Clicking Away Consent: Establishing Accountability and Liability Apportionment in Direct-to-Consumer Healthcare Artificial Intelligence

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Clicking Away Consent

ESTABLISHING ACCOUNTABILITY AND LIABILITY APPORTIONMENT IN DIRECT-TO-CONSUMER HEALTHCARE ARTIFICIAL INTELLIGENCE

> *"When firms can easily divest recipients of entitlements that are part of a legislative regime arrived at only with much difficulty, debate, and compromise, it makes a sham of the apparatus of democratic governance. All of the public input and hard-fought compromises and trade-offs seem like an ironic form of kabuki theatre."*
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> —Margaret Jane Radin[1]

INTRODUCTION

Meet Woebot: a thoughtful and charismatic chat robot powered by innovative artificial intelligence (AI) who aims to provide therapeutic mental health services through the convenience of your phone.[2] Woebot generates conversation and forms bonds with its users through sophisticated AI driven by "clinically tested therapeutic approaches" and evolving user input.[3] The ability of apps like Woebot to provide cost-effective health services to patients who might have limited accessibility to in-person healthcare or human clinical resources has major implications on public health.[4]

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[1] MARGARET JANE RADIN, BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW 40 (2012). Radin discusses the tenets of mutual understanding and voluntariness as central to contract formation and sets forth multiple compelling arguments against allowing and enforcing contracts, specifically boilerplate agreements, that lack these foundational elements. Indeed, lack of voluntariness erodes our "commit[ment] to the moral premise that justifies our legal structure of contract enforcement . . . that people who enter contracts are *voluntarily* giving up something in exchange for something they value more." *Id.* at 15. Such themes of voluntariness and mutual benefits are especially pertinent in the evaluation of electronic contracts for healthcare apps, as this note will further discuss.

[2] *See* Grace Browne, *The Problem with Mental Health Bots*, WIRED (Oct. 1, 2022, 7:00 AM), https://www.wired.com/story/mental-health-chatbots/ [https://perma.cc/3NPX-P9NM].

[3] *What Powers Woebot*, WOEBOT HEALTH, https://woebothealth.com/what-powers-woebot/ [https://perma.cc/G9E5-PBLC].

[4] *See* Shilpa N. Gajarawala & Jessica N. Pelkowski, *Telehealth Benefits and Barriers*, 17 J. FOR NURSE PRACS. 218, 218 (2021) ("Telehealth provides access to

Woebot's emulation of a living-and-breathing therapist is illustrative of the sweeping advancements AI and machine learning are making in the field of health care.[5] AI promises to revolutionize patient treatment with the development of algorithm-driven tools to improve efficiency in clinical care.[6] The data that these tools rely upon are gathered from a wide variety of sources: electronic health records, insurance claims, pharmacy records, and even information from fitness trackers can be sifted through by algorithms in search of patterns.[7] These patterns hold abundant potential for "resource allocation[] and treatment recommendations."[8] In fact, hospitals already implement algorithms for diverse scenarios; AI provides assistance in everything from making predictions about patient life expectancies to detecting the presence of melanoma simply from pictures of skin patches.[9] Medical reliance on AI technology will continue to grow, with the global AI-associated healthcare market projected to see a 35.9 percent compound annual growth rate from 2020 to 2027.[10]

As alluring as machine-driven learning may be given its potentialities, the incorporation of AI into the health care field has been received with trepidation.[11] This fear is understandable given the lack of transparency to the public surrounding the exact mechanisms for creating algorithms and the reasoning followed by the software.[12] Irrespective of whether this opacity is due to the complexity of the mechanisms themselves or whether developers have purposely obscured their techniques out of

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resources and care for patients in rural areas or areas with provider shortages, improves efficiency without higher net costs, reduces patient travel and wait times, and allows for comparable or improved quality of care."); *see also* Browne, *supra* note 2 (discussing the scarcity of mental health workers globally).

    [5] *See* Jennifer Bresnick, *Artificial Intelligence in Healthcare Market to See 40% CAGR Surge*, HEALTH IT ANALYTICS (July 24, 2017), https://healthitanalytics.com/news/artificial-intelligence-in-healthcare-market-to-see-40-cagr-surge [https://perma.cc/D3K9-CNY5].

    [6] W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, 14 SCITECH LAW. 10, 10 (2017).

    [7] *Id.*

    [8] *Id.* (discussing, for example, the likelihood of algorithms to be implemented into "widespread use" in image analysis to aid radiologists and anatomical pathologists).

    [9] *Id.*; Michelle Brubaker, A*rtificial Intelligence Tool Predicts Life Expectancy in Heart Failure Patients*, U.C. SAN DIEGO HEALTH (Nov. 13, 2019), https://health.ucsd.edu/news/releases/Pages/2019-11-13-artificial-intelligence-tool-predicts-life-expectancy-in-patients-with-heart-failure.aspx [https://perma.cc/842K-2ZDD].

    [10] Sarah Schmidt, *5 Key Healthcare Industry Trends to Watch in 2023*, MARKETRESEARCH.COM (Feb. 24, 2023), https://blog.marketresearch.com/5-key-healthcare-industry-trends-to-watch [https://perma.cc/U4C7-AJLR].

    [11] Robin C. Feldman et al., *Artificial Intelligence in the Health Care Space: How We Can Trust What We Cannot Know*, 30 STAN. L. & POL'Y REV. 399, 400, 403–04 (2019).

    [12] *See* Kyle T. Jorstad, *Intersection of Artificial Intelligence and Medicine: Tort Liability in the Technological Age*, 3 J. MED. A.I. 1, 1 (2020).

secrecy, AI in the healthcare system is aptly known as "black-box medicine."[13]

One particular area of concern that stems from this black-box nature of AI relates to tort liability issues.[14] Machine intelligence, while not susceptible to human error, is not impervious to faulty data or faulty algorithms.[15] Furthermore, algorithms are prone to bias, both in form of the exacerbation of biases already present in healthcare (i.e., algorithms that mirror racial or gender biases) and contextual bias (for example, algorithms that do not translate between high and low income contexts).[16]

Errors in any field of healthcare can have significant, life-threatening consequences.[17] Thus, the legal consequences for medical malpractice resulting from negligence can include hefty punitive damages, to hold tortious parties accountable.[18] However, lines of liability are not so easily drawn when AI is involved.[19] Consider again our friendly AI therapist, Woebot: what happens if Woebot's algorithm fails to detect a suicidal patient or recommends a faulty path of treatment?[20] When AI is utilized in healthcare and an AI-based recommendation causes problems in the diagnosis or treatment of a patient, who should bear the risk and responsibility? Should contributory negligence apply to consumers who may not necessarily understand the algorithmic mechanisms of the procedures and treatments they use?

In an effort to escape culpability, some AI developers have required waivers of liability, which ask consumers to

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[13] *See* W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine*, BIG DATA, HEALTH LAW, AND BIOETHICS 295, 295 (Glenn Cohen et al. eds., 2018).

[14] *See generally* Jorstad, *supra* note 12 (discussing the lack of legal framework surrounding AI tort liability issues).

[15] Joelle A. Hallak & Dimitri T. Azar, *The AI Revolution and How to Prepare for It*, TRANSLATIONAL VISION SCI. & TECH. 1, 2 (Mar. 2020).

[16] *See* W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 66, 67–68 (2019); Sharona Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 1, 4–5, 17–23 (2020) (providing numerous examples of algorithmic discrimination relating to "ethnicity, gender, age, socioeconomic status, and disability").

[17] *See Study Suggests Medical Errors Now Third Leading Cause of Death in the U.S.*, JOHNS HOPKINS MED. (May 3, 2016), https://www.hopkinsmedicine.org/news/media/releases/study_suggests_medical_errors_now_third_leading_cause_of_death_in_the_us [https://perma.cc/2YXX-77MG].

[18] Robert W. Shaw, *Punitive Damages in Medical Malpractice: An Economic Evaluation*, 81 N.C. L. REV. 2371, 2372 (2003).

[19] Jorstad, *supra* note 12, at 13–18 (discussing the current framework for AI-related medical malpractice claims and addressing gaps and complexities in the current model).

[20] *See generally* Rebecca Robbins, *As Patients Tell Apps They're Feeling Suicidal, Digital Health Startups Scramble to Respond*, STAT (Mar. 25, 2019), https://www.statnews.com/2019/03/25/patients-suicidal-thoughts-digital-health-apps-response/ [https://perma.cc/WH5W-A5UP] (describing a growing concern for digital health startups to figure out the best course for responding to patients who disclose suicidal thoughts using the apps).

assume the risk of using their software.[21] In the case of health and medical mobile apps, these waivers are often buried in a lengthy "Terms of Service" that a consumer must agree to in order to use the app.[22] An unwitting user may sign away, with the click of a button, their ability to litigate against a developer in the event they are injured.[23] For example, patients seeking to use Woebot must first click on a "next" button that conveys they agree to the following statement:

> Our Services and the Content provided therein are for informational and educational purposes and are not a substitute for the professional judgment and advice of health care professionals. The Content and the Services are not intended to be used for medical diagnosis or treatment. Persons accessing this information assume full responsibility for the use of the information. Woebot is not responsible or liable for any claim, loss, or damage arising from the use of the information.[24]

The statement above, which declares Woebot not liable from damage arising from its advice, is embedded in a multipage, single-spaced agreement that can only be accessed by clicking on a hyperlink entitled "Terms of Service" (i.e., it is not readily available on the same page as the one on which a user would be providing their assent to the relinquishment of their rights).[25] Furthermore, the option to "click away" rights is presented prior to enrollment in the program and prior to receiving more information about the workings of the app itself, when the user is still at the very preliminary stages of exploring what use of Woebot even entails.[26] As such, the contractual relationship between a Woebot user and Woebot's developers lacks mutual understanding and voluntariness at the core of a valid contract.[27]

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[21] Jorstad, *supra* note 12, at 12, 20.

[22] *See* Mark A. Lemley, *Terms of Use*, 91 MINN. L. REV. 459, 460 (2006); *see also* Cheryl B. Preston, *"Please Note: You Have Waived Everything": Can Notice Redeem Online Contracts?*, 64 AM. U. L. REV. 535, 558 (2015) (providing another example of an "incomprehensible" terms of service that a consumer would unlikely read).

[23] *See* Lemley, *supra* note 22, at 460.

[24] *Terms of Service*, WOEBOT HEALTH, https://woebothealth.com/terms-webview/ [https://perma.cc/6DEN-9R7L].

[25] *See id.*

[26] *See infra* Section III.C (discussing concerns surrounding heuristic bias and information asymmetry. These concerns are arguably especially pertinent in contexts where one party does not fully understand the services to which they are consenting).

[27] *See* RADIN, *supra* note 1, at 3 (describing the "story of bargained-for exchange" as representing the "world of voluntary agreement" and the perception of a contract as mutually "involv[ing] consent by each party to give up something of his or her own to obtain something he or she values more" as central to classic and modern contract theories).

The length and complexity of the Terms of Service or End-User License Agreement (EULA) is compounded by the fact that the consumer often does not fully understand the risk applicable to them.[28] As this note will further explore, the tendency for consumers to overestimate their understanding of the terms set forth in a boilerplate contract combined with their tendency to not take such terms seriously, is illustrative of the asymmetrical bargaining power between developers and consumers, and thus, grounds for the invalidation of such contracts.[29]

The law governing waivers lies at the intersection of tort law and contract law, but its application to exculpatory contracts and clauses between AI developers and patients has rarely been considered.[30] Even case law outlining the contractual relationship between providers and patients has only been addressed in select circumstances and jurisdictions.[31]

In *Tunkl v. Regents of University of California*, a controlling case often relied upon by the judiciary, the California Supreme Court adopted a six-factor test to decide whether an exculpatory clause violates public policy.[32] In contrast to previous cases that vaguely invoked public policy and contributed to a haphazard landscape of enforcement and

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[28] *See id.* at 26 (describing the tendency of individuals to underestimate risks as applicable to themselves due to heuristic biases); *see also* Ben Stegner, *8 Ridiculous EULA Clauses You May Have Already Agreed To*, MUO (Aug. 26, 2019), https://www.makeuseof.com/tag/10-ridiculous-eula-clauses-agreed/ [https://perma.cc/7KYC-JK35] (stating "[m]any EULAs contain thousands of words of confusing legalese, which can at times hide crazy terms and conditions").

[29] RADIN, *supra* note 1, at 26; *see also infra* Section III.C (discussing concerns surrounding heuristic bias and information asymmetry).

[30] Jorstad, *supra* note 12, at 13–18 (2020) (offering gaps in the current framework for AI-related medical malpractice claims and outlining the jurisdictional disagreements surrounding treatment of waivers of liability).

[31] *See infra* Section II.B (discussing the landmark case Tunkl v. Regents of University of California, 383 P.2d 441 (Cal. 1963), and its limited progeny). Waivers of liability have otherwise been discussed in the healthcare sphere in the context of nursing homes. *See* Gates v. Sells Rest Home, Inc., 57 S.W.3d 391, 399 (Mo. Ct. App. 2001); STV One Nineteen Senior Living, LLC v. Boyd, 258 So. 3d 322, 325 (Ala. 2018); *see also* Jorstad, *supra* note 12, at 20; WILSON ELSER MOSKOWITZ EDELMAN & DICKER LLP, EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES (2012) [hereinafter EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES].

[32] *Tunkl*, 383 P.2d at 445–46 (reasoning that the six factors to evaluate when identifying transactions affecting the public interest to be (1) whether the transaction "concerns a business . . . suitable for public regulation"; (2) whether the defendant engages in an important public service, "often a . . . practical necessity"; (3) whether the defendant "holds himself out [to the public] as willing to perform this service"; (4) whether the defendant possesses a bargaining advantage; (5) whether the defendant uses a "standard[ ] adhesion contract," forbidding a purchaser from obtaining protection against negligence; and (6) whether the plaintiff or his property is placed "under the control of the seller, subject to the risk of carelessness.").

nonenforcement of waivers,[33] *Tunkl*'s enumerated framework attempted to insert clarity and decisiveness into judicial interpretation.[34] Following the decision in *Tunkl*, a number of states started to strongly consider public policy when determining whether to hold a waiver of liability valid.[35] Courts in these states now balance the bargaining power of the two parties and have often invalidated exculpatory clauses where the party waiving liability is given no opportunity to consider alternatives.[36] While courts have generally been unwilling to uphold liability waivers that shield physicians in malpractice cases based on the reasoning in *Tunkl*,[37] they have occasionally found waivers to be valid where the services sought were experimental, alternative, or outside the medical mainstream.[38]

Aside from the analysis set forth in *Tunkl*, however, the law has unfortunately failed to adapt and keep up with advancing AI, neglecting concerns about holding developers responsible for their creations.[39] Unchecked, AI developers are not incentivized to ensure that their algorithms are free from error.[40] Just as the law surrounding general medical malpractice liability is underdeveloped relative to progresses in medicine,[41] the doctrine for AI waivers of liability lags behind technological innovation.[42] Should AI developers be allowed to require

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[33]   *See, e.g.*, Sears, Roebuck & Co. v. Poling, 81 N.W.2d 462, 465 (Iowa 1957); *see also* Kuzmiak v. Brookchester, Inc., 111 A.2d 425, 428–30 (N.J. Super. Ct. App. Div. 1955) (arguing that the meaning of "public policy" itself is "vague and variable").

[34]   Ryan Martins et al., Comment, *Contract's Revenge: The Waiver Society and the Death of Tort*, 41 CARDOZO L. REV. 1265, 1286–88 (2020).

[35]   *Id.* at 1288.

[36]   *See* EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES, *supra* note 31, at 1.

[37]   *See* Nadia N. Sawicki, *Choosing Medical Malpractice*, 93 WASH. L. REV. 891, 913 (2018).

[38]   *Id.* at 926–28.

[39]   *See* Jorstad, *supra* note 12, at 15 (highlighting the "inadequacies of the legal process for handling machine misdiagnoses"); Andrew D. Selbst, *Negligence and AI's Human Users*, 100 B.U. L. REV. 1315, 1322 (2020) ("[T]here are elements of the AI landscape—such as intense corporate secrecy, the contextual nature of AI, and the speed of AI development—which may prevent legal standards from developing fast enough without outside intervention.").

[40]   Frank Pasquale, *Data-Informed Duties in AI Development*, 119 COLUM. L. REV. 1917, 1918–20 (2019).

[41]   *See* Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7, 14–16 (2011) (contending medical malpractice law is outpaced by medical advances).

[42]   Frank Pasquale, *When Medical Robots Fail: Malpractice Principles for an Era of Automation*, BROOKINGS (Nov. 9, 2020), https://www.brookings.edu/techstream/when-medical-robots-fail-malpractice-principles-for-an-era-of-automation/ [https://perma.cc/W22W-QCPC] ("As courts develop such evolving standards of care, they will also face predictable efforts by owners of AI to deflect liability. Policymakers are struggling to keep pace with the speed of technological

consumers to sign these waivers in order to use their technology? And, if so, should the waivers be held unequivocally enforceable in a court of law?

This note sets out to provide solutions to the moral and legal concerns raised by AI creators' use of liability waivers, specifically in the context of direct-to-consumer healthcare apps, and argues that the seminal case of *Tunkl* provides an excellent framework for the judicial interpretation necessary to ensure accountability and transparency in AI-based treatment.[43] While all six factors examined in *Tunkl* can and should be weighed in reaching a decision, the fourth factor enumerated in *Tunkl*—the bargaining power dynamic between the two parties[44]—should hold controlling weight as it cuts at the very core of contract validity based on mutual understanding and voluntariness. Focusing on the power dynamic between AI developers and consumers is especially important in the healthcare app space because of the heavy influence of information asymmetry and heuristic biases exacerbated by the black-box nature of medicine.[45] This framework should be applied in invalidating exculpatory clauses contrary to public policy and in finding all waivers of liability required to be signed by app users to be presumptively invalid, regardless of categorization of the app (i.e., for both health apps and wellness apps).

Part I of this note briefly sets forth background information surrounding AI use in healthcare and discusses concerns arising from the black-box nature of algorithms, specifically relating to tort liability and apportionment of responsibility. Part II focuses on the use of liability waivers by AI developers to indemnify themselves in the case of medical malpractice and provides an overview of the legal landscape surrounding exculpatory contracts. Part III delves into a proposed solution for increasing transparency and accountability with respect to waivers of liability. This note acknowledges two extreme approaches for dealing with

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development."); Frank Pasquale, *Six Horsemen of Irresponsibility*, 79 MD. L. REV. 105, 109 (2019).

   [43] Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 443–47 (Cal. 1963); *see also* Martins et al., *supra* note 34, at 1286–88 (discussing how, "[u]nlike previous cases invoking public policy, *Tunkl* attempted to provide a clear and decisive framework for courts moving forward").

   [44] *Tunkl*, 383 P.2d at 446.

   [45] *See* RADIN, *supra* note 1, at 24, 26; *see also infra* Section III.C (discussing concerns surrounding heuristic bias and information asymmetry. This note argues that waivers of liability should be presumptively held invalid).

waivers[46] and argues that neither approach of universally holding waivers to be valid or invalid is realistic. Instead, courts should employ a fact-specific inquiry that adheres to the six-factor framework set forth in *Tunkl*, with controlling weight placed on the factor of bargaining dynamics as it relates to the foundational contractual elements of mutual understanding and voluntariness.[47] Centering concerns over bargaining power and voluntariness in judicial interpretation of exculpatory clauses, and thus upholding the principles of contractual freedom, is essential to establishing accountability and transparency in AI healthcare app use.

I.   DIGITAL HEALTH AND DIRECT-TO-CONSUMER ARTIFICIAL INTELLIGENCE IN THE FORM OF HEALTHCARE APPS

A friendly chat robot capable of diagnosing and treating a patient's illnesses through a dynamic, engaging conversation about their symptoms.[48] Life-saving predictive software that incisively mines through hospital data to calculate "a patient's risk of hospital-acquired infections."[49] An ambitious platform enabling hospital administrators, through automation, to switch focus from rote tasks to providing better quality patient care.[50] These are not the farfetched imaginings of a science fiction novel but rather the very real data-driven and algorithm-based technologies currently being developed and implemented around the world.[51]

A.   *The Digitization of Health and Utilizing AI in Care Apps*

The ubiquitous influence of AI reaches all corners of our lives; its integration in the sectors of finance, health care, and criminal justice proves machine-driven algorithms are

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[46] For an overview of the two competing approaches to waiver liabilities—holding all waivers invalid as a matter of public policy or holding all waivers to be valid as signed—see *infra* Section III.A.

[47] For a discussion of how adherence to the six-factor analysis set forth in *Tunkl* is key to increasing transparency and accountability through evaluation of the bargaining dynamic between AI developers and consumers, see *infra* Section III.B.

[48] *See* Sam Daley, *46 AI in Healthcare Examples Improving the Future of Medicine*, BUILT IN (last updated Jan. 3, 2023), https://builtin.com/artificial-intelligence/artificial-intelligence-healthcare [https://perma.cc/XWW6-U9H6] (describing briefly the functionalities and novel aspects of Buoy Health, an AI that assists with patient diagnosis and treatment).

[49] *See id.* (describing briefly the functionalities and novel aspects of the AI H20.ai).

[50] *See id.* (describing briefly the functionalities and novel aspects of the AI Olive).

[51] *See infra* notes 69–71 and accompanying text.

embedded within the fabric of society.[52] Concurrent with the rising reliance on AI technology is the increased demand for health services through electronic platforms. One of the main drivers of this growth has been the impact of AI on mobile healthcare, with AI projected to power 80 percent of the mobile technology used in healthcare apps by 2025.[53] With the Association of American Medical Colleges reporting that the United States could see "an estimated shortage of between 37,800 and 124,000 physicians by 2034,"[54] the need for automation in healthcare is evident.[55] Telemedicine, for example, has seen a large increase in popularity spurred by the COVID-19 pandemic, as patients sought treatment from the safety and convenience of their homes.[56] Apps have also seen growth in usage, with the average monthly hours spent on healthcare apps globally skyrocketing an impressive 40 percent during the pandemic.[57] In a time where many people were socially isolated and physically restricted from leaving their homes, the benefits of using healthcare apps proved multifold.[58]

Currently, there are numerous uses for AI in mobile healthcare, with algorithms helping to make patient treatment more streamlined and convenient.[59] One such utilization of AI is the automated prescription and diagnosis of patients, with AI-powered "chatbots" assessing a patient's symptoms and determining the best course of action.[60] Ada, a popular symptom assessment health app, uses customized, probability reasoning based technology to examine and evaluate user-inputted demographics and ultimately predict likely explanations for a

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[52] Darrell M. West & John R. Allen, *How Artificial Intelligence is Transforming the World*, BROOKINGS (Apr. 24, 2018), https://www.brookings.edu/research/how-artificial-intelligence-is-transforming-the-world/ [https://perma.cc/G36M-A674].

[53] *Id.*

[54] *AAMC Report Reinforces Mounting Physician Shortage*, AAMC (June 11, 2021), https://www.aamc.org/news-insights/press-releases/aamc-report-reinforces-mounting-physician-shortage [https://perma.cc/H9R5-678S].

[55] *See* Julie Davis, *FDA Regulation of Mobile Medical Apps*, AM. BAR ASS'N (July 17, 2017), https://www.americanbar.org/groups/litigation/committees/products-liability/practice/2017/fda-regulation-of-mobile-medical-apps/ [https://perma.cc/9UTR-X5PM].

[56] Oloeg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?*, MCKINSEY (July 9, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality [https://perma.cc/24FE-PH5G]; *see also* Elad Natanson, *Healthcare Apps: A Boon, Today and Tomorrow*, FORBES (July 21, 2020, 2:25 PM), https://www.forbes.com/sites/eladnatanson/2020/07/21/healthcare-apps-a-boon-today-and-tomorrow/?sh=5f1abab01bb9 [https://perma.cc/957M-DZZT].

[57] Natanson, *supra* note 56.

[58] *Id.*

[59] Amelia Scott, *The Rise of Health Mobile Apps and mHealth Applications of AI and ML*, TNT (Oct. 30, 2021), https://www.the-next-tech.com/health/the-rise-of-health-mobile-apps-and-mhealth-applications-of-ai-and-ml/ [https://perma.cc/XWW6-U9H6].

[60] *Id.*

user’s symptoms.[61] Apps such as Ada take advantage of advanced data analytics to tout personalized treatment plans and deliver patient insights.[62] The development of algorithms that can sift through large amounts of medical data with the ability to classify, cluster, and extract information for a patient’s needs allows Ada and other health apps to deliver timely assessments.[63]

Mental health-geared AI chatbots have attracted millions of users.[64] Although users have previously doubted the efficacy of therapist chatbot apps due to their inability to truly replicate human interaction, AI is rapidly advancing to better emulate the personal bonds created between patients and healthcare professionals.[65] According to a cross-sectional, retrospective study of 36,070 Woebot users, consumers were able to relate to the conversational agent presented in the app in a manner comparable to that of human-to-human therapy.[66]

Another impactful use of AI in the mobile healthcare space is the streamlining, through automation, of administrative work such as appointment booking and billing payments.[67] By handing off the administrative grunt work to AI counterparts, healthcare providers are better able to prioritize and allocate resources to improving quality patient care.[68] Some apps have successfully navigated administrative and medical work with the help of AI. Chatbots, like the one used by German telemedicine app TeleClinic, have drastically improved customer service by providing quick, automated answers to patients with administrative queries, while escalating other concerns to human agents.[69] AI has also allowed TeleClinic to

[61] *How Does the Symptom Assessment Work?*, ADA, https://ada.com/help/360000319469/ [https://perma.cc/4JER-UG6M]; *How Do I Complete a Symptom Assessment?*, ADA, https://ada.com/help/360000308885/ [https://perma.cc/MK9Q-5Q39]. Of note, Ada’s disclaimer page acknowledges risk of errors in assessment. *Ada Didn’t Spot a Condition I Had That Turned Out to Be Serious. How Will You Address this Safety Issue?*, ADA, https://ada.com/help/360000705180/ [https://perma.cc/5QH3-YFHG].

[62] Scott, *supra* note 59.

[63] Hannah Johnson, *10 Best AI Based Healthcare Apps You Can Try in 2020*, SWISS COGNITIVE, https://swisscognitive.ch/2020/03/27/10-best-ai-based-healthcare-apps-you-can-try-in-2020/ [https://perma.cc/6RD2-4V3K].

[64] Browne, *supra* note 2.

[65] Alison Darcy et al., *Evidence of Human-Level Bonds Established with a Digital Conversational Agent: Cross-sectional Agent: Cross-Sectional, Retrospective Observational Study*, JMIR FORMATIVE RSCH. 1, 2 (May 2021); *What Powers Woebot*, *supra* note 3.

[66] *See* Darcy et al., *supra* note 65, at 1.

[67] Scott, *supra* note 59.

[68] *See id.*

[69] *How TeleClinic Revolutionized Customer Service in Telemedicine with AI-powered Automation*, ULTIMATE.AI, https://www.ultimate.ai/customer-stories/teleclinic [https://perma.cc/9CPZ-LPTG].

prioritize cases by detecting the urgency of patients' queries.[70] While AI software has helped healthcare make monumental strides, reliance on such software in the course of patient treatment has also been cause for concern for legal scholars, healthcare professionals, and consumers alike.[71]

Despite its exciting potential to revolutionize healthcare and medicine, the black box nature of AI poses considerable risks to providers and patients, who are unable to decipher "the mechanistic underpinnings" of treatment recommendations.[72] Because use of black-box medicine requires trust in the unknowable, tort liability issues abound.[73] Machine intelligence is susceptible to error if faulty algorithms are derived from incomplete or skewed data.[74] Studies on algorithm-based applications used to assess skin cancer risks in adults have shown that such applications could not be relied on to detect all cases of melanoma or other skin cancers.[75] Furthermore, algorithms are prone to biases, and their implementation can uphold and exacerbate existing discriminatory structures within healthcare.[76] For example, studies support differences between treatment recommendations based on patient demographics; if an algorithm is fed data where women were given less intensive care than their male counterparts, the algorithm will then likely perpetuate such undertreatment with its recommendations.[77]

B.   *Regulation of Health and Wellness Apps*

The genre of healthcare apps spans across different industries and includes both health apps and wellness apps.[78] The US Food and Drug Administration (FDA) makes a distinction between apps that constitute medical devices and

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[70]   *Id.*

[71]   *See* Feldman et al., *supra* note 11, at 400–01.

[72]   Price II, *supra* note 13, at 295.

[73]   *See id.* at 300–01.

[74]   Pasquale, *supra* note 40, at 1924.

[75]   *See* Michael Phillips et al., *Assessment of Accuracy of an Artificial Intelligence Algorithm to Detect Melanoma in Images of Skin Lesions*, JAMA NETWORK OPEN (Oct. 16, 2019), at 1–2 (finding that, while an AI algorithm was successful in detecting melanoma by assessing skin lesion images, "the algorithm achieved a specificity of 64.8[percent]," which was lower than the 69.9 percent achieved by clinicians).

[76]   Price II, *supra* note 16, at 68; *see also* Hoffman & Podgurski, *supra* note 16, at 1, 4–5, 17–23 (providing numerous examples of algorithmic discrimination relating to "ethnicity, gender, age, socioeconomic status, and disability").

[77]   Hoffman & Podgurski, *supra* note 16, at 16.

[78]   *See* Alicia Phaneuf, *How mHealth Apps are Providing Solutions to the Healthcare Market's Problems*, INSIDER (Dec. 4, 2019; 11:15 AM), https://www.businessinsider.com/mhealth-apps-definition-examples [https://perma.cc/6JUD-D52G].

those that do not for regulation purposes.[79] FDA guidance finds that health apps that "may be intended for use in the diagnosis of disease . . . or in the cure, mitigation, treatment, or prevention of disease" to constitute medical devices,[80] and are thus subject to more federal oversight than wellness apps that "make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness."[81]

Direct-to-consumer health apps often come in the form of "symptom checker[s]," where a mobile software asks the user to input symptoms they are experiencing and offers diagnostic tools—much as a physician would traditionally administer during an in-person office visit.[82] Use of mobile health apps is encouraged and implemented by healthcare professionals themselves.[83] Physicians and other healthcare practitioners may also use health apps for performing "higher-level medical activities" in the course of a patient's treatment, which could include anything from measuring their "blood glucose levels" to "performing electrocardiograms."[84] Given their preventative and diagnostic intended use, health apps are subject to FDA regulation and must undergo premarket clearance, pass quality checks, bear accurate product labeling, and report adverse outcomes.[85] Health apps are also required to be compliant with the Health Insurance Portability Accountability Act (HIPAA) as they store and aggregate personal information and medical records of their users.[86]

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[79] *Examples of Device Software Functions the FDA Regulates*, FDA (last updated Sept. 29, 2022), https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-device-software-functions-fda-regulates [https://perma.cc/L6GB-CTBP].

[80] *Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion*, FDA (last updated Sept. 29, 2022) [hereinafter *Enforcement Discretion Examples*], https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion [https://perma.cc/ZFH6-FSJZ].

[81] *Examples of Software Functions That Are NOT Medical Devices*, FDA (last updated Sept. 29, 2022), https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-are-not-medical-devices [https://perma.cc/76PY-6LTU].

[82] *See* Daley, *supra* note 48; Julie Davis, *FDA Regulation of Mobile Medical Apps*, AM. BAR ASS'N (July 17, 2017), https://www.americanbar.org/groups/litigation/committees/products-liability/practice/2017/fda-regulation-of-mobile-medical-apps/ [https://perma.cc/5UJ3-2FAP]; *Enforcement Discretion Examples*, *supra* note 80 (describing software that "use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice").

[83] *See* Davis, *supra* note 82.

[84] *Id.*

[85] *See id.*

[86] *See How to Know if Your App Should Be HIPAA Complaint*, MINDSEA, https://mindsea.com/hipaa-compliant/ [https://perma.cc/R6TU-3WHQ].

Wellness apps, which can address everything from diet and physical fitness to spiritual and mental health,[87] are generally subject to less governmental regulation than health apps that are considered medical devices.[88] Of significant concern is that the FDA generally adopts a "hands-off policy" for software that is "not intended for medical use" and leaves the responsibility of preventing consumer harm "to [software] developers and app marketplaces."[89] As discussed below, developers have tried to shirk such responsibility and accountability by having users sign clickwrap agreements and terms of service, often with embedded exculpatory clauses, in order to use their software.

II.   A BURGEONING CONCERN: LIABILITY WAIVERS BETWEEN AI DEVELOPERS AND CONSUMERS

Healthcare is distinctive in that it "always has been a place where individuals must put their faith in that which they do not fully understand."[90] Indeed, healthcare is built on trust, despite there being gaps in knowledge between patients and providers and around the opaque workings of medicine and science. This knowledge gap is mirrored in the development of AI-based healthcare.[91] Because AI-based medicine is aptly characterized as a "black box," many people are reasonably fearful of AI-based healthcare for several reasons.[92]

First, and perhaps most importantly, the algorithms themselves are often prohibitively complicated and not readily understandable by anyone other than their developers, much less the average consumer.[93] Second, lack of government regulation overseeing and ensuring the transparency of algorithms allows developers to keep their inventions opaque and does not incentivize them to make concerted efforts towards increasing the understanding of their consumers.[94] This lack of transparency stands in stark contrast to other areas of law, including patent law, where the government requires explicit

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[87] Natanson, *supra* note 56; *see also Wellness Apps*, UNIV. OF HOUS., https://www.uh.edu/wellness/resources/wellness-apps/ [https://perma.cc/4688-DU3L].

[88] T.J. Kasperbauer & David E. Wright, *Expanded FDA Regulation of Health and Wellness Apps*, 34 BIOETHICS 235, 235 (2020).

[89] *Id.*

[90] *See* Feldman et al., *supra* note 11, at 399.

[91] *Id.*

[92] *Id.* at 400.

[93] *See id.*

[94] *See generally* Kasperbauer & Wright, *supra* note 88 (criticizing the "hands-off" policy adopted by the FDA towards regulating health and wellness apps and calling for heightened FDA requirements).

public disclosure of an invention's workings to support collaboration between innovators and make transactions in the marketplace more efficient, to the benefit of both inventors and consumers.[95] In fact, legal scholars contend that AI's black-box obscurity directly challenges patent law disclosure theory such that enhanced disclosure requirements for AI inventions should be necessary.[96]

An additional complication is that opaque algorithms are also "likely to change over time" given the ever-evolving nature of technology, which further obscures the ability for consumer comprehension.[97] While sometimes this change is spurred by the developer through routine updates,[98] machine-learning can result in the change of AI without developer influence because of its ability to adapt on its own.[99] This built-in autonomy can be frightening for the consumer as they are being subject to an algorithm they do not fully understand that also evolves as it works.[100]

Because the general public and healthcare providers lack understanding of the actual mechanisms of the algorithms used in mobile health apps, liability apportionment for when AI malfunctions or errs is a special cause for concern and an area of tort law that remains largely uncharted, controversial, and jurisdiction-dependent.[101] While the FDA places guidelines and regulations upon apps that are intended for medical use, the responsibility for consumer protection generally falls in the

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[95] *See* Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L.J. 369, 369–73 (2013). One of the main theories behind patent law is that disclosure of an invention's workings benefits the economy through constant spurring of new technology and allowing for inventors to build off each other's ideas. The detail with which a patentee must go into in describing their invention is such that a person of ordinary skill in the art would be able to recreate the invention. Requirements for a valid patent, such as nonobviousness, novelty, and adequate disclosure, necessitate that patentees provide detailed descriptions of the theories and workings behind their inventions. *Id.* at 369–75.

[96] Tabrez Y. Ebrahim, *Artificial Intelligence Inventions & Patent Disclosure*, 125 PENN ST. L. REV. 147, (2020).

[97] Price II, *supra* note 6, at 10; *see* Avraham, *supra* note 41, at 14–16.

[98] Ayo Oladele, *Mobile App Update: Why and How*, VELVETECH (last updated Dec. 12, 2022), https://www.velvetech.com/blog/mobile-app-update/ [https://perma.cc/V8QJ-RLGF].

[99] Edd Gent, *Artificial Intelligence is Evolving All by Itself*, SCI. (Apr. 13, 2020), https://www.science.org/content/article/artificial-intelligence-evolving-all-itself [https://perma.cc/ZB8V-VJ4Z].

[100] *See id.*

[101] *See* EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES, *supra* note 31, at 1 (generally explaining that liability waivers are only effective to the extent they explicitly set forth the risks and the jurisdictional differences in assumption of risk the tort doctrine); *see also Who Gets the Blame When a Digital Health App Is Wrong?*, DIGITAL HEALTH BUZZ! (Jan. 2021), https://digitalhealthbuzz.com/who-gets-the-blame-when-a-digital-health-app-is-wrong/ [https://perma.cc/8M8Q-BVW8] (explaining the practical complications in establishing liability for injury caused by an AI medical misdiagnosis).

hands of developers for the realm of all other health and wellness apps.[102] This increased responsibility is especially problematic when developers try to shirk and contract around their duties.[103]

## A.	*Use of Liability Waivers to Escape Culpability*

One consequential and noteworthy way in which AI developers have tried to escape liability is through the growing use of liability waivers. Through these waivers, developers seek to (and may successfully) indemnify themselves in the case of medical malpractice.[104] Indeed, legal scholars express concern that developers will become increasingly reliant on waivers to escape culpability, with University of Florida Levin College of Law Professor Amy Stein remarking that "it is not so far-fetched to imagine manufacturers of AI-driven devices like robots requiring purchasers to sign an express assumption of risk agreement."[105]

Apportioning liability when AI is involved is especially murky due to the black-box nature of AI-powered medicine.[106] If healthcare providers and the general public do not understand the mechanisms of the algorithm, how can we pin responsibility on consumers using the technology? Should consumers be responsible for understanding the technology before clicking "I agree?" Specifically, pertaining to mobile health apps, should a disclaimer stating that the medical advice provided to the consumer is not a substitute for professional advice from a doctor be enough to free AI developers of all culpability?[107]

In the current legal landscape, most states generally recognize exculpatory clauses to be enforceable if valid.[108] However, state courts do not want to incentivize complete abdication of culpability and have strictly construed terms of contract provisions, even if the contract itself is held as valid.[109]

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[102]	T.J. Kasperbauer & David E. Wright, *supra* note 88, at 235.

[103]	*See* Pasquale, *supra* note 40, at 1917.

[104]	*See* Pasquale, *supra* note 42, at 109.

[105]	Amy L. Stein, *Assuming the Risks of Artificial Intelligence*, 102 B.U. L. REV. 979, 1009–10 (2022); *see also* Phillip Kelly et al., *Man vs Machine: Legal Liability in Artificial Intelligence Contracts and the Challenges That Can Arise*, DLA PIPER (Oct. 6, 2021), https://www.dlapiper.com/en/insights/publications/2021/10/man-vs-machine-legal-liability-artificial-intelligence-contracts [https://perma.cc/LL8N-PVKD].

[106]	*See* Price II, *supra* note 6, at 10–11.

[107]	See *infra* Section III.C for discussion arguing against allowing consumers to click away their rights through Terms of Services presented to them before using a mobile health app given the heavy influence of information asymmetry and heuristic biases at the moment the consumer is given the decision.

[108]	EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES, *supra* note 31, at 1.

[109]	*Id.*

Valid releases of future liability also vary by jurisdiction and between states.[110] For instance, some states highly disfavor the use of exculpatory clauses, with Virginia and Montana prohibiting provisions and exculpatory clauses that universally release parties from future negligence.[111] Along with general strict interpretation of contract provisions in exculpatory clauses, many states[112] also require that the provisions be "clear, unambiguous, and explicit in expressing the intent of the parties" and defining the scope of the waiver of liability.[113]

B.   Tunkl v. Regents of University of California *and its Aftermath*

Still, exculpatory clauses that are valid under a state's statutes can nevertheless be deemed voidable if they are against public policy.[114] Arguably the most influential and seminal case in exculpatory clause precedent is *Tunkl v. Regents of University of California*.[115] Plaintiff Hugo Tunkl was selected to participate in a research project conducted by the University of California at the Los Angeles Medical Center (UCLAMC).[116] Notably, UCLAMC was a nonprofit charitable research hospital operated by the Defendant.[117] Upon admission, Tunkl signed a "Conditions of Admission" document, which included an exculpatory clause, agreeing to release the Defendant from any liability that might result from "negligent or wrongful acts or omissions of its employees," as long as the defendant had "used due care" in hiring the workers.[118] However, at the time of signing, Tunkl was under sedation and experiencing significant pain; he was likely unable to even read the contract.[119] Tunkl unfortunately sustained personal injuries from the negligence of two physicians employed by the defendant and thus brought suit to recover damages.[120]

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[110]   *Id.*

[111]   *Id.* at 13, 20.

[112]   CAL. CIV. CODE § 1668 (West, Westlaw current with ch. 1 of 2023-24 1st Ex. Sess, and urgency legis. through Ch. 2 of 2023 Reg. Sess.); Milligan v. Chesterfield Vill. GP, LLC, 239 S.W.3d 613, 616 (Mo. Ct. App. 2007).

[113]   MATTHIESEN, WICKERT & LEHRER, S.C., EXCULPATORY AGREEMENTS AND LIABILITY WAIVERS IN ALL 50 STATES 9 (2022), https://www.mwl-law.com/wp-content/uploads/2018/05/EXCULPATORY-AGREEMENTS-AND-LIABILTY-WAIVERS-CHART.pdf [https://perma.cc/7FUJ-L2A2].

[114]   Sawicki, *supra* note 37, at 914.

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

[116]   *Id.* at 442.

[117]   *See id.*

[118]   *Id.*

[119]   *Id.* at 442 n.1.

[120]   *Id.* at 442.

The California Supreme Court, in reaching its holding of invalidating the exculpatory clause, centered its reasoning on public policy and adopted a six-factor analysis.[121] The court weighed factors which consisted of (1) whether the transaction "concerns a business . . . suitable for public regulation"; (2) whether the defendant engages in an important public service, "often a . . . practical necessity"; (3) whether the defendant "holds himself out [to the public] as willing to perform this service;" (4) whether the defendant possesses a bargaining advantage; (5) whether the defendant uses "a standard[] adhesion contract," forbidding a purchaser from "obtain[ing] protection against negligence;" and (6) whether the plaintiff or his property "is placed under the control of the seller, subject to the risk of carelessness."[122] These factors have had a lasting impact on how states generally recognize exculpatory clauses and still remain influential on judicial reasoning.[123]

Indeed, post-*Tunkl*, courts across the country "embraced public policy as a driving determinant of waiver validity," and such policy-driven reasoning "created an environment in which exculpatory clauses [were] denied sometimes as a matter of principle and at other times as a matter of pragmatism."[124] Notably, the flexible, fact-specific framework of *Tunkl* allowed for courts to shield a greater number of "sympathetic plaintiffs" who are "under the protective umbrella of . . . public interest," without forcing courts to jump through hoops by having to construct "a strained interpretation of a waiver's language."[125]

Despite wide adaptation of *Tunkl*, however, the legal validity of waivers is far from uniform and has been met with much scrutiny and calls for a reversion to strict, formalist interpretations of contract law.[126] In fact, legal scholars asserted "that the freedom of contract 'ethic is weakening and the scope of public interest is widening,'" as concerns arose that courts were relying too heavily on public policy in invalidating waivers.[127]

Such fears and skepticism were supported by controversial holdings such as *Meiman v. Rehab. Ctr., Inc.*, where the Court of Appeals of Kentucky labeled a waiver as

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[121]   *Id.* at 441–42, 445–46.

[122]   *Id.* at 445–46.

[123]   *See* Alex Conant, *Liability Waivers Are Not a Silver Bullet*, AMINI & CONANT (June 17, 2020), https://aminiconant.com/liability-waivers-a-primer/ [https://perma.cc/Z7P4-Z5XX].

[124]   Martins et al., *supra* note 34, at 1289 (alteration in original).

[125]   *Id.* at 1288–89.

[126]   *Id.* at 1288–92.

[127]   *Id.* at 1289 (quoting Anita Cava & Don Wiesner, *Rationalizing a Decade of Judicial Responses to Exculpatory Clauses*, 28 SANTA CLARA L. REV. 611, 638 (1988)).

"against public policy" under *Tunkl* and reasoned that further discussion was unnecessary.[128] In response to such controversial holdings relying on *Tunkl*, post-1980, "state courts [implemented] partial or modified versions of *Tunkl*" in an effort "to narrow the scope of the public interest grounds for nonenforcement" of liability waivers.[129] Other states, including Ohio and Maryland, "simply rejected *Tunkl*,"[130] and have yet to implement an explicit or decisive public policy evaluation process for waiver enforceability.[131] These states continue to emphasize strict construction as the central analysis for whether a waiver should be held valid because it minimizes concerns surrounding the bargaining process and an overemphasis on public policy.[132] They instead purport that reliance on *Tunkl* interferes with the "inherent market efficiency central to the freedom of contract justification."[133]

Courts continue to carve out exceptions to *Tunkl* in the healthcare space.[134] While *Tunkl*'s lasting legacy has been that courts are generally unwilling to allow physicians to avoid malpractice liability by requiring patients to sign liability waivers,[135] there is growing case law of waivers that have been validated by the court in specific circumstances.[136] For example, exculpatory agreements have been found valid in select cases where services sought were experimental, alternative, or generally outside the medical mainstream.[137] The consequences of this 1980s and 1990s counter to the *Tunkl* revolution have thus been sweeping in multiple jurisdictions across the country and have significant implications on direct-to-consumer healthcare apps.[138] Where once liability waivers seemed to be headed for

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[128] Meiman v. Rehab. Ctr., Inc., 444 S.W.2d 78, 80 (Ky. 1969).

[129] Martins et al., *supra* note 34, at 1289. For example, the Minnesota Supreme Court seemed to do away with some of the factors of the *Tunkl* analysis by adopting a "'two-prong test' for the public interest, [inquiring]: (1) whether a disparity of bargaining power existed between the parties, and (2) whether the type of service being offered or provided was a public or essential service." *Id.*

[130] *Id.* at 1291 (citing Cava & Wiesner, *supra* note 127, at 614–20); *see also* Wolf v. Ford, 644 A.2d 522, 527 (1994) (expressly declining to adopt *Tunkl*'s six-factor test).

[131] Martins et al., *supra* note 34, at 1289–90, 1294; EXPRESS ASSUMPTION OF RISK/WAIVER/EXCULPATORY CLAUSES, *supra* note 31.

[132] Martins et al., *supra* note 34, at 1290.

[133] *Id.* at 1291–92.

[134] *See* Sawicki, *supra* note 37, at 913, 920.

[135] *See* Martins et al., *supra* note 34, at 1286–89.

[136] Sawicki, *supra* note 37, at 913–14.

[137] *See, e.g.*, Spar v. Cha, 907 N.E.2d 974, 982 n.2 (Ind. 2009); Schwartz v. Johnson, 49 A.3d 359, 371 (Md. Ct. Spec. App. 2012).

[138] *See* Martins et al., *supra* note 34, at 1290–92; *see also* Bradley v. Nat'l Collegiate Athletic Ass'n, 464 F. Supp. 3d 273, 295 (D.D.C. 2020) (discussing case law where courts expressly declined to follow the *Tunkl* framework).

extinction as a result of *Tunkl*, they are now burgeoning,[139] much to the detriment of the healthcare app consumer.[140]

III.   BARGAINING DYNAMICS AS THE CORNERSTONE TO INCORPORATION OF THE *TUNKL* FRAMEWORK AND UNIVERSAL TREATMENT OF HEALTH APPS

Given the myriad of concerns surrounding apportionment of liability and its inextricability with politics and public policy, it is no wonder that the use of exculpatory clauses in the healthcare space is a controversial topic that draws polarizing opinions.[141] One judicial perspective argues that waivers have no place in treatment as their use violates the fiduciary responsibilities of doctors to their patients.[142] Closely related to this rationale is the proposal that a business meeting the appropriate standard of care does not need waivers, and allowing the use of waivers may disincentivize AI developers from taking necessary precautions to carefully develop their algorithm.[143]

The other extreme approach to liability waivers is that they should always be upheld. Proponents of this view believe that it is the responsibility of consumers to read the Terms of Service carefully and evaluate the quality of the black-box algorithm before agreeing to waive their right to pursue legal action against developers and before relying on them for diagnosis and treatment of their health.[144] Such proponents fall in line with the theory that a strict adherence to contracts and strict interpretation of waivers will prevent overemphasis on the bargaining process and public policy and instead, emphasize the market efficiency central to contract law.[145]

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[139]   Martins et al., *supra* note 34, at 1289, 1294 (discussing reasons for and against relying on public policy when invalidating exculpatory contracts, as well as scrutiny and criticism surrounding reliance on *Tunkl*).

[140]   *See supra* Section II.A.

[141]   *See* Sawicki, *supra* note 37, at 892 (describing the debate surrounding use of contractual modifications to release physicians from liability as "long-standing"); Interview with Frank Pasquale, Professor at Brooklyn Law School (Sept. 27, 2021).

[142]   Sawicki, *supra* note 37, at 918–24.

[143]   *See infra* notes 159–163 and accompanying text; Interview with Frank Pasquale, Professor at Brooklyn Law School (Sept. 27, 2021).

[144]   *See* Preston, *supra* note 22, at 571.

[145]   *See* Martins et al., *supra* note 34, at 1289.

A. *The Role of Judicial Intervention in Consumer Protection Through Adherence to the Framework Set Forth in* Tunkl

Both extreme approaches, in isolation, are inadequate. Getting rid of liability waivers entirely would likely discourage inventors and developers from creating cutting-edge, innovative technology and algorithms with life-saving potential.[146] The stunting of "entrepreneurial energy" by overregulation and governmental intervention is a key concern to Big Tech; the attitude of "Permissionless Innovation," as espoused by the CATO Institute, posits "that experimentation with new technologies and business models should generally be permitted by default."[147]

However, judicial intervention by means of always upholding waivers in court would likely disincentivize developers from spending time and resources on maximizing the reliability and quality of their software such that risks to consumers are minimized.[148] Furthermore, universal treatment of waivers, as opposed to judicial emphasis on a fact-specific and circumstance-specific inquiry, would invite widespread criticism from skeptics of *Tunkl* and its public-policy focused offspring.

Ideally, a multifaceted approach that involves the legislature, judiciary, and federal government would demand more accountability from both the AI developers themselves and the healthcare professionals implementing the software. There is an exigent need for judges, legislators, and federal agencies to outline the sharing of responsibility and accountability for negative outcomes from black-box medicine as soon as possible, while AI technology is still growing and not universally relied upon.[149] However, judicial interpretation is of particular importance in providing consumer protection by invalidating

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[146] *See* Neil Chilson & Adam D. Thierer, *The Coming Onslaught of 'Algorithmic Fairness' Regulation*s, REGUL. TRANSPARENCY PROJECT FEDERALIST SOC'Y (Nov. 2, 2022), https://rtp.fedsoc.org/wp-content/uploads/The-Coming-Onslaught-of-Algorithmic-Fairness-Regulations.pdf [https://perma.cc/86VC-WJWE]; *see also* Russell Brandom, *The Regulatory Fights Facing Every Major Tech Company*, VERGE (Mar. 3, 2020, 9:20 AM), https://www.theverge.com/2020/3/3/21152774/big-tech-regulation-antitrust-ftc-facebook-google-amazon-apple-youtube [https://perma.cc/ZY7Q-V3KF].

[147] *See* Adam D. Thierer, *Embracing a Culture of Permissionless Innovation*, CATO INST. (Nov. 17, 2014), https://www.cato.org/cato-online-forum/embracing-culture-permissionless-innovation [https://perma.cc/69MA-5LNS].

[148] *See infra* notes 160–163 and accompanying text.

[149] *See* Jorstad, *supra* note 12, at 15 (highlighting "the inadequacies of the legal process for handling machine misdiagnoses").

waivers that are contrary to public policy.[150] The breakneck speed of technological innovation in AI, combined with the slow machinery of legislation and incorporation of provider feedback, is prohibitively limiting.[151]

There is already a solid framework for judicial interpretation of liability waivers through the doctrine set forth in *Tunkl*.[152] This framework should be applied to invalidate exculpatory clauses contrary to public policy and presume all waivers of liability required to be signed by app users to be presumptively invalid, regardless of their categorization as a health app backed by scientific evidence or a wellness app with less empirically based data.

The six factors set forth in the *Tunkl* analysis are all important and should be weighed holistically in evaluating whether an exculpatory clause presented by a mobile healthcare app should be held valid in court. For example, the factor considering whether the defendant holds himself out to the public as willing to perform this service[153] is especially relevant in the mobile healthcare app space. Many of these apps are found in the app marketplace and are readily and easily downloadable by anyone with access to the App Store.[154] As such, the defendant is clearly holding themselves out to the public without discerning between users and their varying needs for the application or varying risks or health conditions they may possess.[155]

Most important to consider is the factor of whether, "[a]s a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possesses a decisive advantage of bargaining strength against any member of the public who seeks his services."[156] Examples of important considerations that should be weighed in assessing the bargaining power dynamic between parties include (1) the existence of other similar software in the market and the ability of the consumer to "shop around" or explore alternatives, (2) the ability of the consumer to comprehend and understand the risks involved with using the software, and (3) whether or not the

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[150] *See* Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963); *see also* Paula D. Vraa & Steven M. Sitek, *Public Policy Considerations for Exculpatory and Indemnification Clauses: Yang v. Voyagaire Houseboats, Inc.*, 32 WM. MITCHELL L. REV. 1315, 1319–23 (2006).

[151] Avraham, *supra* note 41, at 14–16; Pasquale, *supra* note 42.

[152] *See* Martins et al., *supra* note 34, at 1289.

[153] *Tunkl*, 383 P.2d at 445, 447.

[154] *See App Store Review Guidelines*, APPLE, https://developer.apple.com/app-store/review/guidelines/ [https://perma.cc/3W3D-CWS6].

[155] *See id.*

[156] Conant, *supra* note 123.

exculpatory clause was presented in a reasonably accessible and clear and unambiguous manner to the consumer.

Bargaining power is arguably the most important *Tunkl* factor to weigh in a fact-specific inquiry as it is particularly pertinent to direct-to-consumer healthcare apps. There is a large bargaining inequality between AI developers and the average consumer using their mobile healthcare app due to the specialized knowledge needed to develop AI and the opacity of generated algorithms.[157] AI developers are best situated to protect consumers,[158] and they should adhere to their moral responsibility towards consumers by improving the transparency and "explainability" of their research and practices.[159] By holding liability waivers invalid, developers would arguably be incentivized to prevent errors from happening, or at the very least better disclosing risks of using their AI technology.[160] Increased time and effort spent on ensuring training data quality during the product development stage would attack the root of the problem by increasing the reliability of AI and hopefully stagnate reliance on liability waivers.[161]

Developers should focus on bridging the gap in knowledge between AI developers and consumers so that consumers are better aware of what they are getting into and can make an informed decision. This can be achieved by establishing guidelines for developers concerning how easily interpretable and explainable their algorithms are by both providers and other manufacturers (or those of ordinary knowledge in the art).[162] For instance, developers should be incentivized to transparently disclose the machinery behind

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[157]   *See* Stein, *supra* note 105, at 1006–07.

[158]   *See id.* at 1006–07 (noting "not all AI users will be data scientists or engineers"); *see also* Mark Ryan & Bernd Carsten Stahl, *Artificial intelligence Ethics Guidelines for Developers and Users: Clarifying Their Content and Normative Implications*, 19 J. INFO. COMM. & ETHICS IN SOCIETY 61, 66–72 (2021) (discussing ethical concerns surrounding AI development and suggesting guidelines for developers to implement for consumer protection).

[159]   *See* Ryan & Stahl, *supra* note 158, 66–72 (describing "explainability" as the ability of an AI system to provide understandable and clear reasoning behind its decision-making process).

[160]   *See* Stein, *supra* note 105, at 1007–08 (proffering that unavailability of assumption of risk defenses may incentivize better explanations of AI by companies).

[161]   *See* Ryan, *supra* note 158, at 66–67 (addressing the need for AI developers to use data that is "accurate, up-to-date and fit-for-purpose").

[162]   *See* Rantanen, *supra* note 95, at 383. One of the main theories behind patent law is that disclosure of an invention's workings benefits the economy through constant spurring of new technology and allowing for inventors to build off each other's ideas. *See id.* The detail with which a patentee must go into in describing their invention is such that a person of ordinary skill in the art would be able to recreate the invention. *Id.* Here too, app developers should have to disclose the inner workings of their inventions in order to have their app released to the marketplace.

their algorithms in an easily interpretable and explainable manner. Also, developers should be required to seek peer review of algorithms and software to expose and address weaknesses in models by diverse researchers, educators, and data scientists.[163] Further, they should also require extensive development and testing to produce data that objectively demonstrates the effectiveness of the software such that when the technology is integrated into the clinical decision-making process, the patient's outcome (both clinical and qualitative) is improved.[164]

The current nonexistence of such regulations is illustrative of the bargaining power inequality between consumers and AI developers. Consumers are not able to make informed decisions regarding which app to use because they must rely on developers' good faith that algorithm development and testing have been adequately implemented.[165]

B.   *Bargaining Dynamics, the Crucial* Tunkl *Factor, and the "Freedom of Contract"*

The counter-revolution to *Tunkl* and increased reliance on liability waivers is not only dangerous but erroneous.[166] While proponents of strict contract and waiver liability adhesion may argue that the meaning of "public policy" is vague and variable,[167] and that overemphasizing the importance of public policy is at odds with the free market and the principles of contract law,[168] the concepts of public policy and freedom of contract are not incompatible with one another. In fact, upholding freedom of contract is arguably the ultimate preservation of the public interest.[169] As such, the framework provided by *Tunkl* does not fly in the face of contractual freedom, as skeptics may argue,[170] and instead places much needed emphasis on the foundational principles of contract law, which are (1) mutual understanding

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[163]   *See id.*

[164]   *See id.* at 370.

[165]   For example, companies have been found to market their product as a medical device as opposed to a drug to avoid more stringent regulations and testing requirements imposed on drugs by the FDA. *See* Prevor v. U.S. Food & Drug Admin., 67 F. Supp. 3d 125, 128 (D.D.C. 2014).

[166]   *See* Martins et al., *supra* note 34, at 1286 (discussing the idea that "[s]ome courts [have] invoked public policy language in their waiver decisions" and have "viewed upholding freedom of contract as the ultimate preservation of the public interest").

[167]   *Id.* ("As the New Jersey Superior Court [discussed] in 1955, '[t]he meaning of the phrase 'public policy' [was] vague and variable; there are no fixed rules by which to determine what it is—it has been left loose and free of definition.'") (citation omitted).

[168]   *See id.*

[169]   *See* RADIN, *supra* note 1, at 3–4.

[170]   *See* Martins et al., *supra* note 34, at 1289.

between the parties of what is being given and what is being received, (2) freedom, and (3) voluntariness.[171]

Courts can and should invalidate waivers that satisfy the six factors set out in *Tunkl*. However, not all six factors should be weighed equally, and the satisfaction of factor four (bargaining dynamics) should be enough on its own to invalidate an exculpatory clause that violates the contractual principles of mutual understanding and voluntariness. As explored by Professor Margaret Jane Radin, bargaining dynamics in consumer culture are heavily influenced by heuristic bias and information asymmetry, such that consumers are almost never truly entering into a contract freely and voluntarily.[172]

According to psychological research, humans are susceptible to heuristic biases when making decisions in that they are not very efficient at assessing risk.[173] For example, Radin discusses the common fear of airplane crashes over car crashes, despite the higher probability of the former.[174] Humans also have the psychological tendency to believe risks are more likely to happen to others than to themselves.[175] This bias is especially pertinent to contracts as humans are particularly prone to read a boilerplate contract stripping themselves of the right to sue and assume that the risk is inapplicable to themselves.[176]

This mistaken belief in one's infallibility comes into play when consumers quickly scan the Terms of Service print before using a mobile app and check off the box stating that they agree to free developers from liability.[177] Most consumers will not take seriously the risk that they will suffer damage from the use of an app much less that they will need to retain the right to recover for damages.[178] It is therefore imaginable for a healthcare app consumer, when confronted with a disclaimer that the advice given through the app is not to be taken as medical advice from a doctor and that the developer is not liable for damage arising from the use of the information, to completely

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[171] *See* RADIN, *supra* note 1, at 3.

[172] *See id.* at 24–29.

[173] *Id.* at 26.

[174] *Id.*

[175] *Id.*

[176] *See id.*

[177] *See Never Read the Legal Fine Print? Here's How Those Terms and Conditions Can Hurt You*, KSL (Sep. 18, 2019, 8:40 PM), https://ksltv.com/421812/never-read-the-legal-fine-print-heres-how-those-terms-and-conditions-can-hurt-you/ [https://perma.cc/8GL2-NQHW].

[178] *See* RADIN, *supra* note 1, at 26.

ignore the possibility of grievous harm that may befall upon themselves and click away their right to sue.[179]

Information asymmetry also whittles away at the idea of exculpatory clause validity.[180] Radin defines the concept as "a fancy way of saying that recipients of boilerplate have a lot less information about what the clauses in boilerplate mean and what their effects are than do the firms that deploy them."[181] Essentially, even if the standard healthcare consumer app did try to read the clauses in the Terms of Service, they would not have the legal training to understand them.[182] Such lack of knowledge directly contradicts the idea that contracts are built upon informed consent, especially if a consumer is agreeing to something that they do not truly understand at a rudimentary level.[183] For those sincerely concerned about the "freedom of contract," allowing consumers who click "I agree" in situations where there is any kind of nonunderstanding behavior is problematic and contradicts voluntariness.

Bargaining power balance between developers and consumers should be evaluated in the context of whether the consumer is subject to information asymmetry and heuristic biases. These biases can be affected by how desperately (time wise, severity, etc.) a consumer needs the treatment or help of the app and what other technology alternatives are available to the consumer in the App Store.[184] For example, if there are multiple popular fitness apps, consumers have more bargaining power and ability to "shop around."

Although information asymmetry and heuristic biases are arguably inextricable from general exculpatory clauses buried within the Terms of Services, their influence is exacerbated in the case of healthcare apps, where the imbalance between the knowledge of the AI developers and the consumers is extraordinarily heightened. As many consumers are not aware of how AI or its algorithms work, they are even more likely to underestimate the risk that usage of an app might pose to their health.[185] Indeed, waivers of liability involving complicated technology where risks to the consumer are largely murky or

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[179]   *See id.* at 26–27; *Who Gets the Blame When a Digital Health App Is Wrong?*, *supra* note 101.

[180]   RADIN, *supra* note 1, at 24–25.

[181]   *Id.*

[182]   *Id.*

[183]   *See id.* at 3, 24–25.

[184]   *See* Margaret W. Smith, *Information Asymmetry Meets Data Security: The Lemons Market for Smartphone Apps*, 26 J. TRACHTENBERG SCH. PUB. POL'Y & PUB. ADMIN. GEO. WASH. UNIV. 85, 85–87 (2019).

[185]   *See* Stein, *supra* note 105, at 1006–07.

unseen to the naked eye can be differentiated from exculpatory clauses relating to the use of hair salons,[186] and ski slopes;[187] there is more of a justifiable argument that consumers are aware of the risks in engaging in the latter activities. As such, holding consumers accountable for their injuries suffered simply because they tapped their fingers on a box waiving their right to sue would be morally and theoretically at odds with the premises of contract law.

C.   *Distinctions Between Different Mobile Health Applications and Implications on Validity of Waivers of Liability*

Because courts have held that waivers are valid in certain contexts where services sought were experimental or alternative forms of medicine outside of the medical mainstream,[188] it may be tempting to make distinctions between medicinal health apps (i.e., symptom checkers) that intend to diagnose or treat a physical disease versus mental health and therapist-emulating apps.

It may be even more tempting to make the distinction between medicinal health apps and fitness and spirituality apps, which are arguably more experimental types of approaches to health and wellness.[189] Indeed, the FDA's stance is that "well-being and fitness apps" should be separated from "evidence-based therapeutic interventions" when imposing regulations.[190] Perhaps a rationalization for the agency's categorization of these apps as "low risk" lies in the lack of scientific, empirical data confirming the effectiveness of such applications and the absence of highly regulated clinical trials and safety guidelines the app developers have to abide by (similar to when introducing

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[186]   Dixon v. Manier, 545 S.W.2d 948, 949 (Tenn. Ct. App. 1976) (holding an exculpatory clause valid where plaintiff was informed, through a personal explanation from defendant hair stylist, of the risks involved with a hair straightening procedure).

[187]   Squires *ex rel.* Squires v. Goodwin, 829 F. Supp. 2d 1062, 1077 (D. Colo. 2011) (describing the risks of skiing as "inherent").

[188]   Sawicki, *supra* note 37, at 926.

[189]   *See* Alice G. Walton, *The Science of Spirituality: A Psychologist and a Neuroscientist Explain Being 'In the Flow,'* FORBES (Aug. 22, 2017, 12:40 PM), https://www.forbes.com/sites/alicegwalton/2017/08/22/the-science-of-spirituality-a-psychologist-and-a-neuroscientist-explain-being-in-the-flow/?sh=69f451624e0b. [https://perma.cc/EJK7-XL4N].

[190]   Artur Olesch, *How to Verify Health Apps So Doctors Could Prescribe Them*, ICT & HEALTH (Dec. 5, 2019), https://ictandhealth.com/how-to-verify-health-apps-so-doctors-could-prescribe-them/news/ [https://perma.cc/9P2A-YVYB]; *see also* Rachel Kraus, *So Many Health and Wellness Apps Haven't Done Research to Back up Their Claims*, MASHABLE (June 18, 2019), https://mashable.com/article/health-and-wellness-apps-no-research [https://perma.cc/YG4V-QYVD].

a drug into the market).[191] So, for therapist-type apps, where the results of treatment are more subjective and ambiguous, how can effectiveness or even error be confirmed?

While this viewpoint is understandable and compelling, making such distinctions between empirically based apps and more subjective apps both ignores the information asymmetry and bargaining power imbalance that are still at the very heart of liability waivers between AI developers and consumers, and reinforces stigmas against less empirically-based sciences, such as mental health.[192] There is already a hands-off policy by the FDA towards apps that do not intend to diagnose or treat a disease,[193] which leads to dangerous placement of responsibility on AI developers to protect consumers from algorithmic error.[194]

Making distinctions between diagnostic apps and other types of apps when evaluating whether exculpatory clauses signed by patients are valid reinforces the idea that some apps do not need to receive as much federal oversight or should receive different treatment by the government. Mental health apps are very important because they provide better access to care that is often inaccessible, and faulty algorithms can have serious consequences in these spaces.[195] For example, Woebot failed to appropriately detect and respond to users indicating they were experiencing suicidal thoughts and sexual abuse.[196]

Furthermore, making such distinctions between classifications of apps could lead to developers trying to market their app as a wellness or spirituality app, as opposed to a medicinal health app, in an effort to avoid more stringent regulations and testing requirements.[197] Woebot underwent rebranding concurrent with the loosening of FDA oversight, holding itself out previously as an "Emotional Health Assistant" and avoiding the use of medical terminology in its marketing.[198] Waivers of liability used by all healthcare apps, regardless of

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[191] General Wellness: Policy for Low Risk Devices, FDA (Sept. 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices [https://perma.cc/DS7B-KEWT]; *see also* Olesch, *supra* note 190; *see also* Kraus, *supra* note 190 (citing a study of twenty thousand mental health apps, finding no more than 4 percent of the apps were backed by scientific evidence).

[192] *See* RADIN, *supra* note 1, at 38–39.

[193] Kasperbauer & Wright, *supra* note 88, at 235.

[194] *See supra* notes 160–163 and accompanying text.

[195] *See* Browne, *supra* note 2.

[196] *Id.*

[197] This avoidance of regulations through categorization or classification is mirrored in the drug industry, where companies try to market their product as a medical device as opposed to a drug to avoid more stringent regulations and testing requirements imposed on drugs by the FDA. *See* Prevor v. U.S. Food & Drug Admin., 67 F. Supp. 3d 125, 129–30 (D.D.C. 2014).

[198] Browne, *supra* note 2.

whether they are medicinal health apps, fitness apps, mental health apps, or spirituality apps, should be universally subjected to the modified *Tunkl* framework.

CONCLUSION

Fear surrounding AI use in healthcare is extraordinarily valid given the black-box nature of medicine and the lack of algorithm transparency.[199] However, due to the life-saving potentialities of AI in healthcare and the incontrovertible fact that reliance on AI and technology will only increase in the coming decades, the focus should be on ameliorating fears through governmental mechanisms rather than discouraging technological growth.[200]

While consumers should do their best to make informed decisions on whether to use certain AI-powered applications and whether to accept treatment suggestions derived from such technology, there is a drastic knowledge imbalance between consumers and developers as to how black-box software works, and a limit on how much the general public can understand of its complexity.[201] This lack of knowledge exacerbates the heuristic biases and information asymmetry already present in situations where consumers are stripped of their rights to sue simply by consenting to an exculpatory clause hidden within a lengthy Terms of Service.[202] Reliance on consumers clicking "ok" on these waivers of liability before using healthcare apps allows AI developers to wield violative power over consumers in enforcing their contracts when algorithms go awry.[203]

While criticism of courts' reliance on *Tunkl* in holding exculpatory clauses invalid centers upon the idea that overreliance on public policy is at odds with the freedom of contract law, true "freedom" is contingent upon mutual understanding and voluntariness of both parties in entering a contract.[204] Applying the framework outlined in *Tunkl* and upholding concerns over bargaining power and voluntariness is arguably the ultimate preservation of public interest and the principles of contractual freedom. Adhering to a public policy-centered framework in judicial interpretation, as set forth in *Tunkl* and exemplified by the bargaining dynamic factor, is

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[199]   *See supra* Part II.
[200]   *See supra* Section III.B.
[201]   *See supra* Part II.
[202]   *See supra* Section III.C.
[203]   *See supra* Part II.
[204]   *See supra* Part III.

essential to establishing accountability and transparency in AI healthcare use. Lines of liability apportionment must be drawn exigently if consumers' fears are to be quelled—perhaps, if such concrete strides are made, we can harness the exciting potentialities of AI technology while ensuring existing structural inequalities in healthcare are not exacerbated. We may never be able to crack open the proverbial black box, but we can and must safeguard those who place their trust in its mysterious workings.

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