare sys-

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cc/6NNV-R436] (reporting lack of trust in public health agencies—including the Centers for Disease Control and Prevention, the NIH, and the FDA—due to "political interference," "incomplete information," and "confusing messaging"); Josh Michaud, Jen Kates, Stephanie Oum & Anna Rouw, *U.S. Public Health*, *in* HEALTH POLICY 101, 1, 20 (Drew Altman ed., 2025), https://files.kff.org/attachment/health-policy-101-u-s-public-health.pdf [perma.cc/7RDX-K28F] (identifying a "fractured" and not "trustworthy" system with multiple actors and "[t]he politicization of public health science and public health messaging, especially during and after the COVID-19 pandemic" as representing key challenges for public health communication).

[117] *See generally* PWC, 2025 US HEALTHCARE CONSUMER INSIGHTS SURVEY: THE CONSUMER-FIRST ERA OF HEALTH (2025), https://www.pwc.com/us/en/industries/health-industries/library/assets/2025-us-healthcare-consumer-insights-survey.pdf [perma.cc/K8NZ-MZYQ] (revealing an accelerating, consumer-driven shift away from traditional care models toward digital-first healthcare).

[118] *See* Chandrasekaran et al., *supra* note 101, at 12 (noting that "[w]e observed an increase in wearable device usage from 28%–30% in 2019 to 36.36% in 2022, reflecting a broader trend of heightened health awareness, particularly following the COVID-19 pandemic").

[119] Madelyn Knowles, Adriana Krasniansky & Sari Kaganoff, *Screenagers to Silver Surfers: How Each Generation Clicks with Care*, ROCK HEALTH (Mar. 17, 2025), https://rockhealth.com/insights/screenagers-to-silver-surfers-how-each-generation-clicks-with-care/ [perma.cc/46BV-D79P]. This percentage is highest among Gen Z and Millennials, then decreases with each other generation. *Id.*

[120] *See id.* (finding that 64% of Gen Z (ages 18–24) and 65% of Millennials (ages 25–44) "track at least one health metric digitally"). Meanwhile, fifty percent of Gen X, thirty-nine percent of Baby Boomers, and thirty-five percent of the Silent Generation "track at least one health metric digitally." *Id.*; *see also* Chandrasekaran et al., *supra* note 101, at 9 (finding that "[t]he likelihood of using health care wearables declines with age").

[121] Knowles et al., *supra* note 119; *see also* PWC, *supra* note 117, at 4 (showing lower levels of trust in primary care physicians among Gen Z compared to Baby Boomers).

[122] *Preventive Care and Gen Z: How to Close the Gap for Younger Patients*, PHREESIA (2022), https://www.phreesia.com/wp-content/uploads/2022/11/PHR-Infographic-Preventive-Care-and-Gen-Z.pdf [perma.cc/82Q7-GC3N] (reporting that Gen Z patients fall behind older generations in preventive-care use, that forty percent had not had an annual wellness visit, and thirty-six percent had received no preventive care in the prior year). Gen Z respondents said they needed information about when they need preventive care, what preventive care is relevant to them, and where to schedule preventive care. *Id.*

[123] Faiz Aiman Bin Azhar & Jaspaljeet Singh Dhillon, *A Systematic Review of Factors Influencing the Effective Use of mHealth Apps for Self-Care*, 3D INT'L CONF. ON COMPUT. & INFO. SCIS. 191, 193 (2016).

[124] *Id.*

tem.[125] In 2026, consumers arrive at the clinic armed not only with longitudinal health data and self-diagnoses facilitated by the wellness industry, but also with the expectation that care should be collaborative, insight should be individualized, and authority should be distributed.[126] In this evolving landscape, increasing trust in wellness technology coincides with waning trust in traditional healthcare providers and systems.[127]

From another direction, we are seeing a broad government retreat in the healthcare space.[128] Throughout the Biden Administration, courts and legislatures stripped the government of public health authority and shifted responsibility to private actors, such as employers.[129] The second Trump Administration has accelerated the erosion of publicly funded research[130] and regulatory oversight,[131] ceding some of the direction of health innovation to private entities with capital but no public mandate.[132] The One Big Beautiful Bill Act (OBBBA), enacted by Congress in 2025, compounds this retreat by cutting Medicaid funding and rolling back marketplace coverage expansions made under the Affordable Care Act (ACA), leaving millions of people without cov-

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[125] *See* TRUSTED FUTURE, *supra* note 100, at 2, 4 (finding that forty-nine percent of Americans value the greater personal health control connected technologies afford, framing them as tools for taking ownership of one's health outside the doctor's office). Equipped with tools to "diagnose, understand, and manage" diseases, "new health care consumer[s]" approach traditional care delivery as empowered participants:

> The COVID-19 pandemic necessitated and accelerated use and understanding of the benefits of digitalized consumer-facing diagnostics and software . . . . This new health care consumer . . . will be the one[] providing data to the clinician and will expect partnership, ongoing communication, and ongoing bidirectional data sharing in their health and human performance care path.

Trinh et al., *supra* note 100, at 3.

[126] Trinh et al., *supra* note 100, at 3.

[127] PWC, *supra* note 117, at 4, 8.

[128] *See supra* notes 31–32 and accompanying text (highlighting reduced federal health agency authority and funding).

[129] *See* Sharona Hoffman, *Employers and the Privatization of Public Health*, 65 B.C. L. REV. 2405, 2414–19 (2024) (documenting judicial erosion—led by the U.S. Supreme Court—of the federal government's public health authority in the past three decades). At the state and local levels, legislatures have also enacted statutes constraining the exercise of public health authority within states' police powers. *Id.* at 2419–24.

[130] *See* OFF. OF DIR., NAT'L INSTS. OF HEALTH, *supra* note 32, at 1 (establishing a uniform cap on indirect cost rates for NIH research grants).

[131] *See* Scott L. Greer, Holly Jarman, Rachel Kulikoff & Miranda Yaver, *Trump's Second Presidency Begins: Evaluating Effects on the US Health System*, 48 LANCET REG'L HEALTH – AMS. 1, 5–6 (2025) (concluding that the second Trump Administration's first hundred days involved aggressive health-policy actions that undermined governance and research capacity, and that "[w]eakening regulatory agencies will stop new regulations from being considered but also prevent existing regulations from being enforced"); *see also* Exec. Order No. 14192, 90 Fed. Reg. 9065, 9065–66 (Jan. 31, 2025) (requiring agencies to identify at least ten existing regulations for repeal whenever they promulgate a new regulation).

[132] Broad, *supra* note 32.

erage.[133] The rollback of public health and the threatened rollbacks of health insurance programs and protections[134] portend a system in which private investment dictates priorities instead of public needs.

Simultaneously, the Make America Healthy Again (MAHA) initiative, championed by the second Trump Administration, has emphasized lifestyle and wellness.[135] Secretary of Health and Human Services (HHS) Robert F. Kennedy Jr. has suggested that individuals who engage in "unhealthy" behaviors should be ineligible for public assistance.[136] Secretary Kennedy has also explicitly stated that he wants every American to be "wearing a wearable within [the next] four years" as "a way [for] people [to] take control over their own health."[137] Dr. Mehmet Oz, the administrator of the Centers for Medicare & Medicaid Services (CMS), announced that it is "the patriotic duty of all Americans to take care of themselves," and emphasized that healthy people do not consume healthcare resources.[138] Viewed charitably, this framing casts wellness as a means of restoring personal agency in an arena—healthcare—often

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[133] *See* The One Big Beautiful Bill Act (OBBBA), Pub. L. No. 119-21, §§ 71119, 71301, 71303, 139 Stat. 72, 306–15, 321–23 (2025) (amending the Affordable Care Act); *see also* Lindsey Copeland, *Final House Vote on Devastating Health and Food Assistance Cuts*, MEDICARE RTS. CTR. (July 3, 2025), https://www.medicarerights.org/medicare-watch/2025/07/03/final-house-vote-looms-on-devastating-health-and-food-assistance-cuts [perma.cc/5EPK-LAKY] ("Senate Republicans passed a devastating budget bill that would slash Medicaid, Medicare, and SNAP (food assistance) and strip coverage from 17 million Americans to pay for tax cuts that disproportionately benefit high income earners."); Meredith Lee Hill, Jennifer Scholtes & Rachael Bade, *'Don't F—k Around with Medicaid': Trump Moves to Steamroll Megabill Opposition*, POLITICO (May 20, 2025), https://www.politico.com/news/2025/05/20/trump-megabill-opposition-medicaid-00358394 [perma.cc/4TEW-JEYA].

[134] *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-medicaid-and-the-aca/ [perma.cc/Q5XH-DK9P] (discussing President Trump's executive orders rolling back health care protections); 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 [perma.cc/5R2W-7ZH9] (documenting actions by HHS to cancel federal grants to states for public health initiatives).

[135] *See* Exec. Order No. 14212, 90 Fed. Reg. 9833, 9833–34 (Feb. 13, 2025). The Trump Administration's MAHA Commission seeks to address harmful health trends in the United States:

> To fully address the growing health crisis in America, we must re-direct our national focus . . . . This includes fresh thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits . . . . We must ensure our healthcare system promotes health rather than just managing disease.

Id. See generally Make America Healthy Again, THE WHITE HOUSE: PRIORITIES, https://www.whitehouse.gov/issues/maha/ [perma.cc/VQ8C-JCGD] ("President Trump launched the Make American Healthy Again initiative to confront chronic disease, improve nutrition, and lower healthcare costs.").

[136] Weber, *supra* note 35.

[137] Singh, *supra* note 34.

[138] Choi, *supra* note 33.

characterized by opacity and paternalism.[139] By this logic, encouraging individuals to take ownership of their health through the wellness economy fosters autonomy, resilience, and self-efficacy.[140] One can thus understand the shift toward individual responsibility as empowering rather than troubling.[141]

In this morass, wellness appears as an attractive option and, in some cases, perhaps even a viable substitute for some aspects of traditional healthcare. It casts health as a personal project of self-improvement.[142] Within this framing, wellness is a matter of individual choice and civic responsibility.[143] Poor health and well-being, it follows, cannot be attributed to structural inequities or social determinants. Instead, it is a personal failure.[144] Invoking the rhetoric of personal responsibility against institutional overreach further entrenches the belief that health is something one does on one's own. What some have optimistically dubbed "the creative destruction of medicine"[145] is welcomed by many as a personalized, efficient, and convenient alternative.

But when there are no other reasonable options, and when the government or your employer tells you wellness is actually your duty, it ceases to be a choice in any meaningful sense. Instead, it becomes a moral imperative shaped more by necessity than by preference.[146] Medicine is creatively destroyed on

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[139] *See* Jeffrey A. Singer, *Beyond Medical Paternalism: Restoring Control to the Individual,* 2 FREE SOC'Y 35, 35 (2025), https://www.cato.org/sites/cato.org/files/2025-03/Beyond%20Medical%20Paternalism.pdf [perma.cc/9XX8-CPS3] (arguing that healthcare is replete with medical paternalism and bureaucratic policies undermine patient autonomy by restricting access to medicines, physicians, and health information, and calling to restore control to individuals).

[140] *Id.*; *see also* Grossman, *supra* note 56, at 113 (reflecting a longstanding belief in American history in a right to bodily autonomy, including the ability to choose how to protect one's own physical well-being).

[141] *See* Singer, *supra* note 139, at 35 (defining autonomy in healthcare as focused on "empowering individuals to make decisions about their lives, their bodies, and their well-being").

[142] *See* LUPTON, *supra* note 68, at 47.

[143] *See id.* at 46–47 (arguing that neoliberal ideologies of self-responsibility cast health and well-being as individual civic obligations rather than collective or state concerns).

[144] *See id.* at 68 (arguing that self-tracking cultures frame health optimization as a moral obligation of citizenship, implying that poor health reflects an individual's failure to meet that obligation).

[145] *See* ERIC TOPOL, THE CREATIVE DESTRUCTION OF MEDICINE, at v–vi (2012) (defining "the creative destruction of medicine" as the inevitable digital transformation of healthcare, dismantling its outdated, physician-controlled systems and rebuilding them around digitized human data and empowered consumers).

[146] *See* Deborah Lupton, *Quantified Sex: A Critical Analysis of Sexual and Reproductive Self-Tracking Using Apps*, 17 CULTURE, HEALTH & SEXUALITY 440, 449 (2015) (noting that "[t]here is significant potential in these approaches for the stigmatising of and discrimination against individuals who are viewed as not appropriately responsible if they choose not to engage in self-monitoring of health-related behaviours or if they fail to attain norms of behaviour"); *see also* Choi, *supra* note 33 (quoting Dr. Oz as saying it is "the patriotic duty of all Americans to take care of themselves"); Deborah Lupton, *The Digitally Engaged Patient: Self-Monitoring and Self-Care in the Digital Health Era*, 11 SOC. THEORY & HEALTH 256, 260–61, 266 (2013) (arguing that digital health discourse encourages patients to "digitis[e] their bodies," "take control" of their health, and engage in routine self-monitoring, such that patient empowerment becomes "a set of obligations" and the burden of health responsibility shifts "from the state to the individual"); Peter Conrad, *Wellness as Virtue: Morality*

the altar of wellness. Consumers of these products are revealed for the vulnerable actors they are and have always been. Viewed less charitably, and perhaps more realistically, authority figures are increasingly telling citizens that, when it comes to many aspects of basic and preventive health, they are on their own from now on. Not only because it is how things are going to be, but because it is how they ought to be. Individuals, through wellness, should ensure they are and remain healthy. They should never let themselves reach the point where access to more involved care would even be necessary.

C. Healthcare and Wellness as Legally Distinct Domains

Despite the blurring divide between healthcare and wellness, the law still treats them as distinct. Although healthcare at America's founding began as an unregulated enterprise,[147] it is now subject to a significant number of special laws and regulations in recognition of all that makes it exceptional.[148] Courts treat medical relationships differently from ordinary commercial transactions precisely because of the public interests they implicate.[149] Laws and regulations that have developed across the health domain reflect this exceptionalism. For example, the Federal Food, Drug, and Cosmetic Act (FDCA) establishes a comprehensive system for regulating drugs and medical devices, imposing strict premarket review requirements on drugs[150] and high-risk medical devices,[151] and often requiring evidence of safety and efficacy before a product can be marketed.[152]

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and the Pursuit of Health, 18 CULTURE, MED. & PSYCH. 385, 385–89 (1994) (tracing the historical moralization of wellness in American society).

[147] Grossman, *supra* note 56, at 89.

[148] *See supra* notes 69–82 and accompanying text (explaining healthcare exceptionalism).

[149] *See* Mehlman, *supra* note 19, at 62 (arguing physicians must reaffirm fiduciary duties to patients to preserve professionalism against commercial pressures).

[150] *See* 21 U.S.C. § 355(a) (prohibiting the introduction of any new drug into interstate commerce without an approval from the FDA); *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [perma.cc/E7AX-LCCG] (outlining the FDA's review process for drugs).

[151] *See* 21 U.S.C. §§ 360c(a)(1)(C) (defining Class III medical devices as those requiring premarket approval because general controls alone are insufficient "to provide reasonable assurance of its safety and effectiveness"); *id.* § 360e(a) (requiring Class III devices to have pre-market approval). Evidence of safety and efficacy for Class III devices is often provided through pivotal studies, which the FDA defines as one that "is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use." U.S. FOOD & DRUG ADMIN., DESIGN CONSIDERATIONS FOR PIVOTAL CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES GUIDANCE FOR INDUSTRY, CLINICAL INVESTIGATORS, INSTITUTIONAL REVIEW BOARDS AND FOOD AND DRUG ADMINISTRATION STAFF 5 (2013).

[152] *See* 21 U.S.C. § 355(b) (requiring submission of safety and effectiveness for approval of a new drug); *id.* § 355(d) (requiring "substantial evidence" of efficacy and evidence of safety as condition for a drug's approval); *id.* 360e(c) (establishing pre-market approval requirements for Class III medi-

Beyond product regulation, in the context of patient-physician relationships, the law does not seek to remedy the knowledge and power imbalances between patients and physicians but rather works within those realities.[153] Licensure regimes regulate who may deliver care, subjecting providers to ethical codes, fiduciary duties, and disciplinary systems.[154] Informed consent, albeit imperfect, tries to ensure that patients are notified of material risks and protected from physician coercion.[155] Public health mandates[156] and anti-discrimination protections[157] eventually grew to offer alternatives to pure market allocation in the healthcare sphere. Regulations protecting patient privacy, such as the Health Insurance Portability and Accountability Act (HIPAA),[158] as well as

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cal devices, including submission of valid scientific evidence demonstrating reasonable assurance of the device's safety and effectiveness).

[153] *See* Mariner, *supra* note 47, at 8 (explaining that patient rights law accepts rather than corrects the inherent knowledge and power imbalance between physicians and patients, imposing fiduciary duties on physicians).

[154] *See* Mehlman, *supra* note 19, at 3–8 (explaining the "fiduciary nature of the patient-physician relationship," as recognized by courts, medical ethical standards, and scholarly commentators); *About Physician Licensure,* FED'N OF STATE MED. BDS., www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-licensure/ [perma.cc/LBL5-UN46] (providing overview of physician licensing, including states' authority to discipline physicians). *See generally AMA Principles of Medical Ethics*, AM. MED. ASS'N.: CODE OF MED. ETHICS (June 2001), https://code-medical-ethics.ama-assn.org/principles [perma.cc/P8U7-XNNP]. Standards of care defining clinicians' professional obligations to patients are also relevant to medical malpractice lawsuits. Donna Vanderpool, *The Standard of Care*, 18 INNOV. CLIN. NEUROSCI. 50, 50–51 (2021).

[155] *See* Canterbury v. Spence, 464 F.2d 772, 786–87 (D.C. Cir. 1972) (establishing the patient-centered standard for informed consent, requiring a physician to disclose information that an objectively reasonable patient would consider material to their decision); Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972) (holding that patient's consent to treatment must be informed consent). The court emphasized that patients have the right to the "exercise of control over his own body, to determine whether or not to submit to lawful medical treatment." *Id*. Nevertheless, the court explained that, in exercising that right, "the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process," justifying the informed consent requirement. *Id.*; *see also* Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."). *But see* Valerie Gutmann Koch, *Reimagining Informed Consent: From Disclosure to Comprehension*, 14 U.C. IRVINE L. REV. 894, 903–14 (2024) (outlining criticisms of medical informed consent).

[156] *See, e.g.*, Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 201–231, 79 Stat. 286, 353–60 (1965) (codified at 42 U.S.C. §§ 1395–1395mmm (Medicare) and §§ 1396–1396w-6 (Medicaid)) (establishing Medicare and Medicaid as public health-financing programs that shifted access to healthcare for older adults and low-income individuals away from exclusive dependence on private insurance markets and individual ability to pay).

[157] Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in federally funded health programs and activities. 42 U.S.C. § 18116(a); *see* 45 C.F.R. § 92.1 (2024) (implementing ACA antidiscrimination provision).

[158] *See, e.g.*, Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 1177, 110 Stat. 1936, 2029 (1996) (codified at 42 U.S.C. § 1320d-6) (establishing penalties for certain disclosures of individual health information). "Covered entities" are health plans, health care clearinghouses, and health care providers. 45 C.F.R. § 160.103 (2023).

statutory protections governing access to and provision of care under the Emergency Medical Treatment and Labor Act (EMTALA)[159] and the ACA,[160] further underscore the unique nature of healthcare. These legal frameworks suggest that health requires public accountability and cannot be governed solely by the free market.[161] So, even though we have only somewhat recently begun to discuss patients as consumers, the law does not truly treat them as such.[162]

In contrast to healthcare, wellness is subject to few laws and regulations beyond those typically applied to any other consumer transaction.[163] Where "patient rights focus on the relationship between [a] patient[]" and a physician, consumer rights instead center on purchasing decisions.[164] The goal of consumer protection laws, at least in theory, is to correct information asymmetries.[165] The underlying assumption is that consumers are educated and best positioned to make their own decisions.[166] That assumption has significant regulatory consequences. Purveyors of nutritional supplements and cosmetics do not need FDA approval before their products are on the physical or digital shelves.[167] Within its broad authority to regulate devices, the FDA exercises enforcement discretion over low-risk wellness products.[168] It does not regulate

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[159] *See* 42 U.S.C.§ 1395dd(a)–(b) (requiring hospitals to screen, stabilize, and appropriately transfer individuals presenting with emergency medical conditions regardless of insurance status or ability to pay).

[160] *See generally* Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. No. 111-148, 124 Stat. 119, *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (codified as amended at scattered sections of 26 U.S.C. and 42 U.S.C.) (imposing public-law obligations on health insurance and covered health programs, including guaranteed availability of coverage, prohibitions on preexisting-condition exclusions and health-status discrimination, coverage of preventive services and essential health benefits, and nondiscrimination requirements in health programs and activities).

[161] *See* Mariner, *supra* note 47, at 9–10 (identifying ways in which patient and consumer rights differ).

[162] *See id.*, at 7–8 (observing that patients were historically not considered consumers, despite their purchase of health care); Tomes, *supra* note 73, at 529–44 (finding the origin of the idea of patient as consumer in the interwar period of the twentieth century); *see also* JOST, *supra* note 17, at 50–53 (tracing the history of the consumer-driven health care movement); George J. Annas, *A National Bill of Patient's Rights*, 338 NEJM 695, 697 (1998) ("Consumer protection is also important but pales in comparison with the rights of sick people in dealing with physicians and other care givers.").

[163] Zabawa, *supra* note 1, at 492 (observing that "[u]nlike the fields of health law or environmental law, there are not many formal laws addressing wellness because the industry is not subject to much, if any, regulation or oversight").

[164] Mariner, *supra* note 47 at 4.

[165] *Id.* at 5.

[166] *Id.*

[167] *See* U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS POLICY FOR LOW RISK DEVICES, *supra* note 27, at 2 (discussing the FDA's low prioritization of "low risk general wellness products"); *see also* Zabawa, *supra* note 1, at 505–07 (explaining in detail the FDA's approach to supplements, cosmetics, and low-risk wellness products).

[168] U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS POLICY FOR LOW RISK DEVICES, *supra* note 27, at 2; *see* 21 U.S.C. § 321(h) (defining "device").

products intended to "maintain[] or encourag[e]" a healthy lifestyle.[169] As a result, anyone, not just technocrats and venture capitalists, can engage on the supply side of wellness products and services, leaving consumers vulnerable to bad consequences.[170] Although the FDA and the FTC do monitor health claims in advertising,[171] both agencies are understaffed and underfunded,[172] the consumer wellness market is enormous and dynamic, and, as a result, enforcement is quite rare.

Closer examination of the healthcare-wellness divide in various areas of law reveals that, in reality, the two are often difficult to disentangle.[173] Tax law

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[169] *See* 21 U.S.C. § 360j(o)(B) ("The term device . . . shall not include a software function that is intended . . . for maintaining or encouraging a healthy lifestyle . . . ."). The FDA could, in theory, treat any product as a medical device depending on its intended use, based on any source of information, and regardless of explicit labeling, including many consumer wellness products. *See* Patricia J. Zettler, *The FDA's Power Over Non-Therapeutic Uses of Drugs and Devices*, 78 WASH. & LEE L. REV. 379, 388 (2021) (noting that "the FDA does not formally distinguish between therapeutic and non-therapeutic uses of products that meet the definition of a drug or device—a drug is a drug, and a device is a device, whether or not its purpose is therapeutic"). The fact that they have not done so, however, seems to be the clearest indication that they likely will not. Fowler, *supra* note 50, at 96–97. *But see* U.S. FOOD & DRUG ADMIN., WARNING LETTER, WHOOP, INC., No. MARCS-CMS 709755 (July 14, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/whoop-inc-709755-07142025 [perma.cc/53B8-9YRX] (finding that a wearable device's blood pressure estimation feature constitutes a medical device subject to premarket approval requirements because its blood pressure estimations are inherently associated with the diagnosis of hypertension). The FDA distinguished WHOOP's feature from software merely intended to maintain or encourage a healthy lifestyle, finding that a product implying a causal link between a measurement and a disease or condition falls outside that exemption. U.S. FOOD & DRUG ADMIN., *supra*.

[170] *See, e.g.*, Andrew I. Geller, Nina J. Weidle, Beverly J. Wolpert & Robert P Mozersky, *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 NEJM 1531, 1539 (2015) (estimating "that more than 23,000 emergency department visits annually in the United States from 2004 through 2013 were for adverse events associated with dietary supplements"). The FDA does not require safety testing or pre-market approval for dietary supplements. *Id.* at 1532; *see also* AM. PSYCH. ASS'N, APA HEALTH ADVISORY ON THE USE OF GENERATIVE AI CHATBOTS AND WELLNESS APPLICATIONS FOR MENTAL HEALTH 1 (2025), https://www.apa.org/topics/artificial-intelligence-machine-learning/health-advisory-ai-chatbots-wellness-apps-mental-health.pdf [perma.cc/QG93-2JP4] (highlighting increased use of GenAI chatbots and wellness applications for "mental health advice and treatment," and warning that "these technologies . . . lack scientific validation and oversight, often do not include adequate safety protocols, and have not received regulatory approval").

[171] Duranske, *supra* note 46, at 20–21; *see, e.g.*, U.S. FOOD & DRUG ADMIN., *supra* note 169 (noting FDA's review of company's advertising, website, and media to evaluate potential legal violations).

[172] Jeneen Interlandi, *Inside the Collapse of the F.D.A.*, N.Y. TIMES (July 8, 2025), https://www.nytimes.com/2025/07/08/magazine/fda-collapse-rfk-kennedy.html [perma.cc/F7QU-EB7V]; Jacob Plaza, *Federal Understaffing Spotlight: Federal Trade Commission*, REVOLVING DOOR PROJECT (Mar. 12, 2025), https://therevolvingdoorproject.org/under-staffing-federal-trade-commission/ [perma.cc/PC96-89DZ].

[173] Another area of law that may be instructive is insurance law, in which courts are regularly asked to decide whether something is medically necessary and thus, a covered benefit. *See* Mariner, *supra* note 47, at 26 (discussing cases where courts determine whether a hospital choice concerns covered benefits under a health plan contract or the quality of care, for purposes of distinguishing contract and tort claims).

proves instructive.[174] Medical expenses are generally deductible from taxable income.[175] According to the tax code, "medical care" means "for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body."[176] It also includes "transportation primarily for and essential to medical care," "qualified long-term care services," and certain types of insurance premiums.[177]

Section 213 of the tax code reflects a recognition that the money we spend on our health, especially in a medical context, is often considerable and not the result of a voluntary choice, but rather created by needs outside of our control.[178] By contrast, wellness expenses would fall within the general rule of Section 262, which prohibits deductions for "personal, living, or family expenses."[179] Determining whether a particular expense is deductible as a medical expense rather than a personal expense, however, can be challenging[180] and requires a finding of fact.[181] For example, the same product may assume a different role depending on the circumstances.[182] Vitamins would not be tax-deductible when you buy them for yourself as a nutritional supplement, but could be tax-deductible when prescribed by a doctor to treat an illness.[183] When a physician prescribes a weight-loss program, it qualifies as tax-deductible medical care.[184] An identi-

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[174] *See* Zabawa, *supra* note 1, at 501–05 (discussing the intersection of tax and wellness).

[175] *See* I.R.C. § 213(a) (providing a deduction for medical care expenses); *see also* Julie Furr Youngman & Courtney D. Hauck, *Medical Necessity: A Higher Hurdle for Marginalized Taxpayers?*, 51 LOY. L.A. L. REV. 1, 32–33 (2018) (noting that medical expense deductibility is limited in practice, as only 8.8 million taxpayers claimed it in 2015, and the benefit accrues primarily to middle-to-upper-income itemizers whose unreimbursed expenses exceed the statutory threshold).

[176] I.R.C. § 213(d)(1)(A).

[177] *Id.* § 213(d)(1)(B)–(D).

[178] *Id.* § 213(a); *see* David W. Ichel, *Defining "Medical Care": The Key to Proper Application of the Medical Expense Deduction*, 1977 DUKE L.J. 909, 913 ("Extraordinary expenditures for health care are not the result of voluntary choices among gratifications in the distributive sector, but are instead involuntary, intermediate expenditures based upon a malady-created need.").

[179] I.R.C. § 262(a).

[180] Youngman & Hauck, *supra* note 175, at 33.

[181] Ichel, *supra* note 178, at 915. Ichel explains that the factual determination turns in part on whether the expense is related to the "diagnosis, prevention or treatment of a specific [health] defect." *Id.*

[182] For example, as Leigh Osofsky notes, therapy to treat a diagnosed mental illness would count, but therapy for marital counseling would not. Osofsky, *supra* note 88, at 455 (citing *Frequently Asked Questions About Medical Expenses Related to Nutrition, Wellness and General Health*, IRS, https://www.irs.gov/individuals/frequently-asked-questions-about-medical-expenses-related-to-nutrition-wellness-and-general-health [perma.cc/8CJL-3FKD]).

[183] Ichel, *supra* note 178, at 923–24, 924 n.89.

[184] Zabawa, *supra* note 1, at 503 n.82. It is worth noting that an entire industry has emerged to provide letters of medical necessity for tax purposes. *See, e.g.*, Kathleen Ferraro, *Letter of Medical Necessity: Key Components & Examples*, TRUEMED (July 29, 2025), http://www.truemed.com/blog/letter-of-medical-necessity-example [perma.cc/J52H-7DKP] (advertising services that connect consumers with providers who issue letters of medical necessity to support tax-advantaged health purchases).

cal weight-loss program that an individual undertakes independently in the pursuit of wellness, absent physician involvement, is not tax-deductible.[185] The presence or absence of a physician or prescription, however, is not dispositive and was never intended to be under Internal Revenue Code section 213.[186]

In 1949, in *Havey v. Commissioner*, the U.S. Tax Court established a factor-based test for determining whether an expenditure constitutes medical care and is thus deductible for tax purposes.[187] In *Havey,* the court considered whether a taxpayer could deduct travel and lodging expenses at two New Jersey resort hotels in New Jersey and an Arizona resort ranch, incurred on a physician's advice to treat his wife's coronary occlusion.[188] The court articulated a balancing test that considered five relevant questions.[189] First, what was the taxpayer's "motive or purpose"?[190] Second, did a physician suggest or direct the taxpayer to incur the expense?[191] Third, did the treatment bear directly on the physical condition at issue?[192] Fourth, "did the treatment bear such a direct or proximate therapeutic relation to the bodily condition as to justify a reasonable belief the same would be efficacious[?]"[193] Finally, fifth, was the treatment close enough "in the time to the onset or recurrence of the disease or condition as to make" it clear that the disease or condition occasioned the treatment?[194] Weighing each factor, the court ultimately concluded that the expenditures did not qualify as deductible medical expenses.[195]

As the tax law example illustrated in *Havey* shows, the law treats health–care as special and wellness as unexceptional.[196] Nevertheless, tax law has also acknowledged the challenges that can arise in distinguishing between the two,

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[185] Zabawa, *supra* note 1, at 503.

[186] I.R.C. § 213; *see* Ichel, *supra* note 178, at 924 ("That a particular treatment is performed or prescribed by a licensed physician simply cannot be controlling as to the issue of whether the item or service constitutes section 213 medical care.").

[187] Havey v. Comm'r, 12 T.C. 409, 412 (1949).

[188] *Id.* at 409, 412. The cardiologist "advised petitioner to take his wife to the seashore during the humid months of July and August because she lived in an apartment in Pittsburgh and he felt she would be benefited by living at the seashore." *Id.* at 409.

[189] *Id.* at 412.

[190] *See id.* ("Consideration should be accorded the motive or purpose of the taxpayer, but such factor is not alone determinative. To accord it conclusive weight would make nugatory the prohibition against allowing personal, living, or family expenses.").

[191] *See id.* ("[I]t is important to inquire as to the origin of the expense. Was it incurred at the direction or suggestion of a physician[?]").

[192] *See id.* ("[D]id the treatment bear directly on the physical condition in question[?]").

[193] *Id.*

[194] *Id.*

[195] *See id.* at 413 (concluding that the expenses petitioner incurred were not "incurred primarily for the cure, prevention, or alleviation of a disease or physical condition within the meaning" of the tax code).

[196] *See id.* at 411–12 (distinguishing medical expenses from personal or living expenses, even though the latter may be "undoubtedly highly and directly beneficial to the general health").

although other areas of the law do not probe as deeply.[197] As wellness continues to mimic the form and function of healthcare while evading its legal protections, consumer contract law is becoming the primary governance mechanism. In the rare cases where courts consider the distinction between healthcare and wellness in contract disputes, the presence of a physician-patient relationship appears to be the deciding factor.[198] As described above, this is no longer realistic, if it ever was.[199] As the next Part will show, contract law largely sidesteps the threshold question of whether a transaction implicates healthcare or wellness.[200] And even though this approach may have sufficed in the past, the future of wellness requires a more nuanced approach.

II. CONTRACTS IN HEALTHCARE AND WELLNESS

Contracts structure health-affecting transactions across both healthcare and wellness, but they do not play the same governance role. In healthcare, contract law operates against a backdrop of tort, fiduciary duties, professional regulation, and public policy, so courts treat patients as more than ordinary consumers.[201] In wellness, by contrast, contract law is the primary regulatory regime. Terms of service, waivers, and arbitration clauses do the work that health law would ordinarily do in a healthcare context, and courts tend to enforce them as they would any routine consumer bargain.[202] The trouble is that contract doctrine rarely confronts the healthcare-wellness boundary on its own terms. Instead, if it does anything at all, it uses the clinical setting and the presence of a physician as a proxy for when caution is warranted.[203] As wellness

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[197] Even the IRS Commissioner has weighed in on the distinction between medical expenses and personal wellness expenses. *See* Internal Revenue Serv., *IRS Alert: Beware of Companies Misrepresenting Nutrition, Wellness and General Health Expenses as Medical Care for FSAs, HSAs, HRAs and MSAs* (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 [perma.cc/3PY4-MTJC] (quoting IRS Commissioner Danny Werfel as warning that "aggressive marketing" may suggest that expenditures for wellness products may qualify for reimbursement when they in fact do not). Notwithstanding tax law's more comprehensive approach to identifying healthcare than contract law's, Osofsky has argued that it is still overly restrictive. Osofsky, *supra* note 88, at 475.

[198] *See* Curmode v. Alsbrooks, 880 S.E.2d 320, 322–23 (Ga. Ct. App. 2022) (upholding an exculpatory clause in a massage therapy contract, reasoning that the statutory duty of care—which voids such clauses in medical contexts—applies only where a physician-patient relationship exists). The court concluded that no such relationship exists between a patron and licensed massage therapist, drawing a line between healthcare providers who form physician-patient relationships and wellness practitioners who do not. *Id.*

[199] *See supra* Part I.A.

[200] *See infra* Part II.

[201] Mariner, *supra* note 47, at 11–12.

[202] *Id.*

[203] *See, e.g.*, *Curmode*, 880 S.E.2d at 322–23 (voiding exculpatory clauses on public policy grounds only where a physician-patient relationship exists, treating that relationship as the operative proxy for when caution is warranted rather than the clinical or licensed nature of the service).

products increasingly supplement and substitute for care, there is a risk that courts may never treat wellness contracts as anything more than benign consumption. In the process, courts may strip wellness consumers of the modest protections contract law recognizes in healthcare, leaving consumers with "buyer beware" consumer contract defaults just as the stakes begin to resemble those in medicine.

This Part illuminates the divergence in how contract law governs healthcare and wellness transactions—and the consequences that follow—by comparing judicial treatment of analogous contract terms in both contexts. Section A shows how healthcare contracts are constrained by public policy and patient-protective principles.[204] Section B reviews how wellness contracts are treated as ordinary consumer agreements.[205] Section C identifies the doctrinal patterns that emerge from this comparison.[206] This juxtaposition of health and wellness reveals how contract law may ultimately facilitate a subtle erosion of health-related rights in the name of consumer choice.

A. Contracts in Healthcare

Contracts in healthcare are exceedingly common[207]—you've probably signed many of them. But healthcare contracts exist at an intersection of private law's desire for freedom of contract and public policy's imperative to protect patient welfare and the public interest.[208] The provision of healthcare and the patient-provider relationship—at their heart, a form of contractual relationship[209]—are not ordinary commercial bargains.[210] Healthcare provision is special due to its unique economic, physical, and ethical stakes.[211] As a result, contracts in healthcare are subject to limitations imposed by courts and legislatures to safeguard patients.[212] This Section shows how tort, fiduciary duty, professional regulation, and public policy together constrain what healthcare contracts can do—limiting liability waivers, demanding meaningful informed consent, and subjecting arbitration agreements to heightened scrutiny.[213]

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[204] *See infra* notes 207–272 and accompanying text.

[205] *See infra* notes 276–321 and accompanying text.

[206] *See infra* notes 324–350 and accompanying text.

[207] Two of the most famous contracts cases involving the provision of medical care are *Hawkins v. McGee*, 146 A. 641, 644 (N.H. 1929), and *Sullivan v. O'Connor*, 296 N.E.2d 183, 187 (Mass. 1973). Most first-year law students will study them.

[208] *See* BEN TEMPLIN & DAVID H. SPRATT, CONTRACTS: A MODERN COURSEBOOK 13 (3d ed. 2023) ("Freedom of contract stands for the belief that parties should be free to enter agreements without government intervention so long as the agreements do not violate a law.").

[209] *See* Dingle v. Belin, 749 A.2d 157, 169 (Md. 2000) ("[T]he doctor-patient relationship is normally a contractual one . . . .").

[210] *See supra* notes 71–82 and accompanying text (explaining how health is exceptional).

[211] *See supra* Part I.C.

[212] *See infra* notes 215–272 and accompanying text.

[213] *See infra* notes 214–275 and accompanying text.

1. Waivers of Liability and Exculpatory Clauses

A key difference between healthcare contracts and ordinary commercial transactions is the invalidation of pre-treatment liability waivers. Think about the waivers you sign for recreational activities—the ones that provide that "I expressly release and discharge Releasees from any and all liability, claims, demands or causes of action whatsoever arising out of any damage, loss, personal injury or death to me and/or my child/ward, while participating in any of the activities."[214] Although general contract law typically permits parties to agree to waive liability for future negligence, courts can void such clauses in healthcare as against public policy.[215]

In 1963, in *Tunkl v. Regents of the University of California*, the California Supreme Court held that a hospital's pre-admission release from liability for future negligence was void as against public policy.[216] The court found that such exculpatory clauses are unenforceable when they involve transactions that affect the public interest.[217] The court outlined factors to determine whether a transaction implicates the public interest, such as the essential nature of the service, unequal bargaining power, and the use of adhesion contracts.[218] In *Tunkl*, the court determined that the waiver at issue was invalid because the hospital was a public-serving, regulated institution providing critical services, and patients had little choice but to accept its terms.[219] The court rejected distinctions based on the hospital's nonprofit status or whether liability was direct or vicarious, emphasizing that contractual releases cannot override duties of care owed in settings that implicate public welfare.[220]

Virtually all states have followed suit;[221] some explicitly note that an exculpatory clause in a physician-patient context implicates "both the State's interest

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[214] *iFLY Release and Waiver of Liability*, COSTCO, https://www.costco.com/wcsstore/CostcoUSBCCatalogAssetStore/Attachment/100075219WaiverandRelease.pdf [perma.cc/TP6E-GSL3].

[215] Curmode v. Alsbrooks, 880 S.E.2d 320, 322–23 (Ga. Ct. App. 2022).

[216] Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 441–42 (Cal. 1963).

[217] *Id.* at 444–45.

[218] *Id.* at 444–47. The factors are: (1) the business is "of a type generally thought suitable for public regulation"; (2) "[t]he party seeking exculpation . . . perform[s] a service of great importance to the public"; (3) the service is offered to "any member of the public who seeks it"; (4) "the party invoking exculpation" has superior "bargaining strength"; (5) the service is provided through "a standardized adhesion contract of exculpation"; and (6) the purchaser is "placed under the control of the seller, subject to the risk of carelessness." *Id.* Healthcare contracts arguably embody each of these characteristics.

[219] *Id.* at 447–48.

[220] *Id.* at 448.

[221] *See, e.g.*, Cudnik v. William Beaumont Hosp., 525 N.W.2d 891, 895 (Mich. Ct. App. 1994) (noting that "[t]he overwhelming majority of other jurisdictions that have addressed this question have held that such agreements are invalid and unenforceable because medical treatment involves a particularly sensitive area of public interest") (citing *Tunkl*, 383 P.2d at 441); *see also* Olson v. Molzen, 558 S.W.2d 429, 430–32 (1977) (applying the *Tunkl* factors to hold an exculpatory agreement between a patient and an abortion provider void against public policy, where the patient brought a negligence

in the health and welfare of its citizens, as well as the special relationship between physician and patient," and therefore, "it would be against public policy to uphold such . . . agreement[s]."[222] Whether by judicial decision or statute, pre-service medical malpractice releases are generally unenforceable: courts generally refuse to enforce them on public policy grounds, and some states have also prohibited liability waivers in healthcare facility admissions contracts, including in nursing-home, long-term-care, and assisted-living settings.[223]

Narrow exceptions to this general rule against exculpatory agreements tend to arise when the patient, rather than the provider, insists on a course of action and knowingly assumes its risks.[224] Even then, the provider is not freed from liability for independent negligence. For example, in 1985, in *Shorter v. Drury*, the Supreme Court of Washington considered an exculpatory agreement in a medical malpractice wrongful death action involving a Jehovah's Witness who refused blood transfusions on religious grounds and signed a hospital release acknowledging the likely consequences of that refusal.[225] The patient died from a hemorrhage during surgery.[226] The court held that the patient had assumed the risk of the known consequences of refusing blood, but that the release did not insulate the defendant doctor from liability for his own negligence.[227] In other words, a patient may contractually decline aspects of care and bear the attendant risks, but may not prospectively waive the right to competent treatment from the provider more broadly.[228] Any contractual term purporting to exempt a hospital or clinician from liability for malpractice is void ab initio—invalid from the beginning—as contrary to the public interest in patient safety and the integrity of the healthcare relationship.

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action after discovering she remained pregnant following the procedure, by which time it was too late to obtain another abortion). *But see* Colton v. N.Y. Hosp., 414 N.Y.S.2d 866, 875 (App. Div. 1979) (noting that the rationale is different for cases involving experimental procedures).

[222] Ash v. N.Y. Univ. Dental Ctr., 564 N.Y.S.2d 308, 310 (App. Div. 1990).

[223] *See* Tom Baker & Timothy D. Lytton, *Allowing Patients to Waive the Right to Sue for Medical Malpractice: A Response to Thaler and Sunstein*, 104 NW. U. L. REV. 233, 234, 240, 249–50 (2010) (describing the right to sue for medical malpractice as generally treated as nonwaivable and criticizing proposals to allow patients to waive malpractice claims before treatment); Matthew J.B. Lawrence, *In Search of an Enforceable Medical Malpractice Exculpatory Agreement: Introducing Confidential Contracts as a Solution to the Doctor-Patient Relationship Problem*, 84 N.Y.U. L. REV. 850, 851–52 (2009) (noting that courts repeatedly invalidate "medical malpractice exculpatory agreements" under the "'void-for-public-policy' rationale"); *see, e.g.*, MINN. STAT. § 144.6501 subdiv. 2 (2025) (prohibiting long-term care facilities and nursing facilities from using liability waivers); WASH. REV. CODE § 70.129.105 (2025) (same).

[224] *See* Lawrence, *supra* note 223, at 855 & n.17 (observing that although "cases upholding [medical malpractice exculpatory] agreements are difficult to find," they do exist).

[225] Shorter v. Drury, 695 P.2d 116, 118–19 (Wash. 1985).

[226] *Id.* at 119.

[227] *Id.* at 120–22.

[228] *Id.*

Even beyond outright waivers of medical malpractice claims, healthcare contracts cannot unduly restrict patients' rights to recovery, shorten statutes of limitations, or specify an inconvenient forum for suit.[229] Further, hospitals and physicians cannot contract away core duties within the physician-patient relationship, such as physicians' duty not to abandon their patients.[230] The duty not to abandon—or, not to unilaterally terminate the relationship—requires that physicians continue the patient's care until the patient has an opportunity to secure alternative care.[231] Even where a patient acknowledges the practice's right to dismiss patients for non-compliance, the physician must still carry out a dismissal in a manner consistent with their ethical and legal duties, including by providing sufficient notice, referral options, and emergency coverage.[232]

Beyond common law and contract doctrine, state constitutional law may also overlay the healthcare contract landscape. For example, Florida's constitution grants patients the right to access information about "adverse medical incidents," thereby nullifying contractual confidentiality clauses that would otherwise conceal potential provider misconduct.[233]

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[229] *See, e.g.*, TEX. CIV. PRAC. & REM. CODE ANN. § 16.070(a) (West 2025) (prohibiting any contract from shortening the limitations period for bringing suits to less than two years, and rendering any such agreement void and unenforceable); Franks v. Bowers, 116 So. 3d 1240, 1247–48 (Fla. 2013) (voiding a contractual provision capping non-economic damages at $250,000 as contrary to public policy where it deprived patients the statutory protections without commensurate benefits); *see also* Michael F. Cannon, *Reforming Medical Malpractice Liability Through Contract* 5 (Cato Inst., Working Paper No. 3, 2010), https://ciaotest.cc.columbia.edu/wps/cato/0021661/f_0021661_17925.pdf [perma.cc/XU5Q-UYBN] (stating that "contractual limitations on providers' liability for malpractice are largely unenforceable").

[230] *See* Saendy Jung & Rachel H. McDowell, *Abandonment*, STATPEARLS (2022), https://www.ncbi.nlm.nih.gov/books/NBK563285/ [perma.cc/L5UG-6U7Y] ("Abandonment is considered a breach of duty and is defined as unilateral termination of the physician-patient relationship without providing adequate notice for the patient to obtain substitute medical care."). The patient-physician relationship—which "becomes established when a physician affirmatively acts in a patient's care"—"must have been established for abandonment to occur." *Id.*

[231] *Id.*

[232] *See* Payton v. Weaver, 182 Cal. Rptr. 225, 229 (Ct. App. 1982) ("[A] physician who abandons a patient may do so 'only . . . after due notice, and an ample opportunity afforded to secure the presence of other medical attendance.'") (citing Lathrope v. Flood, 6 Cal. Unrep. 637, 639 (1901), *rev'd on other grounds*, 153 Cal. 458 (1902)); *see also* Capps v. Valk, 369 P.2d 238, 240 (Kan. 1962) (acknowledging physicians' right to withdraw from a case, but observing that a physician who does so without providing sufficient notice and opportunity to secure alternative care may nonetheless face liability for abandonment); McGulpin v. Bessmer, 43 N.W.2d 121, 125 (Iowa 1950) (providing that "[a] physician who leaves a patient in a critical stage of [a] disease without reason or sufficient notice to enable him to procure another physician is guilty of culpable dereliction of duty for which he is liable"); Johnson v. Vaughn, 370 S.W.2d 591, 596 (Ky. 1963) (stating the general rule "that a physician is under the duty to give his patient all necessary and continued attention as long as the case requires it").

[233] *See* FLA. CONST. art. X, § 25(a) (establishing patients' "right to have access to any records . . . by a health care facility or provider relating to any adverse medical incident"). "[A]dverse medical incident" encompasses any act or omission by a healthcare provider or facility—including negligence or intentional misconduct—that caused or could have caused patient injury or death. *Id.* § 25(c); *see*

2. Informed Consent

Modern informed consent is another area where the rules governing healthcare differ from those governing consumer contracts.[234] Informed consent forms are ubiquitous in modern healthcare.[235] Patients sign these forms, acknowledging that they have been informed of the relevant risks and benefits and agree to the treatment.[236]

The law treats informed consent in medical care as an affirmative duty of providers, rooted in patients' right to autonomy, rather than a mere contractual obligation.[237] In 1972, in the landmark case *Canterbury v. Spence*, the U.S. Court of Appeals for the District of Columbia held that a physician has a duty to disclose all material risks and alternatives that a reasonable patient would consider significant in making a decision.[238] This duty to disclose exists independently of any specific questions the patient may ask.[239] As the court noted, "Caveat emptor is not the norm for the consumer of medical services."[240] Instead, the "[d]uty to disclose is more than a call to speak merely on the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision."[241] The doctrine of informed consent is subject to valid criticism as being overly legal and process-oriented rather than a mechanism to ensure meaningful comprehension and choice.[242] But it has laudable goals.[243] It is grounded in

also Fla. Hosp. Waterman, Inc. v. Buster, 984 So. 2d 478, 488, 492 (Fla. 2008) (holding that Florida's constitutional right to know about adverse medical incidents, established by constitutional amendment in 2004, applies retroactively to existing hospital records previously shielded from disclosure).

[234] It is worth noting that some scholars believe that informed consent is primarily a creature of tort and does not implicate contract or quasi-contract. *See generally* Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 908 (1994) (observing that "[t]ort law has largely eclipsed consent-contract approaches to the problem of health-care-related injuries"); Nadia N. Sawicki, *Choosing Medical Malpractice*, 93 WASH. L. REV. 891, 909–13 (2018) (explaining that informed consent developed as a negligence action and observing that courts remain resistant to contractual modification of the doctor-patient relationship's default tort duties).

[235] *See, e.g.*, ST. CHARLES HEALTH SYS., PATIENT PROCEDURAL INFORMED CONSENT FORM 1–2, https://stcharleshealthcare.org/sites/default/files/Documents/Surgery%20Scheduling/8056%20Patient%20Procedural%20Informed%20Consent.pdf [perma.cc/G87C-YGL4] ("The Practitioner has given me a general description of the Treatment, and has explained to me, in a way I understand, that there may be other possible treatments, including the option of obtaining a second opinion from a different health care provider, and that there are risks to the Treatment.").

[236] *Id.*

[237] James F. Childress & Marcia Day Childress, *What Does the Evolution from Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?*, 22 AM. MED. ASS'N J. ETHICS 423, 424 (2020).

[238] Canterbury v. Spence, 464 F.2d 772, 786–87 (D.C. Cir. 1972).

[239] *Id.* at 783 n.36.

[240] *Id.*

[241] *Id.*

[242] *See* Koch, *supra* note 155, at 903–14 (surveying criticisms of informed consent); Childress & Childress, *supra* note 237, at 424 (same).

the idea that the patient's right to know and self-determination should shape the scope of disclosure rather than the physician's prerogative.[244]

As an example of the interplay between contract and tort, a signed, adequate consent form can defeat both a battery claim—which arises where a patient did not consent to the procedure itself[245]—and a negligence claim for lack of informed consent—which arises where the patient consented to the procedure but was not adequately informed of its risks, benefits, and alternatives.[246] A signed consent form does not, however, waive the patient's right to sue for malpractice if the provider was otherwise negligent, and is only one evidentiary consideration among many.[247] Though a patient may, in some circumstances, waive their right to informed consent,[248] any clause hidden in the boilerplate of an intake form purporting to waive the provider's duty to disclose would likely be unconscionable or void as contrary to public policy.

Although it often takes the form of a contractual clause in practice, informed consent in healthcare is viewed as a continuous duty and a process rather than merely a one-time exchange. Even after signing a consent form, a competent patient retains the right to withdraw consent or refuse treatment at any time, a right protected by both common law and constitutional principles.[249] For example, the law recognizes that competent adults have a right to refuse life-saving treatment, and no prior contract can compel treatment against the patient's will.[250] This highlights how patient rights take precedence over rote contractual

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[243] *See* Koch, *supra* note 155, at 898 (summarizing the goals of the doctrine of informed consent, including promoting patient autonomy and informed decision-making, regulating physician disclosures, and protecting against injuries).

[244] *Id.* at 897. In addition to development through the common law, many states have codified informed consent requirements by statutory enactment. *Id.* at 901 & n.33; *see, e.g.*, FLA. STAT. § 766.103(3) (2025); GA. CODE ANN. § 31-9-6.1(a) (2025), IND. CODE § 34-18-12-2 (2025); LA. REV. STAT. ANN. § 1299.40 (2025).

[245] Koch, *supra* note 155, at 899–900.

[246] *See id.* at 900 (noting that "[a] claim of lack of informed consent requires the same elements required to establish a traditional negligence claim"). The elements are: "(1) a duty of care to provide the plaintiff with adequate disclosure, (2) breach of that duty, (3) harm or injury to the plaintiff, and (4) a causal link between the injury and the breach of duty." *Id.*

[247] *See* Waller v. Aggarwal, 688 N.E.2d 274, 276 (Ohio Ct. App. 1996) (explaining that a signed consent form neither authorizes negligent performance of a procedure nor waives the patient's right to sue for malpractice); *see also* Edward L. Raab, *The Parameters of Informed Consent*, 102 TRANS. AM. OPHTHALMOL. SOC'Y 225, 226 (2004) ("A claim of lack of informed consent usually accompanies an allegation of medical malpractice for wrongful diagnosis or treatment.").

[248] *See* Spar v. Cha, 907 N.E.2d 974, 983 (Ind. 2009) (noting that "[m]any jurisdictions recognize either by judicial ruling or statute that a patient may waive her right to informed consent").

[249] Bankert *ex rel.* Bankert v. United States, 937 F. Supp. 1169, 1183 (D. Md. 1996) (quoting Mack v. Mack, 618 A.2d 744, 755 (Md. 1993) (noting that "a corollary to the [informed consent] doctrine is the patient's right, in general, to refuse treatment and to withdraw consent to treatment once begun") (alteration in original).

[250] *See* Cruzan *ex rel.* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 281 (1990) (holding that the Constitution "protects an interest in . . . refusing life-sustaining medical treatment"); *In re* Quinlan,

enforcement. Ultimately, the law's goal is to safeguard patient autonomy and promote trust, not merely enforce contracts, recognizing that true consent in healthcare is meaningful only if well-informed, continuous, and voluntary.

3. Arbitration Agreements

Businesses often include arbitration clauses in commercial contracts to require parties to resolve any disputes outside of open court and to submit legal claims to binding arbitration.[251] Healthcare providers have likewise used binding pre-treatment arbitration agreements to avoid jury trials in malpractice or negligence disputes.[252] Despite their popularity among healthcare providers, there are many known problems inherent in these arbitration clauses, including their secrecy,[253] inability to influence the development of judicial contract doctrine,[254] arbitrators' bias in favor of repeat players,[255] arbitrators' ability to "manifestly disregard the law,"[256] and inability to appeal decisions.[257] Notwith-

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355 A.2d 647, 663 (N.J. 1976) (discussing the right to privacy and suggesting that "this right is broad enough to encompass a patient's decision to decline medical treatment under certain circumstances").

[251] A.B.A., BENEFITS OF ARBITRATION FOR COMMERCIAL DISPUTES 2, https://jusmundi.com/en/document/pdf/publication/en-benefits-of-arbitration-for-commercial-disputes [perma.cc/AG6P-49UA].

[252] *See* Sarah Sachs, *The Jury Is Out: Mandating Pre-Treatment Arbitration Clauses in Patient Intake Contracts*, 2018 J. DISP. RESOL. 117, 120–21 (documenting the rise and prevalence of mandatory arbitration clauses in healthcare contracts); *see*, *e.g.*, Fredericksburg Care Co., L.P. v. Perez, 461 S.W.3d 513, 528 (Tex. 2015) (enforcing a pre-treatment arbitration agreement between a patient and healthcare provider).

[253] *See* Sachs, *supra* note 252, at 117 (highlighting the popularity of pre-treatment mandatory arbitration agreements in the healthcare industry). *But see* E. Gary Spitko, *Arbitration Secrecy*, 108 CORN. L. REV. 1729, 1733–34 (2023) (noting that arbitration secrecy—the confidentiality of arbitration proceedings and awards—may shield improper or discriminatory practices from public scrutiny, hinder victims from gathering evidence of patterns of misconduct, and undermine both specific and general deterrence by concealing adverse arbitration awards); *see also* Cynthia Estlund, *The Black Hole of Mandatory Arbitration*, 96 N.C. L. REV. 679, 680 (2018) (explaining arbitration secrecy as a product of contract law confidentiality norms).

[254] *See* Myriam Gilles, *The Day Doctrine Died: Private Arbitration and the End of Law*, 2016 U. ILL. L. REV. 371, 408 (arguing that mandatory arbitration clauses in standard form contracts foreclose both individual and class litigation, effectively removing disputes from the judicial system altogether).

[255] David Horton & Andrea Cann Chandrasekher, *After the Revolution: An Empirical Study of Consumer Arbitration*, 104 GEO. L.J. 57, 83 (2015).

[256] *See* Michael H. LeRoy, *Are Arbitrators Above the Law? The "Manifest Disregard of the Law" Standard*, 52 B.C. L. REV. 137, 138 (2011) (" 'Manifest[] disregard [for] the law' . . . means the arbitrator knew the law but deliberately ignored it."); Stephen J. Ware, *Default Rules from Mandatory Rules: Privatizing Law Through Arbitration*, 83 MINN. L. REV. 703, 719–20 (1999) (finding that arbitrators often make decisions by ignoring "principles of substantive rules of law"); *see also* U.S. Trinity Energy Servs., L.L.C. v. Se. Directional Drilling, L.L.C., 135 F.4th 303, 309 (5th Cir. 2025) (rejecting the argument that "manifest disregard of the law remains viable 'as an independent ground for review *or* as a judicial gloss on the enumerated grounds for vacatur set forth [under the FAA]'").

[257] *See* Hall St. Assocs., L.L.C. v. Mattel, Inc., 552 U.S. 576, 588–90 (2008) (holding that courts cannot review awards beyond the FAA's express terms); *see also* LeRoy, *supra* note 256, at 139–40 (reviewing courts' treatment of arbitral finality after the Supreme Court's ruling in *Hall Street Associates*).

standing, these agreements are generally enforceable under the Federal Arbitration Act (FAA), which makes arbitration agreements "valid, irrevocable, and enforceable" and creates "national policy favoring arbitration."[258] Courts have observed that arbitration is particularly beneficial for the healthcare industry, noting that "arbitration agreements between physicians and patients are not per se void as against public policy," though they should be "closely scrutinized."[259]

Several arbitration cases in healthcare involve nursing homes. In 2012, in *Marmet Health Care Center v. Brown*, the U.S. Supreme Court invalidated a West Virginia court's blanket refusal to enforce nursing home arbitration agreements.[260] The Court unanimously held that the state's blanket bar of predispute arbitration agreements for personal-injury or wrongful-death claims in nursing homes on public policy grounds violated the FAA's mandate to enforce arbitration agreements in contracts involving interstate commerce.[261] In other words, states cannot indiscriminately apply heightened hurdles to arbitration clauses solely because the context is healthcare, as that would conflict with federal law.[262]

Even so, general contract defenses still apply to arbitration agreements,[263] including fraud, duress, and unconscionability.[264] These defenses are particularly common in healthcare, given that intake contracts are typically presented on a take-it-or-leave-it basis—leaving patients with no meaningful opportunity to negotiate their terms—and that patients are uniquely vulnerable as contract-

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[258] *See* 9 U.S.C. § 2 (providing that arbitration agreements "shall be valid, irrevocable, and enforceable"); Southland Corp. v. Keating, 465 U.S. 1, 10 (1984) ("In enacting [the FAA], Congress declared a national policy favoring arbitration and withdrew the power of the states to require a judicial forum for the resolution of claims which the contracting parties agreed to resolve by arbitration."). The FAA favors enforcement of arbitration clauses and preempts state laws that uniquely target or hinder arbitration. AT&T Mobility LLC v. Concepcion, 563 U.S. 333, 343 (2011) (holding that the FAA preempts state law).

[259] *See, e.g.*, Buraczynski v. Eyring, 919 S.W.2d 314, 316, 319 (Tenn. 1996).

[260] *See* Marmet Health Care Ctr., Inc. v. Brown, 565 U.S. 530, 533 (2012) (quoting *Concepcion*, 563 U.S. at 341) (stating that "[w]hen state law prohibits outright the arbitration of a particular type of claim, the analysis is straightforward: The conflicting rule is displaced by the FAA") (alteration in original).

[261] *Id.*

[262] *Id.*; *see* Elizabeth G. Thornburg, *Contracting with Tortfeasors: Mandatory Arbitration Clauses and Personal Injury Claims*, 67 LAW & CONTEMP. PROBS. 253, 253 (2004) ("States may not carve out areas in which arbitration is thought to be inappropriate or in need of special regulation; any state law that is specifically directed at arbitration, as opposed to contracts generally, is preempted by the FAA.").

[263] *See Concepcion*, 563 U.S. at 343 (confirming that generally applicable contract defenses can still invalidate arbitration clauses); *see also* Christopher R. Drahozal, *FAA Preemption After* Concepcion, 35 BERKELEY J. EMP. & LAB. L. 153, 173 (2014) ("*Concepcion* does not preempt all or even most state unconscionability doctrine as applied to arbitration agreements.").

[264] *See* Dr.'s Assocs., Inc. v. Casarotto, 517 U.S. 681, 687 (1996) ("[G]enerally applicable contract defenses, such as fraud, duress, or unconscionability, may be applied to invalidate arbitration agreements without contravening [the FAA].").

ing parties.[265] In Arizona, for example, courts have refused to enforce an arbitration agreement because the clause was beyond the patient's reasonable expectations and not explained, effectively an adhesion contract in a stressful context.[266] Other courts object to the secretive nature of arbitration in cases involving physical injury or death, noting that "arbitrations will not generate bad publicity for defendants. Some injuries alleged are so egregious that if they are proven, they should be made known publicly; a lack of transparency in critical issues may be against public policy because the consumer has the right to be informed."[267]

Likewise, some state legislatures have statutes regulating medical malpractice arbitration agreements.[268] These laws don't outlaw arbitration but impose conditions to protect patients' rights.[269] In 2019, CMS promulgated a final rule prohibiting long-term care facilities from requiring arbitration as a condition of admission or continued care, mandating that any arbitration agreement be explained, and requiring residents to retain the right to rescind it within thirty days.[270] Even the American Arbitration Association (AAA) has a policy against pre-dispute arbitration agreements between individual patients and healthcare service providers for healthcare claims on due process grounds.[271]

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[265] *See, e.g.*, Peavy *ex rel*. Peavy v. Skilled Healthcare Grp., Inc., 470 P.3d 218, 227 (N.M. 2020) (holding that an arbitration agreement between a nursing home operator and its residents was unconscionable because it was unreasonably and unfairly one-sided). The court concluded that the agreement was unreasonably and unfairly one-sided because the agreement exempts the drafting party's likeliest claim but requires the non-drafting party to arbitrate their likeliest claim. *Id.* at 225–26.

[266] In 1992, in *Broemmer v. Abortion Services of Phoenix, Ltd.*, the Supreme Court of Arizona explained:

> Plaintiff was under a great deal of emotional stress, had only a high school education, was not experienced in commercial matters, and is still not sure "what arbitration is." Given the circumstances under which the agreement was signed and the nature of the terms included therein, . . . [the court] conclude[s] that the contract fell outside plaintiff's reasonable expectations and is, therefore, unenforceable. Because of this holding, it is unnecessary for us to determine whether the contract is also unconscionable.

840 P.2d 1013, 1017 (Ariz. 1992).

[267] Garcia v. HCR ManorCare, LLC, 44 Pa. D. & C.5th 16, 28 (Ct. C.P. 2014).

[268] *See generally* AM. MED. ASS'N ADVOC. RES. CTR., STATE LAWS CHART II: LIABILITY REFORMS (2025), https://www.ama-assn.org/system/files/mlr-state-laws-chart-II.pdf [perma.cc/9GBT-UA7B] (summarizing state laws regulating arbitration).

[269] *Id.*; *see, e.g.*, CAL. HEALTH & SAFETY CODE § 1363.1 (West 2025) (requiring health plans that mandate binding arbitration to explicitly disclose that fact to enrollees, including its use for medical malpractice claims); ALASKA STAT. § 09.55.535 (2025) (permitting arbitration agreements in health care contracts, provided arbitration is optional rather than a condition of receiving services, and that the patient retains a thirty-day right to revoke); 710 ILL. COMP. STAT. 15/8 (2025) (conditioning health care arbitration agreements on voluntariness, procedural fairness, and patient reaffirmation at discharge).

[270] 42 C.F.R. § 483.70(m) (2024).

[271] AM. ARB. ASS'N, HEALTHCARE POLICY STATEMENT, https://go.adr.org/rs/294-SFS-516/images/aaa_healthcare_policy_statement.pdf?version=0 [perma.cc/48U8-8CK5].

The organization refuses to administer such arbitrations "relate[d] to medical services, such as negligence and medical malpractice disputes, unless all parties agreed to submit the matter to arbitration after the dispute arose."[272]

These examples illustrate that although arbitration agreements in healthcare are not categorically prohibited, they are subject to meaningful regulatory and institutional constraints designed to protect patient rights.[273] Moreover, contract defenses are particularly relevant given the unique characteristics of healthcare, which often implicate public policy and unconscionability.[274] The overall trend is to balance the FAA's mandate to enforce arbitration agreements—which reflects a strong federal preference for arbitration as an efficient alternative to litigation[275]—with the imperative of patient protection, ensuring that dispute resolution agreements do not become an unfair tool to shield providers from accountability.

B. Contracts in Wellness

Although the wellness economy increasingly blurs the line with healthcare, it does so without importing the physician-patient relationship, the clinical site of care, or the tangible risks of physical harm that help justify healthcare's treatment in contract doctrine. In medicine, the stakes are often life, bodily integrity, and access to essential care. It is, therefore, unsurprising that courts are willing to police healthcare contracting with heightened sensitivity to public policy and unequal bargaining power. The wellness cases discussed here[276] do not, on their face, rise to that level, which helps explain why they are analyzed as ordinary consumer contracts. Even so, the available decisions reveal that, at present, courts tend not to consider public policy or unconscionability in the context of wellness, as they do in healthcare. As wellness products increasingly replicate aspects of care, that approach may matter more than it seems. This Section shows how courts treat consumer agreements, en-

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[272] *Id.*; *see also* AM. ARB. ASS'N ET AL., HEALTHCARE DUE PROCESS PROTOCOL 10, 16 (1998), https://www.adr.org/media/y5hmngqe/healthcare-due-process-protocol.pdf [perma.cc/5F93-7RKX] (providing that patients' consent to alternative dispute resolution should not be a condition of receiving care and that binding forms of dispute resolution in patient disputes should only be used post-dispute).

[273] *See supra* notes 268–272 and accompanying text (describing the limits placed on arbitration concerning healthcare agreements).

[274] *See supra* notes 263–267 and accompanying text (providing examples of defenses utilized against arbitration agreements).

[275] *See supra* notes 258–259 and accompanying text (summarizing federal policy favoring arbitration).

[276] It is difficult to find an exhaustive account of cases involving consumer wellness products and services because there is no one catch-all term to describe the wellness economy that is commonly used in law or regulation. As a result, searches for relevant wellness litigation often require searching in general product categories or by product name.

forcing sweeping disclaimers, minimal clickwrap assent, and arbitration clauses without the public-policy scrutiny that healthcare contexts receive.[277]

1. Waivers of Liability and Exculpatory Clauses

Waivers of liability and exculpatory clauses are common in wellness products and services. For example, in its terms of service, Woebot—an AI-powered mental health chatbot—disclaims responsibility for how users interpret or act on the chatbot's content and requires users to release the company from all related liability.[278]

Unlike healthcare contracts, where public-law values cabin a provider's ability to limit liability,[279] courts reviewing wellness contracts enforce sweeping warranty disclaimers and exclusive-remedy clauses. In 2015, in *Frenzel v. AliphCom*, a federal district court held that Jawbone's UP fitness tracker wristband, which purported to measure activity, caloric intake, and sleep, came within a one-year "repair-or-replace" warranty that expressly displaced all other warranties and remedies.[280] Because the consumer replaced the band once within that window, Jawbone had fully satisfied its warranty obligation, and the consumer had no remaining claims regardless of the device's subsequent performance—logging erroneous sleep and calorie data.[281] The court dismissed both express and implied warranty claims because Jawbone's limited warranty narrowed the sole remedy to repair or replacement, and Jawbone had already complied.[282] No matter how inaccurate or short-lived the tracker turned out to be, Jawbone owed nothing more.

In other cases, plaintiffs have challenged waivers and exculpatory clauses in their original complaints.[283] These arise in response to clauses that purport to "waive [their] property rights,"[284] such as when using an at-home DNA test purporting to provide health results, or that require consumers to use a bio-

[277] *See infra* notes 278–323 and accompanying text.

[278] *Woebot Health Terms of Service*, *supra* note 6.

[279] *See supra* Part II.A.

[280] Frenzel v. Aliphcom, No. 14-cv-03587, 2015 WL 4110811, at *1, *13 (N.D. Cal. July 7, 2015).

[281] *Id.* at *2, *13.

[282] *Id.* at *13.

[283] *See, e.g.*, Complaint at 11, 20, Tompkins v. 23andMe, Inc., 840 F.3d 1016 (9th Cir. 2016) (No. 5:13-cv-05682); *see also* Brief of Appellants at *1, Curmode v. Alsbrooks, 880 S.E.2d 320 (Ga. Ct. App. 2022) (No. A22A0801), 2022 Ga. App. Ct. Briefs Lexis 142 (challenging the enforceability of the exculpatory clause in the massage therapy services agreement, arguing the clause was void as against public policy).

[284] Complaint, *supra* note 283, at 11, 20.

metric wearable at their "own risk."[285] These issues, however, were presumably resolved privately in arbitration proceedings.[286]

These examples do not exactly shock the conscience, but it is easy to imagine a wearable device that a user relies on to identify or manage a potentially life-threatening health condition, an at-home test that informs important health decisions, or a chatbot that provides mental health services. If courts become accustomed to viewing contracts for wellness products as no different from any other consumer contract, it will be challenging to distinguish cases in which wellness products cross the line into health.

2. Consent

The bedrock principle of informed consent in healthcare[287] is notably absent in even the most sophisticated wellness products and services. This makes sense, given that concepts of consent differ across industries and subjects.[288] Instead, in the wellness industry, consumers are subject to the mass-market terms of service that dominate most common consumer transactions, particularly those conducted online.[289] At least in theory, consumers consent by performing a minimal act of assent, such as clicking "I agree."[290] Scholars and regulators have widely acknowledged that this process is flawed.[291] People do not read the terms presented to them, likely struggle to understand them if they do, and those terms are subject to unilateral modification—meaning consumers would need to read them frequently to stay fully apprised of their contents.[292] Still, it is how companies notify users of their terms and conditions.

Courts' willingness to enforce these minimal assent mechanisms is well illustrated in wellness litigation. In 2024, in *Toth v. Everly Well, Inc.*, a consumer bought Everlywell's at-home "Food Sensitivity Test," created an online account to obtain results, and—by ticking a required checkbox—assented to a hyper-linked "User Agreement."[293] When the test's results were inaccurate, she filed a putative class action alleging deceptive marketing and misuse of medical

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[285] Houtchens v. Google LLC, 649 F. Supp. 3d 933, 943 (N.D. Cal. 2023).

[286] *See Tompkins*, 840 F.3d at 1033 (upholding the enforceability of the arbitration agreement); *Houtchens*, 649 F. Supp.3d at 944 (same).

[287] *See supra* notes 234–250 and accompanying text (describing informed consent).

[288] Prevailing models of consent, such as privacy's notice-and-choice paradigm, are different than with other types of agreements. *Compare* Koch, *supra* note 155, at 897 (highlighting informed consent as the predominant model of consent in healthcare); *with* Ari Ezra Waldman, *Privacy, Notice, and Design*, 21 STAN. TECH. L. REV. 74, 77 (2018) (noting notice-and-choice as the predominant model of consent in privacy).

[289] Mark A. Lemley, *Terms of Use*, 91 MINN. L. REV. 459, 460 (2006).

[290] *Id.* at 466.

[291] *Id.* at 469, 478; Fowler et al., *supra* note 48, at 5.

[292] Fowler et al., *supra* note 48, at 4–5; Jessica L. Roberts & Jim Hawkins, *When Health Tech Companies Change Their Terms of Service*, 367 SCIENCE 745, 745 (2020).

[293] Toth v. Everly Well, Inc., 118 F.4th 403, 406–07 (1st Cir. 2024).

data, claiming that Everlywell "deceptively markets its tests and misleads consumers into providing their personal medical information for Everlywell's commercial use."[294] In her complaint, she argued, among other things, that Everlywell had not provided reasonable notice of the terms or obtained her assent. [295] The consent in question was on the website's account-creation page and required the consumer to click a checkbox indicating that they had read and accepted the terms and conditions.[296] The words "Terms and Conditions" were "highlighted in green font and embedded with a link" to those terms.[297] The First Circuit agreed with the lower courts' rulings that a binding clickwrap contract had been formed.[298] Because the valid contract contained an arbitration agreement, the panel thus affirmed dismissal in favor of arbitration.[299]

In 2016, in *Tompkins v. 23andMe*, the U.S. Court of Appeals for the Ninth Circuit similarly subordinated informed consent concerns—including a lack of meaningful disclosure—to the mechanics of online contract formation.[300] Although 23andMe, a direct-to-consumer genetics testing company, made health claims about its products, the district court noted that "[t]he existence of an agreement between 23andMe and its customers implicates the law of Internet-based contract formation."[301] At the time, plaintiffs encountered terms of service at multiple points.[302] First, when visiting the website to purchase a testing kit, the consumer could—but was not required to—click a link to the company's terms at the bottom of the webpage.[303] Then, when registering a kit upon receipt, the consumer was prompted to click on a box indicating agreement to the multipage terms of service.[304] Nevertheless, the court concluded that the latter action was satisfactory assent to the terms of the agreement.[305]

In these specific examples, it appears that plaintiffs avoided significant physical harm from the wellness products and services.[306] Nevertheless, for

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[294] *Id.* at 408.

[295] *Id.* at 408–09.

[296] *Id.* at 408.

[297] *Id.* at 407.

[298] *Id.* at 409–11.

[299] *Id.* at 416.

[300] Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1020 (9th Cir.).

[301] Tompkins v. 23andMe, Inc., No. 5:13-CV-05682, 2014 WL 2903752, at *5 (N.D. Cal. June 25, 2014), *aff'd*, 840 F.3d 1016 (9th Cir. 2016).

[302] *Tompkins*, 840 F.3d at 1020.

[303] *Id.*

[304] *Id.*

[305] *Id.* at 1021 ("All the named plaintiffs in the present action purchased a DNA test kit, created an online account with 23andMe to register their DNA kits, and assented to the Terms of Service."); *Tompkins*, 2014 WL 2903752, at *9 (finding the same).

[306] *See* Toth v. Everly Well, Inc., 118 F.4th 403, 408 (1st Cir. 2024) (noting the plaintiff's allegations of deceptive marketing and misleading consumers); *Tompkins*, 840 F.3d at 1021 (reviewing how plaintiffs filed lawsuits against the company "for unfair business practices, breach of warranty, and misrepresentations about the [product's] health benefits").

example, false results from a food sensitivity test could foreseeably lead a consumer to eat something they are in fact allergic to, resulting in injury or death.[307] Although it may make sense that wellness products and services, including the ones discussed here, are not held to the same high level of informed consent standards as healthcare, hiding a product's scientific limitations in terms and conditions that people do not read or understand is becoming increasingly untenable for the most sophisticated segments of the wellness market. This raises important questions about whether clicking "I agree" is sufficient in wellness contexts—particularly where the product purports to deliver meaningful medical or health information to consumers.

3. Arbitration Agreements

Finally, arbitration is a frequently discussed issue in the identified wellness cases. In 2023, in *Houtchens v. Google*, two consumers who purchased Fitbit smartwatches filed a lawsuit against the manufacturer, alleging breach of implied warranty and unjust enrichment.[308] Google—Fitbit's parent company—moved to compel arbitration, pursuant to Fitbit's online Terms of Service.[309] Applying California contract principles and the FAA, the district court held that a binding agreement to arbitrate existed because Fitbit's account-creation process was a classic clickwrap agreement: users had to tick a box stating, "I agree to the Fitbit Terms of Service," with the hyperlinked terms displayed in blue text beside the checkbox on an uncluttered screen.[310] The court concluded that the agreement provided consumers "reasonably conspicuous notice" of the terms and by ticking the box, plaintiffs unambiguously manifested assent, even if they did not remember seeing it.[311] Because the arbitration clause incorporated the AAA's Consumer Rules, the court found clear and unmistakable evidence that the parties had delegated threshold questions of arbitrability—including scope and enforceability—to an arbitrator.[312] Further, the court concluded that the arbitration agreement was not procedurally unconscion-

[307] *See, e.g.*, Class Action Complaint at 1, Toth v. Everly Well, Inc., 118 F.4th 403 (1st Cir. 2024) (No. 1:23-cv-11043) (alleging the defendants' food sensitivity test was scientifically invalid and incapable of accurately identifying adverse food reactions, contrary to the consensus of major medical organizations); *see also* Cassandra Willyard, *Home Medical Tests Miss the Mark*, NATURE (July 3, 2025), www.nature.com/articles/d41586-025-02106-8 [perma.cc/86PK-LGT2] (arguing that "the information consumers get from . . . wellness tests is often inaccurate, unnecessary, confusing, or even harmful").

[308] Houtchens v. Google LLC, 649 F. Supp. 3d 933, 936–37 (N.D. Cal. 2023).

[309] *Id.* at 937.

[310] *Id.* at 939–42.

[311] *Id.*

[312] *Id.* at 944.

able because users could opt out within thirty days, and any substantive unconscionability challenges belonged in arbitration, given the valid delegation.[313]

Likewise, in 2019, in *Ciccio v. SmileDirectClub*, consumers filed suit in the U.S. District Court for the Middle District of Tennessee—later joined by a class that included dentists—alleging that SmileDirect deceptively marketed its at-home dental aligner service.[314] SmileDirect moved to compel arbitration pursuant to the "Informed Consent" agreement that each customer had to click through online.[315] The agreement required that all disputes be resolved through AAA arbitration, while carving out claims within small-claims-court jurisdiction.[316] The district court held that the clickwrap created a valid contract, and because the clause incorporated the AAA Consumer Rules, the parties had clearly and unmistakably delegated all gateway questions of arbitrability—including scope and enforceability—to the arbitrator.[317] When a later consumer tried to arbitrate, however, an AAA administrator refused to proceed under the AAA's Healthcare Policy Statement, which restricts pre-dispute arbitration agreements in healthcare contexts.[318] The customer returned to court, and the district court declined to compel arbitration.[319]

On appeal, the U.S. Court of Appeals for the Sixth Circuit reversed, emphasizing that the contract's incorporation of AAA rules delegated every gateway issue to the arbitrator and that an AAA administrator could not override that delegation by applying the Healthcare Policy Statement.[320] The panel held that whether the policy applied was itself a question of arbitrability for the arbitrator, not a basis for the courts or the administrator to derail the proceeding, and remanded with instructions to compel arbitration.[321]

Arbitration is tricky. As noted above, the FAA prevents states from indiscriminately imposing heightened hurdles to arbitration clauses.[322] Nevertheless, as wellness products increasingly implicate public health and safety, there

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[313] *Id.*

[314] Ciccio v. SmileDirectClub, LLC, No. 3:19-cv-00845, 2019 WL 8298262, at *1 (M.D. Tenn. Dec. 2, 2019), *rev'd*, 2 F.4th 557 (6th Cir. 2021). The class representative, who used SmileDirect's dental aligners "as an alternative to traditional orthodontic treatment," alleged that the aligners worsened her condition. *Id.*

[315] *Id.*

[316] *Id.* at *1, *2.

[317] *Id.* at *3.

[318] Ciccio v. SmileDirectClub, LLC, 2 F.4th 577, 580 (6th Cir. 2021); AM. ARB. ASS'N, *supra* note 271.

[319] *Ciccio*, 2 F.4th at 589 (Clay, J., dissenting).

[320] *Id.* at 586–88.

[321] *Id.* at 582.

[322] *See supra* note 262 and accompanying text (describing how arbitration is protected federally from targeted state regulation).

are good reasons to closely consider general contract defenses that routinely appear in discussions of healthcare arbitration agreements.[323]

C. Doctrinal Disconnects in Wellness

Contract law accounts for public law values in a healthcare setting by invalidating waivers, treating consent as more than a checkbox, and scrutinizing clauses with an eye toward public policy.[324] These constraints reflect a longstanding recognition that health is exceptional.[325] When similar clauses arise in a wellness context, however, courts do not engage in the same analysis.[326] By adjudicating disputes involving wellness products and services as something categorically distinct from health, courts refuse to question whether wellness can ever cross into regulated healthcare territory. In doing so, they are routing health governance from public safeguards to private ordering, a shift that externalizes risk onto patients as consumers, rewards regulatory arbitrage, and fractures the protections our healthcare system once strove to provide. This Section identifies the doctrinal patterns that emerge from a comparison of healthcare and wellness contracts.[327]

1. Formal Assent Over Functional Stakes

Courts prioritize formal assent, enforcing boilerplate terms in wellness contracts without regard for their clinical overtones or physiological risks. Regardless of whether the product facilitates genetic analysis,[328] diagnostic interpretation,[329] biometric monitoring,[330] or cognitive enhancement,[331] the prevailing judicial question is largely procedural. In other words, did the user click "I agree?" If so, the underlying purpose of the transaction is legally irrelevant.

By treating these wellness transactions as ordinary consumer contracts, courts collapse health-affecting products and services into formalistic questions of the visibility of terms of service. Courts resolve these disputes through the logic of e-commerce. The widely acknowledged flaws of this system are

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[323] *See supra* notes 263–267 and accompanying text (discussing the usage of contract defenses in arbitration issues involving healthcare).

[324] *See supra* Part II.A.–B.

[325] *See supra* Part I.

[326] *See supra* Part II.B.

[327] *See infra* notes 328–350 and accompanying text.

[328] Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1020 (9th Cir. 2016).

[329] Toth v. Everly Well, Inc., 118 F.4th 403, 407 (1st Cir. 2024).

[330] Houtchens v. Google LLC, 649 F. Supp. 3d 933, 937 (N.D. Cal. 2023); McLellan v. Fitbit, Inc., No. 3:16-cv-00036, 2018 WL 3549042, at *1–2 (N.D. Cal. July 24, 2018).

[331] LeDoux v. Outliers, Inc., No. 3:24-cv-05808, 2025 WL 523908, at *1 (W.D. Wash. Feb. 18, 2025).

ignored.[332] So long as the seller's interface clears a low threshold of visibility, it can essentially write its own terms. The result is a mismatch between the health-affecting potential of wellness products and services and the doctrines that typically govern healthcare.

This represents a notable departure from health law, where patients can withdraw their informed consent at any time, and courts routinely override otherwise agreed-upon contractual terms to protect patient welfare.[333] Even though clickwrap contracts do exist in healthcare, particularly in billing, they are not as pervasive or permissive as in consumer transactions. In healthcare, the law recognizes that contracts often occur in contexts of unequal knowledge and stakes, invalidating exculpatory clauses or scrutinizing arbitration more rigorously, regardless of what the patient technically agreed to.[334] In wellness, however, the form of the agreement appears to be what primarily dictates the outcome.[335] In contract disputes at the healthcare-wellness boundary, courts tend to treat the existence of a physician-patient relationship as the decisive factor.[336] Beyond that, it is merely a matter of formal assent.

2. Formal Disclaimers Over Actual Product Functions

Courts defer to disclaimers in terms of service or packaging that frame health-affecting products as nonmedical.[337] Companies frequently position

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[332] *See* Uri Benoliel & Shmuel I. Becher, *The Duty to Read the Unreadable*, 60 B.C. L. REV. 2255, 2257–59 (2019) (finding that courts routinely enforce online consumer contracts against consumers under the duty to read doctrine, despite empirical evidence that such contracts are thematically unreadable); Ian Ayres & Alan Schwartz, *The No-Reading Problem in Consumer Contract Law*, 66 STAN. L. REV. 545, 546–47 (2014) (observing that consumers rarely read standard form contracts—and that this failure undermines both meaningful consent and competitive pressure on firms to improve contract quality); Florencia Marotta-Wurgler, *Will Increased Disclosure Help? Evaluating the Recommendations of the ALI's "Principles of the Law of Software Contracts*," 78 U. CHI. L. REV. 165, 179–81 (2011) (finding that even among shoppers required to explicitly acknowledge a standard form contract, only 3 out of 205 actually read it, and that mandating assent does little to increase meaningful readership of online consumer contracts); Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 671–72 (2011) (finding that online boilerplate is almost always ignored regardless of how prominently it is disclosed).

[333] *See supra* Part II.A.

[334] *See supra* Part II.A.

[335] *See supra* Part II.B.

[336] *See* Curmode v. Alsbrooks, 880 S.E.2d 320, 322–23 (Ga. Ct. App. 2022) (enforcing exculpatory clause for massage-therapy services provided at a wellness spa because, unlike medical malpractice claims, the statutory duty of care depends on a physician-patient relationship, and the massage therapist was not a physician).

[337] *See, e.g.*, Tompkins v. 23andMe, 840 F.3d 1016, 1022–24 (9th Cir. 2016) (treating a consumer-genetics company's health claims as legally irrelevant to contract formation analysis); Toth v. Everly Well, 118 F.4th 403, 410–11 (1st Cir. 2024) (same).

their services as wellness, optimization, or lifestyle tools.[338] They choose this language carefully, often as a business decision to evade regulatory scrutiny.[339] And courts appear to be adopting these framings wholesale without questioning the product's obvious health-affecting functionalities.[340]

Courts often analyze terms of service for health-affecting consumer products under ordinary contract principles, without separately interrogating the health-related uses of the products and services in question.[341] This deference persists even where products strongly resemble healthcare.[342] These cases reveal an emerging judicial tendency to treat disclaimers as fact. So long as a company disavows therapeutic intent by burying the relevant disclaimers in terms of service, courts deciding contract disputes do not probe deeper. This dynamic allows companies to present their products with the aesthetic and imprimatur of medicine while avoiding the legal and ethical obligations that come with it.

3. Formal Descriptions Over Actual Intent

Plaintiffs rely on wellness products and services for overtly medical or diagnostic reasons. They might want to enhance cognitive function,[343] straighten their teeth,[344] investigate symptoms or sensitivities,[345] monitor biometric data

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[338] *See, e.g.*, Complaint at 4, LeDoux v. Outliers, Inc., No. 3:24-cv-05808 (W.D. Wash. Sep. 25, 2024) (explaining how nootropics are marketed as "supplements for the improvement of cognitive functioning and the support of brain health").

[339] Simon et al., *supra* note 30, at 2. *But see* U.S. FOOD & DRUG ADMIN., *supra* note 169 (finding that WHOOP's "wellness" framing of its blood pressure feature did not insulate the product from FDA device regulation, and that product disclaimers were "insufficient to outweigh the fact that the product is, by design, intended to provide a blood pressure estimation . . . associated with diagnosis of a disease").

[340] *See* Simon et al., *supra* note 30, at 7; *see also* Jodi Scott, *AI Wellness or Regulated Medical Device? A Lawyer's Guide to Navigating FDA Rules—and What Could Change Next*, HOGAN LOVELLS (July 9, 2025), https://www.hoganlovells.com/en/publications/ai-wellness-or-regulated-medical-device-a-lawyers-guide-to-navigating-fda-rulesand-what-could [perma.cc/AMU3-CUJC] (advising companies to market products as "lifestyle, mental fitness, or behavior change" tools and to "[a]void medical claims entirely" to bypass FDA jurisdiction).

[341] *See, e.g.*, LeDoux v. Outliers, Inc., No. 3:24-cv-05808, 2025 WL 523908, at *6–9 (W.D. Wash. Feb. 18, 2025) (analyzing whether a consumer who purchased allegedly adulterated nootropic supplements was bound by the seller's online arbitration provision under ordinary clickwrap and browsewrap contract-formation principles, without treating the product's asserted cognitive-enhancement purpose or alleged health harms as altering the terms-of-service analysis). A plaintiff who purchased nootropic supplement kits marketed as "a natural alternative to stimulant-based medications like Adderall" alleged that the "products actually contained" stimulants, causing her to test positive at a routine drug screening and resulting in her removal from her position and loss of employment benefits. *Id.* at *1.

[342] *See* Toth v. Everly Well, Inc., 118 F.4th 403, 416 (1st Cir. 2024) (affirming dismissal in favor of arbitration in dispute over at-home food sensitivity testing despite the plaintiff's allegations of deceptive marketing of personal medical data); Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1020 (9th Cir. 2016) (enforcing arbitration agreement in dispute over direct-to-consumer genetic health reporting).

[343] *LeDoux*, 2025 WL 523908, at *1–2.

[344] Ciccio v. SmileDirectClub, LLC, No. 3:19-cv-00845, 2019 WL 8298262, at *1 (M. D. Tenn. Dec. 2, 2019), *rev'd*, 2 F.4th 557 (6th Cir. 2021).

for health tracking,[346] or assess genetic predispositions.[347] Yet, in each case, courts' analysis appears to give no weight to these motivations.[348] Courts resolve disputes through the lens of generic consumer protection, which prohibits wellness products and services from overselling their health-enhancing capabilities.[349] This often waters down concerns about safety and efficacy claims, reducing them to questions about whether they were mere puffery.[350]

Courts enforcing wellness contracts do not explicitly reject the rationales that justify patient protection. Instead, the wellness framing allows courts to pretend they were never implicated at all.

III. CONTRACTS AT THE EDGE OF HEALTHCARE AND WELLNESS

A slow transformation of health law is unfolding in consumer contract disputes. Courts will decide, one term of service at a time, what obligations private actors owe when offering something that functions like healthcare but calls itself wellness and happens outside a brick-and-mortar clinic. This Part asks how contract law can meet the realities of the wellness industry of the future.[351] Section A of this Part introduces a factor-based test to determine whether a wellness product or service functionally substitutes as healthcare and argues that, in such instances, courts must recognize the heightened stakes, even if the transaction defies traditional health law labels.[352] Section B then

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[345] *Toth*, 118 F.4th at 416.

[346] *See* McLellan v. Fitbit, Inc., No. 3:16-cv-00036, 2018 WL 3549042, at *1 (N.D. Cal. July 24, 2018) (noting consumers' use of Fitbit device to "monitor and track heart rates"); Brickman v. Fitbit, Inc., No. 3:15-cv-02077, 2017 WL 5569827, at *5 (N.D. Cal. Nov. 20, 2017) (noting consumers' use of Fitbit device to track sleep quality).

[347] *Tompkins*, 840 F.3d at 1020.

[348] *See* Curmode v. Alsbrooks, 880 S.E.2d 320, 322 (Ga. Ct. App. 2022) (enforcing an exculpatory clause in a wellness spa contract on the ground that no physician-patient relationship existed without examining the therapeutic nature of the services or patient's reasons for seeking them). Appellants argued that the framing ignored "the exploding massage therapy industry as part of a healthcare regimen of treatment, the vulnerability of . . . patients . . . and the necessity of skill, training, and licensure of practicing massage therapy." Brief of Appellants at *2, Curmode v. Alsbrooks, 880 S.E.2d 320 (Ga. Ct. App. 2022) (No. A22A0801), 2022 Ga. App. Ct. Briefs Lexis 142.

[349] *See generally* 15 U.S.C. § 45 (prohibiting "unfair or deceptive acts or practices"); *id.* § 52 (prohibiting the dissemination of false advertisements for "foods, drugs, devices, services, or cosmetics"); *supra* notes 171–172 and accompanying text (noting FDA and FTC jurisdiction). State consumer protection laws are also relevant here. *See* LeDoux v. Outliers, Inc., No. 3:24-cv-05808, 2025 WL 523908, at *13–14 (W.D. Wash. Feb. 18, 2025) (dismissing consumer protection claim, under Washington consumer protection law, despite allegations that the defendants deceptively marketed nootropic supplements as safe, natural alternatives to prescription medication).

[350] *See, e.g.*, McLellan v. Fitbit, Inc., No. 3:16-cv-00036, 2018 WL 2688781, at *2 (N.D. Cal. June 5, 2018) (rejecting Fitbit's argument that wellness product marketing constituted inactionable puffery where promotional materials made specific, measurable claims about heart rate tracking functionality, and distinguishing such claims from general slogans).

[351] *See infra* notes 352–459 and accompanying text.

[352] *See infra* notes 355–369 and accompanying text.

draws on contract law's history of adaptation, showing how courts can use existing doctrines such as public policy, unconscionability, warranties, and the duty of good faith to reflect the risks associated with health-affecting consumer agreements.[353] Finally, Section C makes the normative case for taking a closer look at this subset of wellness contracts and addresses common objections.[354]

A. Rethink Categorizations: A Functional Test for Wellness

Courts cannot address the risks of the wellness economy if they start from the wrong assumptions. That is precisely what happens, however, when courts treat wellness products as ordinary consumer agreements without regard for how consumers use them, their similarity to healthcare, or user vulnerability.[355] This Section argues that courts should reconsider their categorical assumptions when adjudicating contracts involving wellness products and services that functionally replace professional healthcare by looking beyond the label to examine function and purpose. Courts routinely look beyond form when classifying commercial transactions—for example, evaluating substance over form in contract, tax, and regulatory contexts—and assessing the function of products in the wellness economy is squarely within that tradition.[356]

As described above, various areas of law, such as tax, take a factor-based approach when assessing whether something constitutes healthcare or wellness.[357] This approach informs the development of a new factor-based test for wellness products and services, as proposed in this Article. The goal is to adopt the underlying logic that courts could look beyond formal categories to assess how a product is used, by whom, and to what end. This should not include making normative judgments about the value, scientific merit, or medical efficacy of a specific product or service.[358] To align doctrine with the reality of the wellness economy, courts should adopt a functional approach to categorization that looks beyond disclaimers and marketing language to assess, on a case-by-case basis, what the product or service at the heart of the transaction actually does for the individual using it.

Courts adjudicating disputes involving wellness products and services could apply the following five-factor test to determine whether heightened

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[353] *See infra* notes 370–417 and accompanying text.

[354] *See infra* notes 419–459 and accompanying text.

[355] *See supra* Part II.C.

[356] *See, e.g.*, U.C.C 9-109(a)(1) (A.L.I. & UNIF. L. COMM'N 2022) ("[T]his article applies to: a transaction, *regardless of its form*, that creates a security interest in personal property or fixtures by contract . . . .") (emphasis added); *see supra* notes 190–194 (reviewing tax law's approach to substance over form).

[357] *See supra* notes 190–194 and accompanying text (explaining the test utilized in *Havey v. Commissioner*).

[358] *See* Ichel, *supra* note 178, at 928 (criticizing judicial interpretation of the medical deduction as "mandat[ing] a normative judgment" not required by the statutory text).

contractual scrutiny is warranted: (1) whether the product or service functionally substitutes for healthcare; (2) whether the consumer uses it to address a specific condition, symptom, or health-related vulnerability rather than for general lifestyle enhancement; (3) how the product is framed and marketed, including the full ecosystem of representations beyond formal disclaimers; (4) the risks of harm arising from misplaced reliance on the product; and (5) the vulnerability of the user population and the structural asymmetries embedded in the transaction. Each factor is discussed in turn.[359]

1. Functional Substitute for Healthcare

First, courts could consider whether the wellness product or service functionally substitutes for formal, provider-delivered healthcare. The inquiry is not whether the wellness offering is actually medicine, but whether users rely on it *in place of* formal diagnostics, treatment, or care. Nor is FDA clearance or approval dispositive—a product may functionally substitute for care regardless of its regulatory classification.[360] This substitutional role may be especially salient where consumers face barriers to accessing formal healthcare. For example, this factor would be implicated where a consumer uses an AI chatbot as therapy to manage depression in an area with few or no available mental health services.[361]

2. Consumer Purpose and Health Objective

Second, courts could ask whether the consumer reasonably uses the product or service to address a specific condition, symptom, or health-related vulnerability rather than for general lifestyle enhancement or overall well-being. This includes whether the consumer would have sought out the product or service but-for that health objective. This purpose-based lens parallels the U.S. Tax Court's functional analysis in *Havey v. Commissioner* and avoids making a formal diagnosis or physician involvement dispositive.[362] Thus, the relevant question is whether a condition that altered the consumer's perceived need for

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[359] *See infra* Part III.A.1–5.

[360] *See supra* notes 168–171 and accompanying text (describing the limits of regulatory authorities' power over wellness products).

[361] Arfan Ahmed et al., *A Review of Mobile Chatbot Apps for Anxiety and Depression and Their Self-Care Features*, 1 COMPUT. METHODS PROGRAMS IN BIOMED. UPDATE 1, 2 (2021) (noting that "[t]he huge effect of social stigma and mental illness shaming have prevented a considerable number of patients from seeking the proper medical help"). "This gap could be minimized through the usage of mental health chatbot apps assisting mental health professionals via self-care (self-management) approaches." *Id.*

[362] Havey v. Comm'r, 12 T.C. 409, 412 (T.C. 1949); *see* Ichel, *supra* note 178, at 926 (explaining that whether an expense qualifies as medical care depends on the nature and purpose of the services rendered rather than the provider's title or credentials, and describing *Havey* as adopting a balancing test focused on the taxpayer's purpose, physician involvement, relationship to the claimed condition, therapeutic efficacy, and temporal proximity).

intervention resulted in the transaction. To extend the previous example, a court would distinguish between a consumer using an AI chatbot to manage depressive symptoms versus a consumer using the same product simply to become more mindful.[363]

3. Marketing Ecosystem and User Expectations

Third, courts could assess how the product is framed and marketed to consumers. This extends beyond disclaimers to capture the full ecosystem of representations, including featured user testimonials, influencer endorsements, user interfaces, and the language of marketing and advertisements. These design choices can shape user reliance in ways that create expectations of health-related outcomes, even where the seller avoids making explicit disease claims. Not every representation will rise to this level—some claims will no doubt amount to puffery[364]—but courts could consider consumer perceptions holistically, asking what a reasonable person in the consumer's position would conclude about or expect from the wellness product's functionalities.[365] In this way, courts can treat a wellness app that is clear and explicit about its limits differently from one that implicitly suggests therapeutic efficacy.[366]

4. Risks of Misplaced Reliance

Fourth, courts could consider the risks of harm that arise from misplaced reliance on the wellness product. This includes physical, psychological, or financial harms that result from the product failing to deliver the consumer's hoped-for results, displacing safer or more effective alternatives, or inducing health-affecting behaviors based on opaque or unvalidated metrics. Here, the inquiry focuses on the relationship between the product's representations and the consumer's resulting choices, rather than on clinical efficacy. Imagine, again, a consumer using an app or chatbot for therapy. Although a consumer may benefit, research notes that over-reliance on mental health wellness apps can result in social isolation and insufficient support in times of acute mental health

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[363] *See* Ahmed et al., *supra* note 361, at 2 (identifying apps available in the Apple and Google Play Stores that claim to diagnose, track, and cure depression).

[364] *See, e.g.*, McLellan v. Fitbit, Inc., No. 3:16-cv-00036, 2018 WL 2688781, at *2 (N.D. Cal. June 5, 2018) (distinguishing inactionable puffery from actionable misrepresentations where marketing materials made specific, measurable claims about product functionality).

[365] This is consistent with the *Restatement (Second) of Contracts* provision on standardized agreements, which provides that a party who manifests assent to a standardized agreement is not bound by terms that the drafting party has reason to believe the other would not have assented to had they known of the particular term. RESTATEMENT (SECOND) OF CONTRACTS § 211(3) (A.L.I. 1981).

[366] *See* Ahmed et al., *supra* note 361, at 2 (finding that mental health chatbot apps uniformly disclaim therapeutic intent in user agreements while simultaneously marketing CBT and mindfulness features as therapeutic interventions).

crisis.[367] The consequences can be severe, including worsening of a mental health condition, harm to self or others, and the inability to find or keep a job.

5. Vulnerability and Structural Asymmetry

Fifth, and finally, courts could scrutinize the plaintiff's vulnerability and, more broadly, the user population the product targets, as well as the structural asymmetries embedded in the transaction.[368] When wellness products target consumers in states of emotional distress, chronic illness, or emotional or financial precarity, the public policy case for heightened scrutiny is stronger.[369] In these cases, courts could reject the fiction that such transactions are fully volitional or involve evenly matched parties.

6. Applying the Test: Illustrative Scenarios

Taken together, these factors provide a way to distinguish wellness contracts that genuinely involve voluntary lifestyle enhancement from those that function as a substitute for healthcare. They also allow courts to acknowledge the legal and moral complexity of these transactions without exceeding their institutional competence or turning judges into arbiters of contested medical knowledge. This test does not require courts to determine whether a product "works" or to referee emerging scientific fields. Instead, it centers contract analysis on function and context. As is the case with other factor-based tests, no single factor is dispositive, and not all factors will be relevant in all cases. The different factors may be given different weights depending on the circumstances of each particular case.

We can see how these factors might apply in practice through a series of hypothetical scenarios. Consider parents of a child with a developmental disorder who buy an expensive neurofeedback device marketed with vague testimonials about unlocking potential. The product's terms of service include a sweeping liability waiver and an arbitration clause. The device proves ineffective, and the parents lose a critical window for alternative, proven therapies. Under the proposed test, the product is functionally substituting for therapy, the purpose is

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[367] *See* M.D. Romael Haque & Sabirat Rubya, *An Overview of Chatbot-Based Mobile Mental Health Apps: Insights from App Description and User Reviews*, 11 JMIR MHEALTH & UHEALTH 654, 666 (2023) (noting that "[t]oo much reliance on technology can pose risks, such as isolation and insufficient assistance during times of crisis").

[368] This is consistent with existing approaches to contract law, like unconscionability. RESTATEMENT (SECOND) OF CONTRACTS § 208 ("If a contract or term thereof is unconscionable at the time the contract is made a court may refuse to enforce the contract . . . ."). Unconscionability analysis already empowers courts to consider "gross inequality of bargaining power." *Id.* at § 208 cmt. d.

[369] This consideration has direct analogues in healthcare contract doctrines. *See* Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 442 (Cal. 1963) (identifying unequal bargaining power as a key factor in voiding exculpatory clauses).

to address a specific condition, the risk of harm is high given the lost opportunity for intervention, and the user—a minor—is particularly vulnerable.

Other hypotheticals may require more discretion. Imagine a consumer with anxiety who buys crystal wristbands that claim to realign chakras and alleviate stress. The packaging is laden with wellness jargon and a fine-print disclaimer that it is not intended to treat any disease. The consumer relies on it, forgoes therapy, and their condition worsens. A judge might balk at granting heightened protection to someone relying on what, to some, may appear to be obvious quackery. Though the consumer certainly satisfies some elements of the test, it does not necessitate that this product be treated any differently than any other consumer product. This flexibility is the strength of a factor-based test.

B. Apply Familiar Doctrines at the Healthcare-Wellness Boundary

Once courts determine, through application of the five-factor test, that a wellness transaction functionally substitutes for healthcare, they can then assess the enforceability of contested contract terms using doctrines already available in contract law. They can turn to public policy, unconscionability, warranties, good faith, and consent, applying each with sensitivity to the health-related risks and information asymmetries inherent in these transactions. These doctrines provide courts with tools to scrutinize common clauses, such as liability waivers, disclaimers of responsibility, risk-shifting provisions, and, perhaps, though less likely, even arbitration clauses, in contracts at the boundaries of healthcare and wellness.

1. Public Policy

Clauses such as liability waivers, common in wellness contracts, often run counter to consumers' reasonable assumptions about risks and rights. This is particularly true when the product's external messaging implicitly suggests the ability to monitor symptoms, deliver behavioral recommendations, or serve as a substitute for clinical care. Once courts determine that a transaction straddles the line into quasi-healthcare territory, they could scrutinize these clauses and potentially invalidate them under longstanding public policy principles.

The *Restatement (Second) of Contracts* Section 178 provides that courts may void terms that contravene public policy, particularly when they implicate bodily integrity, safety, or vulnerable populations.[370] It gives weight to the par-

[370] RESTATEMENT (SECOND) OF CONTRACTS § 178(1); *see also* Farshad Ghodoosi, *The Concept of Public Policy in Law: Revisiting the Role of the Public Policy Doctrine in the Enforcement of Private Legal Arrangements*, 94 NEB. L. REV. 685, 697 (2016) ("[T]he modern doctrine of public policy rests on the idea that enforcing a contract is a matter of public law. Delivering justice is a public affair and is done at the public expense and, therefore, should be monitored. Public resources should not be employed for the execution of an agreement that is injurious to public morality or interest.").

ties' expectations, the "forfeiture that would result if enforcement were denied," and "any special public interest" in enforcing particular terms.[371] Though courts are reluctant to declare contracts void as against public policy,[372] such decisions do happen. As the Supreme Court of California discussed in *Tunkl v. Regents of the University of California*, courts could pay close attention to whether: the business operates in a field that is appropriate for government oversight; the service is essential or significantly beneficial to the public; the service is available to anyone who seeks it without meaningful restriction; the provider holds a stronger bargaining position than the consumer; the agreement is presented on a take-it-or-leave-it basis; and the consumer is placed in the provider's hands, relying on their care and competence.[373] This approach would help to allocate risk more appropriately to the party better able to avoid risk.

By using the factor-based test proposed above, courts can more readily recognize when a product implicates the same interests found in more traditional healthcare contexts. Contracts involving wellness products and services that offer diagnostic-like insight, physiological regulation, or therapeutic relief for a consumer unable to afford or access traditional care may trigger many of these concerns. In these cases, courts could treat duties of safety, disclosure, and accountability as non-waivable.[374]

2. Unconscionability

Conditions such as information asymmetry, urgency, or distress are often present in a medical context and, depending on the circumstances, can render certain clauses in a hospital admission form or an emergency room payment contract unenforceable.[375] These circumstances map well onto contracts for wellness products and services, which may likewise deliver procedurally dense, non-negotiable terms at points of cognitive overload or desperation.[376] This is particularly relevant in wellness contexts involving products unsup-

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[371] RESTATEMENT (SECOND) OF CONTRACTS § 178(2).

[372] Friedrich Kessler, *Contracts of Adhesion—Some Thoughts About Freedom of Contract*, 43 COLUM. L. REV. 629, 630–31 (1943).

[373] Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 444–47 (Cal. 1963).

[374] Public policy provides a stronger basis than unconscionability for treating certain duties as categorically non-waivable, as the two doctrines are conflated but operate differently:

> The difference between public policy and unconscionability as defenses has long been murky, and they are often conflated. However, most cases voiding clauses on grounds of public policy focus on terms that, no matter how they are used, would be void. In other words, there is no need to examine their use in a particular contractual context; the term is so offensive that it is automatically void as to all.

Jacob Hale Russell, *Unconscionability's Greatly Exaggerated Death*, 53 U.C. DAVIS L. REV. 965, 1018 (2019).

[375] *See supra* Part II.A.

[376] *See supra* Part II.B.

ported by scientific research, which may lack any public documentation on their safety and efficacy. The doctrine of unconscionability provides courts with a familiar yet underused tool to address these dynamics.[377] As commonly understood, it allows courts to refuse to enforce a contract or an individual clause when procedural flaws—such as complex, non-negotiable terms delivered at moments of suffering or urgency—and substantive injustice—such as inflated prices, liability waivers, or exaggerated claims—suggest a fundamentally unfair bargain.[378]

In the context of consumer wellness products, the terms of service often disclaim efficacy, limit remedies, or restrict dispute resolution.[379] Contrary to conventional wisdom, unconscionability defenses are not categorically futile arguments.[380] Although successful unconscionability challenges remain statistically rare,[381] success rates are significantly higher when contracts involve low-income, natural persons presented with online or standardized terms, or

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[377] Unconscionability is recognized in both the UCC as well as the common law:

> (1) If the court as a matter of law finds the contract or any clause of the contract to have been unconscionable at the time it was made the court may refuse to enforce the contract, or it may enforce the remainder of the contract without the unconscionable clause, or it may so limit the application of any unconscionable clause as to avoid any unconscionable result[;] (2) When it is claimed or appears to the court that the contract or any clause thereof may be unconscionable the parties shall be afforded a reasonable opportunity to present evidence as to its commercial setting, purpose and effect to aid the court in making the determination.

U.C.C. § 2-302 (A.L.I. & UNIF. L. COMM'N 2023); *see* RESTATEMENT (SECOND) OF CONTRACTS § 208 (providing that a court finding a contract or term unconscionable at formation may "refuse to enforce the contract" entirely, sever the offending term, or limit its application to "avoid an[] unconscionable result"). Of note, the distinction between voiding a term as against public policy and voiding it as unconscionable is frequently blurred in practice—courts often reach the same result under either doctrine without clearly differentiating between them. Russell, *supra* note 374, at 982.

[378] TEMPLIN & SPRATT, *supra* note 208, at 396–97. *But see* Brian M. McCall, *Demystifying Unconscionability: A Historical and Empirical Analysis*, 65 VILL. L. REV. 773, 812 (2020) (identifying a significant minority of cases that did not require proving both prongs and noting that "a two-pronged evidentiary standard for unconscionability may not be as universally entrenched in the law as is commonly believed").

[379] *See, e.g.*, *Woebot Health Terms of Service*, *supra* note 6 (providing that, by agreeing to terms of service, the consumer agrees "to resolve any dispute . . . through binding, individual arbitration rather than in court and [the consumer is] waiving [their] right to a trial by jury or to participate as a plaintiff or class member in any purported class action or representative proceeding"); *Oura Terms of Use*, OURA (July 23, 2025), https://ouraring.com/terms-and-conditions?srsltid=AfmBOoq2mysqC6EMLhzj-gcaJl_92pcM3V1T4IXRBYH27yRBhaKlZ8yl [perma.cc/TN8L-HLX4] (disclaiming responsibility for any health problems resulting from information provided through its biometric tracking services, and requiring users to assume all risk for any changes made to sleep or activity based on its outputs).

[380] Russell, *supra* note 374, at 973–77.

[381] *See* McCall, *supra* note 378, at 824 (observing that "[a]pproximately 3 out of every 4 [unconscionability] claims between 2013 and 2017 were unsuccessful. That means that we can reasonably conclude that most claims will fail").

clauses such as penalty provisions, exculpations, and limitations on implied warranties.[382]

The characteristics that support a successful unconscionability claim are present in wellness markets.[383] The doctrine's requirement of both process-based and outcome-based unfairness provides a natural framework for evaluating contexts in which the asymmetries of information, power, and trust depart sharply from the assumptions of arm's-length exchange.[384] The five-factor test is also consistent with the more tailored approach some courts take when analyzing unconscionability.[385]

Courts already recognize that patients are not typical consumers.[386] Wellness consumers turning to consumer products rather than medicine out of desperation, stigma, or cost may be functionally indistinguishable in their susceptibility.[387] Unconscionability can account for this vulnerability by attending to relational coercion and market distortions in health-adjacent transactions. Like courts that decline to enforce hospital arbitration clauses during admission or scrutinize emergency room cash-pay contracts,[388] wellness agreements should be evaluated by considering the realities of dependency and constraint rather than through the lens of formal consent that currently dominates.[389] As well-

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[382] *See* McCall, *supra* note 378, at 804 (finding that successful unconscionability claims most commonly involved preprinted form contracts, inequality of bargaining power, and unrepresented parties); Larry A. DiMatteo & Bruce Louis Rich, *A Consent Theory of Unconscionability: An Empirical Study of Law in Action*, 33 FLA. ST. U. L. REV. 1067, 1097 (2006) (finding that consumers succeeded in unconscionability claims at nearly three times the rate of merchants, and that standardized form contracts were present in the majority of litigated cases).

[383] McCall, *supra* note 378, at 804.

[384] *See supra* Part I.B.

[385] Under the "tailored" approach, courts identify the specific consumer before them rather than an abstract reasonable person:

> To answer either whether the consumer lacked meaningful choice or entered into a fundamentally unfair bargain, the court cannot help but have some consumer in mind by which to evaluate whether the contract is too surprising or unfair. But *which* consumer? Is it the specific, subjective individual sitting in front of the court in all of their factual complexity? . . . [This] approach would be "tailored."

Russell, *supra* note 374, at 989–991; *see, e.g.*, James v. Nat'l Fin., LLC, 132 A.3d 799, 819–21 (Del. Ch. 2016) (centering unconscionability analysis on individual consumer's actual circumstances, and rejecting expert testimony about hypothetically rational uses of high-cost credit as insufficient to justify loan terms that could not plausibly benefit the particular borrower before the court).

[386] *See* Hall & Schneider, *supra* note 47, at 667 ("The law already recognizes consumers' susceptibility, patients' vulnerability, and doctors' power in numerous ways; protecting patients when they must be consumers logically extends that recognition.").

[387] *Id.* at 667.

[388] *Id.* at 668–69, 669 n.141.

[389] *See supra* Part II.C.

ness products increasingly fill gaps left by retreating healthcare access, courts may find unconscionability arguments more compelling.[390]

3. Warranties

In the wellness economy, companies frequently cultivate consumer reliance through pseudo-clinical language, sleek digital interfaces, and endorsements that invoke medical authority.[391] These practices can give rise to express warranties under the Uniform Commercial Code (UCC) Section 2-313,[392] even in the absence of formal guarantees.[393] Courts have recognized that representations made by sellers, whether in marketing or design, can constitute express warranties when they form part of the basis of the bargain.[394]

Many of the factors proposed above take into account how the product functions and is marketed, as well as how and why consumers use it. If courts determine that a wellness product functions like healthcare, they should then consider whether express warranties are implicated. In health-adjacent markets, a more protective interpretive standard—akin to the "least sophisticated consumer" test used in debt collection[395]—might better capture how ordinary consumers understand wellness claims. Under this objective standard, the relevant question is not what a reasonable, informed consumer would understand,

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[390] *See* Russell, *supra* note 374, at 980–81 (theorizing that the rise in successful unconscionability claims after the 2008 financial crisis, particularly in the consumer credit sphere, were at least partially attributable to judges' shifting view on the morality of certain lending practices and desire to exact revenge on the entities judges perceived as responsible).

[391] *See supra* Part I.

[392] *See* U.C.C. § 2-313(1)(a) (A.L.I. & UNIF. L. COMM'N 2023) ("Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.").

[393] *See* U.C.C. § 2-313(2) (explaining that even without formal warranty language or specific intent to create a warranty, representations that form the basis of the bargain can create an express warranty).

[394] *Id.*; *see, e.g.*, Caldwell v. Nordic Nats., Inc., 709 F. Supp. 3d 889, 908 (N.D. Cal. 2024) (providing that, under the UCC, "a plaintiff only needs to show that the goods 'do not conform to the promises or affirmations of fact made on the container or label if any'") (citing Milan v. Clif Bar & Co., No. 18-cv-02354, 2019 WL 3934918, at *3 (N.D. Cal. Aug. 20, 2019)); *see also In re* 5-hour Energy Mktg. & Sales Pracs. Litig., No. MDL 12-2438, 2017 WL 385042, at *11 (C.D. Cal. Jan. 24, 2017) (explaining that the plaintiff need not allege the product lacked fitness for ordinary use, and that the plaintiff could state a breach of implied warranty claim based upon misrepresentations made on the product's label); Clark v. Hershey Co., No. C 18-06113, 2019 WL 913603, at *6 (N.D. Cal. Feb. 25, 2019) (same).

[395] Courts "almost universally" employ a "least sophisticated debtor" standard when deciding if debt collection violates Section 807 of the Fair Debt Collection Practices Act (FDCPA). Jensen v. Pressler & Pressler, 791 F.3d 413, 418–19 (3d Cir. 2015); *see* 15 U.S.C. § 1692e ("A debt collector may not use any false, deceptive, or misleading representation or means in connection with the collection of any debt."). "The [least sophisticated consumer] standard is an objective one, meaning that the specific plaintiff need not prove that *she* was actually confused or misled, only that the objective least sophisticated debtor would be." *Jensen*, 791 F.3d at 419 (citing Pollard v. Law Off. of Mandy L. Spaulding, 766 F.3d 98, 103 (1st Cir. 2014)).

but what the least sophisticated consumer in that market would conclude from the seller's representations—a threshold that better reflects the reality of how wellness products are marketed and consumed.[396]

In parallel, the implied warranty of merchantability under UCC section 2-314 provides an additional backstop.[397] This provision requires that goods be fit for the ordinary purposes for which such goods are used.[398] It applies automatically by operation of law whenever a merchant—here, a wellness company—sells goods of the kind they ordinarily deal in.[399] Therefore, if consumers are purchasing wellness products with health outcomes in mind and courts use the factor-based test—particularly whether consumers use the product to address a specific condition or health-related vulnerability rather than general lifestyle enhancement—courts might reasonably define the "ordinary purpose" of those goods as health-related under UCC Section 2-314.[400] That would mean wellness products must function in ways reasonably consistent with healthcare, regardless of disclaimers.

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[396] *See* Clomon v. Jackson, 988 F.2d 1314, 1318 (2d Cir. 1993) ("The basic purpose of the least-sophisticated-consumer standard is to ensure that the FDCPA protects all consumers, the gullible as well as the shrewd. This standard is consistent with the norms that courts have traditionally applied in consumer-protection law."); *see also Jensen*, 791 F.3d at 418 (quoting Rosenau v. Unifund Corp., 539 F.3d 218, 221 (3d Cir. 2008)) (explaining that the standard "is 'lower than the standard of a reasonable [person],'" although "it 'preserv[es] a quotient of reasonableness and presume[s] a basic level of understanding and willingness to read with care'") (alteration in original).

[397] U.C.C. § 2-314(1).

[398] Specifically, the standard requires that goods:

> (a) pass without objection in the trade under the contract description; and (b) in the case of fungible goods, are of fair average quality within the description; and (c) are fit for the ordinary purposes for which such goods are used; and (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and (e) are adequately contained, packaged, and labeled as the agreement may require; and (f) conform to the promise or affirmations of fact made on the container or label if any.

Id. § 2-314(2)(a)–(f).

[399] *Id.* § 2-314(1); *see id.* § 2-314 cmt. 11 (noting that the warranty is "so commonly taken for granted that its exclusion" requires special precaution). The UCC defines a "merchant" as:

> [A] person who deals in goods of the kind or otherwise by his occupation holds himself out as having knowledge or skill peculiar to the practices or goods involved in the transaction or to whom such knowledge or skill may be attributed by his employment of an agent or broker or other intermediary who by his occupation holds himself out as having such knowledge or skill.

Id. § 2-104(1).

[400] *See id.* § 2-314(2)(c) (requiring goods be "fit for the ordinary purposes for which such goods are used"); *supra* Part III.A.2. (setting forth the second factor in the Article's proposed factor-based test). The first and third factors may also be relevant here. *See supra* Part III.A.1. & .3.

Many wellness offerings—such as supplements, wearables, and other technologies—fit squarely within the scope of the UCC.[401] In these contexts, courts could hold companies to the expectations that they help construct, whether through explicit representations or cultivated consumer inference. Although wellness companies could adapt and disclaim merchantability, they would need to do so in a manner consistent with the UCC,[402] ultimately contributing to improved consumer understanding of their rights and the product's limitations.

4. Good Faith and Fair Dealing

Some wellness companies bury risk disclosures in hyperlinks or deep within user interfaces, while simultaneously using clinical language, imagery, and design to cultivate therapeutic trust. In doing so, they achieve technical compliance with disclosure and consent requirements to avoid liability, while structurally undermining the informed reliance those requirements are meant to protect. The doctrine of good faith and fair dealing exists to address such gaps between formal legality and substantive expectation.[403]

The implied duty of good faith and fair dealing prohibits a party from exploiting a contract's terms to undermine its core purpose.[404] The implied duty of good faith and fair dealing is difficult to define, and is often described in the negative as "not operating in bad faith."[405] It applies to the performance and enforcement of all contracts, unless there is an exception.[406] Where a consumer lacks meaningful bargaining power relative to a wellness company, or is par-

[401] The UCC applies to the sale of goods. U.C.C. § 2-102(1). It defines "goods" as "all things (including specially manufactured goods) which are movable at the time of identification to the contract for sale other than the money in which the price is to be paid, investment securities . . . and things in action." *Id.* § 2-105(1).

[402] *See id.* § 2-316(2) (requiring that any disclaimer of implied warranty of merchantability mention merchantability by name and, if in writing, be conspicuous); *id.* § 2-316(3)(a) (providing that even broader disclaimer language must, in common understanding, plainly call the buyer's attention to the exclusion of the warranties); *id.* § 2-316(1) (rendering disclaimers inoperative to the extent they cannot be reasonably construed as consistent with affirmative representations made by the seller).

[403] *See* RESTATEMENT (SECOND) OF CONTRACTS § 205 (A.L.I. 1981) ("Every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement."); U.C.C. § 1-304.

[404] TEMPLIN & SPRATT, *supra* note 208, at 548; *see also* RESTATEMENT (SECOND) OF CONTRACTS § 205 cmt. a ("Good faith . . . emphasizes faithfulness to an agreed common purpose and consistency with the justified expectations of the other party . . . .").

[405] TEMPLIN & SPRATT, *supra* note 208, at 548; *see* U.C.C. § 1-201(b)(20) (defining "[g]ood faith" as "honesty in fact and the observance of reasonable commercial standards of fair dealing"). The UCC also has a definition of "good faith" specific to merchants. *Id.* § 2-104 cmt. 2 (providing that "in the case of a merchant 'good faith' includes observance of reasonable commercial standards of fair dealing in the trade"); RESTATEMENT (SECOND) OF CONTRACTS § 205 cmt. a (explaining that good faith "excludes . . . conduct characterized as involving 'bad faith' because they violate community standards of decency, fairness, or reasonableness").

[406] RESTATEMENT (SECOND) OF CONTRACTS § 205 cmt. a. The duty "does not deal with good faith in the formation of a contract." *Id.* at § 205 cmt. c.; TEMPLIN & SPRATT, *supra* note 208, at 552.

ticularly vulnerable, the resulting contract may be substantively unfair despite formal validity. Imposing a duty of good faith and fair dealing allows courts to avoid inequitable results that the express terms would otherwise permit.[407] In other words, it ensures that parties do not use formal rights to subvert the spirit of the agreement.

In healthcare, this insight has guided judicial reluctance to enforce contracts formed during periods of vulnerability[408] or asymmetrical trust.[409] That same logic should inform how courts interpret wellness contracts that perform similar functions. When companies encourage reliance on therapeutic benefit but then hide behind procedural formalism, they violate not just fairness norms but the assumptions that undergird good faith.

5. Consent

In the commercial context, contract law assumes that parties to a contract have read the terms of the agreement before signing, even if they have not.[410] The so-called "duty to read" also applies to click- and browse-wrap contracts, which are common in terms of service agreements.[411] This formalist approach presupposes consumer diligence and sophistication that does not reflect reality.[412] Even if consumers do not read these terms, courts will enforce them.[413] Contract law rests on the fiction that consent can be presumed from formal acts like signing, clicking, and proceeding.[414] Wellness contracts often rely on that fiction to shift risk, obscure information, and reassign responsibility to the user. They do so by presenting dense terms through clickwrap structures, while assuming a meaningful agreement.

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[407] TEMPLIN & SPRATT, *supra* note 208, at 552.

[408] Hall & Schneider, *supra* note 47, at 667–69.

[409] *Id.* at 669–70.

[410] TEMPLIN & SPRATT, *supra* note 208, at 38–39.

[411] There is no actual duty to read in the sense that if you do not read, you have breached a duty. If you do not read, you simply take a risk. *Id*.; *see also* Benoliel & Becher, *supra* note 332, at 2256 ("The duty to read doctrine . . . holds contracting parties responsible for the written terms of their contracts, whether or not they actually read them.").

[412] *See* Nili Steinfeld, *"I Agree to the Terms and Conditions": (How) Do Users Read Privacy Policies Online? An Eye-Tracking Experiment*, 55 COMPUTS. HUMAN BEHAV. 992, 995–96 (2016) (finding that nearly eighty percent of participants who could accept terms and conditions without being shown the policy did not click the link to read them, with the whole group spending an average of only five seconds on the policy page).

[413] *See, e.g.*, Fteja v. Facebook, Inc., 841 F. Supp. 2d 829, 838–41 (S.D.N.Y. 2012) (concluding that consumer assented to the Terms of Service and therefore a forum selection clause, where the consumer clicked a button to agree to the Terms, even though the consumer must go to another webpage to view those Terms).

[414] *Id.* at 839 ("[C]licking the hyperlinked phrase . . . prompt[s the consumer] to examine terms of sale that are located somewhere else. Whether or not the consumer bothers to look is irrelevant.").

Nevertheless, courts do not need to import the health law doctrine of informed consent[415] to address this problem—nor does this Article argue for doing so, as these are distinct concepts with distinct legal consequences. Where wellness products market themselves as substitutes for clinical care, however, the standard of meaningful consent may need to rise accordingly. Although it is often focused on objective manifestations of assent, contract law also recognizes that consent is not merely a matter of form. It is also a function of context, comprehension, and voluntariness.[416] When the factor-based test indicates that a wellness product is something more than just a lifestyle enhancement, companies should bear some corresponding duty to ensure that consumers understand the nature, risks, and limitations of the transaction.[417]

C. The Case for Contract

Health law's exceptionalism—its acknowledgment of vulnerability, asymmetry, and public interest—is treated as inapplicable in a wellness context because we accept the assumption that wellness is not health, even when it is virtually indistinguishable.[418] Rather than recognizing the proximity of wellness's consequences to healthcare's legal arsenal—tort, fiduciary duty, or medical malpractice regimes—courts relegate them to simple contract disputes.[419] But contract law is not only a source of the challenges that arise when wellness substitutes for healthcare, it also offers promising, adaptable, and individualized solutions appropriate to the current time and scope of the wellness market. This Section presents the normative argument that courts could adopt these modest doctrinal recalibrations to meet the challenges of the wellness econo-

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[415] *See supra* Part II.A.2. (discussing the informed consent requirement in healthcare contracts).

[416] TEMPLIN & SPRATT, *supra* note 208, at 46.

[417] Several areas of contract law impose statutory requirements that contract terms be written in plain, understandable language, reflecting the legislative recognition that formal assent is meaningful only where consumers can actually understand what they are agreeing to. *See, e.g.*, 29 C.F.R. § 1625.22(b)(3) (2026) (requiring that the waivers of the right to sue under the Age Discrimination in Employment Act (ADEA) be written in a manner understandable to the average person eligible for the program in which the waiver is used); *see also* Michael L. Rustad, *Why a New Deal Must Address the Readability of U.S. Consumer Contracts*, 44 CARDOZO L. REV. 521, 531 (2022) (identifying minimum readability requirements for consumer contracts in state statutes to ensure understanding).

[418] *See supra* Part I.A–.B.

[419] *See* Ryan Martins, Shannon Price & John Fabian Witt, *Contract's Revenge: The Waiver Society and the Death of Tort*, 41 CARDOZO L. REV. 1265, 1267–68, 1279, 1294–297 (2020) (arguing that modern waiver doctrine increasingly makes contract "the principal gatekeeper to tort," and using fitness-center and spa injury cases to show how courts treat negligence claims against consumer-service providers as governed by contractual waivers rather than tort's public-law duties); *see also* Mariner, *supra* note 47, at 22 ("[I]f contract law is the dominant legal paradigm for consumer rights, contract obligations that ignore important concerns of patient care may displace important patient rights now governed by tort law.").

my, addresses common objections, and considers how the proposed contract law solution can complement other efforts.[420]

1. Why Contract?

Contract law governs the wellness economy.[421] Wellness companies have thrived under the light regulatory touch, slowly encroaching into the more regulated healthcare market in both form and function.[422] For better or worse, courts are already adjudicating these disputes through a contract lens.[423] Thus, the right question is not whether to bring contract law into a more prominent role in health governance, or even whether it is the right approach at all. It is steadily happening regardless. Instead, the question is how contract law can continue to dominate in this space with a clearer view of the stakes.

Focusing on contract law is not a surrender to the status quo. Contract law, albeit imperfect, has advantages over other approaches. Unlike top-down regulation, contract adjudication is incremental, context-sensitive, and doctrinally conservative in form,[424] even when it is ambitious in effect. It does not impose broad, sweeping limits on what companies can make or what individuals can do with their own bodies. Instead, its flexibility empowers courts to incorporate their own and the community's sense of justice.[425]

Merely incorporating a clause into the terms of service does not obligate courts to apply every default contract rule.[426] This adaptability to market con-

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[420] *See infra* notes 421–459 and accompanying text.

[421] The use of contract law to invalidate certain terms within terms of service also opens the door to tort as a remedy for consumers harmed by wellness products. Nevertheless, further discussion of tort claims is outside the scope of this Article.

[422] *See* Simon et al., *supra* note 30, at 6–7 (observing that regulatory flexibility has allowed producers to offer device-like products as non-devices through disclamatory language to evade FDA oversight).

[423] *See supra* Part II.B.

[424] The public policy doctrine undergirding contract law may limit its development:

> [B]ecause public policy defenses rely on the factually intense and inherently conservative common law for their articulation, public policy doctrine is self-limiting. That is: unlike legislation, if we are wrong about the balance of costs and benefits . . . contracts create, courts will reverse course, and with less difficulty than gridlocked legislatures.

David A. Hoffman & Erik Lampmann, *Hushing Contracts*, 97 WASH. U. L. REV. 165, 170 (2019).

[425] Kessler, *supra* note 372, at 638.

[426] These contract rules are not a guarantee, however:

> This will not do any harm if we remain fully aware that the use of the word "contract" does not commit us to an indiscriminate extension of the ordinary contract rules to all contracts. . . . Consequently, courts have made great efforts to protect the weaker contracting party and still keep "the elementary rules" of the law of contracts intact.

Kessler, *supra* note 372, at 633.

ditions and social change is part of contract law's history.[427] So, even though objective theory still dominates contract law, reasonableness remains relevant, and important pockets of subjective inquiry remain.[428]

To be clear, a court applying the five-factor test and deciding that a wellness offering is more akin to healthcare than wellness does not necessitate or even legally permit a court to apply all the regulations of healthcare to that wellness product.[429] Such a decision does not transform a company into a covered entity under HIPAA, nor does it create a physician-patient relationship between a consumer and an AI chatbot. It simply allows courts to apply existing contract law in light of the specific context, taking into account the similar considerations they would in analyzing a healthcare contract.

Courts can preserve institutional modesty while still acknowledging that certain subsets of the wellness economy implicate more than ordinary consumer interests. They can recognize that it can involve some or all of the same elements that make healthcare exceptional.[430] And if and when harm arises from reliance on products that are functionally medical but legally wellness, contract law does not need to pretend that formal assent alone is dispositive. It offers a doctrinal middle ground between regulatory overreach and complete abdication to the free market.

Modern contract law often prides itself on neutrality and efficiency, invoking the principles of freedom of contract and market choice as limiting factors on judicial intervention.[431] But pure freedom of contract is not a good fit

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[427] *See* Walter F. Pratt Jr., *American Contract Law at the Turn of the Century*, 39 S.C. L. REV. 415, 418 (1988) (noting that judges, recognizing that doctrines of the past were no longer adequate for the needs of a changing commercial world, modified those doctrines to embrace the greater uncertainty that characterized new commercial agreements); *see, e.g.*, Williams v. Walker-Thomas Furniture Co., 350 F.2d 445, 449 (D.C. Cir. 1965) (adapting unconscionability doctrine to the mass consumer credit market by fashioning a flexible, circumstances-based standard where existing doctrine had not reached, and drawing on newly enacted UCC provisions as persuasive authority to develop the common law in response to changed commercial conditions).

[428] The objective standard does not eliminate subjective inquiry entirely:

> [T]he question of whether to tailor is not addressed by the general consensus that contract law now follows an "objective theory of assent," rather than one focused on the contracting parties' subjective mindset. But the objective standard still requires a view of "reasonableness," which in turn is often explained as something that is *reasonable from the standpoint of a similarly situated party*—which can be defined either so narrowly or so broadly that the objective inquiry can easily collapse into a subjective (or nearly subjective) one.

Russell, *supra* note 374, at 991–92.

[429] *See supra* notes 158–160 and accompanying text (providing examples of healthcare-specific legislation).

[430] *See supra* Part I.

[431] TEMPLIN & SPRATT, *supra* note 208, at 13 (describing freedom of contract to be "the belief that parties should be free to enter agreements without government intervention so long as the agree-

for health-affecting products and services or consumers who resemble patients.[432] When courts enforce clauses that foreclose redress or uphold disclaimers that disavow responsibility for harms in wellness transactions, they endorse a regime in which companies can offer health-affecting interventions with none of the duties traditionally attached to care.[433] Meanwhile, these same companies can rush to offer cheap products and services that often fail to work, all while profiting from consumer data.

The impact of the proposed factor-based test is likely to be modest at first. Nevertheless, a measured, case-by-case solution is attractive given the nascent, poorly understood risks and the dynamic field. Consider the proposed fifth factor, which asks courts to consider consumer vulnerability.[434] Research on consumer wearables shows that women,[435] urban residents,[436] privately insured individuals,[437] and those with higher incomes[438] are also more likely to use wearable technology, suggesting that socioeconomic privilege leads to access and engagement. Meanwhile, older adults, lower-income populations, and individuals with limited digital literacy face notable barriers to adoption, even when they own smart devices.[439] Some studies suggest that usage remains comparatively low in racially diverse and economically disadvantaged com-

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ments do not violate a law[,] [u]nder [which] courts would not interfere in private bargaining by deciding whether a contract represents a fair deal").

[432] As some scholars have noted:

> The standard "freedom of contract" view works dreadfully in the medical context. Patients are not conventional consumers. They are strangers in a strange land, vulnerable because they are sick and because the market for health care is incomprehensible and dangerous. In their need, patients build relationships of dependence and trust with the people who care for them. That justifies courts in deploying contractual supervisory doctrines to set heightened standards of good faith and fair dealing, standards that give patients a remedy when providers set unreasonable fees in unreasonable ways.

Hall & Schneider, *supra* note 47, at 688.

[433] *See* Martins et al., *supra* note 419, at 1283–84 (noting that strict construction of exculpatory contracts reflects a longstanding judicial aversion to allowing parties to escape responsibility for negligent harm, but that courts have applied the doctrine inconsistently, often enforcing broad waivers despite purporting to limit them).

[434] *See supra* Part III.A.5.

[435] Chandrasekaran et al., *supra* note 101, at 9.

[436] Ashwini Nagappan, Adriana Krasniansky, & Madelyn Knowles, *Patterns of Ownership and Usage of Wearable Devices in the United States, 2020–2022: Survey Study*, 26 J. MED. INTERNET RSCH. 1, 2 (2024).

[437] *Id.* at 6.

[438] Chandrasekaran et al., *supra* note 101, at 9.

[439] Omolola Adepoju, Patrick Dang, Holly Nguyen & Jennifer Mertz, *Equity in Digital Health: Assessing Access and Utilization of Remote Patient Monitoring, Medical Apps, and Wearables in Underserved Communities*, 61 INQUIRY: J. HEALTH CARE ORG., PROVISION & FIN. 1, 4 (2024).

munities, a pattern that may reflect broader systemic inequities in digital health access.[440]

Nevertheless, the importance of this intervention increases over time. Research studies identifying these patterns regularly call for greater equity in access, particularly as wearables become increasingly central to both commercial wellness and clinical care infrastructure.[441] The sophistication of products in this market and investment in their development are only growing.[442] The government is loudly pushing Americans to use wellness products to take control of their own health.[443] What begins now as a modest intervention may eventually prove to be an important safeguard.

2. Why Now?

The wellness economy thrives on regulatory arbitrage.[444] It exploits the gray zones between health and lifestyle, public and private, care and consumption.[445] It is reinforced by the current orientation of contract law toward deference, formalism, and efficiency.[446] This environment has been a key driver of the wellness market's economic success.

But regulation and traditional health law are not coming to the rescue for wellness. Regardless of how a court characterizes wellness, traditional statutory healthcare protections that attach to covered entities would still not apply,[447] nor would the legal protections that accompany a true physician-patient relationship.[448] Legislating new protections or reversing course on agency approaches would take time. And it is unclear whether such approaches would be feasible or even desirable.

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[440] Chandrasekaran et al., *supra* note 101, at 2; Adepoju et al., *supra* note 439, at 5; *see* Lovedeep S. Dhingra et al., *Use of Wearable Devices in Individuals With or At Risk for Cardiovascular Disease in the US, 2019 to 2020*, 6 JAMA NETWORK OPEN 1, 5 (2023) (noting these trends among individuals with cardiovascular disease); Ethan H. Kim et al., *Association of Demographic and Socioeconomic Indicators with the Use of Wearable Devices Among Children*, 6 JAMA NETWORK OPEN 1, 8 (2023) (finding similar trends among children); Sukh Makhnoon et al., *Awareness, Use, Motivations and Methods of Accessing Genetic Testing in 2022 in the United States*, 15 FRONTIERS GENETICS 1, 7 (2024) (confirming this pattern in DTC genetic testing).

[441] Chandrasekaran et al., *supra* note 101, at 13; Adepoju et al., *supra* note 439, at 4; Dhingra et al., *supra* note 440, at 8; Nagappan et al., *supra* note 436, at 6.

[442] *What Is the Future of Wellness?*, *supra* note 23, at 2.

[443] *See supra* notes 135–138 and accompanying text (providing examples of government actions promoting wellness).

[444] *See supra* Part II.B.

[445] Simon et al., *supra* note 30, at 13.

[446] *See supra* Part II.B–.C.

[447] *See supra* notes 158–160 and accompanying text (describing healthcare-specific statutes).

[448] *See* Mehlman, *supra* note 19, at 61–62 (noting that traditional physician-patient protections are already eroding within formal medical relationships as physicians lose professional autonomy to corporate actors).

Nevertheless, when courts treat wellness as a shield that renders all health protections inapplicable, the long-term consequence is a deliberate ignorance of the variability in quality, reliability, and oversight of health-affecting products and services. As wellness companies optimize for engagement, scale, and monetization without regulatory guardrails, the risk is what Cory Doctorow describes as "enshittification."[449] Through the enshittification of health, products and services degrade in accuracy, privacy, and utility as user needs are subordinated to profit and growth. By deferring to the wellness label and refusing to scrutinize function or harm, courts help create the conditions that enable this degradation. As wellness products increasingly take on functions traditionally performed by healthcare, they also erode health law's authority by deliberately reallocating governance away from public oversight and toward private ordering, punching innumerable small holes in the system.[450] In this way, wellness is another tool for deregulating health, and companies learn that by manipulating language, they can manipulate the law, and that courts will not intervene.

Some will argue that asking courts to scrutinize wellness contracts will chill innovation in the wellness space or exceed their institutional role. That, perhaps, they lack the big-picture wisdom to make decisions better left to policymakers.[451] But these are familiar arguments raised in every context where courts are asked to mediate power and information asymmetries in markets. This is also where contract law has significant benefits over other possible solutions. It only binds parties to the agreement, not the entire industry,[452] allowing for case-by-case determinations. Judicial engagement with contracts involving wellness products and services that simulate health can operate through the incremental development of common law principles to avoid overregulating a market that can also offer tangible benefits.

Others may worry that the proposed test is too vague or that courts lack the competence to distinguish care from everyday commerce. But doctrinal tools already exist to navigate functional ambiguity. Courts routinely apply complex, factor-based tests in a variety of contexts, including intellectual

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[449] Cory Doctorow coined the term "enshittification" to describe the process by which platforms slowly become worse while exploiting their users. He notes that, "[f]irst, they are good to their users; then they abuse their users to make things better for their business customers; finally, they abuse those business customers to claw back all the value for themselves. Then, they die." Cory Doctorow, *The 'Enshittification' of TikTok*, WIRED (Jan. 23, 2023), https://www.wired.com/story/tiktok-platforms-cory-doctorow/ [perma.cc/BR2F-VK7P].

[450] QUINN SLOBODIAN, CRACK-UP CAPITALISM: MARKET RADICALS AND THE DREAM OF A WORLD WITHOUT DEMOCRACY 3 (2023).

[451] Kessler, *supra* note 372, at 636.

[452] *See* Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 378 (2007) ("[C]ontract law binds only those who are parties to the agreement, not the whole world.").

property disputes,[453] corporate veil-piercing,[454] and federal employment tax classification cases.[455] Contract law is no different.[456] Courts considering contract disputes also have experience looking beyond form to consider function,[457] and are accustomed to accounting for how a contract came into being.[458] Of course, doing so requires judgment, but that is what courts do. The functional approach proposed here gives them the scaffolding to assess wellness contracts without policing medical truth claims or evaluating scientific validity. It asks only that courts take seriously the relational and embodied context in which these contracts operate.

3. Looking Forward

Embracing the role of contract law in wellness governance does not preclude other efforts to regulate consumer wellness products and services, nor does it diminish the need for broader reforms. It does not preempt regulation, diminish the importance of regulatory oversight, or excuse political disinvestment in products and services that impact health. Courts cannot force Congress to act or agencies to regulate. What they can do is interpret contracts, and how they do that will shape the normative terrain on which broader governance fights unfold. Approaching wellness contracts with an eye toward shrinking the current

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[453] For example, courts weigh ten factors to determine whether a "likelihood of confusion" exists between two trademarks (the "*Lapp* test")—the standard that forms the basis of liability for trademark infringement. Interpace Corp. v. Lapp, Inc., 721 F.2d 460, 462–63 (3d Cir.1983). An even more notorious IP balancing factor test is fair use analysis. *See* 17 U.S.C. § 107 (setting forth four factors to evaluate fair use in copyright cases); David Nimmer, *"Fairest of Them All" and Other Fairy Tales of Fair Use*, 66 LAW & CONTEMP. PROBS. 263, 267–73 (2003) (summarizing fair use case outcomes based on the four-factor analysis).

[454] *See* Manichean Cap., LLC v. Exela Techs., Inc., 251 A.3d 694, 706 (Del. Ch. 2021) ("Delaware courts consider a number of factors in determining whether to disregard the corporate form and pierce the corporate veil . . . ."); Jonathan Macey & Joshua Mitts, *Finding Order in the Morass: The Three Real Justifications for Piercing the Corporate Veil*, 100 CORN. L. REV. 99, 107–08 (2014) (identifying thirteen factors that courts consider when determining whether to pierce the corporate veil).

[455] There are at least twenty factors that courts can examine when determining whether an individual is an independent contractor or employee. Rev. Rul. 87-41, 1987-1 C.B. 296, 298–99.

[456] *See, e.g.*, Bonebrake v. Cox, 499 F.2d 951, 960 (8th Cir.1974) (establishing the predominant purposes test to determine whether a hybrid contract is for the sale of goods); *see also* RESTATEMENT (SECOND) OF CONTRACTS § 241 (A.L.I. 1981) (providing factors to determine whether a contract has been materially breached); Fritz v. Nationwide Mut. Ins. Co., No. 1369, 1990 WL 186448, at *4–5 (Del. Ch. Nov. 26, 1990) (discussing ten factors that guide the analysis of unconscionability).

[457] *See, e.g.*, U.C.C. 9-109(a)(1) (A.L.I. & UNIF. L COMM'N 2023) ("[T]his article applies to . . . a transaction, *regardless of its form*, that creates a security interest in personal property or fixtures by contract . . . .") (emphasis added).

[458] Russell, *supra* note 374, at 1016; *see also* James v. Nat'l Fin., LLC, 132 A.3d 799, 814, 819–21 (Del. Ch. 2016) (explaining that unconscionability is evaluated in light of the contract's "setting, purpose and effect," including the parties' relative bargaining power, use of boilerplate terms, circumstances surrounding execution, and exploitation of unsophisticated or undereducated parties, and applying those factors to rescind a high-interest consumer loan).

chasm between healthcare and wellness protections does not address all the problems of the wellness economy, but it refuses to pretend there are none.

If we want to know anything meaningful about the wellness economy, especially as it often operates outside the FDA's requirements for demonstrating safety and efficacy, we may need to learn it through litigation. But as it currently stands, the terms in standard-form contracts effectively hide potentially significant problems from the public. As a result, we must weigh private interests in freedom of contract with society's competing interest in transparency and accountability. As we move toward an increasingly wellness-focused future, it may be one of the few possible safeguards available.

Ultimately, scholars have long cautioned that transforming patients into mere consumers heralds a loss of important rights, and that conceptualizing healthcare as indistinguishable from any other market commodity changes how we think about medicine and vulnerable people.[459] But failing to see any similarities between patients and consumers in the wellness economy likewise contributes to those risks.

CONCLUSION

Wellness is increasingly taking on the form and functions of traditional healthcare. At the same time, public involvement and accountability in health are waning. The result is a growing market for sophisticated consumer products and services that resemble and may someday even replace aspects of healthcare, but with none of the protections typically afforded to patients. By treating these wellness transactions as ordinary consumer exchanges, courts entrench a legal order where terms of service govern health-affecting transactions rather than professional duty or public law. If wellness continues to grow in scale and importance, these courts may, whether through indifference or complicity, lay the groundwork for deregulatory reforms that make wellness and contract law the future of healthcare governance.

This troubling potential future is embodied by a more modest problem in the present. Wellness currently blurs the line that once separated it from healthcare, although courts uncritically enforce its contracts. But courts can acknowledge this creep rather than ignore it. They can consider factors like whether the product substitutes for formal healthcare; whether the consumer used it to address a specific health-related vulnerability rather than for general

[459] Mariner, *supra* note 47, at 3; *see also* Annas, *supra* note 162, at 696 ("Attempts to transform the physician-patient relationship into a business transaction fundamentally threaten not just physicians as professionals but people as patients."); Edmund D. Pellegrino, *First Annual Nicholas J. Pisacano Lecture: Words* Can *Hurt You: Some Reflections on the Metaphors of Managed Care*, 7 J. AM. BD. FAM. PRAC. 505, 505 (1994) ("The greatest peril I see in all the talk about health care reform is that . . . . [i]nstead of trusting in the physician's ethical commitments, [patients] will have to be guided by the principle of *caveat emptor*.").

well-being; how the product is marketed and whether that shapes reasonable user reliance; the potential for harm arising from misplaced trust in the product; and the structural asymmetries and user vulnerabilities that may undermine the voluntariness of the transaction. In doing so, they can use familiar contract tools—public policy, unconscionability, warranties, and good faith—to protect consumers in ways similar to how they protect patients.

This is not a call to regulate wellness identically to healthcare, but an invitation to take it seriously on its own terms. As wellness increasingly shapes how people understand and manage their health, courts can apply the same principled, restrained contract doctrines they already use in clinical contexts. Doing so need not stifle innovation or limit consumer choice. Instead, it can ensure that wellness evolves alongside, rather than in place of, the legal and ethical commitments that define healthcare.