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Regulating the Revolution: A Legal Roadmap to Optimizing AI in Healthcare

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ABSTRACT

The integration of artificial intelligence (AI) into healthcare holds immense potential to enhance efficiency, quality, and access, but also elicits profound ethical and legal challenges necessitating thoughtful governance. This article undertakes a comprehensive analysis of the multifaceted landscape of regulating medical AI to foster responsible innovation aligned with societal values. It surveys key drivers compelling adoption, while scrutinizing risks of algorithmic bias, privacy breaches, dehumanized care, and workforce disruption. Reforms to professional licensing and scope of practice are examined to balance innovation and quality of care. The opaque "black box" nature of AI systems is analyzed to elucidate issues of accountability, fairness, and discrimination. Appraisal of the FDA's novel regulatory approach offers constructive analysis and parallels to the Boeing 737 Max crisis are drawn. Complex legal considerations including liability, privacy, consent, and cybersecurity are investigated to advocate balanced policymaking among stakeholders.

Overall, the article argues for regulatory dynamism, interdisciplinary collaboration, and human-centered design in governing healthcare AI. It advocates stimulating innovation under oversight, addressing workforce impacts, and keeping technological prowess subordinate to human values and medical ethics. With prudent regulation centered on moral principles, this technological frontier can be navigated to equitably enhance medicine without forfeiting trust, transparency, and justice. Law bears profound responsibility in shaping an ethical and compassionate future for healthcare.

INTRODUCTION

In 2023, a lawyer stood before Judge P. Kevin Castel, offering a baffling excuse: "I did not comprehend that ChatGPT could fabricate cases."[1] He had filed a legal brief full of fake

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judicial opinions and legal citations, all generated by a popular artificial intelligence (AI) large language model (LLM) known as ChatGPT.[2] This incident, patently mortifying for the attorney who has since become infamous as the "ChatGPT lawyer,"[3] metamorphosed into fodder for late-night television humor and internet memes. Such a reaction may be explained by the denouement of his conduct: the opposing counsel unearthed the fraudulent references, leading the judge to dismiss the plaintiff's case and impose sanctions on the attorney who uncritically and

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1.   Benjamin Weiser & Nate Schweber, *The ChatGPT Lawyer Explains Himself*, N.Y. TIMES (June 8, 2023), https://www.nytimes.com/2023/06/08/nyregion/lawyer-chatgpt-sanctions.html.

2.   *Id.* ChatGPT is the large language model (LLM) chatbot released to the public in 2022 by the San Francisco-based startup OpenAI. Timothy B. Lee & Sean Trott, *A Jargon-Free Explanation of How AI Large Language Models Work*, ARS TECHNICA (July 31, 2023, 6:00 AM), https://arstechnica.com/science/2023/07/a-jargon-free-explanation-of-how-ai-large-language-models-work. LLMs constitute an innovative form of AI leveraging deep learning to comprehend, interpret, and generate human-like text. *Id.* Constructed on neural networks encompassing extensive layers and parameters, these models can discern and replicate intricate linguistic patterns when trained on massive text datasets. *Id.* Such technological architecture enables diverse capabilities including translation, summarization, question-answering, and text generation, significantly advancing natural language processing. *What is Natural Language Processing?*, IBM, https://www.ibm.com/topics/natural-language-processing (last visited Nov. 22, 2023). LLMs now pervade myriad industries, powering applications from customer service chatbots to tools assisting legal research. Grace Lau, *10 Real-Life Chatbot Use Cases Across Different Industries*, DIALPAD: BLOG, https://www.dialpad.com/blog/chatbot-use-cases (last visited Nov. 22, 2023). However, their very complexity renders these AI systems a focal point of continuing research and innovation. Refining large language models' computational architecture and training methodology remains imperative to attenuate risks like incoherent reasoning, factual inaccuracies termed "hallucinations," and bias. Brian J. Aboze, *Risks of Large Language Models: A Comprehensive Guide*, DEEPCHECKS (Aug. 7, 2023), https://deepchecks.com/risks-of-large-language-models.

3.   Weiser & Schweber, *supra* note 1.

naively relied on the chatbot.[4] Though judicial resources and those of the opposition were undoubtedly squandered in countering the AI hallucinations in the brief,[5] no parties suffered irremediable harm.[6] Yet, one must consider an alternative scenario. Envision a doctor or nurse depending solely on erroneous AI advice in an emergency care environment, resulting in severe patient injury—this would be no laughing matter.

The integration of AI into healthcare offers remarkable potential to enhance efficiency, expand access, and improve outcomes. However, this technological transformation also elicits profound legal and ethical dilemmas that warrant judicious examination. This Article analyzes the multifaceted landscape of regulating AI in medicine to foster responsible innovation that aligns with societal values.

Part I surveys the drivers propelling AI adoption, including demographics, economics, and the elusive quest for quality, cost containment, and access. It highlights AI's promise in augmenting human expertise through data-driven diagnostics, clinical decision support, remote monitoring, and administrative automation.[7] However, risks of algorithmic bias, privacy

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4. Lyle Moran, *Judge in ChatGPT Case Most Troubled by Attorneys' Lack of Candor*, LEGALDIVE (June 26, 2023), https://www.legaldive.com/news/chatgpt-lawyer-fake-cases-lawyer-uses-chatgpt-sanctions-generative-ai/653925.

5. In the context of AI and chatbots, "hallucinations" refer to the generation of information, concepts, or ideas that are not grounded in the data on which the model was trained. *See* Ellen Glover, *What is an AI Hallucination?*, BUILTIN (Oct. 2, 2023), https://builtin.com/artificial-intelligence/ai-hallucination. These hallucinations can manifest as incorrect facts, fictional scenarios, or illogical conclusions that don't align with reality or established knowledge. *Id.* Hallucinations in AI models may arise from various factors, including model architecture, training data, or the specific query's context, and may pose challenges in applications where accuracy and reliability of information are crucial. *Generative AI Hallucinations: Why They Occur and How to Prevent Them*, AI DATA (July 6, 2023), https://www.telusinternational.com/insights/ai-data/article/generative-ai-hallucinations. These incidents demonstrate the importance of human oversight and verification in the utilization of AI-generated content.

6. Opinion and Order, Mata v. Avianca, Inc., No. 1:22-CV-01461-PKC (S.D.N.Y. June 22, 2023), ECF No. 55 (dismissing case as time barred under Montreal Convention).

7. *See* W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 420–24 (2015) (discussing benefits and policy considerations for "black-box medicine," the use of computational models to make healthcare decision).

breaches, dehumanized care, and workforce disruption temper this optimism.[8]

Part II examines legal considerations including liability, privacy, informed consent, and cybersecurity. It advocates thoughtful balancing of interests between patients, providers, and technology firms.[9] Achieving the promise of AI in medicine without undermining ethical healthcare requires guidelines fostering accountability and human control.[10]

Part III examines necessary reforms to professional licensure and scope of practice laws to enable beneficial task shifting and team-based care without compromising quality or accountability.[11] Adjusting educational requirements and reconsidering traditional hierarchies can facilitate the integration of AI. However, human discernment remains irreplaceable in nuanced judgment and relationship-centered aspects of medicine.[12]

Part IV analyzes the opaque black box nature of AI systems that hinders comprehension of medical recommendations.[13] This exacerbates issues of accountability, fairness, and perpetuation of biases against marginalized communities when algorithms entrench societal prejudices.[14] Mitigation strategies encompass developing interpretable models, ongoing bias monitoring,

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8. *See* Roger A. Ford & W. Nicholson Price II, *Privacy and Accountability in Black-Box Medicine*, 23 MICH. TELECOMM. & TECH. L. REV. 1, 3–4 (2016).

9. *See* Charlotte A. Tschider, *Medical Device Artificial Intelligence: The New Tort Frontier*, 46 BYU L. REV. 1551 (2021) (arguing a tort regime would complement FDA AI regulation to adequately balance interests in a changing technological landscape).

10. Mason Marks, *Algorithmic Disability Discrimination*, *in* DISABILITY, HEALTH, L. & BIOETHICS 253–54 (I. Glenn Cohen et al. eds., 2020).

11. This balanced policy aim is shared by the FDA. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy,* 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007) (discussing dual role of FDA in protecting consumers and incentivizing innovation).

12. *See* Nathan Cortez, *Regulating Disruptive Innovation,* 29 BERKELEY TECH. L.J. 175, 194–96 (2014) (describing harms of medical software malfunction and relation of harms to innovation).

13. AI is described as a "black box" because a system's complex mathematical operations make it extremely difficult, and in many cases, presently impossible, for humans to understand how an AI makes a decision. Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 HARV. J.L. & TECH. 889, 897, 905 (2018).

14. *See* W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 65, 67–68 (2019) (noting health algorithms can mirror existing racial and gender biases in healthcare).

diverse data collection, and interdisciplinary collaboration.[15] Compliance with anti-discrimination mandates remains paramount.[16]

Part V appraises the FDA's Software Precertification Program that shifts focus from product-based to firm-based approval, applied upstream on developers.[17] While innovative, it risks complacency and barriers for younger firms. Lessons from catastrophic failures of software updates on Boeing's 737 Max airplanes expose dangers of insufficient scrutiny even with sophisticated and established developers.[18] This section recommends that enhancements to this innovative program should emphasize transparency and continuing oversight.[19]

The Article concludes by contending that meticulous governance and collaboration can harness AI's potential while safeguarding equity and ethics. It advocates calibrating regulation to stimulate growth under oversight, proactively addressing workforce impacts, and keeping technological prowess subordinate to human values and dignity.

Overall, it argues for regulatory dynamism, interdisciplinary efforts, and human-centered design in governing medical AI.[20] Humanity stands at the cusp of a

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15.   *See* DAVID FREEMAN ENGSTROM ET AL., GOVERNMENT BY ALGORITHM: ARTIFICIAL INTELLIGENCE IN FEDERAL ADMINISTRATIVE AGENCIES (2020), https://www.law.stanford.edu/wp-content/uploads/2020/02/ACUS-AI-Report.pdf (discussing how the administrative state will need to employ mitigation strategies to responsibly integrate the use of AI).

16.   *Id.* at 80 (noting AI tools challenge antidiscrimination law and have been found to violate equal protection). *See generally* W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421 (2017) (discussing AI regulation approaches for FDA).

17.   *Digital Health Software Precertification (Pre-Cert) Pilot Program*, U.S. FOOD & DRUG ADMIN. (Sept. 26, 2022), https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program.

18.   BOEING 737 MAX FLIGHT CONTROL SYSTEM JOINT AUTHORITIES TECHNICAL REVIEW, OBSERVATIONS, FINDINGS, AND RECOMMENDATIONS (2019), https://www.faa.gov/sites/faa.gov/files/2022-08/Final_JATR_Submittal_to_FAA_Oct_2019.pdf (final JATR submitted to the Federal Aviation Administration regarding Boeing incidents).

19.   This policy is broadly reflected in the JATR's recommendations. *Id.* at III–XIII.

20.   *See* A. Michael Froomkin et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning*, 61 ARIZ. L. REV. 33, 38 (2019) (arguing humans-in-the-loop is an essential requirement of the standard of care in diagnostics).

technological transformation within healthcare. With prudent regulation centering ethics and human interests, this frontier can be navigated to equitably enhance medicine without forfeiting fundamental ideals of trust, transparency and justice. Law's constructive role is indispensable in sculpting a compassionate and ethical future for AI in medicine.

I. THE COMPLEX FORCES PROPELLING AI ADOPTION IN HEALTHCARE

The integration of artificial intelligence (AI) into healthcare is being driven by a confluence of intensifying pressures, including demographic trends, systemic economics, and the ongoing pursuit of quality, cost control, and access. This section explores these key forces compelling healthcare's technological transformation.

A. DEMOGRAPHIC SHIFTS: AGING POPULATIONS AND CHRONIC DISEASE

The rapid growth in the geriatric population, coupled with increasing chronic disease rates across age groups, is straining healthcare systems beyond capacity.[21] The complex needs of elderly patients and those with chronic conditions often require costlier interventions and specialized care.[22] Simultaneously, shortfalls in the availability of assisted living facilities, in-home support, and unpaid caregivers further burden the system.[23]

These dynamics contribute to resource scarcity, workforce burnout, and rising expenditures, with Medicare costs for elderly patients expected to more than double from $829 billion in 2021 to $1.8 trillion by 2031.[24] Innovative solutions like AI and

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21. Christopher R. Carpenter et al., *Optimal Older Adult Emergency Care: Introducing Multidisciplinary Geriatric Emergency Department Guidelines From the American College of Emergency Physicians, American Geriatrics Society, Emergency Nurses Association, and Society for Academic Emergency Medicine*, 62 J. AM. GERIATRICS SOC'Y 1360, 1360–61 (2014) (finding the rapid growth in the geriatric population, combined with increasing chronic disease rates, is straining healthcare systems beyond capacity and healthcare systems must adapt to meet the unique needs of the aging population to ensure the provision of comprehensive and multidisciplinary care).

22. *Id.* at 1361.

23. *See* SUSAN C. REINHARD ET AL., AARP PUB. POL'Y INST., VALUING THE INVALUABLE: 2019 UPDATE 1, 3 (2019).

24. Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, KFF (Jan. 19, 2023),

telehealth that can enhance efficiency and personalize care are increasingly necessary to meet the needs of aging and chronically ill populations.

B. SHORTAGES IN THE HEALTHCARE WORKFORCE

Shortfalls in the physician labor supply, projected to reach up to 124,000 nationally by 2034, further strain capacity.[25] Lengthy training pathways and geographic/specialty maldistribution of practitioners exacerbate these shortages.[26] Growing administrative burdens on clinicians also decrease time spent with patients, functionally reducing the workforce.[27]

These shortages, arising from multifaceted causes, contribute to reduced access, crowded emergency departments, clinician burnout, and worsened patient outcomes.[28] Targeted AI applications, such as automated image analysis and intelligent diagnostic assistance, could aid clinicians in managing excessive workloads.[29] However, this must be balanced with safeguards against over-reliance on algorithms.

C. THE ELUSIVE QUEST FOR QUALITY, ACCESS, AND AFFORDABILITY

Systemic failings in delivering quality, affordable, and accessible care further highlight the need for transformative solutions like AI. Despite spending over $4.3 trillion on healthcare annually, the U.S. still experiences substantial gaps in access with millions uninsured and underinsured.[30]

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https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing.

25. IHS MARKIT, THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2019 TO 2034 at 6 (2021), https://www.aamc.org/media/54681/download.

26. *See* Candice Chen et al., *Toward Graduate Medical Education (GME) Accountability: Measuring the Outcomes of GME Institutions*, 88 ACAD MED. 1267, 1271 (2013).

27. Tait D. Shanafelt et al., *Changes in Burnout and Satisfaction With Work-Life Integration in Physicians and the General US Working Population Between 2011 and 2020*, 97 MAYO CLINIC PROC. 491, 492 (2022).

28. *Id.* at 492, 503 (noting these effects stemming from COVID-19 related shortages).

29. *See* Eric J. Topol, *High-Performance Medicine: The Convergence of Human and Artificial Intelligence*, 25 NATURE MED. 44, 47 (2019).

30. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-

Preventable medical errors persist as a leading cause of death, illuminating deficits in care quality.[31] Meanwhile health expenditure costs continue to climb, representing nearly 18% of Gross Domestic Product (GDP) and creating unsustainable financial burdens.[32]

Targeted applications of automation, robotics, remote diagnostics, predictive analytics, and telehealth may enhance capacity, quality, and affordability. However, conscientious oversight is essential to ensure human values are not sacrificed. Overall, the immense pressures stemming from demographic, workforce, and systemic failings propel the urgency for innovative approaches like AI. Yet integration must remain tethered to ethics through thoughtful governance.

In conclusion, this constellation of intensifying challenges forms the backdrop necessitating healthcare's technological evolution. But as discussed below, AI's promise must be judiciously balanced with safeguards against associated risks. With prudence and wisdom, this imminent revolution can be navigated to expand access and improve healthcare while retaining the ethical foundations of trust, empathy, and human dignity.

II. NAVIGATING THE COMPLEX LEGAL LANDSCAPE OF HEALTHCARE AI

The integration of AI into healthcare elicits a complex legal landscape with implications for liability, privacy, informed consent, and cybersecurity. This section examines key considerations and advocates balanced policymaking that thoughtfully weighs the interests of patients, providers, and technology developers.

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and-reports/nationalhealthexpenddata/nhe-fact-sheet (last visited Aug. 20, 2023).

31. Thomas L. Rodziewicz et al., *Medical Error Reduction and Prevention*, NAT'L LIBR. OF MED. (May 2, 2023), https://pubmed.ncbi.nlm.nih.gov/29763131/.

32. Andrea M. Sisko et al., *National Health Expenditure Projections, 2018-27: Economic and Demographic Trends Drive Spending and Enrollment Growth*, 38 HEALTH AFFS. 491, 492 (2019).

A. RECONCEPTUALIZING LIABILITY FRAMEWORKS

The attribution of liability in cases involving harm from AI healthcare technologies remains legally ambiguous.[33] Questions emerge regarding whether flaws stem from negligent oversight by providers deploying the tools versus inadequate design by developers.[34] Traditional paradigms of medical malpractice and product liability law do not neatly map onto this new terrain.[35]

A reconceptualization of liability frameworks is needed to ensure fair recourse without chilling innovation.[36] This may necessitate carefully apportioning liability between users and creators of AI systems based on levels of control and foreseeability of harms.[37] It will also require grappling with the reality of no-fault adverse events due to inherent limitations or uncertainties within even state-of-the-art AI.[38]

B. REINFORCING PATIENT PRIVACY AND DATA SECURITY

Robust legal safeguards for healthcare data privacy and security are imperative as AI systems generate, analyze, and utilize vast amounts of sensitive patient information.[39] Breaches could have dire personal consequences and undermine public trust.[40] While the Health Insurance Portability and Accountability Act (HIPAA) furnishes baseline federal protections, the rapid evolution of technologies like cloud computing, mobile apps, and wearable devices creates new risks

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33. *See* Froomkin et al., *supra* note 20, at 51 (noting the complicated questions involved in whether the use or failure to use technology constitutes negligence).

34. *See* Ryan Abbott, *The Reasonable Computer: Disrupting the Paradigm of Tort Liability*, 86 GEO. WASH. L. REV. 1, 5 (2018) (distinguishing between user and designer liability for technology harms).

35. *See* Andrew D. Selbst, *Negligence and AI's Human Users*, 100 B.U. L. REV. 1315 (2020) (surveying how AI disrupts and challenges traditional tort law).

36. *See* David C. Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence*, 89 WASH. L. REV. 117 (2014) (arguing society needs to adapt new liability rules for AI).

37. *Commission White Paper on Artificial Intelligence: A European Approach to Excellence and Trust*, at 22, COM (2020) 65 final (Feb. 19, 2020).

38. *See* Abbott, *supra* note 34, at 44.

39. *See* Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL'Y, L. & ETHICS 143, 147 (2017).

40. *See* Sharona Hoffman & Andy Podgurski, *In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information*, 48 B.C. L. REV. 331, 335 (2007).

not fully addressed under current protocols.[41] Regularly updating security requirements and limiting permissible uses of patient data through legislative amendments can help mitigate emerging vulnerabilities.[42] Comprehensive measures encompassing encryption, access controls, employee training, and coordination between healthcare and technology firms will bolster defenses.[43] Ongoing regulatory vigilance and proactive policies are vital to reinforce privacy rights and values in the age of healthcare AI.[44]

C. ENSURING MEANINGFUL INFORMED CONSENT

The integration of AI redefines the meaning of informed consent in healthcare, necessitating renewed policy attention. The frequent opacity of AI systems poses barriers to clinicians transparently conveying their recommendations' rationale.[45] The use of patient data for continual machine learning also merits disclosure and consent.

Establishing clear guidelines can help actualize meaningful patient consent rights.[46] These may encompass requirements to furnish simplified explanations of AI systems' diagnostic/treatment basis and describe how personal data might be utilized for training algorithms. However, excessive verbosity risks overwhelming patients with technicalities.[47] The

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41. *See* Peng Zhao et al., *Mobile Applications for Pain Management: An App Analysis for Clinical Usage*, 19 BMC MED. INFORMATICS & DECISION MAKING, May 2019, at 6 (finding none of thirty-six pain management phone applications surveyed were HIPAA compliant).

42. *See* Nicolas P. Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65, 105–6 (2014).

43. Clemens Scott Kruse et al., *Security Techniques for the Electronic Health Records*, 41 J. MED. SYS. 127, 128 (2017); Narjis Batool et al., *Role of HR Technology and Training for the Development of Employees*, 5 INT'L J. BUS. & MGMT. FUTURE 1, 2 (2021); Rahul Kapoor & Joon Mahn Lee, *Coordinating and Competing in Ecosystems: How Organizational Forms Shape New Technology Investments*, 34 STRATEGIC MGMT. J. 274, 291 (2012).

44. *See* Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information*, 72 MD. L. REV. 682 (2013).

45. Nadine Bienefeld et al., *Solving the Explainable AI Conundrum by Bridging Clinicians' Needs and Developers' Goals*, 6 NPJ DIGIT. MED., May 2023, at 1.

46. *See* Andrew L. Beam & Isaac S. Kohane, *Big Data and Machine Learning in Health Care*, 319 JAMA 1317, 1318 (2018).

47. *See* Nutifafa Cudjoe Amedior, *Ethical Implications of Artificial Intelligence in the Healthcare Sector* (iSTEAMS Accra Bespoke Multidisciplinary Innovations Conf., 2023),

ideal balance fosters comprehension without overburdening patients.

Additionally, consent provisions surrounding secondary uses of health data merit examination, given potential public benefits like improved predictive modeling.[48] Overall, reconceptualizing informed consent for the age of medical AI will necessitate nuanced policymaking balancing transparency, patient empowerment, and practicality.[49]

D. PROMOTING CYBERSECURITY THROUGH COORDINATION

The increasing digitalization of healthcare elevates risks of disruptive cyberattacks, necessitating collaborative action to bolster cyber-defenses.[50] Promoting coordination between healthcare entities and technology developers can facilitate implementation of robust safeguards tailored to evolving threats.[51] Government initiatives can also catalyze cybersecurity progress by disseminating best practices, fostering information sharing, and providing technical guidance.[52]

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https://www.isteams.net/_files/ugd/185b0a_eadb23684afa4d3bb887ddbfc5698a a5.pdf (highlighting the ethical implications of AI in healthcare, including privacy and security, bias and discrimination, transparency and explainability, responsibility and accountability, informed consent, and human interaction and empathy, and recommending that clear guidelines for responsible use be established, along with maintaining the importance of human interaction and empathy in patient care, to enhance healthcare outcomes while safeguarding patient rights and welfare). *But see* Suzanne Kawamleh, *Against Explainability Requirements for Ethical Artificial Intelligence in Health Care*, 3 AI & ETHICS 901 (2022) (challenging the notion that explainability is a requirement for the ethical use of AI in healthcare and arguing that meeting existing legal standards for informed consent does not necessarily require explainability, suggesting that clear guidelines should focus on ensuring informed consent rather than solely on explainability).

48.   Charles Safran et al., *Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper*, 14 J. AM. MED. INFORMATICS ASS'N., Jan.–Feb. 2007, at 2.

49.   *See* Adam J. Andreotta et al., *AI, Big Data, and the Future of Consent*, 37 AI & SOC'Y 1715, 1715–16 (2022).

50.   Frank Cremer et al., *Cyber Risk and Cybersecurity: A Systematic Review of Data Availability*, 47 GENEVA PAPERS ON RISK & INS. ISSUES & PRAC. 698, 698 (2022).

51.   *See* Hemant Taneja, *How Tech Companies Can Help Fix U.S. Health Care*, HARV. BUS. REV. (Apr. 28, 2020), https://hbr.org/2020/04/how-big-tech-can-help-fix-u-s-health-care.

52.   *See* Lisa Pino, *Improving the Cybersecurity Posture of Healthcare in 2022*, U.S. DEP'T OF HEALTH & HUM. SERVS. BLOG (Feb. 28, 2022),

Legislatures must ensure adequate legal remedies against entities negligent in fulfilling cybersecurity duties.[53] Ultimately, cybersecurity in the context of healthcare AI will hinge on proactive, cooperative efforts spanning both public and private spheres.

The road ahead promises to be complex, yet thoughtful policymaking and cooperation can help foster healthcare AI's immense potential while safeguarding essential patient rights and interests. With prudence and wisdom, law can play a constructive role in guiding this technological transformation.

III. REFORMING LICENSURE AND SCOPE OF PRACTICE THOUGHTFULLY TO ENABLE RESPONSIBLE AI INTEGRATION

Integrating AI into healthcare obliges thoughtfully re-evaluating professional licensing regimes and scope of practice limitations. Doing so promises to facilitate prudent task shifting and collaborative care teams leveraging AI, while retaining focus on humanistic medicine.

A. EXPANDING LICENSING JUDICIOUSLY TO ALLOW NEEDED TASK SHIFTING

Current licensing systems and scope of practice laws often impede optimal reallocation of duties between physicians and allied health professionals like nurse practitioners (NPs), pharmacists, and paramedics.[54] These rigid boundaries reflect a traditional, physician-centric paradigm misaligned with team-based care.[55] Cautiously recalibrating certain restrictions could enable beneficial shifting of routine clinical tasks to such professionals aided by AI tools, enhancing efficiency and access.

For instance, an AI diagnostic assistant could support NPs in managing stable chronic conditions during routine visits,

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https://www.hhs.gov/blog/2022/02/28/improving-cybersecurity-posture-healthcare-2022.html.

53.   *See* ANDREW NOLAN, CONG. RSCH. SERV., R43941, CYBERSECURITY AND INFORMATION SHARING: LEGAL CHALLENGES AND SOLUTIONS 3–5 (2015).

54.   Lusine Poghosyan et al., *Nurse Practitioners as Primary Care Providers With Their Own Patient Panels and Organizational Structures: A Cross-Sectional Study*, 74 INT'L J. NURSING STUD. 1, 2 (2017).

55.   *See* Ruth Kleinpell et al., *Addressing Barriers to APRN Practice: Policy and Regulatory Implications During COVID-19*, 14 J. NURSING REGUL. 13, 13–14 (2023).

while still referring more complex cases to physicians.[56] Such supervised autonomy can expand access and convenience for patients without sacrificing quality.[57] Licensed pharmacists could utilize AI-based clinical decision support systems to treat minor conditions, relieving overburdened physicians, a non-AI preview of which was seen with pharmacy-based COVID-19 vaccinations.[58] With proper training, oversight, and incremental implementation informed by data, targeted licensing adaptations can unlock healthcare improvements through AI integration.

However, regulators must ensure practitioners given expanded duties have appropriate qualifications and supervision.[59] Rapidly authorizing uncontrolled autonomy could jeopardize quality and safety. Implementation should be gradual and evidence-based, with empirical outcomes guiding expansion.[60] Continuous education on judiciously leveraging AI and appreciating its limitations is equally vital to prevent overreliance. Overall, striking the right balance can facilitate beneficial task shifting through AI without compromising care standards.

B. INCENTIVIZING CROSS-DISCIPLINARY EDUCATION AND COLLABORATIVE CARE TEAMS

The siloed practice model must give way to integrative teams of diverse professionals leveraging complementary abilities.[61] Modernizing licensure frameworks to foster such

56. *See* Atul Gawande, *Cowboys and Pit Crews*, NEW YORKER (May 26, 2011), https://www.newyorker.com/news/news-desk/cowboys-and-pit-crews.

57. *Cf.* NAT'L ACADS. OF SCIS., ENG'G, AND MED. ET AL., THE FUTURE OF NURSING 2020-2030: CHARTING A PATH TO ACHIEVE HEALTH EQUITY 99, 119 (Mary K. Wakefield et al. eds., National Academies Press 2021) (arguing that more autonomy for nurses increases patients' quality of care).

58. *See generally* Muhammad Ahmer Raza et al., *Artificial Intelligence (AI) in Pharmacy: An Overview of Innovations*, 13 INNOVATIONS IN PHARM., Dec. 2022 (surveying AI developments in medical field).

59. *See* Kleinpell et al., *supra* note 55 (discussing removal of practice barriers).

60. *Cf.* Robyn Cody et al., *Complexity as a Factor for Task Allocation Among General Practitioners and Nurse Practitioners: A Narrative Review*, 21 BMC FAM. PRAC., Feb. 2020, at 1–2 (considering division of labor by complexity as nurses fill roles previously handled by general practitioners).

61. *See* Gawande *supra* note 56.

cross-disciplinary groups can catalyze innovation.[62] However, truly enabling this paradigm shift requires equally reinventing healthcare education.

Reformed curricula preparing clinicians, data scientists, engineers, ethicists, and administrators for collaborative practice are crucial.[63] Medical training can no longer remain confined to purely clinical knowledge; fluency in data analytics, systems thinking, and AI ethics is also vital.[64] Technology degrees must likewise encompass humanistic skills and considerations. Regulators should shape accreditation standards, funding incentives, and payment policies to nurture team-based, AI-enabled healthcare retaining human focus.[65]

C. UPHOLDING HUMAN DISCERNMENT'S IRREPLACEABLE ROLE

However, certain irreducible care aspects will continue demanding profoundly human faculties, including complex diagnosis, high-stakes decisions, and therapeutic relationships.[66] AI should complement, not supplant, human discernment and judgment, which remain healthcare's ethical and practical cornerstones.[67] Thus, adapting licensure and scope of practice policies must be judicious, enabling AI integration while retaining physician oversight of nuanced clinical judgment. The art of medicine, encompassing wisdom, empathy, and ethics, cannot be automated. With prudence, law can promote harmonious human-AI collaboration, retaining healthcare's irreplaceable human essence. Technological

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62. *See generally* Richard G. Booth et al., *How the Nursing Profession Should Adapt for a Digital Future*, BMJ, June 2021, at 3.

63. Cristian Lieneck et al., *Interprofessional Education and Research in the Health Professions: A Systematic Review and Supplementary Topic Modeling*, 12 EDUC. SCI., Nov. 2022, at 1–2.

64. *Cf.* Topol, *supra* note 29, at 52 (forecasting symbiotic future between human and machine intelligence in medicine).

65. *See generally* Amy Abernethy et al., *The Promise of Digital Health: Then, Now, and the Future*, NAM PERSP., June 2022, at 2.

66. *See* Emily Harris, *Large Language Models Answer Medical Questions Accurately, But Can't Match Clinicians' Knowledge*, 330 JAMA 792 (2023) (discussing how AI and humans must complement each other rather than compete).

67. Michelle M. Mello & Neel Guha, *ChatGPT and Physicians' Malpractice Risk*, JAMA HEALTH F., May 2023, at 1.

progress should expand, not contract, our conception of medicine as a fundamentally humanistic endeavor.[68]

IV. ILLUMINATING THE BLACK BOX—PROMOTING EXPLAINABLE AND UNBIASED AI

The opaque black box nature of many AI systems poses formidable obstacles for healthcare integration by hindering trust, accountability, and perpetuating discrimination. This section delves into the implications and necessary mitigation strategies.

A. THE NEED FOR EXPLAINABLE AI IN HEALTHCARE

As discussed above, in medicine, comprehending the rationale behind AI recommendations is paramount. However, the complexity of machine learning models often renders them inscrutable black boxes, even to experts.[69] This lack of transparency compromises informed consent and patient trust while obscuring accountability.[70] Research initiatives to enhance algorithmic interpretability and develop explainable AI (XAI) are thus essential.[71] XAI aims to illuminate the key data features and decision pathways underlying AI systems' outputs without excessively sacrificing performance. By enabling better understanding of model behaviors and limitations, XAI can engender trust and refine oversight.[72]

B. PREVENTING ALGORITHMIC BIAS AND DISCRIMINATION

A significant concern is that black box algorithms may silently entrench societal biases and discriminate against marginalized groups.[73] If the training data incorporates

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68. Fabrice Jotterand & Clara Bosco, *Keeping the "Human in the Loop" in the Age of Artificial Intelligence*, 26 SCI. ENG'G ETHICS 2455, 2457–60 (2020).

69. *See* Finale Doshi-Velez et al., *Accountability of AI Under the Law: The Role of Explanation* (Berkman Klein Ctr. Working Grp., Working Paper, 2017) (discussing AI opaqueness and need for decision explanations).

70. *See generally id.* (discussing relationship between transparency and accountability).

71. *See* Andrew D. Selbst & Solon Barocas, *The Intuitive Appeal of Explainable Machines*, 87 FORDHAM L. REV. 1085, 1130 (2018) (defining explainable AI in terms of documentation conveying the subjective policy choices guiding model development).

72. *See* Finale Doshi-Velez & Been Kim, *Towards A Rigorous Science of Interpretable Machine Learning*, ARXIV, Mar. 2017, at 3.

73. *See* Price II, *supra* note 7, at 67–68.

distorted historical patterns, AI risks perpetuating injustice.[74] Mitigating this danger requires comprehensive bias testing, diverse data collection, and partnerships with affected communities.[75] Ongoing audits and impact assessments must track model performance across patient demographics to identify issues early.[76] Overall, bias detection and prevention mechanisms are paramount to uphold professional medical ethics and patient trust.[77]

C. ENSURING LEGAL COMPLIANCE AND HUMAN OVERSIGHT

Rigorous compliance with federal and state anti-discrimination laws remains imperative as AI capabilities grow.[78] Providers deploying these tools bear responsibility for ensuring impartial care.[79] Continual human oversight over model outputs provides an additional safeguard, allowing clinicians to override incorrect or dangerous recommendations.[80]

Through concerted efforts encompassing education, transparent design, testing, community engagement, and proactive policies, healthcare systems can foster AI that upholds justice and equality while improving care. But achieving this requires sustained collaboration between medicine, law, technology, ethics, and society.

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74.   *Id.*

75.   *See generally* Davy van de Sande et al., *Algorithmic Fairness Audits in Intensive Care Medicine: Artificial Intelligence for All?*, 26 CRITICAL CARE, Oct. 2022, 1–2.

76.   *Id.* at 2.

77.   *Id.*

78.   *See* Press Release, Equal Emp. Opportunity Comm'n, EEOC Launches Initiative on Artificial Intelligence and Algorithmic Fairness (Oct. 28, 2021), https://www.eeoc.gov/newsroom/eeoc-launches-initiative-artificial-intelligence-and-algorithmic-fairness.

79.   *Cf.* Sharona Hoffman, *Big Data and the Americans with Disabilities Act*, 68 HASTINGS L.J. 777, 779 (2017) (arguing ADA requires amendment to recognize novel employment discrimination issues created by big data).

80.   *See generally* Selbst & Barocas, *supra* note 71 (advocating for documented explainability to involve the human in AI decision-making).

V. APPRAISING THE FDA'S NOVEL REGULATORY APPROACH FOR AI-BASED MEDICAL DEVICES

A. THE SOFTWARE PRECERTIFICATION PROGRAM: AN OVERVIEW

The Food and Drug Administration's (FDA) traditional approach to regulating medical devices and Software as a Medical Device underwent a significant transformation with the unveiling of the Software Precertification (Pre-Cert) Program in 2017.[81] While this initiative has been framed as an innovative response to evolving technological landscapes,[82] a careful critique exposes potential shortcomings and raises substantial questions about its underlying principles and ultimate efficacy.

Historically, the FDA's method of device regulation relied on a comprehensive risk-based classification system, subjecting individual products to a meticulous and product-centric premarket approval process.[83] The Pre-Cert Program, by contrast, focuses on the assessment and endorsement of software developers themselves, representing a profound shift in regulatory philosophy.[84] The pilot program's enlistment of nine corporations, including recognized industry leaders such as Apple, Fitbit, and Johnson & Johnson, manifests the FDA's commitment to this innovative approach.[85]

B. CRITICISMS AND CONCERNS REGARDING THE SOFTWARE PRECERTIFICATION PROGRAM

The ambitious Pre-Cert Program seeks to harmonize regulatory frameworks with the unique features of AI algorithms, a goal that adds layers of complexity to an already intricate analysis. The program's intent is to establish a flexible pathway for pre-certified companies to provide limited information before marketing a new tool or, in specific cases, to

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81.   *See* Press Release, U.S. Food & Drug Admin., FDA Selects Participants for New Digital Health Software Precertification Pilot Program (Sept. 26, 2017), https://www.fda.gov/news-events/press-announcements/fda-selects-participants-new-digital-health-software-precertification-pilot-program.

82.   *Id.*

83.   Jeffrey Shuren et al., *FDA Regulation of Mobile Medical Apps*, 320 JAMA 337, 337 (2018).

84.   *See* News Release, U.S. Food & Drug Admin., FDA Selects Participants for New Digital Health Software Precertification Pilot Program (Sept. 26, 2017), https://www.fda.gov/news-events/press-announcements/fda-selects-participants-new-digital-health-software-precertification-pilot-program.

85.   *Id.*

circumvent premarket review altogether.[86] The FDA's stated goal is to apply insights from this initial initiative to foster a more adaptable approach to digital health technology, aligning regulation with the peculiar and iterative nature of AI algorithms.[87]

Unlike conventional Software as a Medical Device products, which remain static prior to FDA premarket approval, AI algorithms involve a process known as machine learning.[88] This autonomous process allows AI algorithms to learn and improve from experience, without specific programming for individual tasks.[89] While AI's functionality rests on recognizing intricate patterns in data and making informed decisions based on these findings, the continuous growth through machine learning may outpace regulatory abilities, leading to unexpected challenges and oversights.

The program's aspiration to streamline the regulatory process and encourage innovation is laudable, yet the specific criteria for participation are unclear. The demand for a proven commitment to quality and organizational excellence in software development lacks clear definition, creating potential inconsistencies and arbitrary interpretations. Moreover, focusing assessments on developers instead of individual products can present inherent risks, possibly diluting the scrutiny of specific products and creating concerns over potential compromises in patient safety.

Persistent concerns linger regarding the potential pitfalls of this novel approach. Critics argue that certifying developers based on abstract principles of organizational excellence is vague and difficult to objectively verify.[90] This emphasis on organizational quality may lead to complacency if safety is presumed due merely to developers' reputations. In addition, it may unintentionally benefit prominent, entrenched entities

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86. *Id.*

87. *Id.*

88. *See* STUART J. RUSSELL & PETER NORVIG, ARTIFICIAL INTELLIGENCE: A MODERN APPROACH 2 (3d ed. 2009).

89. *Id.*

90. Theodore T. Lee & Aaron S. Kesselheim, *U.S. Food and Drug Administration Precertification Pilot Program for Digital Health Software: Weighing the Benefits and Risks*, 168 ANNALS OF INTERNAL MED. 730, 730 (2018).

while creating obstacles for nascent companies devoid of extensive histories to manifest this abstract excellence.

Furthermore, the Pre-Cert paradigm may expose the system to regulatory capture and diminish its independence over time, as regulators forge closer connections with developers. The recurring certification process, lacking concrete details, could become a mere formality, devoid of true scrutiny. As discussed below, the crisis with the Boeing 737 Max serves as a poignant reminder of how even the most reputable developers can pose significant public risks without rigorous and impartial oversight.

C. LESSONS FROM THE BOEING 737 MAX CRISIS

Founded in 1916, Boeing has long and storied history in the aviation industry.[91] Together with its main rival Airbus, it accounts for over 90% of the passenger jet market.[92] However, the ill-fated crashes of the Boeing 737 Max jets, which culminated in the loss of 346 lives, unmask regulatory fissures with profound resonance in the domain of healthcare regulation.[93] This grievous misstep's origins extend to the Federal Aviation Administration's (FAA) delegation of certification responsibilities to Boeing—a decision imbued with unanticipated peril.[94] A parallel may be drawn with the FDA's Pre-Cert Program, which, eschewing meticulous evaluation of individual digital health artifacts, pivots to endorse software developers through the nebulous metric of "organizational excellence."[95] Yet, the harrowing Boeing tragedy delivers an

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91.   Trefis Team, *How Airbus Has Grown Over the Years to Dethrone Boeing as the Largest Commercial Aircraft Maker*, FORBES (Jan. 6, 2020), https://www.forbes.com/sites/greatspeculations/2020/01/06/how-airbus-has-grown-over-the-years-to-dethrone-boeing-as-the-largest-commercial-aircraft-maker/?sh=7e80a04c3a59.

92.   *Id.*

93.   Dominic Gates, *Q&A: What Led to Boeing's 737 MAX Crisis*, SEATTLE TIMES (Nov. 22, 2020), https://www.seattletimes.com/business/boeing-aerospace/what-led-to-boeings-737-max-crisis-a-qa/.

94.   BOEING 737 MAX FLIGHT CONTROL SYSTEM JOINT AUTHORITIES TECHNICAL REVIEW, *supra* note 18, at IV ("[T]he team determined that the process did not adequately address cumulative effects, system integration, and human factors issues.").

95.   *See* U.S. Food & Drug Admin., *supra* note 81 ("The goal of this new approach is for the FDA to, after reviewing systems for software design, validation and maintenance, determine whether the company meets quality standards and if so, to precertify the company.").

unambiguous warning that even the most venerable industry stewards may subordinate safety to competitive exigencies in the absence of stringent and independent oversight.[96]

The technical debacle within the Boeing 737 Max's Maneuvering Characteristics Augmentation System (MCAS) software system laid bare a precarious lack of redundancy and vulnerability to a singular point of failure, precipitating fatal plunges when errant sensor activation occurred.[97] Astonishingly, this grave deficiency escaped the scrutiny of both Boeing engineers and delegated FAA authorities during the accelerated certification process, underlining the perils of haste and organizational myopia.[98]

The aftermath of the initial crash saw both FAA and Boeing acknowledging the MCAS's role, yet settling on a mere procedural checklist for pilots as a sufficient remedial measure.[99] This decision betrayed a tragic underestimation of real-world complexities, culminating in a second and avoidable catastrophic crash, with the loss of 346 lives within a mere five months.[100]

This poignant episode yields instructive lessons for the regulatory landscape. First, the delegation of decision-making authority to regulated entities engenders inherent conflicts of interest, risking exploitation to attenuate oversight, as evidenced by Boeing's maneuvering with the MCAS system to evade mandatory simulator training for pilots to appease large customers like Southwest Airlines.[101] Second, historical organizational repute offers no prophylactic assurance against future shortcomings, as executives, navigating pressures to enhance competitiveness and shareholder value, may falter. Third, a certification paradigm predicated upon hypothetical predictions rather than comprehensive, real-world evaluation invites peril.

These insights bear significant relevance and immediacy for the FDA's emerging Pre-Cert Program. Guided by this somber illustration of regulatory failure, even among companies

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96. Gates, *supra* note 93 (attributing the 737 Max crashes to FAA delegation of testing and certification to Boeing).

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

historically recognized for excellence, the FDA is faced with the imperative task of assiduously guarding against potential regulatory capture and complacency. The cornerstone of Pre-Cert must rest upon concrete, impartial criteria, reinforced by continuous verification, and must transcend assumptions rooted merely in reputation. The Boeing tragedy unambiguously revealed that even firms of the highest repute may prioritize competitive advantages and profit over safety, absent rigorous independent oversight.[102]

Regulatory robustness also benefits industry. Similar to the widespread public distrust that now shadows Boeing's assurances of safety and quality, patients may become increasingly dubious of Pre-Cert's developer-centric regulatory approach, unless the FDA scrupulously ensures quality. The crisis accentuates the necessity for transparency, obligatory disclosures, ongoing verification, procedural fail-safes, and a regulatory focus that prioritizes public rather than corporate interest.

The ultimate safeguard in the complex interplay of healthcare innovation must lie in diligent post-approval surveillance and proactive caution, supplanting an uncritical and perilous reliance on corporate integrity. The focus should be on creating a regulatory framework that adapts to the dynamic nature of technological advancement, recognizing potential pitfalls, and building in safeguards that prioritize patient welfare over commercial interests.[103]

Enhancing Pre-Cert requires commitments to transparency, participation of diverse non-industry stakeholders, and continuing impartial review processes that concretely verify standards are met over time. Striking a thoughtful balance between enabling innovation and safeguarding the public is imperative. While an innovative concept, Pre-Cert warrants very careful, ongoing refinement and monitoring to fulfill AI's healthcare promise without compromising welfare or equality. Though rapidly advancing technology strains regulatory capacity, maintaining steadfast impartiality and prioritizing ethics remain indispensable.[104]

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102. Natalie Kitroeff et al., *The Roots of Boeing's 737 Max Crisis: A Regulator Relaxes its Oversight*, N.Y. TIMES (July 27, 2019), https://www.nytimes.com/2019/07/27/business/boeing-737-max-faa.html.

103. *See* Lee & Kesselheim, *supra* note 90, at 731.

104. Natalie Kitroeff et al., *supra* note 102.

VI. CONCLUSION

The integration of AI into healthcare promises remarkable enhancements but remains fraught with legal and ethical intricacies necessitating thoughtful governance. This Article has undertaken a detailed analysis of the multifaceted dimensions regulating this technological frontier. It has scrutinized the drivers compelling AI adoption while surfacing associated risks and concerns. The examination of necessary reforms to professional licensing and scope of practice conveys the nuances in balancing innovation and quality. Elucidating the opacity of AI systems lays bare the ethical perils of reduced transparency and algorithmic bias. Rigorous appraisal of the FDA's novel regulatory approach offers constructive analysis to enhance safety and oversight. Additionally, the Article delves into essential legal considerations surrounding liability, privacy, consent, and cybersecurity. The unifying theme is the need for dynamism, collaboration, and human-centric design in governance. Meticulous oversight and proactive policies to address workforce impacts are vital, while stimulating growth and retaining human control. Overall, the analysis advocates integrating AI thoughtfully, upholding moral principles and patient welfare.

At this crossroads of technological transformation, law bears profound responsibility in shaping an ethical future. With meticulous governance centered on ethics and equitable access, the promises of medical AI can be fulfilled without undermining trust, transparency, and dignity. Science offers tremendous power to heal and enhance life. But wisdom lies in constraining this power under moral boundaries. Law's indispensable role is aligning scientific capabilities with conscience. By balancing innovation and regulation judiciously, we can create a future where technology serves all humanity equally—healing without harming, uplifting without dividing, and empowering without exploiting. With ethics as compass, and justice as cause, law can help steer science towards human progress and collective flourishing.

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