

MALPRACTICE BY THE AUTONOMOUS AI PHYSICIAN

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Abstract

AI is currently capable of making autonomous medical decisions, like diagnosis and prognosis, without the input of humans. Liability for this “practice of medicine” by an Autonomous AI Physician currently falls in a tort law gap when it cannot be sufficiently connected to humans involved with the AI because neither human-centric nor product-centric causes of action provide a mechanism for recovery. To fill this liability gap, this Article proposes a framework that governs liability under existing tort law by focusing on control of the AI’s injury-causing output to assign liability to creators, organizations, individual providers, and the Autonomous AI Physician with limited legal personhood. Other scholars have suggested bridging this gap by either assigning all tort liability to humans or circumventing tort law altogether. These approaches either subvert tort law’s primary goals, require significant structural change, or offer only a piecemeal solution to the problem. The control framework laid out in this Article provides a functional and comprehensive solution for governing injuries caused by the Autonomous AI Physician that both balances the benefits and risks of technological innovation in healthcare and advances tort law’s compensation and deterrence goals.

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INTRODUCTION

The Autonomous AI Physician is deep learning artificial intelligence (AI) that can autonomously “practice medicine.” More precisely, it can make medical decisions using algorithmic reasoning without input from a human physician.¹ These medical decisions, like diagnosing an eye disease or reading a chest x-ray, are considered medical practice when performed by human physicians.² When a human physician misdiagnoses a patient or misreads a chest x-ray, potential liability for injuries caused by those decisions is governed by medical

1. See *Oxipit Awarded CE Mark for First Autonomous AI Medical Imaging Application*, OXIPIT (Mar. 29, 2022), <https://oxipit.ai/news/first-autonomous-ai-medical-imaging-application> [perma.cc/FJ3Q-VLD5] (explaining autonomous AI imaging analysis); Press Release, Food & Drug Admin., FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems (Apr. 12, 2018), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye> [perma.cc/SR7N-32PX] (explaining autonomous detection of ophthalmological disease).

2. See Food & Drug Admin., *supra* note 1 (“IDx-DR is the first device authorized for marketing that provides a screening decision without the need for a clinician to also interpret the image or results, which makes it usable by health care providers who may not normally be involved in eye care.”).

negligence law.³ But what if the Autonomous AI Physician misdiagnoses a patient, leading to the wrong (or no) treatment, thereby causing a patient harm? To-date, no court has considered this question.⁴ Also, a court presented with this question today would not be able to answer it under existing tort law.⁵ This article provides a functional and comprehensive tort liability framework for injuries caused by the Autonomous AI Physician that both balances the benefits and risks of technological innovation in healthcare and advances tort law's compensation and deterrence goals.

Consider the following scenario:

An Autonomous AI Physician, authorized by the Food and Drug Administration (FDA), is owned by a large healthcare organization which implemented the AI in its oncology department to improve treatment outcomes for cancer patients. The Autonomous AI Physician uses a vast amount of complex data to predict the previously unknown origin of a patient's cancer.⁶ To reach this prediction, the AI engages in unpredictable and opaque but highly reliable algorithmic reasoning that humans cannot understand.⁷ The AI's technical ability to do this is explained below in Section I.A. A human oncologist then relies on the AI's prediction to prescribe treatment. The prediction turns out to be wrong, and the prescribed treatment plan is ineffective, causing the patient to experience loss of chance for a better outcome. The patient then sues the AI developer, the healthcare organization, and the human oncologist for damages.

Tort law would govern this case.⁸ However, existing tort liability can only compensate the patient for this injury if the injury can be sufficiently connected to human or organizational actions.⁹ Product liability law might compensate the patient if the injury was related to the creators' design or manufacture of the AI

3. See Christy Bieber, *Medical Negligence: Legal Definitions & Examples*, FORBES: ADVISOR, <https://www.forbes.com/advisor/legal/medical-malpractice/medical-negligence> [perma.cc/ZQ3S-CMWF] (Oct. 13, 2022, 5:05 AM) (providing a basic overview of medical negligence); see also RYAN ABBOTT, *THE REASONABLE ROBOT: ARTIFICIAL INTELLIGENCE AND THE LAW* 66 (2020) (proposing a modification of strict liability to hold manufacturers liable when the AI's actions are negligent).

4. See Jason Chung & Amanda Zink, *Hey Watson — Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine*, 11 ASIA PAC. J. HEALTH L. & ETHICS 51, 51, 67 (2018) (“Courts have traditionally deemed it impossible for machines to have legal liability as they are not legal persons. . . . Regarding the human-centric categories, both negligence and vicarious liability as causes of action appear to require personhood.”).

5. *Id.*

6. See Zubair Ahmad et al., *Artificial Intelligence (AI) in Medicine, Current Applications and Future Role with Special Emphasis on Its Potential and Promise in Pathology: Present and Future Impact, Obstacles Including Costs and Acceptance Among Pathologists, Practical and Philosophical Considerations. A Comprehensive Review.*, DIAGNOSTIC PATHOLOGY, Mar. 17, 2021, at 16, 24, <https://doi.org/10.1186/s13000-021-01085-4> [perma.cc/ZR4M-BHLE] (noting that deep learning, a subset of machine learning AI, generally increases the complexity of AI decisions by using several layers of artificial neural networks (ANN)).

7. See Guang Yang et al., *Unbox the Black-Box for the Medical Explainable AI via Multi-Modal and Multi-Centre Data Fusion: A Mini-Review, Two Showcases and Beyond*, 77 INFO. FUSION 29, 30–31 (2022). <https://doi.org/10.1016/j.inffus.2021.07.016> (noting that as the layers of ANNs grow deeper, the AI's algorithmic reasoning process becomes opaquer and difficult for humans to understand).

8. Bieber, *supra* note 3; ABBOTT, *supra* note 3 at 60.

9. ABBOTT, *supra* note 3 at 60.

or if the creator failed to warn of reasonably foreseeable risks.¹⁰ Organizational liability might compensate the patient if the injury stemmed from the healthcare organization's adoption and implementation of AI.¹¹ Medical malpractice might compensate the patient if the human oncologist was negligent.¹² In this case, let us assume the following: (1) the AI functioned as designed by creators and there was no known risk of a wrong prediction that required a warning under the applicable facts; (2) the healthcare organization was reasonable in its clinical implementation of the AI; and (3) the human oncologist neither knew nor should have known that the prediction was incorrect. In this scenario, the wrong prediction and resulting injury stem solely from the Autonomous AI Physician's algorithmic medical decision-making process.

Currently, there is no tort law cause of action that confronts injuries caused by the AI's autonomous medical decision-making process.¹³ This is because the process through which the Autonomous AI Physician arrives at a medical decision is often unpredictable, severing the connection between the AI's "thinking" and human actors involved in the creation and use of the Autonomous AI Physician.¹⁴ Additionally, because AI is currently not considered a legal person, it cannot be assigned direct liability as a human physician could.¹⁵ As a result, medical injuries caused by the AI's autonomous decision making currently fall in a tort law gap—between products liability, organizational liability, and medical negligence.¹⁶

Some scholars suggest bridging this gap by modifying products liability or negligence doctrines to impute blame for injuries caused by the AI's autonomous actions to humans associated with the AI.¹⁷ These approaches subvert tort law's goal of compensating for, and deterring socially blameworthy

10. See Charlotte A. Tschider, *Medical Device Artificial Intelligence: The New Tort Frontier*, 46 *BYU L. REV.* 1551, 1555–56 (2021), <https://digitalcommons.law.byu.edu/lawreview/vol46/iss6/7> [perma.cc/2SSA-GGBD] (discussing the practical and regulatory challenges injured patients would face if they filed products liability cases involving medical devices, such as an Autonomous AI Physician); ABBOTT, *supra* note 3 at 54.

11. See generally Benny Chan, *Applying a Common Enterprise Theory of Liability to Clinical AI Systems*, 47 *AM. J. L. & MED.* 351 (2021) (proposing "that physicians, manufacturers of clinical AI systems, and hospitals be considered a common enterprise for the purposes of liability.").

12. Bieber, *supra* note 3; ABBOTT, *supra* note 3 at 62–63.

13. Chung & Zink, *supra* note 4 at 51, 67; ABBOTT, *supra* note 3 at 55–63.

14. KARTIK HOSANAGAR, *A HUMAN'S GUIDE TO MACHINE INTELLIGENCE: HOW ALGORITHMS ARE SHAPING OUR LIVES AND HOW WE CAN STAY IN CONTROL* 106 (Penguin Books 2020).

15. Chung & Zink, *supra* note 4 at 73–76; ABBOTT, *supra* note 3 at 63.

16. E.g., Chung & Zink, *supra* note 4 at 66–68 (explaining these categories of tort liability).

17. See ABBOTT, *supra* note 3 at 55–66 (proposing a modification of strict liability to hold manufacturers liable when the AI's actions are negligent); Omri Rachum-Twaig, *Whose Robot Is It Anyway?: Liability for Artificial-Intelligence-Based Robots*, 2020 *U. ILL. L. REV.*, 1141, 1167–73 (2020) (suggesting supplementing existing legal liability rules to create quasi-safe harbors or predetermined levels of care); Pinchas Huberman, *A Theory of Vicarious Liability for Autonomous-Machine-Caused Harm*, 58 *OSGOODE HALL L.J.* 233, 254–277 (2021) (proposing legal agency, but not personhood for AI, so that humans can be liable under a theory of vicarious liability); Mitja Kovac, *Autonomous Artificial Intelligence and Uncontemplated Hazards: Towards the Optimal Regulatory Framework*, 13 *EUR. J. RISK REGUL.* 94, 108–113 (2022) (suggesting an expansion of both strict liability for manufacturers and vicarious liability for human principals as well as a detailed set of regulatory measures to govern AI development, use, and liability); ANNA BECKERS & GUNTHER TEUBNER, *THREE LIABILITY REGIMES FOR ARTIFICIAL INTELLIGENCE: ALGORITHMIC ACTANTS, HYBRIDS, CROWDS* 79–84 (2022) (proposing legal agency for AI to expand vicarious liability for AI users when they delegate tasks, which AI accomplishes via algorithmic autonomy).

behavior, without unduly burdening socially desirable activity by either: (1) unfairly assigning liability to humans for unforeseeable and unpreventable harms or (2) discouraging beneficial innovation while failing to improve patient safety.¹⁸ Other scholars note that contractual, regulatory, or no-fault approaches to liability for AI-caused harm could circumvent the application of tort law altogether.¹⁹ These approaches would either require significant structural change, legislative action, and/or present only piecemeal approaches in the case of the Autonomous AI Physician's liability. Jason Chung and Amanda Zink propose legal personhood for even non-autonomous medical AI, namely IBM's Watson for Oncology, to hold it directly responsible for breaches of standards of care applicable to medical students.²⁰ I incorporate the concept of limited legal personhood for AI but expand on this idea as it relates to the Autonomous AI Physician's "practice of medicine" and the applicable standard of care.²¹

Overall, by building on the foundation laid by these and other legal scholars' treatment of the theoretical, doctrinal, and practical implications of autonomous AI decision making for medical liability law, I suggest a comprehensive tort law framework for governing injuries caused by the Autonomous AI Physician to eliminate the tort law gap illustrated above. This functional approach will enable courts to adjudicate injuries caused by the Autonomous AI Physician under familiar legal principles, does not require structural changes to tort law doctrine, and is not dependent on legislative or regulatory action. Additionally, maintaining a tort-based system for governing medical injuries by the Autonomous AI Physician balances the benefits and risks of medical AI by encouraging innovation of beneficial, but legally responsible, AI.²²

The liability framework presented in this article governs liability for medical injuries caused by the Autonomous AI Physician under various existing tort law causes of action by focusing on who or what controlled the AI's injury-causing output. This control-based framework recognizes that the Autonomous AI Physician expresses characteristics of both medical devices (during development and maintenance) and medical practitioners (during post-market clinical use).²³ As a result, while general safety and effectiveness of the

18. ABBOTT, *supra* note 3, at 50 (describing the risks to traditional policy goals of tort law posed by AI).

19. See Kyle T. Jorstad, *Intersection of Artificial Intelligence and Medicine: Tort Liability in the Technological Age*, 3 J. MED. A.I., Dec. 30, 2020, at 1, 21–23 (recognizing various liability approaches including no-fault liability and contractual assignment of liability); George Maliha et al., *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629, 637–39 (2021) (recognizing contractual assignment of liability and no-fault special adjudication systems as options); Kovac, *supra* note 17 at 101, (noting that given the high costs of tort law, ex ante regulation of autonomous AI might be a more cost-effective way to prevent accidents).

20. See Chung & Zink, *supra* note 4, at 68–77 (discussing personhood for autonomous AI); Scott J. Schweikart, *Who Will Be Liable for Medical Malpractice in the Future? How the Use of Artificial Intelligence in Medicine Will Shape Medical Tort Law*, 22 MINN. J.L. SCI. & TECH. 1, 18–19 (2021) (discussing personhood for autonomous AI).

21. See *infra* Section II.B (exploring legal personhood for the Autonomous AI Physician); *infra* Section II.C (articulating the reasonable AI Physician standard of care).

22. See ABBOTT, *supra* note 3, at 50–70 (articulating a theoretical framework for "reasonable robots").

23. See *infra* Section I.C (defining the Autonomous AI Physician framework); *infra* Section I.D (examining regulatory capacity for addressing issues presented by the Autonomous AI Physician).

Autonomous AI Physician is amenable to governance by regulatory structures designed (or yet to be designed) for medical AI products, liability for individual patient injuries should be governed by a mix of existing product-centric and human-centric tort theories, depending upon the injury-causing output of the AI.²⁴ For tort law to functionally assign liability under human-centric theories, it must recognize the Autonomous AI Physician as a legal person that can be sued directly for medical malpractice, act as an agent for purposes of assigning vicarious liability to other parties, and be held to its own standard of care.²⁵ In addition to function, recognizing the Autonomous AI Physician as a legally responsible and insurable medical provider fills the current liability gap by distributing risks to humans associated with the AI through insurance *outside* of the tort system based on their roles in the AI's creation and use rather than arbitrarily and unfairly assigning legal liability through the tort system when such liability is not otherwise justified by the tort doctrines of either negligence or strict liability.²⁶

In Part I, I provide an overview of medical AI and its current abilities and limitations. I then introduce the Autonomous AI Physician as medical AI that autonomously engages in opaque and often unpredictable algorithmic reasoning to perform tasks ordinarily considered medical practice. I discuss how the Autonomous AI Physician manifests qualities of both medical products subject to the FDA's existing or future regulatory structures and human medical practitioners subject to ordinary medical liability. I conclude Part I by discussing the liability gap created when the Autonomous AI Physician's "practice of medicine" causes a patient injury, and why this liability gap cannot be filled by simply assigning liability to humans associated with the AI without undermining fundamental tort principles.

In Part II, I articulate a framework focused on control of the AI's injury-causing output to govern medical injuries caused by the Autonomous AI Physician, which I subsequently refer to as the "control framework."²⁷ To establish this framework, I drew from my experience as both a civil litigator and legal scholar to craft a comprehensive liability solution for the Autonomous AI Physician grounded in both legal practice and theory. I begin by discussing why control over the AI's injury-causing output is a valid basis for attaching liability to legally responsible parties in the tort system. Following this, I show how the party or parties in control of this output could then be held liable under various causes of action in tort, which can include one or more of the following: medical malpractice; vicarious liability; organizational liability; and products liability.

24. See *infra* Section I.D (detailing regulations for medical AI systems).

25. See Chung & Zink, *supra* note 4, at 66–67 (categorizing certain theories of tort liability as either "human-centric" or "machine-centric").

26. See *infra* Section I.E (detailing this "liability gap"); see also Chung & Zink, *supra* note 4, at 68–73 (describing the shortcomings of extant tort liability structures and advocating for a functional approach which treats medical AI systems as akin to a medical student); Huberman, *supra* note 17, at 239 (arguing "a vicarious liability approach offers a pragmatic doctrinal solution that rests on plausible theoretical foundations.").

27. I introduced the basic idea for this control framework in a book chapter and now expand this idea to provide further justification for its creation and a comprehensive framework for its application. Mindy Nunez Duffourc & Dominick S. Giovanniello, *The Autonomous AI Physician: Medical Ethics and Legal Liability*, in AI, LAW & BEYOND (Henrique Sousa Antunes & Arlindo Oliveira eds., forthcoming 2023).

Next, I establish that to function, this framework requires assigning limited legal personhood to the Autonomous AI Physician, so that its “practice of medicine,” when negligent, can be governed by human-centric liability theories, including vicarious and direct liability. Drawing heavily from Chung and Zink’s recommendation that courts view IBM’s Watson for Oncology as a legal person, I argue that limited legal personhood for the Autonomous AI Physician is the best way to integrate it into existing tort law governing liability for medical injuries.²⁸ Aside from enabling AI’s capacity as a litigant in medical malpractice cases, I add a new reason for assigning limited legal personhood to the Autonomous AI Physician—the creation of a unique standard of care that attaches directly to the Autonomous AI Physician’s “practice of medicine.”²⁹

While I briefly touch upon a philosophical justification for the Autonomous AI Physician’s legal personhood by recognizing its status as a social “actant,” I primarily justify legal personhood through a doctrinal lens. Courts have long accepted doctrinal justifications for legal personhood for corporations and ships, and more recently, some environmental objects.³⁰ Of course, as I discuss, legal personhood for non-human entities is malleable and should be carefully calibrated to enable legal protection for risks to humans.³¹ As a result, I argue that the Autonomous AI Physician’s legal personhood, while limited, should enable it to be both a legal agent and a direct litigant in medical malpractice cases.

Finally, I propose holding the Autonomous AI Physician to its own standard of care—that of a reasonable Autonomous AI Physician in the same specialty. This standard accounts for the autonomous AI’s unique abilities, which easily exceed human performance in some respects and drastically fall below human performance in others.³² It positions the Autonomous AI Physician as a new type of medical expert subject to a corresponding standard of care. I recognize current limitations on defining the applicable standard of care both because of my own lack of expertise in computer science and medicine, and because of the newness of the technology. Nevertheless, I summarize various possibilities for determining a reasonable Autonomous AI Physician standard of care and call for further interdisciplinary collaboration to propose workable solutions for defining the standard of care for a reasonable Autonomous AI Physician.

28. See Chung & Zink, *supra* note 4, at 68–77 (“The simple legal classification of Watson as a legal person would allow us to circumvent a key problem that we face now—the prospect of every case requiring a detailed existential analysis of what Watson represents and does.”); *infra* Section II.B (extending this recommendation to the Autonomous AI Physician).

29. *Infra* Section II.C.; Huberman, *supra* note 17, at 258 (examining suggestions to hold Autonomous AI Physicians to the “reasonable person” standard); Chung & Zink, *supra* note 4, at 68–74 (comparing suggestions to apply the standard of a reasonable medical student to IBM’s Watson).

30. Chung & Zink, *supra* note 4, at 77 (“Legal personhood is merely a pre-existing legal fiction used to hold entities, not just natural persons, accountable.”); e.g., *Sierra Club v. Morton*, 405 U.S. 727, 741–43 (1972) (Douglas, J., dissenting) (drawing upon existing doctrinal considerations of ships and corporations to argue for extending standing, in environmental cases, to “inanimate object[s] about to be despoiled, defaced, or invaded”).

31. See *infra* Section II.B (exploring the edges of legal personhood for artificial entities).

32. See *infra* Section II.C (contrasting human and AI abilities to set a proper reasonable standard of care).

In Part III, I demonstrate how various liability constellations might emerge after an Autonomous AI Physician causes a medical injury using the control framework set out in Part II. I articulate several possible scenarios for the Autonomous AI Physician’s liability. In each scenario, I demonstrate how liability would be governed under the control framework for an Autonomous AI Physician with legal personhood.

I. THE BIRTH OF THE AUTONOMOUS AI PHYSICIAN

Digital transformation in the healthcare industry, which “refers to the adoption of new technologies that enables the shift towards secure, high-quality care,” is well underway.³³ Electronic medical records, digital imaging, e-health, telemedicine, digital patient communities, and wearable health technologies have all become permanent features in healthcare.³⁴ In this digital transformation era, “data is the new oil . . . and AI is the new refinery.”³⁵

A. *AI and Autonomy*

AI generally refers to the ability of algorithms to perform tasks that typically require human intelligence.³⁶ Rule-based AI systems, also known as expert systems, follow a set of pre-programed “if-then” rules to make decisions.³⁷ While they are highly predictable, and thus useful in situations where decision making is governed by clear and articulable rules, like the tax code, they are not resilient and will fail when confronted with more dynamic problems.³⁸ This limitation is crucial, because, “the vast range of human experience and decision making cannot be governed by a simple set of articulable rules.”³⁹ Rule-based AI is also more susceptible to manipulation by bad faith actors and is incapable of learning from its own mistakes.⁴⁰ But perhaps the most important limitation of predictable rule-based AI is its inability to solve problems using knowledge that defies current human expertise.⁴¹ As Kartik Hosanagar observes, “[e]xpert systems are restricted to the wisdom of experts, wisdom that will, by definition, never fall into the realm of ‘undiscovered knowledge.’”⁴²

Machine learning is a subset of AI that allows algorithms to continuously learn by using data and experience to improve performance.⁴³ Opposed to a

33. Sascha Kraus et al., *Digital Transformation in Healthcare: Analyzing the Current State-of-Research*, 123 J. BUS. RSCH., 557, 558 (2021).

34. *See id.* at 558 (discussing developments like “self-tracking, big data and predictive analytics, e-health, mobile health, participative medical research” and others).

35. Oriol Pujol, *The Concept of “AI”. Opacity and Societal Impact*, in *ARTIFICIAL INTELLIGENCE AND THE LAW 23* (Pablo García Mexía & Francisco Pérez Bes eds., 2021).

36. Chung & Zink, *supra* note 4, at 53.

37. HOSANAGAR, *supra* note 14 at 106.

38. *Id.* at 103–104.

39. *Id.* at 107.

40. *Id.* at 107–08, 115.

41. Pujol, *supra* note 35, at 28.

42. HOSANAGAR, *supra* note 14, at 113.

43. Pujol, *supra* note 35, at 28.

“rule-based” approach, machine learning algorithms employ a “data-based” approach by detecting patterns in large data sets to inform its decision making.⁴⁴ Though more resilient than rule-based AI, machine learning models are less predictable.⁴⁵ Machine learning technology makes AI “capable of receiving sensory input, setting targets, assessing outcomes against criteria, making decisions, and adjusting behavior to increase its likelihood of success—all without being directly controlled by people.”⁴⁶

Deep learning, a subset of machine learning, increases the complexity of AI decisions by using several layers of artificial neural networks (ANN) designed to mimic the human brain’s decision-making process.⁴⁷ Deep learning can be visualized as a “massive flow chart” in which each ANN layer represents an algorithmic reasoning and decision making process that will lead to another layer until, “eventually, the machine will arrive at one final answer from among a potentially infinite number of competing outcomes.”⁴⁸ As the layers of ANNs grow deeper, the AI’s reasoning process becomes more opaque, presenting the “black-box problem.”⁴⁹ “Black box” AI generally refers to “models that are sufficiently complex that they are not straightforwardly interpretable to humans,” meaning that humans cannot understand the algorithmic reasoning process underlying the AI’s output.⁵⁰ There is usually a direct relationship between the layers of ANNs and the AI’s accuracy and opacity.⁵¹ In addition, the deeper the AI (measured by the layers of neural networks), the more unpredictable it becomes.⁵² According to Jenna Burrell, “[m]achine learning models that prove useful (specifically, in terms of the ‘accuracy’ of classification) possess a degree of unavoidable complexity.”⁵³

Black-box AI models are capable of improving their accuracy as they collect and analyze more and more data.⁵⁴ Unlike “locked” algorithms that, once

44. See, e.g., *How FDA Regulates Artificial Intelligence in Medical Products*, PEW (Aug. 5, 2021), <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products> [perma.cc/BBM7-F9FU] (“ML algorithms can learn to decipher patterns in patient data at scales larger than a human can analyze while also potentially uncovering previously unrecognized correlations.”).

45. HOSANAGAR, *supra* note 14, at 104.

46. ABBOTT, *supra* note 3, at 113.

47. Ahmad et al., *supra* note 6, at 16, 24.

48. Jorstad, *supra* note 19, at 3.

49. Guang Yang et al., *supra* note 7 at 30–31.

50. Jeremy Petch et al., *Opening the Black Box: The Promise and Limitations of Explainable Machine Learning in Cardiology*, 38 CAN. J. CARDIOLOGY 204, 204 (2022) (noting that a model can also be called a black-box either because the algorithmic reasoning process is intentionally concealed by the developer or because the end-user does not have sufficient expertise to understand the code underlying the process); see also Jenna Burrell, *How the Machine ‘Thinks’: Understanding Opacity in Machine Learning Algorithms*, BIG DATA & SOC’Y, Jan.–June 2016, at 1, 5 (distinguishing between forms of opacity).

51. See Guang Yang et al., *supra* note 7, at 30–31 (noting that as the layers of ANNs grow deeper, the AI’s algorithmic reasoning process becomes opaquer and more difficult for humans to understand).

52. HOSANAGAR, *supra* note 14, at 104.

53. Burrell, *supra* note 50, at 5.

54. FOOD & DRUG ADMIN., *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD): Discussion Paper and Request for Feedback*, 1, 3 (2019) [hereinafter FDA Discussion Paper], <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf> [perma.cc/GDN3-YT5K].

put into use, will always produce the same output in response to the same input, “adaptive” algorithms allow an AI system to continuously learn.⁵⁵ Adaptive AI systems are dynamic and evolve to improve their performance once in use; “[h]umans, however, are not usually involved in this change: AI learns independently of its creator.”⁵⁶ This independence provides, like the opacity of deep neural networks, another source of unpredictability.⁵⁷ As a general rule, the “more intelligent and dynamic” the AI, the less interpretable and less predictable it is, a phenomenon that Hosanagar calls the “predictability-resilience” paradox.⁵⁸

An AI’s autonomy stems from its ability to engage in algorithmic reasoning to complete tasks that were once reserved for humans, as well as the limits on humans’ ability to know, understand, and predict how or why a deep-learning algorithm produced a certain output.⁵⁹ Sometimes AI is described as “autonomous” only when its output is not subjected to human oversight or when there is no human “in the loop.”⁶⁰ In this case, autonomous medical AI is defined as an “AI system that provides direct treatment or diagnosis/screening recommendations without physician interpretation.”⁶¹ I do not subscribe to this limited view of AI autonomy for the Autonomous AI Physician. While the human’s role in reviewing or implementing an AI’s decision might help measure “automation,” Monika Simmler and Ruth Frischknecht distinguish this from the AI’s “autonomy.”⁶² Automation considers the level of human involvement between the AI’s output and execution—does a human need to approve execution of the AI’s decision?⁶³ Autonomy, on the other hand, considers the level of “independence of the technical component while completing an assigned task”—can a human predict and/or understand the AI’s decision-making process?⁶⁴ Simmler and Frischknecht establish a five-level taxonomy for

55. *Id.* at 3.

56. Tschider, *supra* note 10 at 1560.

57. *Id.* (“The net effect of unsupervised learning systems . . . is that creators can no longer understand their creations as the algorithms themselves become complex and unreadable.”).

58. HOSANAGAR, *supra* note 14, at 104–06. (“Today, some of the most accurate machine learning models that computer scientists can build are also the most opaque. As machines become more intelligent and dynamic they also become more unpredictable.”).

59. Wojciech Samek et al., *Explainable Artificial Intelligence: Understanding, Visualizing and Interpreting Deep Learning Models*, ARXIV (Aug. 28, 2017), <https://arxiv.org/pdf/1708.08296.pdf> [perma.cc/7RH5-32P6] (noting that artificial intelligence systems often outperform people in games like poker by acting in ways that their creators cannot comprehend).

60. Michael D. Abramoff et al., *Lessons Learned About Autonomous AI: Finding a Safe, Efficacious, and Ethical Path Through the Development Process*, 214 AM. J. OPHTHALMOLOGY 134, 134 (2020) (“[A]utonomous AI systems in healthcare are AI systems that make clinical decisions without human oversight.”); Aaron Gin & Bryan Helwig, MCDONNELL BOEHLEN HULBERT & BERGHOFF LLP, *FDA Signals Fast-Track Approval for AI-Based Medical Devices*, BLOOMBERG L. (May 9, 2018, 1:26 PM), <https://news.bloomberglaw.com/tech-and-telecom-law/fda-signals-fast-track-approval-for-ai-based-medical-devices-1> [perma.cc/8FCR-68E7] (“[I]t may be more desirable for a human to remain ‘in the loop’ to make clinical judgments, administer therapies, etc.”).

61. Michael D. Abramoff et al., *Automated and Computer-Assisted Detection, Classification, and Diagnosis of Diabetic Retinopathy*, 26 TELEMEDICINE & E-HEALTH 544, 545 (2020).

62. Monika Simmler & Ruth Frischknecht, *A Taxonomy of Human–Machine Collaboration: Capturing Automation and Technical Autonomy*, 36 AI & SOC’Y 239, 243 (2020).

63. *See id.* at 243–44 (describing the five levels of automation, the highest of which, the fifth, is defined by the artificial intelligence system acting without any human approval).

64. *Id.* at 244.

autonomy, according to which they classify machine learning algorithms as Level Four or Level Five if it is connected to another system that gives it access to new training data.⁶⁵ They explain the basis for this high level of autonomy:

Once a system can learn, it can no longer be completely determined or tracked, because the input and pathway for reaching the output may change. Due to machine learning, an intelligent system possesses a considerable amount of autonomy. Such a system is not only undetermined [or unpredictable] due to a specifically implemented and randomized variable, it is capable of changing its behavior base and becomes adaptable to the environment. The output and single steps toward execution are thus variable and can be permanently adapted. This again marks an increase in opacity as it hampers the comprehensibility of the system's action. The human part can no longer comprehend the criteria and circumstances by which the actions of the technical system are coordinated.⁶⁶

The “Autonomous” part of the Autonomous AI Physician is derived from the opaque and often unpredictable nature of the deep-learning algorithmic reasoning process that it uses to make decisions that, when made by a human, would constitute the practice of medicine, regardless of whether a human physician oversees the AI's use.⁶⁷

B. Medical AI Technologies

The spectrum of AI technologies contributing to the healthcare industry's digital transformation is wide.⁶⁸ It can include direct-to-consumer health apps and products like chatbots that assess symptoms, virtual fitness trainers, and watches that detect and alert users of irregular heart rhythms.⁶⁹ Straddling the home-clinical boundary, physicians can access the vital signs of patients at home using AI-based remote monitoring technologies, and emergency dispatchers can detect cardiac arrest over the phone using AI that analyzes a caller's words, voice, and breathing patterns.⁷⁰ In the clinical setting, healthcare providers use various AI-based technologies to manage patients' treatment ranging from AI that helps position patients for CT scans⁷¹ to AI that can predict early-stage heart disease⁷² and acute kidney failure.⁷³ Within this ever-expanding spectrum, many

65. *Id.* at 246.

66. *Id.*

67. HOSANAGAR, *supra* note 14, at 106 (“Today, some of the most accurate machine learning models that computer scientists can build are also the most opaque. As machines become more intelligent and dynamic they also become more unpredictable.”).

68. *E.g.*, Kraus et al., *supra* note 33, at 558 (noting AI contributions to healthcare's digital transformation).

69. Sara Gerke, *Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y, L., & ETHICS 433, 445 (2021).

70. *Id.* at 446 (describing remote monitoring technology); Sara Gerke et al., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, in ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295, 299 (Adam Bohr & Kaveh Memarzadeh eds., 2020).

71. Yadong Gang et al., *A Comparison Between Manual and Artificial Intelligence-Based Automatic Positioning in CT Imaging for COVID-19 Patients*, 31 EUR. RADIOLOGY 6049, 6051 (2021).

72. Gerke et al., *supra* note 70, at 299.

73. ABBOTT, *supra* note 3, at 2.

AI-technologies still function, like traditional medical devices, as tools “use[d] in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease”⁷⁴ But AI is becoming increasingly capable of autonomous medical decision-making, making it less like a tool used by humans and more like a medical practitioner.⁷⁵ For example, deep-learning AI can currently match the performance of human radiologists in diagnosing tuberculosis in chest x-rays⁷⁶ and detecting lesions in mammograms,⁷⁷ and pediatricians in diagnosing a range of common pediatric illnesses.⁷⁸ AI even outperforms human physicians in some tasks, including staging and grading lung cancer.⁷⁹ It can also provide early diagnosis of Alzheimer’s disease.⁸⁰ Based on its current performance and continued growth, the potential for autonomous medical AI to drastically improve healthcare quality and access is undeniable.⁸¹

Of course, autonomous medical AI technology does not come without risks.⁸² Despite its impressive performance in medical diagnosis, prognosis, and image analysis, deep-learning AI has important limitations.⁸³ It cannot yet distinguish between causation and correlation, engage in conceptual thinking, demonstrate human common sense, or analyze information across several knowledge domains.⁸⁴ In one case, medical AI trained to triage pneumonia patients classified patients with history of asthma as low-risk because the data indicated better outcomes for those patients.⁸⁵ Here, the AI failed to understand causation—asthmatic patients received a higher level of care following a pneumonia diagnosis, which produced better outcomes—and used a correlation in the data to make an unreliable prediction.⁸⁶

74. 21 U.S.C. § 321(h)(1)(B).

75. Walker Morrell et al., *The Oversight of Autonomous Artificial Intelligence: Lessons from Nurse Practitioners as Physician Extenders*, 9 J.L. & BIOSCIENCES 1, 2 (2022).

76. Paras Lakhani & Baskaran Sundaram, *Deep Learning at Chest Radiography: Automated Classification of Pulmonary Tuberculosis by Using Convolutional Neural Networks*, 284 RADIOLOGY 574, 575 (2017).

77. Thijs Kooi et al., *Large Scale Deep Learning for Computer Aided Detection of Mammographic Lesions*, 35 MED. IMAGE ANALYSIS 303, 311 (2017).

78. Huiying Liang et al., *Evaluation and Accurate Diagnoses of Pediatric Diseases Using Artificial Intelligence*, 25 NATURE MED., 433, 433 (2019).

79. Hye Yoon Chang et al., *Artificial Intelligence in Pathology*, 53 J. PATHOLOGY & TRANSLATIONAL MED. 1, 8 (2019).

80. TOM TAULLI, ARTIFICIAL INTELLIGENCE BASICS: A NON-TECHNICAL INTRODUCTION 80 (2019).

81. See Brian R. Jackson et al., *The Ethics of Artificial Intelligence in Pathology and Laboratory Medicine: Principles and Practice*, 8 ACAD. PATHOLOGY, Jan.–Dec. 2021 at 1, 1 (noting “[t]here is great enthusiasm for the potential of these AI tools to transform and improve healthcare.”); Ahmad et al., *supra* note 6, at 14 (noting that AI’s compatibility with smart phones could enable increased access to low-cost medical expertise).

82. Alvin Powell, *AI Revolution in Medicine*, HARV. GAZETTE (Nov. 11, 2020), <https://news.harvard.edu/gazette/story/2020/11/risks-and-benefits-of-an-ai-revolution-in-medicine> [perma.cc/66L2-SWG8] (“[E]ven those who see AI’s potential value recognize its potential risks.”).

83. TAULLI, *supra* note 80, at 86.

84. *Id.* at 86–87.

85. Rich A. Caruana et al., *Intelligible Models for Healthcare: Predicting Pneumonia Risk and Hospital 30-Day Readmission*, in PROCEEDINGS OF THE 21TH ACM SIGKDD INTERNATIONAL CONFERENCE ON KNOWLEDGE DISCOVERY AND DATA MINING 1721 (2015).

86. See *id.* (noting that the models the researchers discuss in the article incorrectly concluded that asthma lowers risk of dying from pneumonia when in fact it increases such risk).

AI also fails to display important human attributes, “like touch, compassion, empathy, context, and other human elements” crucial to the art of medical practice.⁸⁷ The importance of human contact in medicine became painfully apparent when a physician gave a patient a terminal cancer diagnosis from the screen of a “videoconference” robot that stood on the side of the patient’s “bad ear.”⁸⁸

There are other legal and ethical concerns attendant with the use of medical AI, including data privacy, security, and bias.⁸⁹ As a result, effective regulatory structures and human supervision of medical AI are necessary for patient safety.⁹⁰ Nevertheless, the rapidly growing investment in medical AI, computing power, and big data will result in increasingly more sophisticated and autonomous medical AI.⁹¹ And “[w]hile difficult to predict the exact trajectory of AI’s continued development, it is self-evident that AI is poised to take over a growing range of activities that were once the exclusive province of people.”⁹² Medical practice is included in that range of activities, making way for the Autonomous AI Physician.⁹³

C. *The Autonomous AI Physician*

I have previously defined the Autonomous AI Physician considering both its abilities and limitations as, “artificial intelligence that is capable of performing acts ordinarily considered medical practice (diagnosis, prognosis, development of a treatment plan, etc.) using algorithmic reasoning to make medical decisions *without a human involved in that medical decision-making process.*”⁹⁴

Currently, I impose a normative limitation that prohibits the Autonomous AI Physician from being “the sole medical decision maker for an individual patient” for patient safety reasons.⁹⁵ In other words, the Autonomous AI Physician’s ability to manage a patient’s care from presentation to diagnosis and treatment without any involvement or oversight by a human medical practitioner should be carefully restricted.⁹⁶ Although not a perfect comparison, the Autonomous AI Physician can be related to human medical interns, medical residents, physicians’ assistants, and nurse practitioners, all of whom are

87. Frank Griffin, *Artificial Intelligence and Liability in Health Care*, 31 HEALTH MATRIX 65, 86 (2021).

88. *See id.* (citing Julia Jacobs, *Doctor on a Video Screen Told a Man He Was Near Death, Leaving Relatives Aghast*, N.Y. TIMES (Mar. 9, 2019), <https://www.nytimes.com/2019/03/09/science/telemedicine-ethical-issues.html> [perma.cc/9FZA-GZCL]).

89. Duffour & Giovannello, *supra* note 27.

90. Axel Voss (Rapporteur), Eur. Parliament, Special Comm. on A.I. in a Digit. Age, *Report on Artificial Intelligence in a Digital Age*, at 14 (Apr. 5, 2022), https://www.europarl.europa.eu/cmsdata/246872/A9-0088_2022_EN.pdf [perma.cc/F3B5-VTAY].

91. ABBOTT, *supra* note 3, at 30–31.

92. *Id.* at 35.

93. *See, e.g.*, Jackson et. al, *supra* note 81, at 1 (“Growing numbers of artificial intelligence applications are being developed and applied to pathology and laboratory medicine.”).

94. Duffour & Giovannello, *supra* note 27.

95. *Id.*

96. I admit now that this restriction may be unnecessary in circumstances where the Autonomous AI Physician has proven highly reliable and the risk of allowing it to be a sole medical decision maker might be outweighed by the benefits of its use, for example by providing new avenues for access to medical care.

medical practitioners with the ability to conduct certain acts of medical practice but whose scope of practice is limited and/or requires physician oversight or supervision.⁹⁷ As a result, the Autonomous AI Physician, which is capable of making medical decisions related to a patient's care while simultaneously exhibiting a level of autonomy and being subject to oversight, will generally serve as part of a larger treatment team.⁹⁸ This arrangement can occur in a large healthcare organization that provides both primary and secondary care, but it can also occur in smaller primary and ambulatory care settings.⁹⁹ As part of a treatment team, the Autonomous AI Physician might diagnose patients, classify cancer cells, read radiographs, predict patient outcomes, or determine the best course of treatment.¹⁰⁰

The Autonomous AI Physician is not a futuristic concept.¹⁰¹ Current medical AI technologies are already capable of medical diagnosis, which describes “the process of determining the nature of a disease or disorder and distinguishing it from other possible conditions.”¹⁰² As a tool, a traditional medical device, like an MRI machine or an AI-driven medical technology, like a smart patient monitor, will assist a human physician in the diagnostic process.¹⁰³ In contrast, the Autonomous AI Physician, which can autonomously conduct the diagnostic process using its own learning and reasoning mechanisms, is less like a tool or product and more like a human member of the medical treatment team.¹⁰⁴ For example, IDx-DR, an FDA authorized AI-based application, can autonomously diagnose patients with diabetic retinopathy using deep-learning image analysis.¹⁰⁵ In the European Union, ChestLink, an autonomous AI that reads chest-x-rays, just received a CE mark, clearing its path

97. Morrell et al., *supra* note 75, at 1 (arguing that involved parties should supplement the “device-centered” regulatory approach to AI systems with one that treats AI systems as a “physician extender” like nurse practitioners).

98. *Id.* at 3 (“A-AI products may be capable of exercising independent judgement in the care of patients but will likely augment, support, and extend (and not replace) the work of physicians.”).

99. Bill Frist & Michael Abramoff, *If We're Serious About Healthcare Equity and Access, We Must Support Autonomous AI*, THE HILL (Oct. 17, 2020, 11:00 AM), <https://thehill.com/opinion/healthcare/521522-if-were-serious-about-healthcare-equity-and-access-we-must-support> [perma.cc/5N2E-FESG] (describing how healthcare systems could use autonomous AI in primary care settings to diagnose diseases); Liz Kwo, *Contributed: Top 10 Use Cases for AI in Healthcare*, MOBIHEALTHNEWS (July 1, 2021, 4:29 PM), <https://www.mobihealthnews.com/news/contributed-top-10-use-cases-ai-healthcare> (noting that emergency staff is already using AI to lower the risk of a fatal heart attack) [perma.cc/HE5H-2HJ7].

100. *E.g.*, Kwo, *supra* note 100 (“This AI analysis occurred in less than a day, a process that would have usually taken months or years, enabling the development of a treatment for the Ebola virus.”).

101. Lakhani & Sundaram, *supra* note 76, at 574 (documenting use of AI in tuberculosis screening).

102. Robert Edwin Rakel, *Diagnosis*, BRITANNICA, <https://www.britannica.com/science/diagnosis> [perma.cc/BX9F-22YX] (last visited Feb. 18, 2023); see Mindy N. Duffourc, *Are You My Doctor? Defining the Doctor-Patient Relationship in the Global Age of E-health*, 28 TULANE J. INT'L & COMPAR. L. 311, 319–20 (2020) (stating that diagnosis is typically considered medical practice); Berdyck v. Shinde, 613 N.E.2d 1014, 1021–22 (Ohio 1993) (explaining that nurses are prohibited from making diagnosis because such conduct constitutes medical practice).

103. Ben Clark, *Autonomous v. Assistive AI: How to Unlock Real Value in Healthcare*, DIGIT. DIAGNOSTICS (June 18, 2018), <https://www.digitaldiagnostics.com/newsroom/autonomous-vs-assistive-ai-how-to-unlock-real-value-in-healthcare> [perma.cc/J74W-GAMM] (“Assistive AI can take measurements and help physicians make decisions, working like a second set of eyes to review medical images, for example.”).

104. *Id.* (“Autonomous AI solutions are capable of actually making clinical and treatment decisions that impact patient care and outcomes.”).

105. Food & Drug Admin., *supra* note 1.

to the healthcare market in the EU.¹⁰⁶ AI can also accomplish tasks that have eluded human physicians, for example predicting tumor origin for “metastatic cancers of unknown origin.”¹⁰⁷ Beyond diagnosis, Sara Gerke predicts that given current investments in both AI and robotics, “[t]he use of autonomous systems as robot surgeons is also not far from reality.”¹⁰⁸

The Autonomous AI Physician expresses itself as both a medical product and a medical practitioner.¹⁰⁹ It manifests as a medical product during its design, manufacture, and maintenance.¹¹⁰ As a result, its development as a machine capable of medical practice in the first place along with any physical components of the Autonomous AI Physician are machine-based characteristics of the technology.¹¹¹ On the other hand, it more closely resembles a medical practitioner when it autonomously performs actions, like diagnosis, that are considered the practice of medicine when performed by humans.¹¹² This ability to “practice medicine” is a human-based characteristic of the technology.¹¹³

D. *Regulating the Autonomous AI Physician*

The Autonomous AI Physician’s expression of human and machine characteristics means that it cannot be contained solely by the legal structures applicable to medical products.¹¹⁴ Like human physicians, the Autonomous AI Physician should demonstrate both competency and accountability.¹¹⁵ For humans, a combination of accreditation, licensing, and certification processes, “defines the nature and length of training for health professionals, their ability to perform particular tasks or work in certain jurisdictions, and the maintenance and development of their skills and competencies.”¹¹⁶ The Autonomous AI Physician does not attend medical school, take board exams, or attend continuing medical education to establish and maintain competency.¹¹⁷ Instead, its competency to “practice medicine” is determined by its developers and

106. OXIPIT, *supra* note 1.

107. Khoa A. Tran et al., *Deep Learning Cancer Diagnosis, Prognosis and Treatment Selection*, 13 GENOME MED., Sept. 27, 2021, at 8.

108. Gerke, *supra* note 69, at 443–44.

109. Morrell et al., *supra* note 75, at 2.

110. *See id.* at 7 (describing products that could perform functions without oversight from a physician).

111. *Id.* at 8–10 (proposing for collaborative products, which physicians design “collaborative protocols” to assist in their operation, that physicians be responsible for such protocols’ design and efficacy).

112. *Id.* at 10 (describing a supervisory model where the device diagnoses ailments, but the physician oversees each diagnosis and treatment made by the A-AI product, “with greater oversight and controls”).

113. *Id.*

114. *See generally* Gerke et al., *supra* note 70, at 306–27 (discussing the legal challenges posed by using AI in healthcare under both American and European legal frameworks).

115. *Id.* at 296–97 (American government report “stressed the need to improve fairness, transparency, and accountability-by-design” for AI systems).

116. INST. OF MED. OF THE NAT’L ACADS., HEALTH PROFESSIONALS EDUCATION: A BRIDGE TO QUALITY 98 (Ann C. Greiner & Elisa Knebel eds., 2003).

117. *See* Griffin, *supra* note 87, at 94–95 (Reducing learning curves and preparing hospitals and surgeons to safely use AI devices falls at least partially to the manufacturer.”).

manifests as a machine-based quality of the AI that is subject to the U.S. Food and Drug Administration's (FDA) regulatory structures for medical devices.¹¹⁸

The FDA is in the process of developing a regulatory framework to ensure that Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) has a positive impact on patient care.¹¹⁹ The FDA defines SaMD as, “software intended to be used for one or more medical purposes [those intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions] that perform these purposes without being part of a hardware medical device.”¹²⁰ The FDA has also clarified that software that does not provide the basis for its recommendations will be considered a medical device and not exempt from FDA regulatory oversight as clinical decision support software.¹²¹ In the case of the Autonomous AI Physician, the FDA's regulatory scheme will likely encompass both premarket approval requirements (to ensure initial competency) and postmarket monitoring and evaluation requirements (to ensure continued competency).¹²² According to the FDA, this “total product lifecycle-based regulatory framework” would enable the FDA to provide a reasonable assurance of “safety and effectiveness” while “embrac[ing] the iterative improvement power of artificial intelligence and machine learning-based software as a medical device.”¹²³

Still, there remains skepticism about the FDA's ability to regulate “highly iterative, autonomous, and adaptive” medical AI systems.¹²⁴ Gerke raises serious safety concerns regarding the FDA's approach, which is admittedly in flux.¹²⁵ She proposes a new regulatory framework to “tighten . . . oversight of health AI to adequately protect patients' health.”¹²⁶ Her proposal includes a broader definition of medical devices, stricter and consolidated pre-market approval procedures, special requirements for black-box AI, continuous monitoring, and a systems approach to health AI that demands human factors research and training programs to improve safety and efficacy.¹²⁷ Tschider

118. See FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SaMD) ACTION PLAN 1, 1–7 (2021), <https://www.fda.gov/media/145022/download> [perma.cc/T4Z9-RANK].

119. *Id.* at 1.

120. *Software as a Medical Device (SaMD)*, FOOD & DRUG ADMIN. (Dec. 4, 2018), <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd> [perma.cc/ELE8-M5K5].

121. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 9 (2022), <https://www.fda.gov/media/109618/download> [perma.cc/7XYG-A5CZ].

122. See *id.* (discussing FDA's approach to clinical decision support and its recommendations for regulation). While Gerke examines and proposes solutions for deficiencies in current FDA regulation of AI-based technologies, she confirms that black-box AI using deep-learning software, like the Autonomous AI Physician, currently fall within FDA's regulatory scheme because its inputs and logic cannot be explained. Gerke, *supra* note 69, at 455–46.

123. *Artificial Intelligence and Machine Learning in Software as a Medical Device*, FOOD & DRUG ADMIN. (Sept. 22, 2021), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> [perma.cc/LE65-UHQ9].

124. FDA Discussion Paper, *supra* note 54, at 3.

125. See generally Gerke, *supra* note 69 (arguing for a new regulatory framework for AI-based medical devices).

126. *Id.* at 480.

127. See generally *id.* (recommending a wide range of proposals to regulate AI devices).

doubts the FDA’s capability to regulate black-box systems altogether, opining that “a comprehensive and effective ex ante solution [is] nearly impossible for innovative, adaptive technologies.”¹²⁸

However well the FDA ultimately regulates the Autonomous AI Physician, the tort system will still be called upon to adjudicate cases stemming from AI-caused patient injuries.¹²⁹ Like a human physician—however well-educated, -trained, and -supervised—the Autonomous AI Physician—however well-designed, -developed, and -monitored—will make mistakes that injure patients.¹³⁰ These mistakes will likely occur in the AI’s unpredictable and inarticulate deep-learning process, which bears some resemblance to the human mind.¹³¹ Indeed, “[h]uman decision-making may not only lack transparency but also have poorer explainability than AI’s.”¹³² This is because, like humans, autonomous algorithms encounter David Autor’s Polanyi’s paradox, which describes the ability to “know more than we can tell.”¹³³ Hosanagar illustrates the Polanyi paradox as follows:

Imagine you had to describe what your mother’s face looked like in a way that would enable someone else to pick her out of a crowd. While you could, of course, find your own mother among a group of thousands of people, someone using your written description would likely struggle to identify her even among only a few dozen.¹³⁴

Because both human and autonomous AI decision making often relies on this kind of uninterpretable “knowing,” their capacity to make wrong decisions that cannot be predicted by developers or prevented by regulators manifests as a human-based quality of the Autonomous AI Physician.¹³⁵ Considering its potential to improve healthcare, unpredictability should not be a bar to the uptake of the Autonomous AI Physician; however, like a human physician, it must be accountable when its autonomous decision-making breaches a legal standard of care and causes patient harm.¹³⁶

E. *The Liability Gap*

Liability for the Autonomous AI Physician’s negligent “practice of medicine” falls in the gap between human-centric and product-centric theories of tort liability.¹³⁷ A traditional application of tort law would treat the

128. Tschider, *supra* note 10, at 1615.

129. *Id.* at 1556 (“Without an effective regulatory-tort allocation model, manufacturers may not create life-saving devices due to upfront regulatory compliance expense, and without regulatory oversight, patients and physicians may forego cutting-edge solutions due to safety concerns.”).

130. See Morrell et al., *supra* note 75, at 15 (describing medical malpractice standards as applied to human physicians and noting “[w]hether and how these standards would be applied to the physician oversight of A-AI products remains to be seen.”).

131. See ABBOTT, *supra* note 3, at 138.

132. *Id.* at 137.

133. HOSANAGAR, *supra* note 14, at 108.

134. *Id.*

135. *Id.*

136. See Rachum-Twaig, *supra* note 17, at 1153 (“Thus, to the extent that we accept the desirability of AI-based robots, we must also accept a significant degree of unpredictability.”).

137. Chung & Zink, *supra* note 4, at 65–67.

Autonomous AI Physician as a medical product, but this approach fails to account for its ability to “perform tasks previously undertaken exclusively by humans.”¹³⁸ Namely, the Autonomous AI Physician presents liability challenges when its “practice of medicine” causes injury; neither the existing human-centric nor machine-centric liability regimes adequately account for its unique composition as a machine designed to autonomously practice medicine, a human action.¹³⁹ Human-centric liability theories, including medical malpractice and vicarious liability, cannot currently govern liability for the Autonomous AI Physician’s autonomous decision making because it is not a legal person, and thus, cannot be directly liable for its own negligence or act as an agent for vicarious liability.¹⁴⁰ On the other hand, products liability will fail to provide a viable cause of action for injuries caused by the Autonomous AI Physician in many cases.¹⁴¹

There are several reasons why products liability does not provide a comprehensive solution for Autonomous AI Physician liability. First, compliance with FDA regulations may preempt product liability claims.¹⁴² If the Autonomous AI Physician’s creators obtain pre-market approval (PMA), the most stringent of the FDA’s review and approval processes, product liability claims against the manufacturer for injuries caused by the Autonomous AI Physician would be preempted under the Medical Device Amendments Act.¹⁴³ Further, even if the Autonomous AI Physician receives FDA clearance under an abbreviated review process rather than full PMA, product liability claims may still be preempted if the AI was a component of a device that did receive PMA approval.¹⁴⁴ Finally, preemption might also apply if the FDA’s ultimate regulatory approach for medical devices like the Autonomous AI Physician is considered a “similarly stringent approval process” as the PMA process.¹⁴⁵ Assuming, *arguendo*, that product liability claims against the Autonomous AI Physician’s manufacturer are not preempted, the often unpredictable and opaque nature of a deep-learning AI’s autonomous decision-making process still makes products liability an ineffective vehicle for assigning liability.¹⁴⁶ This is primarily because products liability is grounded in deterring the human behaviors of product manufacturers based on defective manufacturing, defective

138. Huberman, *supra* note 17, at 239.

139. See Chung & Zink, *supra* note 4, at 80 (discussing the necessary tort-law flexibility required to effectively integrate AI-based medical technologies as a supplement for the moral judgment of humans).

140. See *id.* at 51, 67 (“Courts have traditionally deemed it impossible for machines to have legal liability as they are not legal persons. . . . Regarding the human-centric categories, both negligence and vicarious liability as causes of action appear to require personhood.”).

141. *Id.* at 68; Rachum-Twaig, *supra* note 17, at 1154–57; BECKERS & TEUBNER, *supra* note 17, at 74–76; Woodrow Barfield, *Liability for Autonomous and Artificially Intelligent Robots*, 9 PALADYN, J. BEHAV. ROBOTICS 193, 196–98 (2018); Kovac, *supra* note 17, at 11–13; Schweikart, *supra* note 20, at 14–15; Jorstad, *supra* note 19, at 10–11, 14–15.

142. Tschider, *supra* note 10, at 1555–56.

143. *Id.* at 1573–76 (discussing preemption under the Medical Devices Amendments Act and subsequent cases).

144. *Id.* at 1579.

145. *Id.* at 1580.

146. Rachum-Twaig, *supra* note 17, at 1155.

design, or failure to warn.¹⁴⁷ There is no product liability cause of action that encompasses the unpredictable and autonomous machine-mimicking-human behaviors that underly the Autonomous AI Physician's medical decision making.¹⁴⁸ It is important to recognize again that the unpredictability of autonomous AI is not a fault, but a feature of the technology.¹⁴⁹ As discussed above, "[s]elf-learning algorithms are frequently designed to outsmart the limits of the human mind and draw conclusions that are beyond human comprehension."¹⁵⁰ The Autonomous AI Physician's unpredictability is often precisely what enables its potential to offer novel, more effective, or more efficient diagnosis, prognosis, or treatment recommendations.¹⁵¹ Paradoxically, this unpredictability also places the Autonomous AI Physician's potential harm-causing behavior beyond the manufacturer's ability to prevent or mitigate the harm through manufacture, design, or warning.¹⁵² As Tschider observes, "[w]ith AI, potential risks can only be anticipated to a limited extent because the algorithm making the decisions is a completely different algorithm in clinical trials than when used post-trial."¹⁵³

As a result, if the harm-causing behavior stems from the Autonomous AI Physician's autonomous decision-making process, holding a manufacturer liable under an existing products liability cause of action would be difficult, if not impossible.¹⁵⁴ In the case of an alleged design defect, "there may be no design or manufacturing flaw that served as a causative factor in an accident" when the AI is designed to be unpredictable.¹⁵⁵ Even if there is a design defect, it would be difficult to prove, and even more difficult to show that a reasonable alternative design existed as required to sustain a products liability claim for defective design.¹⁵⁶ A failure to warn claim faces two doctrinal hurdles. First, it requires foreseeable harm; another obstacle generated by the AI's unpredictable nature.¹⁵⁷ Second, the learned intermediary doctrine shifts liability from the

147. *Id.*

148. Here is where Abbott's proposal of manufacturers' liability based on the AI's negligence suffers a doctrinal flaw. Strict liability of manufacturers for product injuries grounds liability in certain human behaviors (manufacture, design, warn), not product behaviors. Negligence is also grounded in human behavior that falls below a certain standard of care. Products cannot be negligent because they are not humans subject to behavioral standards of care. As a result, there is no doctrinal path in products liability to substitute negligence of a product's actions for strict liability for a manufacturer's behavior, because there is no manufacturer behavior in which to ground liability. What Abbott proposes is essentially vicarious liability for manufacturers based on negligent product behaviors, which requires the product to have agency, and therefore personhood. *See* ABBOTT, *supra* note 3, at 50–66.

149. Rachum-Twaig, *supra* note 17, at 1153.

150. BECKERS & TEUBNER, *supra* note 17, at 40.

151. Ahmad et al., *supra* note 6, at 3.

152. Huberman, *supra* note 17, at 235.

153. Tschider, *supra* note 10, at 1572.

154. *See* Huberman, *supra* note 17, at 237 ("AAs' [autonomous agents] harmful effects may be principally untraceable to tortious actions of designers, manufacturers, or users. If so, under traditional tort doctrine, the cost of harm resulting from AAs' emergent behaviours will simply lie where it falls.") (footnote omitted).

155. Barfield, *supra* note 142, at 196.

156. *See* Rachum-Twaig, *supra* note 17, at 1155–56 (arguing traditional tort-doctrine notions of foreseeability render alternative design showings extremely difficult); BECKERS & TEUBNER, *supra* note 17, at 76 (similar).

157. Rachum-Twaig, *supra* note 17, at 1156 ("Central to our idea of fully AI-based products is the expectation that such products perform, at least to a certain extent, in an unforeseeable manner.").

manufacturer to the healthcare provider for failing to warn patients of known risks associated with a medical device.¹⁵⁸

While many injuries caused by the Autonomous AI Physician will fall outside of the scope of products liability, some will not. For example, manufacturing defects may be a source of liability for clear equipment malfunction.¹⁵⁹ Additionally, there is potential for manufacturer liability under a products liability theory for failure to conduct post-market monitoring and failure to mitigate or warn healthcare providers against risks that become known to the manufacturer.¹⁶⁰ As a result, products liability is incorporated into the control framework for liability proposed in Part II.

II. A CONTROL FRAMEWORK TO GOVERN LIABILITY

Because the Autonomous AI Physician expresses traits of both a medical product and a medical practitioner, it requires an equally dynamic approach to legal liability.¹⁶¹ There is no current single legal liability solution for the Autonomous AI Physician, but there are several theories of tort liability that can provide a functional solution when merged under the central idea of control.¹⁶² For the control framework to function, tort law must recognize the Autonomous AI Physician's ability to exercise control over its own decision making by granting it limited legal personhood, so that the law can recognize and govern its negligence, i.e., failure to comply with a behavioral standard of care.¹⁶³ Relatedly, recognizing the Autonomous AI Physician as a legal person for the limited purpose of assigning tort liability also allows the law to attach a standard of care to the Autonomous AI Physician that accounts for its unique abilities, which are not comparable to any existing human medical practitioner.¹⁶⁴

Ryan Abbott challenges the legal community to find “not necessarily more or less law but the right law” to govern AI as it becomes increasingly more present and influential in society.¹⁶⁵ This control framework for liability for the Autonomous AI Physician attempts to respond to Abbott's challenge as it relates to autonomous medical AI that serves as part of a patient care team.¹⁶⁶ It surrenders to the fact that there is no one-size-fits-all solution for AI liability,

158. Schweikart, *supra* note 20, at 14–15.

159. Maliha et al., *supra* note 19, at 632–34.

160. Rachum-Twaig, *supra* note 17, at 1169–70.

161. See Maliha et al., *supra* note 19, at 634–35 (arguing for a balanced liability system which “avoid[s] undue burdens on physicians and frontline clinicians” and “promot[es] safe AI/ML development and integration.”).

162. See Griffin, *supra* note 87, at 104 (“Current legal frameworks for products liability, medical malpractice, and ordinary negligence are likely to provide the foundation for liability analysis of AI systems with some twists specific to AI.”).

163. See Chung & Zink, *supra* note 4, at 52–53, 67 (supporting legal personhood for medical AI, including the implications of control and vicarious liability, as “both negligence and vicarious liability as causes of action appear to require personhood.”).

164. *Id.* at 70. (AI like IBM's Watson enjoys “abilities that natural persons cannot hope to match—such as the ability to review many more cases and parse through much more relevant literature than any human.”).

165. ABBOTT, *supra* note 3, at 3.

166. *Id.*; see also Chung & Zink, *supra* note 4, at 52–53 (arguing in favor of treating Watson like a medical student, as both “perform complex work as part of the direct patient care team but do not have the autonomy and decision-making authority of attending physicians or even residents.”).

requiring the “difficult work of thinking through the implications of AI in different settings.”¹⁶⁷ Likewise, it does not pretend to offer a liability solution for all AI in healthcare, but instead seeks to participate in the ongoing scholarship that attempts to “[c]alibrat[e] diverse legal rules carefully to a variety of technology-specific digital risks” by focusing on liability for the risk of harm to humans presented by the Autonomous AI Physician.¹⁶⁸ Finally, the control framework operates as a functional solution to liability for the Autonomous AI Physician under existing legal rules rather than proposing a liability model that requires significant structural changes in liability law.¹⁶⁹

A. *Parties that Control the Autonomous AI Physician*

The control framework determines liability by focusing on who or what has control over the AI output that caused the injury.¹⁷⁰ Control features as a primary basis for liability in tort law.¹⁷¹ Namely, liability in tort accrues when a person breaches a duty of care and causes harm to another by an act or omission or when “something of which he is possessed or something or someone over whom he has control has caused harm to another.”¹⁷² Although control in tort law is generally highlighted in the context of liability for harm caused by third parties or objects over which an otherwise nonnegligent tortfeasor has control, when first-person acts or omissions lead to tort liability, there is an implicit understanding that the party had control over their own actions or omissions.¹⁷³ This idea of first-person control is reinforced by the principle that “a person is made responsible for the control of his physical being,” for example, in the case of spreading disease.¹⁷⁴ As a result, the control framework operates using a broad view of control to include control over both first-party and third-party actions and omissions.¹⁷⁵

The control framework seeks to identify the action/function output of the Autonomous AI Physician that caused the injury without the need to understand exactly why the AI’s injury-causing output occurred.¹⁷⁶ This approach admittedly depends on effective ex ante regulation of the Autonomous AI Physician to govern its development and safety for market use as a medical

167. ABBOTT, *supra* note 3, at 3; *see also* Maliha et al., *supra* note 19, at 634 (suggesting a balanced liability system).

168. BECKERS & TEUBNER, *supra* note 17, at 14.

169. *See* Chung & Zink, *supra* note 4, at 80 (“To invent sweeping new legal regimes that comprehensively spell out AI legal rights and responsibilities in the hopes of regulating all forms of AI would be a Sisyphean task given current levels of innovation.”).

170. *See* Schweikart, *supra* note 20, at 8 (recognizing control as “[a] key aspect of AI, as it relates to medical tort law”).

171. *See id.* (finding control “may influence liability across a spectrum of different parties” in medical AI applications).

172. Warren A. Seavey, *Principles of Torts*, 56 HARV. L. REV. 72, 75 (1942).

173. *See id.* at 77–81 (discussing tort law duties based on control).

174. *Id.* at 78.

175. *See id.* at 77–79 (“Once the duty to protect others has been found, the consequences of an intentional or negligent failure to act are the same as where there has been intentionally wrongful or negligent activity.”).

176. *See* Chung & Zink, *supra* note 4, at 75 (“Watson cannot fully explain the rationale for its decisions. It can cite medical literature, but it cannot explain why it selected a particular treatment for a particular patient.”) (citation omitted).

product.¹⁷⁷ Allowing regulatory structures to govern safety as it relates to the machine-centric qualities of the Autonomous AI Physician's design and development allows the control framework to govern liability based on the objective quality of the AI's injury-causing output.¹⁷⁸ This output may manifest as a machine-centric quality subject to products liability, but it is more likely to manifest as the human-centric "practice of medicine" subject to negligence law.¹⁷⁹

In the case of the Autonomous AI Physician, several parties can exhibit control over its injury-causing behavior.¹⁸⁰ Creators (designers, developers, and manufacturers) can exhibit control over the Autonomous AI Physician's hardware and software components.¹⁸¹ Healthcare organizations can exhibit control over the AI's implementation and continued use in clinical practice.¹⁸² Individual healthcare providers can exhibit control by providing human oversight for the AI's medical decision making.¹⁸³ Finally, the Autonomous AI Physician itself exhibits control over its own algorithmic decision making.¹⁸⁴ Control over an injury-causing action by the Autonomous AI Physician is not necessarily mutually exclusive to one party.¹⁸⁵ Instead, several parties can simultaneously exhibit control over the Autonomous AI Physician leading to potential liability for one or more parties.¹⁸⁶ As a result, the control framework follows the functional approach proposed by Chung and Zink by allowing parties to "be identified and classified by the capacity and the authority they have to commit (or share responsibility for) the tort, whether they be human or AI."¹⁸⁷

1. Control by Creators

Creators maintain some control over the Autonomous AI Physician once it enters the market and begins "practicing medicine."¹⁸⁸ As a result, products

177. See Kovac, *supra* note 17, at 107–12 (recognizing several regulatory possibilities to ensure safety of AI, including detailed standards for AI operations and functions, regulatory limits on AI abilities, sector-specific safety standards, and ex ante registration of AI).

178. See *id.* at 113 ("[T]he debate regarding the different ways of controlling hazardous activities may be reduced to a question of efficient *ex ante* safety regulation. In other words, regulatory intervention is, from the law and economics perspective, the best option for governing AI systems.")

179. See Chung & Zink, *supra* note 4, at 70 (arguing Watson should be "analogized to a medical student").

180. See Maliha et al., *supra* note 19, at 630 ("Physician liability over use of AI/ML is inextricably linked to the liability of these other actors," such as "health systems and AI/ML device manufacturers.")

181. *Id.* at 633–34 ("[M]edical algorithm developers, like the manufacturer of any product, could be liable for injuries that result from poor design, failure to warn about risks, or manufacturing defects.")

182. *Id.* at 631.

183. *Id.*

184. See Jorstad, *supra* note 19, at 13 (noting the "limited to nonexistent control physicians, hospitals, or even AI manufacturers exert over the machine's diagnosing").

185. See Chung & Zink, *supra* note 4, at 71 (noting even medical residents "are still considered to be in a trainee capacity, working under supervisory control.")

186. *Id.* at 73 (attributing to injury lawyer Max Kennerly the notion that even in patient-injury cases involving exclusively human practitioners, "a limbo often arises in which it is unclear who is even involved in the patient's care, making the attribution of fault difficult.")

187. *Id.* at 76.

188. See Maliha et al., *supra* note 19, at 630 (noting physician malpractice claims would be "inextricably linked to the liability of . . . other actors" like "AI/ML device manufacturers").

liability theories can still be applied for certain injury-causing actions or functions over which the creators can control.¹⁸⁹ For example, malfunctions caused by errors in the original source code or training data or manufacturing defects in the physical components of an Autonomous AI Physician can still lead to products liability when those errors and defects cause an AI action or function to injure a patient.¹⁹⁰ Additionally, creators may have a duty to monitor the AI's performance and the quality of its autonomous AI decision making once it is on the market, the failure of which may lead to products liability.¹⁹¹ Finally, once creators become aware of a particular risk expressed in the Autonomous AI Physician's autonomous algorithmic processes, duties to prevent and/or warn of the same or similar risks can arise.¹⁹²

On one hand, the Autonomous AI Physician does not cease to be a medical product, which obliges its creators to comply with standards of care that ensure product safety.¹⁹³ In fact, it is likely that FDA regulations that ultimately govern AI development and monitoring will play a role in setting the standard of care for manufacturers of the Autonomous AI Physician, providing manufacturers with some protection when those standards are met and serving as evidence of negligence when those standards are breached.¹⁹⁴ On the other hand, creators lose control over the Autonomous AI Physician once it begins exhibiting actions akin to human medical decision making, which are unpredictable by design.¹⁹⁵ In this case, the Autonomous AI Physician is acting more like a human and less like a product, making products liability an ill-suited source of liability for injuries caused by the AI's autonomous decision making.¹⁹⁶

While some scholars suggest modifying products liability to impose liability on manufacturers for injuries caused by the Autonomous AI Physician's unforeseeable and unpreventable actions, this approach violates main tenets of tort law.¹⁹⁷ The imposition of liability in the absence of human negligence or

189. *Id.* at 631.

190. *See id.* (noting "algorithm developers may have to contend with liability" in medical contexts).

191. *See* Rachum-Twaig, *supra* note 17, at 1169–71 (suggesting duties to monitor and related duties to warn and patch for AI manufacturers and developers).

192. *Id.* at 1156.

193. *See id.* at 1154 ("Products liability law seems to be the most adequate arena for discussing liability for AI-based robots.").

194. *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 108 (D. Conn. 2014) (citing *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011)) ("[A] failure to warn claim may be based on a violation of the FDA's continuing reporting requirements"); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 247 (S.D.N.Y. 2013); *Simmons v. Boston Sci. Corp.*, No. 12-cv-07962, 2013 WL 1207421, at *9–10 (C.D. Cal. Mar. 25, 2013) (noting that a violation of FDA regulations can form the basis of a products liability claim); *Jorstad*, *supra* note 19, at 10–11 (noting the availability of limited immunity for compliance with FDA regulations); *see Maliha et al.*, *supra* note 19, at 640 (noting that FDA regulations will likely affect the standard of care).

195. *See* Rachum-Twaig, *supra* note 17, at 1146 (describing the distinction between the actions of creators and the actions of the resulting robots).

196. *See* Chung & Zink, *supra* note 4, at 69–71 (describing the control medical practitioners exercise over medical students and its analogous descriptive force for AI-based medical solutions).

197. *See* ABBOTT, *supra* note 3, at 51 (proposing modifying strict liability to hold manufacturers liable when the AI's actions are negligent); *see* Kovac, *supra* note 17, at 108–112 (suggesting expanding both strict liability for manufacturers and vicarious liability for human principals as well as a detailed set of regulatory measures to govern AI development, use, and liability).

control is essentially strict liability.¹⁹⁸ Strict liability is justified as a departure from fault-based liability when the party bearing the costs of the accident is the party best situated to prevent the accident—this is the case for manufacturers who are best situated to eliminate product defects.¹⁹⁹ However, in the case of the Autonomous AI Physician, manufacturers may not be better situated than any other party to prevent unforeseeable accidents caused by the AI’s autonomous decision-making, undermining the normative justification for applying strict product liability.²⁰⁰

Second, imposing strict liability for unforeseeable accidents caused by the AI’s autonomous decision-making will not necessarily result in fewer accidents.²⁰¹ As Abbott observes, “more liability for manufacturers does not necessarily translate to fewer accidents if a product is safer than the existing standard.”²⁰² This is because when the Autonomous AI Physician performs tasks better than humans, assigning those tasks to the AI rather than humans will prevent more accidents than further improving the performance of the Autonomous AI Physician itself.²⁰³ This potential for strict liability to increase injuries caused by medical errors by discouraging automation in favor of safer and/or less legally risky AI development, when AI is already safer than humans, exemplifies why Abbott’s principle of “AI legal neutrality” (which treats AI and humans performing the same tasks the same for the purpose of benefiting humans), is a valid approach.²⁰⁴

In the case of the Autonomous AI Physician, “legal neutrality” is violated when the law imposes more liability for AI practicing medicine than it does for humans practicing medicine.²⁰⁵ Instead, applying the control framework to govern the Autonomous AI Physician under products liability only when creators exercise control over its machine-centric qualities satisfies both Abbott’s principle of “legal neutrality” and tort law’s goals by recognizing that, “[s]ociety has interests in sometimes competing values: reducing injuries and compensating victims as well as encouraging economic growth and progress. One way that tort law attempts to achieve a balance is by permitting recovery in negligence, only where there has been socially blameworthy conduct.”²⁰⁶

198. Rachum-Twaig, *supra* note 17, at 1162–63 (citing Gregory Keating to describe the distinction as “fault liability makes *wrongful* agency the fundamental basis of responsibility for harm accidentally done; strict liability makes *agency* itself the fundamental basis of responsibility.”) (citation omitted).

199. *Id.* at 1162; *see also* ABBOTT, *supra* note 3, at 55 (“Businesses are often in the best position to prevent product injuries and can distribute liability through insurance.”).

200. *See* Rachum-Twaig, *supra* note 17, at 1163 (“[S]ince the main feature of AI-based robots is that they may act in a manner unforeseeable or unexplainable by humans, in many cases none of the stakeholders will be better situated to assess the risks involved in their operation and the problem of imperfect information will apply equally to all stakeholders.”).

201. ABBOTT, *supra* note 3, at 9.

202. *Id.*

203. *Id.* at 58–59.

204. *Id.* at 9.

205. *See id.* (“When AI has more liability than a person, it makes automation costlier. This is not a desirable outcome.”).

206. *Id.* at 50.

2. *Control by Healthcare Organizations*

Healthcare organizations can exercise control over the Autonomous AI Physician's integration into treatment process as well as control over the Autonomous AI Physician as an agent of the organization.²⁰⁷ First, healthcare organizations that utilize the Autonomous AI Physician to care for patients have control over the AI's selection, implementation in clinical practice, training associated with integration of the AI, and organizational oversight related to the AI's ongoing use and capacity to "practice medicine."²⁰⁸ The organization's direct control over the Autonomous AI Physician's integration into the organization gives rise to corresponding duties of care to protect patients through the organizational process associated with using the AI as part of the medical treatment team.²⁰⁹ The corporate negligence doctrine already imposes direct liability for healthcare organizations that fail to exercise due care in the selection and hiring of physicians, maintenance of facilities and equipment, training and supervision of employees, and implementation of protocols and procedures.²¹⁰ These existing duties of care can also govern the selection, training, maintenance, use, and supervision of the Autonomous AI Physician.²¹¹

Second, the healthcare organization can exercise control over the Autonomous AI Physician as an agent of the organization.²¹² As a result, the healthcare organization would be vicariously liable for harm caused by the Autonomous AI Physician while in course and scope of providing medical care to patients.²¹³ Pinchas Huberman compares Autonomous AI machines to employees and proposes giving them legal agency so that AI-caused harm can be compensated under a theory of vicarious liability.²¹⁴ Like Huberman's theory, the control framework views the Autonomous AI Physician as an agent of the healthcare organization, but unlike Huberman's theory, it advocates for limited legal personhood, which allows the Autonomous AI Physician to be assigned negligence, indemnity, agency, and standards of care.²¹⁵ As discussed in Section

207. See Maliha et al., *supra* note 19, at 631 ("[H]ealth systems may be liable for failing to provide training, updates, support, maintenance, or equipment for an AI/ML algorithm.").

208. *Id.* at 632.

209. See *id.* (recognizing "health systems have a well-defined duty to provide safe equipment and facilities and to train their employees," thus making them responsible, at least in part, for the AI).

210. *Id.*; see generally S. Allan Adelman & Julie Robertson, *Emerging Trends in Healthcare Liability*, in AHLA SEMINAR MATERIALS (Am. Health L. Ass'n P06190005) [perma.cc/Q8VG-6FXF] (describing various duties of health care facilities, such as maintaining appropriate facilities, equipment, personnel, and procedures); Yvonne K. Puig, *Liability Overview: New Theories and Challenges*, in AHLA SEMINAR MATERIALS (Am. Health L. Ass'n P02150124) [perma.cc/KPQ8-95XW] (describing various large medical malpractice verdicts); 3 SUMMARY PA. JURIS. 2D, *Torts* § 37:45 (2d ed.) (theories of direct hospital liability).

211. See Maliha et al., *supra* note 19, at 631 (stating health systems may be liable for failing to "provide training, updates, support, maintenance, or equipment for an AI/ML algorithm.").

212. Duffourc & Giovanniello, *supra* note 27.

213. STEVEN E. PEGALIS, *AMERICAN LAW OF MEDICAL MALPRACTICE* § 6:20 (3d ed. 2022) ("A hospital would be liable for the negligent act of a physician, nurse or any other 'employee' acting within the scope of his employment for the hospital under the doctrine of respondeat superior.").

214. See generally Huberman, *supra* note 17 (suggesting "the doctrinal form of vicarious liability is a promising strategy to ground tort liability for autonomous-machine-caused harm.").

215. Compare *id.* with Duffourc & Giovanniello, *supra* note 27 (articulating the basic idea for the control framework).

II.B, limited legal personhood for the Autonomous AI will enable its functional integration into the existing tort law framework.²¹⁶

3. *Control by Individual Healthcare Providers*

Individual healthcare providers that work in conjunction with the Autonomous AI Physician to provide patient care exercise control over the Autonomous AI Physician's role on the medical treatment team.²¹⁷ As a result, they have a corresponding duty to integrate the Autonomous AI Physician into the patient's care in accordance with existing standards governing the use of AI in the clinical treatment process.²¹⁸ Breaches of such standards specific to the Autonomous AI Physician's proper role as a provider could constitute direct liability for the individual human healthcare provider.²¹⁹

Individual providers also exert control over the Autonomous AI Physician vis-à-vis human supervision and oversight.²²⁰ As a result, individual healthcare providers can be liable to patients for failure to properly supervise and oversee the Autonomous AI Physician's "practice of medicine."²²¹ Duties to supervise and oversee members of a medical treatment team are already established in the case law, and a breach of these duties can lead to direct or vicarious liability.²²² For example, "[a] supervising physician who provides inadequate supervision to a physician assistant may be directly liable for his or her own negligence."²²³ Direct liability for failure to supervise is more likely when a statute specifically delineates supervisory duties.²²⁴ Otherwise, physicians are held vicariously liable for the acts or omissions of providers over which they exercise general control or supervisory authority.²²⁵ In the case of physician assistants, the Tennessee Supreme Court held that, "as a general matter, a physician assistant stands in an agency relationship with his or her supervising physician when the physician assistant is providing authorized medical services within the scope of the parties' joint protocol."²²⁶ Similarly, an individual provider's failure to supervise or oversee the Autonomous AI Physician's "practice of medicine" can result in (1) direct liability when specific supervisory duties are delineated and

216. *Infra* Section II.B.

217. *See* Chung & Zink, *supra* note 4, at 69 (comparing Watson, an analogous Autonomous AI Physician, to medical students who act under the supervision of licensed medical practitioners).

218. *See* Maliha et al., *supra* note 19, at 632 ("Physicians have a duty to independently apply the standard of care for their field, regardless of an AI/ML algorithm output.").

219. *Cf. id.* at 633 (describing vicarious liability for health systems and physicians for AI/ML applications).

220. *See* Rachum-Twaig, *supra* note 17, at 1148 ("There may well be cases in which the use of AI will be part of a human-supervised process and could be encompassed by the current legal doctrines.").

221. *Cf. id.* at 1152 (noting existing shortcomings in personhood-agency analysis, wherein AI products are not considered legal persons, leading "current tort doctrines and basic tort principles [to] fall short.").

222. *Lopez v. Ledesma*, 505 P.3d 212, 214–19 (Cal. 2022).

223. *Id.* at 219.

224. *See id.*; *see also* Schnell v. New Milford Med. Grp., LLC, No. LLI-cv-20-6026993-S, 2021 WL 6101170, at *4 (Conn. Super. Ct. Nov. 19, 2021) ("The legislature imposes upon a supervising physician . . . the duty to adequately supervise a physician's assistant.").

225. W.R. Habeeb, Annotation, *Liability of One Physician or Surgeon for Malpractice of Another*, 85 A.L.R. 2d 889, § 4 (1962) ("A physician or surgeon is liable for the negligence or malpractice of a physician or surgeon acting in the case as his assistant.").

226. *Cox v. M.A. Primary & Urgent Care Clinic*, 313 S.W.3d 240, 254 (Tenn. 2010).

the breach of those duties causes a patient injury and/or (2) vicarious liability when the provider has general supervisory duties and the AI causes a patient injury while acting in the scope its agency.²²⁷

Finally, individual providers exercise control in the collaborative treatment arrangement, and thus can be held jointly liable with the Autonomous AI Physician when they diagnose and treat a patient together.²²⁸ “There is authority in support of the rule that where the physicians were jointly employed or acted jointly in the case, each may be liable for the malpractice of the other.”²²⁹ This is especially true when an individual provider observed or should have observed malpractice of another physician and allowed the treatment to continue without objection.²³⁰ Though related to supervision and oversight, the duty to intervene in the patient’s treatment when an individual provider knew or should have known that the Autonomous AI Physician’s “practice of medicine” was negligent can form a separate basis for vicarious liability.²³¹

4. *Control by the Autonomous AI Physician*

The Autonomous AI Physician has control over its own algorithmic decision making.²³² The parameters of this control are defined by the AI’s autonomy and the lack of control by other parties.²³³ The Autonomous AI Physician has autonomy over the learning and reasoning processes that takes place in the algorithm’s artificial neural networks, which can be described as the “mind of the robot.”²³⁴ Conversely, as discussed above, humans involved with the creation and use of the Autonomous AI Physician lack control over the AI’s autonomous algorithmic decision making.²³⁵ This is because, “AI is becoming multifaceted and therefore potentially capable of mobilising a diversity of resources in order to achieve objectives that are potentially incomprehensible to humans, let alone controllable or foreseeable.”²³⁶ Acknowledging that the Autonomous AI Physician has control over its own algorithmic decision making is an important step toward repairing the “major flaw in the current legal

227. *Id.*

228. *Habeeb, supra* note 226, § 9.

229. *Id.*

230. *Ales v. Ryan*, 64 P.2d 409, 420 (Cal. 1936) (“A physician is answerable for the acts of another, operating jointly, for the acts and omissions of the other which, exercising reasonable diligence, he should have observed.”); *Conrad v. Lakewood Gen. Hosp.*, 410 P.2d 785, 788 (Wash. 1966) (finding liability could be based on physician’s failure to remove a surgical instrument or in failing to observe another physician’s failure to remove the instrument).

231. *See Chung & Zink, supra* note 4, at 69 (arguing for treating AI like Watson as a medical student, noting that “clinical faculty member[s] may be held either directly or vicariously liable for the conduct of students under [their] purview.”).

232. *See ABBOTT, supra* note 3, at 60 (“Autonomous AI is given tasks to complete and functionally determine for itself the means of completing those tasks.”).

233. *See Barfield, supra* note 142, at 193 (discussing how robots are becoming more independent from human supervisory control and the possibility that humans be completely taken out of the robot’s decision-making processes).

234. *Id.* at 194.

235. *See id.* at 193–94 (noting legal complications inherent in AI, specifically related to how “robots with machine learning, may not learn or reason like humans do, and that can make their outputs difficult to predict, explain, and analyze under current legal schemes.”).

236. *Kovac, supra* note 17, at 105.

approach to autonomous robots” that results from the law’s inability to govern liability for “errors resulting from the autonomous robot’s ‘thinking.’”²³⁷

Of course, recognizing that the Autonomous AI Physician exercises some control over its own “practice of medicine” is of little legal consequence if it is not a legal person subject to tort liability.²³⁸

B. *Legal Personhood for the Autonomous AI Physician*

Legal personhood for the Autonomous AI Physician is necessary to integrate it into the control framework for liability.²³⁹ Recognizing the Autonomous AI Physician as a legal person for the limited purposes of assigning liability for its malpractice allows it to both be directly liable under a theory of medical malpractice and serve as an agent under a theory of vicarious liability.²⁴⁰ It also enables the Autonomous AI Physician to participate in the procedural aspects of medical malpractice litigation as a litigant capable of asserting comparative fault and other defenses to malpractice and participating in the discovery process.²⁴¹ Finally, because people, not products, are held to behavioral standards of care, personhood enables the law to assign a standard of care for the Autonomous AI Physician that corresponds to its unique ability to practice medicine.²⁴²

Legal personhood does not magically transform AI into a person with full-fledged human rights and responsibilities.²⁴³ It is instead, “a pre-existing legal fiction used to hold entities, not just natural persons, accountable.”²⁴⁴ Beckers and Teubner warn against the “android fallacy,” which mistakenly conflates the concept of personality with humanity.²⁴⁵ While it is beyond the scope of this paper to capture the complete philosophical discussion surrounding personhood for AI, Beckers and Teubner, relying on Latour’s neologism, provide a convincing justification for viewing the Autonomous AI Physician as a non-human societal actor worthy of legal personhood in certain circumstances.²⁴⁶ They note that the law already recognizes corporations as limited legal persons

237. Barfield, *supra* note 142, at 196.

238. *See id.* at 201–03 (highlighting difficulties in assigning liability since algorithms are not subject to malpractice claims and are not considered professionals).

239. *See* Chung & Zink, *supra* note 4, at 70–71 (explaining that legal personhood is required for certain failures, such as a physician failing to properly consider an AI’s recommendations, especially given their potential diagnostic accuracy).

240. *See id.* at 66–72 (arguing in favor legal personhood to allow for liability under human-centric theories, like medical malpractice and vicarious liability).

241. *See id.* at 74 (“Allowing Watson to be a party to lawsuits should help clarify the degree of its involvement in patient care and establish who may have deviated from Watson’s recommended treatment options and for what reasons.”).

242. *See id.* at 66 (explaining medical malpractice claims require showing a “defendant failed to conform to the required standard of care either by his acts or failure to act.”).

243. *Id.* at 76–77 (“The legal concept of personhood—in contrast to the term’s colloquial usage—is also flexible enough to encompass AI and it would be easy to create a legal definition of personhood that fits both current and evolving levels of AI.”).

244. *Id.* at 77.

245. BECKERS & TEUBNER, *supra* note 17, at 122.

246. *Id.*

because they have the capacity to act.²⁴⁷ Corporations' action capacity, they argue, stems not from the mere combination of their human members' actions, but rather from the distinct organizational decision chains that govern corporate action.²⁴⁸ In this view, algorithms, viewed as "mathematically formalized information flows" with the capacity to act are, like corporations, non-human "actants" capable of participating in society.²⁴⁹

Regardless of the philosophical debate regarding AI personhood, there is a convincing doctrinal reason for assigning personhood to the Autonomous AI Physician: the ability to hold it responsible for injury-causing actions under existing legal theories.²⁵⁰ Legal personhood for non-humans in the interest of functional legal doctrine is not a novel concept.²⁵¹ In 1972, Justice Douglas reminded the Court of the longstanding acceptance of non-human legal personality when making a plea for similar treatment of "environmental objects."²⁵² Legal personhood for corporations can be traced back to ecclesiastical law's notion of the "corporate sole," which recognized an office as a legal entity distinct from the individual holding the office.²⁵³ And while corporations are commonplace litigants today, "[e]arly jurists considered the conventional corporation to be a highly artificial entity."²⁵⁴ In 1819, Chief Justice Marshall observed that, "[a corporation] is an artificial being, invisible, intangible, and existing only in contemplation of law."²⁵⁵

The law's willingness to recognize non-human devices as legal persons for the sake of function also extends to ships.²⁵⁶ In 1902, the Court explained:

A ship is born when she is launched, and lives so long as her identity is preserved. Prior to her launching she is a mere congeries of wood and iron—an ordinary piece of personal property—as distinctly a land structure as a house, and subject only to mechanics' liens created by state law and enforceable in the state courts. In the baptism of launching she receives her name, and from the moment her keel touches the water she is transformed, and becomes a subject of admiralty jurisdiction. She acquires a personality of her own; becomes competent to contract, and is individually liable for her obligations, upon which she may sue in the name of her owner, and be sued in her own name.²⁵⁷

The Autonomous AI Physician can present as an "artificial being, invisible, intangible," like a corporation, but like a ship, it also experiences a form of

247. *Id.*

248. *Id.*

249. *Id.*

250. See Chung & Zink, *supra* note 4, at 62 (noting that we should "judge AI's capabilities in a functional and outcome-driven, rather than theoretical manner").

251. *Sierra Club v. Morton*, 405 U.S. 727, 742 (1972).

252. *Id.* at 742 (Douglas, J., dissenting).

253. *Id.* at 742 n.3 (Douglas, J., dissenting).

254. *Id.* at 743 n.4 (Douglas, J., dissenting).

255. *Id.* at 743 n.4 (Douglas, J., dissenting) (quoting *Trs. of Dartmouth Coll. v. Woodward*, 17 U.S. 518, 636 (1819) (Marshall, C.J.)).

256. *Id.* at 742 (Douglas, J., dissenting).

257. *Tucker v. Alexandroff*, 183 U.S. 424, 438 (1902).

transformation when it becomes more than an algorithm or product and exhibits autonomous and self-learning abilities.²⁵⁸

Finally, Justice Douglas would be delighted to know that his plea for legal personhood for environmental entities has been answered in some jurisdictions.²⁵⁹ In 2006, the Tamaqua Borough in Pennsylvania recognized that “ecosystems” have enforceable legal rights.²⁶⁰ In 2014, the New Zealand government recognized the Urewera National Park as a legal entity.²⁶¹ In 2016, the Uttarakhand High Court in India recognized two rivers as legal persons, noting that “the concept of legal person (or what the judges call a ‘juristic person’) can evolve according to the needs of society.”²⁶² In 2018, the Columbian Supreme Court declared the section of the Amazon rainforest within the country’s border to be an “entity subject of rights.”²⁶³ Thus far, there is no need for legal personhood for the Autonomous AI Physician to protect it (for the sake of humans).²⁶⁴ Instead, legal personhood for the AI is based on the need to protect humans from risks caused by the AI.²⁶⁵

Legal personhood status for non-human entities and the scope of attendant rights and duties depend on the entities’ role in law and society.²⁶⁶ As a result, the purpose of legal personhood for AI is based on an evaluation of its “normative position within legal relations—their impact on rights and duties of legal persons—not to conceptualize their general metaphysical character.”²⁶⁷ I agree with Abbott that AI should only be treated as a legal person when such treatment benefits humans.²⁶⁸ Additionally, legal personhood is not a zero-sum classification, but rather “a divisible bundle of rights and duties [that] is flexible enough to be used in different ways for a variety of actor constellations.”²⁶⁹ For example, while legal personhood for corporations and ships provides for their functional integration into private law, personhood for environmental entities serves to ensure their protection and survival for the benefit of humans.²⁷⁰ The parameters of the Autonomous AI Physician’s legal personhood can be defined

258. *Woodward*, 17 U.S. at 636.

259. *See Sierra Club*, 400 U.S. at 742 (Douglas, J., dissenting) (arguing for standing for trees).

260. SCHUYLKILL COUNTY, BOROUGH OF TAMAQUA, PA., GEN. LEGIS. Ch. 260, art. VI, § 260-61 (2006), <http://files.harmonywithnatureun.org/uploads/upload666.pdf> [perma.cc/G779-3TQF].

261. Joshua C. Gellers, *Earth System Law and the Legal Status of Non-Humans in the Anthropocene*, 7 EARTH SYS. GOVERNANCE 1, 6 (2021).

262. *Id.*

263. Anastasia Moloney, *Colombia’s Top Court Orders Government to Protect Amazon Forest in Landmark Case*, THOMSON REUTERS (Apr. 6, 2018, 9:46 A.M.), <https://www.reuters.com/article/us-colombia-deforestation-amazon/colombias-top-court-orders-government-to-protect-amazon-forest-in-landmark-case-idUSKCN1HD21Y> [perma.cc/RD6X-99SM].

264. *Cf. Chung & Zink*, *supra* note 4, at 79–80 (envisioning “combining the analytical and problem-solving capabilities of machines with the moral judgment of humans” and noting “[t]he law must be flexible to facilitate such a future.”).

265. ABBOTT, *supra* note 3, at 4.

266. *Id.*

267. Huberman, *supra* note 17, at 256.

268. *See* ABBOTT, *supra* note 3, at 4 (stating that treating AI as if it morally deserves rights should only be justified if this would benefit people).

269. BECKERS & TEUBNER, *supra* note 17, at 13.

270. *See* ABBOTT, *supra* note 3, at 127 (stating companies as artificial persons can sue and be sued); BECKERS & TEUBNER, *supra* note 17, at 34 (stating that autonomy for environmental law “defines threshold values for liability for damages given a scientifically determined gradualised scale of ecological degradation”).

by determining which legal duties and rights it must be given to realize the doctrinal justification for its creation: the ability to assign responsibility for wrongdoing.²⁷¹ Using this approach, the Autonomous AI Physician should be able to act as a legal agent of healthcare organizations and human practitioners and directly sue and be sued when it acts as a medical practitioner.²⁷²

1. *Legal Agency*

Granting legal personhood to the Autonomous AI Physician so that it can act as an agent for healthcare organizations and human practitioners involved in its clinical use is necessary for vicarious liability to function in the control framework.²⁷³ “An agency relationship requires: ‘(1) the principal to acknowledge that the agent will act for it; (2) the agent to manifest an acceptance of the undertaking; and (3) control by the principal over the actions of the agent.’”²⁷⁴ Here, the control framework runs into a doctrinal hurdle: the Autonomous AI Physician does not have the requisite volition to be a legal agent.²⁷⁵ Huberman relies on the composite agency theory to solve this problem.²⁷⁶ He imputes intention from the human principal (who remains unidentified in his approach) to the autonomous AI agent.²⁷⁷ As a result, he stops short of recommending legal personhood for autonomous AI, concluding that, “[i]t is problematic to assess AAs’ tortious actions independently—abstracted from the deployment relation—as this severs AAs’ (tortious) actions from their source of intentionality.”²⁷⁸

Under the control framework, the doctrine of apparent agency is a solution to the Autonomous AI Physician’s lack of volition that is compatible with limited legal personhood for the Autonomous AI Physician.²⁷⁹ Apparent agency is established when a party represents that another is his agent thereby causing a third party to justifiably rely on the care or skill of the party appearing to be the agent.²⁸⁰ In the case of the Autonomous AI Physician with legal personhood,

271. See BECKERS & TEUBNER, *supra* note 17, at 3 (noting a growing gap between responsibility and liability and discussing participation in the ongoing scholarship that attempts to “calibrat[e] diverse legal rules carefully to a variety of technology-specific digital risks”).

272. See Chung & Zink, *supra* note 4, at 76–77 (invoking the flexibility of legal personhood as a virtue in the context of harms caused by medical AI).

273. See Huberman, *supra* note 17, at 257 (discussing deployers’ vicarious liability and noting “without legal personhood status, it is not clear that AAs can comprise legal agency relations and cause, by their own acts, legal effects for deployers.”).

274. *Franza v. Royal Caribbean Cruises, Ltd.*, 772 F.3d 1225, 1236 (11th Cir. 2014) (quoting *Whetstone Candy Co. v. Kraft Foods, Inc.*, 351 F.3d 1067, 1077 (11th Cir. 2003)).

275. See Huberman, *supra* note 17, at 264 (“Pursuant to standard accounts of agency, therefore, absent mental states and consciousness, AAs cannot be agents at all.”).

276. *Id.* at 271–274.

277. *Id.* at 274.

278. *Id.*

279. See Chung & Zink, *supra* note 4, at 76 (“legal concept of personhood . . . is also flexible enough to encompass AI”).

280. *Franza*, 772 F.3d at 1249 n.17 (“Many courts use the terms apparent agency, apparent authority, ostensible agency, and agency by estoppel interchangeably.”); see also RESTATEMENT (SECOND) OF AGENCY § 267 reporter’s notes (1958) (AM. L. INST., updated 2022) (“theory of agency by estoppel . . . is the equivalent of apparent authority and based on the same elements.”) (citing *Whitlow v. Good Samaritan Hosp.*, 536 N.E.2d 659, 662 (Ohio Ct. App. 1987)).

a healthcare provider's implementation and use of the AI in clinical practice is likely sufficient to qualify as a representation to the patient that the AI is an agent of the hospital, a representation on which the patient can reasonably rely to expect a certain level of care and skill from the Autonomous AI Physician.²⁸¹

The doctrine of apparent agency is often allowed to hold healthcare organizations liable for patient injuries caused by various healthcare providers providing care in the organization.²⁸² In hospital settings, many courts find that “apparent agency is established when the plaintiff proves that he or she looked to the principal to provide services and the principal, not the plaintiff, selected the specific person who actually provided the services and caused the plaintiff's injury.”²⁸³ On the other hand, the doctrine of apparent agency generally will not operate to hold a hospital liable when a doctor-patient relationship was independently established prior to the hospital stay.²⁸⁴ In the case of the Autonomous AI Physician, which will always be part of a larger medical treatment team within a healthcare organization, it is likely that a patient will neither look to the Autonomous AI Physician—rather than the hospital—for provision of care, nor establish a prior independent doctor-patient relationship

281. See cases cited *infra* note 285.

282. Several jurisdictions allowed theories of apparent agency, ostensible agency, or agency by estoppel for actions against various healthcare practitioners. See *Stewart v. Midani*, 525 F. Supp. 843, 851 (N.D. Ga. 1981) (emergency room provider); *Calderone v. Kent Cnty. Mem'l Hosp.*, 360 F. Supp. 2d 397, 400 (D.R.I. 2005) (emergency room provider); *Vanaman v. Milford Mem'l Hosp., Inc.*, 272 A.2d 718, 722 (Del. 1970) (emergency room provider); *Brown v. Coastal Emergency Servs., Inc.*, 354 S.E.2d 632, 636 (Ga. Ct. App. 1987) (emergency room provider); *Gilbert v. Sycamore Mun. Hosp.*, 622 N.E.2d 788, 795 (Ill. 1993) (emergency room provider); *Wilkins v. Marshalltown Med. & Surgical Ctr.*, 758 N.W.2d 232, 236 (Iowa 2008) (emergency room provider); *Popovich v. Allina Health Sys.*, 946 N.W.2d 885, 891 (Minn. 2020) (emergency room provider); *Houghland v. Grant*, 891 P.2d 563, 564, 568 (N.M. Ct. App. 1995) (emergency room provider); *Martell v. St. Charles Hosp.*, 523 N.Y.S.2d 342, 350 (N.Y. Sup. Ct. 1987) (emergency room provider); *Wilson v. Grant*, 258 P.3d 689, 695 (Wash. Ct. App. 2011) (emergency room provider); *Pamperin v. Trinity Mem'l Hosp.*, 423 N.W.2d 848, 855 (Wis. 1988) (emergency room provider); *Mejia v. Cmty. Hosp. of San Bernardino*, 122 Cal. Rptr. 2d 233, 236 (Cal. Ct. App. 2002) (radiologist); *Roessler v. Novak*, 858 So. 2d 1158, 1162 (Fla. Dist. Ct. App. 2003) (radiologist); *Gunther v. Staten Island Hosp.*, 640 N.Y.S.2d 601, 602 (App. Div. 1996) (radiologist); *Jennison v. Providence St. Vincent Med. Ctr.*, 25 P.3d 358, 364–65, 367 (Or. Ct. App. 2001) (radiologist); *Cefaratti v. Aranow*, 141 A.3d 752, 764, 766–67, 771 (Conn. 2016) (surgeons); *Jones v. HealthSouth Treasure Valley Hosp.*, 206 P.3d 473, 480–81 (Idaho 2009) (anesthesiologist); *Sword v. NKC Hosps., Inc.*, 714 N.E.2d 142, 149, 151 (Ind. 1999) (anesthesiologist); *Williams v. St. Claire Med. Ctr.*, 657 S.W.2d 590, 595–96 (Ky. Ct. App. 1983) (anesthesiologist); *Butler v. Domin*, 15 P.3d 1189, 1197 (Mont. 2000) (anesthesiologist); *Sharsmith v. Hill*, 764 P.2d 667, 672 (Wyo. 1988) (pathologist); *Diller v. Munzer*, 34 N.Y.S.3d 608, 610 (N.Y. App. Div. 2016) (neonatologist); *Shepard v. Sisters of Providence*, 750 P.2d 500, 504, *appeal after remand at* 793 P.2d 1384 (Or. Ct. App. 1990) (resident); *Whitlow v. Good Samaritan Hosp.*, 536 N.E.2d 659, 662 (Ohio Ct. App. 1987) (physician in outpatient clinic); *Debbas v. Nelson*, 885 A.2d 802, 815 (Md. 2005) (physician in hospital); *Hunt v. Mercy Med.*, 710 A.2d 362, 377 (Md. Ct. Spec. App. 1998) (physician in hospital); *Capan v. Divine Providence Hosp.*, 430 A.2d 647, 649 (Pa. Super. Ct. 1980) (physician in hospital); *Burless v. W. Va. Univ. Hosps., Inc.*, 601 S.E.2d 85, 94 (W. Va. 2004) (physician in hospital).

283. *Cefaratti*, 141 A.3d at 766–67 (citing cases from Alaska, Illinois, Kentucky, Michigan, Mississippi, Montana, Nevada, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, West Virginia, Wisconsin, and Wyoming).

284. See *Davis v. Hoffman*, 972 F. Supp. 308, 312 (E.D. Pa. 1997) (no apparent agency when patient had a pre-existing relationship with a physician prior to receiving treatment in the hospital); *Brown ex rel. Brown v. St. Vincent's Hosp.*, 899 So. 2d 227, 230, 234–35, 243 (Ala. 2004) (no apparent agency for obstetric care); *Street v. Washington Hosp. Center*, 558 A.2d 690, 692–93 (D.C. 1989) (no apparent agency when patient's husband referred her to a physician in a non-emergency); *Rodrigues v. Miriam Hosp.*, 623 A.2d 456, 462 (R.I. 1993) (no apparent agency for actions of specialist called by patient's personal physician).

with the Autonomous AI Physician.²⁸⁵ As a result, the circumstances surrounding the Autonomous AI Physician's use in most large clinical settings is probably enough to support apparent agency.²⁸⁶

Once apparent agency is established, the scope of the agency relationship between the Autonomous AI Physician and its principal should be governed by the risks associated with the provision of medical care offered by the healthcare provider.²⁸⁷ If those risks manifest and cause injury to a patient, then the human-centric theory of vicarious liability becomes available for the apparent AI agent just as it would in the case of a human agent or employee.²⁸⁸ Relying on Huberman's focus on enterprise risk as the primary justification for vicarious liability, as long as the autonomous AI agent's negligence "relate[s] to characteristic risks of enterprise," vicarious liability can apply under current law.²⁸⁹ For example, when a drunk coast guard employee ran into a drydock wall, a court found the government vicariously liable, noting that, "since vicarious liability attaches to general ongoing risk of enterprise, an employee's particular tortious act need not be foreseeable to the employer as a real and substantial risk in the negligence sense."²⁹⁰ Similarly, in the case of the Autonomous AI Physician, the healthcare organization can be vicariously liable for injuries caused by the AI's actions, even if unforeseeable, as long as they can be classified as risks characteristic of the organization's enterprise—the provision and organization of medical treatment.²⁹¹ On the other hand, the principal will not be liable when the agent's tortious action causes harm that falls outside of the scope of the risks associated with the enterprise.²⁹²

2. *Direct Liability*

In addition to acting as an agent for the purposes of vicarious liability, legal personhood for the Autonomous AI Physician allows it to be directly liable for its own acts of negligence.²⁹³ Direct liability for the Autonomous AI Physician is important for four reasons. First, it eliminates the inherent unfairness in arbitrarily assigning liability to humans who had no control over the AI's injury causing behavior.²⁹⁴ Assigning liability to humans in the absence of either

285. *But see* Chung & Zink, *supra* note 4, at 70 (noting IBM's marketing and concluding "[m]achine or not, Watson most definitely is, and is marketed as, a member of the team.>").

286. *See, e.g., id.* at 56 (stating that AI Watson is being used by physicians to provide a language interface for the delivery of general and patient specific information, and further elaborating that Watson is being taught to conduct traditionally human duties, such as patient interviews).

287. *E.g.,* RESTATEMENT (THIRD) OF AGENCY § 2.03 cmt. a (AM. L. INST. 2006) (apparent authority scope).

288. *See* Rachum-Twaig, *supra* note 17, at 1159–60 (analyzing negligence, specifically breach, in the context of AI-based robots).

289. Huberman, *supra* note 17, at 246.

290. *Id.* at 246 (citing *Ira S. Bushey & Sons, Inc. v. United States*, 398 F.2d 167 (2d Cir. 1968)).

291. *See id.* at 247 (stating that determination of vicarious liability turns on judging the strength of the connection between an employees' tortious acts and the risks of enterprise).

292. *See id.* at 249 ("In the absence of the right kind of relation between the enterprise risk and the ensuing tortious act, there is no vicarious liability, even if some of the policy goals could still be advanced.>").

293. *See* Chung & Zink, *supra* note 4, at 69–70 (recommending legal personhood to allow for direct liability under existing theories of medical malpractice).

294. *See* Maliha et al., *supra* note 19, at 635 (noting "inconsistent or unclear legal decisions against developers could stifle innovation.>").

human negligence or control over the Autonomous AI's medical decision-making essentially imposes strict liability on humans for the AI Physician's medical malpractice.²⁹⁵ As discussed above, the policy reasons underlying the imposition of strict liability are not justified in the case of malpractice by the Autonomous AI Physician because liability for its unpredictable decision-making will likely not result in a better Autonomous AI Physician or safer medical care.²⁹⁶ Instead, to avoid legal risks, creators will be encouraged to increase predictability while healthcare organizations and providers decrease uptake, both of which, as a result of the "predictability-resilience paradox," will decrease or even eliminate the potential for deep learning autonomous AI to deliver health benefits to patients.²⁹⁷

Second, direct liability allows the Autonomous AI Physician to be a named litigant in cases involving medical injuries thereby enabling its participation in discovery and ability to file claims for indemnity, contribution, comparative fault, contributory negligence.²⁹⁸ These procedural aspects of medical malpractice litigation are crucial to determining why and how medical errors occurred.²⁹⁹ In terms of discovery, parties to litigation are subject to stricter standards for producing information than non-parties.³⁰⁰ Although the Autonomous AI Physician cannot give a deposition, it can produce potentially relevant electronic information regarding its training, activities within the healthcare organization, and involvement in the subject case that might be otherwise privileged.³⁰¹ As a litigant, the Autonomous AI Physician also has the right to request discovery from other named parties further aiding the truth-seeking goal of discovery.³⁰² Having a voice in discovery separate from a human or organization associated with its use avoids conflicts of interest and gives the Autonomous AI Physician the opportunity to expose negligence of other parties through discovery, including those that might be its principal in an agency relationship.³⁰³

Relatedly, as a named litigant, the Autonomous AI Physician can plead affirmative defenses of comparative fault against co-defendants or third parties and contributory fault against a plaintiff when the facts of the case support such

295. See Rachum-Twaig, *supra* note 17, at 1162–64 (criticizing application of strict liability to AI-based robots, namely due to "personhood and agency problems").

296. See, e.g., ABBOTT, *supra* note 3, at 9 ("more liability for manufacturers does not necessarily translate to fewer accidents if a product is safer than the existing standard").

297. See HOSANAGAR, *supra* note 14, at 104 ("Today, some of the most accurate machine learning models that computer scientists can build are also the most opaque. As machines become more intelligent and dynamic they also become more unpredictable.").

298. See Chung & Zink, *supra* note 4, at 73 (noting that allowing the AI to be named as a litigant can help determine its involvement in the alleged malpractice and "aid in the establishment of truth"); see also STUART M. SPEISER ET AL., AMERICAN LAW OF TORTS §§ 7:16, 13:2 (3d ed. 2018) (outlining affirmative defenses generally and stating that comparative fault apportions liability in relation to each party's degree of negligence).

299. See Chung & Zink, *supra* note 4, at 73 (noting that allowing the AI to be named as a litigant can help determine its involvement in the alleged malpractice and "aid in the establishment of truth").

300. See *id.* ("[T]hose named in a lawsuit have a higher evidentiary burden than non-party witnesses.").

301. See *id.* at 73–74 (stating that if the AI is named as a defendant in a civil suit, claimants may be able to gain greater access to electronic logs to determine the AI's exact involvement in the case).

302. See *id.* at 74 (joining medical students—and therefore AI-based robots by extension—as parties "helps with the attribution of responsibility for faults.").

303. *Id.*

claims.³⁰⁴ Likewise, other defendants may assert claims of comparative fault against the Autonomous AI Physician. In medical malpractice litigation, these claims help ensure that all possible negligent parties are involved.³⁰⁵ Such information is not only crucial for accountability but is also important for preventing future similar errors.³⁰⁶ This would prevent uncontested finger-pointing to the Autonomous AI Physician by human defendants who are trying to escape liability for their own negligent actions.³⁰⁷

Affirmative defenses can also serve to limit a defendant's liability to correspond with its percentage of liability in jurisdictions that apply a comparative fault scheme.³⁰⁸ In the case of joint and several liability or vicarious liability, allowing the Autonomous AI Physician to sue or be sued for contribution and indemnity, respectively, serves similar doctrinal purposes.³⁰⁹ In the case of joint and several liability, a party can seek contribution from a joint tortfeasor for the portion of the amount paid to satisfy a judgment or settlement that corresponds with the tortfeasor's "comparative share of responsibility."³¹⁰ In the case of vicarious liability, indemnity allows a party who "was not liable except vicariously for the tort of the indemnitor" to recover the amount paid in judgment or settlement from the negligent indemnitee.³¹¹

Causes of action for comparative fault, contribution, and indemnity inject equity into liability scenarios that involve more than one tortfeasor, a common occurrence in medical negligence lawsuits.³¹² As a result, eliminating a party's ability to access these doctrines shakes the foundation of tort law.³¹³ Huberman admits that his composite agency approach precludes the principal from seeking indemnity from the autonomous AI agent because there is no legal identity separation between the two.³¹⁴ This problem also extends to the doctrines of comparative fault and contribution.³¹⁵ Giving the Autonomous AI Physician

304. SPEISER ET AL., *supra* note 299, §§ 7:16, 13:2.

305. *See e.g.*, *Betesh v. United States*, 400 F. Supp. 238, 243 (D.D.C. 1974) (medical negligence suit involving multiple doctors); *Marina Emergency Med. Grp. v. Superior Ct.*, 84 Cal. App. 4th 435, 437 (Cal. Ct. App. 2000) (medical negligence suit that involved care from two doctors and comparative indemnity).

306. *See Chung & Zink, supra* note 4, at 74 (noting that allowing AI to be a party to a lawsuit would help provide clarity as to the degree of its involvement in patient care).

307. *See* cases cited *supra* note 306.

308. *See* SPEISER ET AL., *supra* note 299, § 13:2 (comparative fault apportions liability in relation to each party's degree of negligence); *In re New Eng. Compounding Pharm., Inc. Prods. Liab. Litig.*, 251 F. Supp. 3d 294, 297–98 (D. Mass. 2017) (an affirmative defense of comparative fault allows a party to plead the negligence of another party to decrease its liability). Most U.S. jurisdictions have adopted some form of comparative fault. *See* RESTATEMENT (THIRD) OF TORTS: APPOINTMENT OF LIAB. § 1 cmt. a. (AM. L. INST. 2000) (outlining the general concept of comparative fault and its applications to tort law).

309. *See* RESTATEMENT (THIRD) OF TORTS: APPOINTMENT OF LIAB. § 10 cmt. a (AM. L. INST. 2000) (outlining the effects of joint and several liability); *id.* § 22 (outlining indemnity).

310. *Id.* § 23.

311. *Id.* § 22.

312. *See e.g.*, *Betesh v. United States*, 400 F. Supp. 238, 243 (D.D.C. 1974) (multiple doctors).

313. *See* Huberman, *supra* note 17, at 235 (stating that the possibility of autonomous-machine-caused harm generates significant doctrinal and theoretical challenges for assigning tort liability because of liability gaps).

314. Huberman, *supra* note 17, at 251–52.

315. *See* SPEISER ET AL., *supra* note 299, § 13:2 (comparative fault apportions liability in relation to each party's degree of negligence).

limited legal personhood solves this problem by allowing it to both sue and be sued for indemnity, contribution, and comparative fault.³¹⁶

Third, direct liability for the Autonomous AI Physician with legal personhood makes it an insurable medical practitioner.³¹⁷ Because the Autonomous AI Physician will usually be considered an apparent agent of the healthcare organization in which it practices, the healthcare organization or provider that employs it in clinical practice should be responsible for securing its malpractice insurance; this insurance should be mandatory.³¹⁸ In large healthcare organizations, the Autonomous AI Physician will likely be covered under the organization's commercial insurance or self-insurance just as hospital employees, like nurses, who provide medical services in the organization.³¹⁹ In smaller private primary care or ambulatory settings, the Autonomous AI Physician can either be covered under a larger policy that covers nurses and other organizational risks or it can be covered as a separate medical practitioner.³²⁰ Medical malpractice insurance is generally required either by state law, hospital regulations, or health insurance companies, but, in any case, should be mandatory for the Autonomous AI Physician.³²¹

Medical malpractice insurance for the Autonomous AI Physician serves several practical purposes. Insurance will provide a defense for the Autonomous AI Physician in the case of a medical malpractice claim.³²² As a result, the Autonomous AI Physician's procedural actions, including discovery and pleading, would be conducted vis-à-vis the human attorney assigned by the insurance company to represent it in litigation.³²³ Additionally, providing the Autonomous AI Physician with its own attorney could avoid conflicts of interest that might arise when some combination of the AI, the healthcare organization, human doctors, or creators are joint tortfeasors.³²⁴ Practically, this is not a major

316. See, e.g., Huberman, *supra* note 17, at 256–57 (discussing the “scope of legal agency relations between deployers and AAs,” discussing suability and indemnity).

317. See Jessica S. Allain, *From Jeopardy! to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems*, 73 LA. L. REV. 1049, 1066–67 (2013) (noting that if courts “consider Watson more analogous to a physician rather than [] equipment . . . hospitals could potentially be able to obtain separate insurance policies to cover the risk of Watson causing injury just like they insure their healthcare provider employees.”).

318. See *id.* (“Because Watson cannot be held financially responsible for making restitution, hospitals will likely carry much of this burden if vicariously liable.”).

319. See *id.* (“just like [hospitals] insure their healthcare provider employees”).

320. See *id.* at 1067 (Despite this potential burden, however, separate insurance policies and a streamlined liability standard will likely encourage hospitals to purchase and use artificial intelligence systems.”).

321. See D. Bowen Berry, *The Physician's Guide to Medical Malpractice*, 14 BAYLOR UNIV. MED. CTR. PROC. 109, 109–12 (2001) (noting various requirements related to malpractice insurance).

322. See *id.* at 109 (“The [insurance] carrier has 2 primary obligations under a medical malpractice policy: the duty to defend and the duty to indemnify.”).

323. See *id.* (“An insurance carrier will generally retain counsel for a physician when a lawsuit is filed . . .”).

324. See, e.g., Huberman, *supra* note 17, at 281 (“[A]gents' conflicts of interest are a real concern, so fiduciary duties serve to ensure agents act only for the interests of their principals.”). *But see* Allain, *supra* note 318, at 1076 (“Separating fault between the physicians, Watson, and the hospital will be an incredibly fact-based, complex inquiry that may be unrealistic.”).

departure from what currently happens on the ground in tort litigation.³²⁵ Defense attorneys are already generally appointed by the provider's malpractice insurer, and insurance professionals, rather than the individual providers, handle most of the litigation management in coordination with the attorneys.³²⁶ However, the policyholder, as the healthcare organization that employs the Autonomous AI Physician, should be required to designate a legal representative for the Autonomous AI Physician in the case of conflicts of interest with the healthcare organization.³²⁷ Again, attorneys already represent non-human legal persons, like businesses, requiring them to manage client interests through legal representatives and deal with conflicts of interest between the parties or as a result of insurance coverage disputes.³²⁸ In response to the question: How would an attorney even represent an AI? My answer is: Likely, very similar to the way one would represent a hospital, medical school, daycare, hotel, construction company, Mardi Gras krewe, Office of the Fire Marshal, etc. Litigators are just as dynamic and resilient as the Autonomous AI Physician.

Medical malpractice insurance will also cover the costs of settlement and judgments when the Autonomous AI Physician commits malpractice. Third, malpractice insurance that covers harm caused by the Autonomous AI Physician's "practice of medicine" that is separate from products liability insurance that covers harm caused by the AI's product-based features can help fairly distribute insurance costs for the Autonomous AI Physician.³²⁹ Creators might obtain insurance to cover the products-centric actions of the Autonomous AI Physicians, while healthcare organizations might insure the AI's human-centric "practice of medicine."³³⁰ Finally, as Stern, et al. point out, "well-designed AI liability insurance has the potential to mitigate liability risks and uncertainties for stakeholders, and to do so in a way that is aligned with patient, physician, and health care organization leadership interests."³³¹ This is because liability insurance will increase the uptake of beneficial medical AI by reducing the risk of legal liability for stakeholders but also because insurance companies will perform a "credentialling function" in its desire to reduce risks caused by AI that it insures.³³²

Fourth, direct liability for the Autonomous AI Physician sidesteps the "black box" problem for liability purposes by judging the AI's behavior under

325. Berry, *supra* note 322, at 109 ("Typically, the carrier will assign a lawyer who has been approved to work on its cases, and a carrier will often honor a physician's request for a specific attorney. The carrier pays the fees of the lawyer it ultimately retains.").

326. *Id.*

327. See Huberman, *supra* note 17, at 281 (discussing conflicts of interest).

328. See Allain, *supra* note 318, at 1078 ("Because Watson is not capable of filing or answering lawsuits, the hospital or business that owns Watson will have to act on his behalf, as the board of directors does for a corporation.").

329. See Huberman, *supra* note 17 at 249 ("Enterprises are generally in good position to obtain liability insurance and spread its costs to consumers through higher prices.").

330. See Rachum-Twaig, *supra* note 17, at 1164–67 (exploring the applications of no-fault mandatory insurance, common in the automotive industry, to AI-based robots).

331. Ariel Dora Stern et al., *AI Insurance: How Liability Insurance Can Drive the Responsible Adoption of Artificial Intelligence in Health Care*, 3 NEJM CATALYST: INNOVATIONS IN CARE DELIVERY, April 2022, at 2.

332. *Id.* at 6.

objective standards of care regardless of why that behavior occurred.³³³ This approach is consistent with tort law's use of an objective standard of care, which ignores an actor's subjective intentions or blameworthiness.³³⁴ When a human physician causes an injury, the fact that they exercised their best judgment in good faith is irrelevant to determining whether the applicable standard of care is breached.³³⁵ Conversely, if a human doctor mistakenly performs an action other than the one intended or performs an action for the wrong reasons, but that action complies with the standard of care, there will be no negligence.³³⁶ There is no reason to judge the Autonomous AI Physician's "practice of medicine" any differently. As Huberman puts it, focusing liability on the technical reasons for an AI's action is like "attempting to beat a chess-playing-computer by inspecting its internal design and calculating its many lines of code."³³⁷ Instead, applying an objective standard of care to the Autonomous AI Physician allows liability to attach to objectively substandard behavior without facing the obstacles posed by the AI's inability to explain how or why it reached a medical decision.³³⁸ The objective standard applicable to the Autonomous AI Physician is the reasonable AI physician standard of care, discussed below.

C. *The Reasonable AI Physician Standard of Care*

Medical malpractice occurs when a medical practitioner breaches a standard of care owed to a patient and that breach causes damages.³³⁹ Once a legal person subject to liability for medical malpractice, the Autonomous AI Physician should be held to its own standard of care based on its unique capabilities to outperform humans in some respects while underperforming humans in others.³⁴⁰ The Moravec Paradox situates an AI's capabilities in relation to humans by explaining that, "[i]t is comparatively easy to make computers exhibit adult level performance on intelligence tests or playing checkers, and difficult or impossible to give them the skills of a one-year-old when it comes to perception and mobility."³⁴¹ As a result, standards of care for human medical practitioners cannot be the measure by which the Autonomous

333. While intention is important in the context of agency creation, it does not factor into a negligence determination. *E.g.*, Huberman, *supra* note 17, at 258 ("Tort law does not typically judge the inner mechanisms causing actions, such as actors' intentionality, nor does it judge the tortfeasors' subjective blameworthiness.").

334. *Id.*

335. See *Morlino v. Med. Ctr. of Ocean Cnty.*, 706 A.2d 721, 733 (N.J. 1998) ("The physician's exercise of judgment is to be evaluated not on the basis of the physician's good faith or honesty, but solely on whether it falls below an objective standard of care."); *Shumaker v. Johnson*, 571 So. 2d 991, 994 (Ala. 1990) (noting that "a growing number of jurisdictions have abandoned the 'good faith' rule in recent years," and collecting cases); *Hirahara v. Tanaka*, 959 P.2d 830, 835 (Haw. 1998) ("The jury must focus on whether the physician breached the standard of care. His or her exercise of 'best judgment' is superfluous to this determination.").

336. *Morlino*, 706 A.2d at 733.

337. Huberman, *supra* note 17, at 265.

338. See Jorstad, *supra* note 19, at 3–4 (explaining the "black box" problem).

339. Gary E. Marchant & Lucille M. Thomas, *AI Healthcare Liability: From Research Trials to Court Trials*, 12 J. HEALTH & LIFE SCI. L. 23, 38 (2019).

340. See *id.* at 38–39 (discussing changing the standard of care as AI surpasses human physicians).

341. TAULLI, *supra* note 80, at 130 (quoting HANS MORAVEC, MIND CHILDREN: THE FUTURE OF ROBOT AND HUMAN INTELLIGENCE 15 (1988)).

AI Physician is judged.³⁴² While some scholars suggest a graduated approach to the standard of care that adopts a reasonable human standard up until the point that the AI exceeds human performance, this approach fails to account for the fact that a single AI can simultaneously fall above and below human performance depending on the task.³⁴³

The Autonomous AI Physician is better viewed as a new type of medical specialist. Applying different standards of care to different medical specialists is already ingrained in medical negligence law through the requirement for medical professionals to “exercise the amount of care, skill, and diligence exercised generally in the community by doctors engaged in the same field.”³⁴⁴ The Autonomous AI Physician will merely become a part of the framework for setting the standards of care for medical specialists.³⁴⁵ Cardiologists are held to a standard of care for cardiologists; neurosurgeons are held to a standard of care for neurosurgeons; radiologists are held to their own standard of care, and so on and so forth. Now enters the Autonomous AI Physician, whose actions should be judged by the standard of care for a reasonable Autonomous AI Physician in the relevant field.

Defining the reasonable Autonomous AI Physician standard of care is the challenge. Expert testimony is generally required to establish both the applicable standard of care and a breach of that standard.³⁴⁶ In a malpractice case against the Autonomous AI Physician, human experts in both medical and computer science will likely present testimony in their respective areas of expertise regarding the applicable standard of care depending on the facts of the case.³⁴⁷ Just as the law does not require a human physician to be the best physician in his field, the reasonable Autonomous AI Physician is not required to be the best functioning algorithm on the market but, instead, must perform its “practice of medicine” within an acceptable range depending on its field of practice.³⁴⁸ But how would a court determine the acceptable range? Of course, the current state of medical science and practice will play a part, but how these concepts are applied to determine reasonableness of an Autonomous AI Physician’s actions

342. Huberman suggests the “reasonable person” standard. Huberman, *supra* note 17, at 258. Chung & Zink suggest applying the standard of a reasonable medical student to IBM’s Watson. Chung & Zink, *supra* note 4, at 68–74.

343. Abbott proposes a reasonable person standard until the point at which AI becomes safer than humans. ABBOTT, *supra* note 3, at 69. Beckers and Teubner take a similar approach, suggesting that the reasonable human standard applies until the AI is more reliable than human, at which point the reasonable AI standard applies. BECKERS & TEUBNER, *supra* note 17, at 85–86. It is outside of the scope of this paper to discuss how the standard of care for human physicians might change as medical AI is introduced into clinical practice, but I note that medical negligence law accommodates shifting standards of care based on developments in the profession and medical science and technology. As a result, a human doctor might be required to use AI to augment his practice if that is the applicable standard of medical care, but that is a standard of care applicable to the human doctor, not the Autonomous AI Physician.

344. *Betesh v. United States*, 400 F. Supp. 238, 247 (D.D.C. 1974).

345. *See id.* (the reasonable standard of care accounts for “the community” and “the same field”).

346. *See* H. H. Henry, Annotation, *Necessity of Expert Evidence to Support an Action for Malpractice Against a Physician or Surgeon*, 81 A.L.R.2d 597 §2 (1962) (“The overwhelming weight of authority supports the view that ordinarily expert evidence is essential to support an action for malpractice against a physician or surgeon.”).

347. *See* Jorstad, *supra* note 19, at 16 (discussing expert testimony applications for AI physicians).

348. BECKERS & TEUBNER, *supra* note 17, at 86.

is a task that requires further interdisciplinary work.³⁴⁹ As of now, there are several possible approaches that may combine to determine the applicable standard of care.³⁵⁰

Woodrow Barfield, an engineer and lawyer, suggests that defining a test harness or automated test framework, which gauges how the AI would perform under various conditions, could be used to determine the applicable standard of care for AI.³⁵¹ He explains:

The goal of the test harness is to be able to quickly and consistently test algorithms against a fair representation of the problem being solved. The outcome of testing multiple algorithms against the harness is an estimation of how a variety of algorithms perform on the problem against a chosen performance measure and such tests could result in a standard being developed (which could be used in a tort action to define a reasonably prudent algorithm). The results will also give an indication of how learnable the problem is.³⁵²

Other tech-based approaches to defining the reasonable AI standard of care include AI “cross-testing” and the “nearest neighbor” method.³⁵³ AI “cross-testing” involves presenting the same data to several other comparable AI physicians practicing in a similar patient population to compare algorithmic output.³⁵⁴ As Jorstad notes however, “cross-testing” requires the presence of comparable AI algorithms in clinical practice, which will present a problem if cases reach a court before enough AI physicians reach the market.³⁵⁵

The nearest neighbor method seeks to determine the Autonomous AI Physician’s “gross accuracy in all previous similar cases” to judge whether its output in the subject case was reasonable.³⁵⁶ For example, if an Autonomous AI Physician has a high accuracy rate for diagnosing a certain kind of breast cancer, its failure to diagnose breast cancer with comparable data input in the subject case might not be negligent because the AI has shown that the standard by which it diagnoses this type of cancer is reliable.³⁵⁷ Of course, the converse is true, even if a human doctor would have not breached the standard of care for diagnosis based on the facts in the subject case. For this method, a high accuracy rate serves as a potential representation of reasonableness, not itself as an absolute basis for judging the breach of the standard of care.³⁵⁸

Jorstad notes that using the “nearest neighbor” method would place the AI in the “role of both defendant and expert witness.”³⁵⁹ While true, this is not an

349. Marchant & Thomas, *supra* note 340, at 38–40.

350. *Id.*

351. Barfield, *supra* note 142, at 201.

352. *Id.*

353. Jorstad, *supra* note 19, at 16.

354. *Id.*

355. *Id.*

356. *Id.*

357. *See id.* (“Comparing the machine’s gross accuracy in all previous similar cases will yield a measure of whether the plaintiff’s diagnosis was reasonable compared to similarly situated patients.”).

358. *Id.*

359. *Id.*

unusual phenomenon in medical malpractice cases.³⁶⁰ Defendant physicians, as experts themselves, often testify about the standards of care applicable to their own treatment in the case.³⁶¹ It is up to a judge or jury to judge the weight and credibility of this testimony.³⁶² Of course, unlike a human physician, the Autonomous AI Physician is more likely to testify against itself if the “nearest neighbor” method produces a result that supports finding a breach of the standard of care.³⁶³ In this case, should the “nearest neighbor” method results be produced during discovery, the plaintiff could save a substantial amount of time and money on litigation costs.³⁶⁴

In addition to the technical approaches outlined above, government and industry standards can play a role in defining the applicable standard of care for the Autonomous AI Physician. Although compliance with these standards will likely not be the sole consideration for determining whether the standard was breached, they can support findings of reasonableness or negligence just as evidence-based standards in medicine factor into malpractice determinations for human physicians.³⁶⁵

Of course, the medical standards of care that would be applicable to humans performing the same medical acts in question can provide a baseline to anchor the standard of care applicable to the Autonomous AI Physician.³⁶⁶ A preliminary question would seek to determine whether a human physician performing the same act of medical practice with the same information would have breached the standard of care applicable to human physicians.³⁶⁷ Following this, factors specific to the Autonomous AI Physician’s practice under the circumstances can be used to adjust the standard of care above or below this baseline.³⁶⁸ Such factors might include the reason for the AI’s clinical use (because it exceeded human performance or because it provided new access to medicine) and the AI’s technical capabilities (ability to draw from vast amounts of medical literature or inability to touch).³⁶⁹

Ultimately, in cases against the Autonomous AI Physician, litigants will likely use a combination of the above approaches as well as any new approaches

360. PEGALIS, *supra* note 214, § 8:1 (surveying usage of expert testimony to establish the appropriate standard of care, noting “a malpractice defendant himself or herself may provide the expert testimony”).

361. *Id.*

362. Jorstad, *supra* note 19, at 16.

363. *Id.*

364. *See id.* (“Evidence that the machine’s reasoning was correct in most analogous cases may substantiate that the standard of care was met, replacing the role of expert witnesses for the defense.”).

365. *See* Edward P. Monico et al., *The Impact of Evidence-Based Medicine and Evolving Technology on The Standard of Care in Emergency Medicine*, 3 INTERNET J. L., HEALTHCARE, & ETHICS, 2004, at 2–5 (discussing how an evidence-based model contrasts the traditional, community-based standard of care in malpractice suits).

366. Marchant, *supra* note 338, at 38–40.

367. *Id.*

368. *See id.* (discussing how, in instances where AI surpasses a comparable human physician, the standard of care may be adjusted accordingly).

369. *See, e.g.*, Jane Collingwood, *Artificial Intelligence in Medical Diagnosis*, S. MED. ASS’N (Oct. 7, 2021), <https://sma.org/ai-in-medical-diagnosis> [perma.cc/TPV3-ZL82] (articulating use cases and limitations for AI in medicine).

developed through future interdisciplinary collaboration in this area.³⁷⁰ It will be up to judges to determine which approaches are allowed as evidence. However, as the case law develops in this area, legal standards of care for the Autonomous AI Physician will organically develop along with it.

III. LIABILITY CONSTELLATIONS UNDER THE CONTROL FRAMEWORK

The following scenarios illustrate how the control framework might govern liability for injuries caused by the Autonomous AI Physician.

A. *Bad Training Data*

In this “bad data” scenario, an Autonomous AI Physician trained with data from a young and healthy population provides an incorrect treatment recommendation for high blood pressure for an older patient.³⁷¹ The injury-causing action/output is the treatment recommendation. An analysis of liability for involved parties under the control framework proceeds as follows:

Creator(s). The creator(s) who trained the AI during its development as a medical product, could face a products liability claim if they failed to warn users of the foreseeable injuries associated with using the AI in an older patient population.³⁷² Depending on the nature and delivery of information provided about the AI’s training and whether it complied with FDA regulations for such medical devices, the creator may face liability for failure to warn or may be entitled to immunity for complying with the applicable regulations.³⁷³ Another potential basis for liability for the creator could be based on product or manufacturing defect associated with an age-related safety feature.³⁷⁴ For example, if the creators designed the AI to recognize the age of the patient, for example based on facial features, and to either refrain from providing a treatment recommendation or provide a treatment recommendation with a warning to the human medical practitioner based on the AI’s age determination, but the AI failed to do this.

The Healthcare Organization. The healthcare organization that employed the AI might have direct organizational liability for employing an Autonomous AI Physician that was not competent to treat its patient population, or for failing to have procedures in place to ensure that the clinical use of the Autonomous AI Physician is safe for patients it treats.³⁷⁵ The Autonomous AI Physician would also be an apparent agent of the hospital providing in-patient treatment to the

370. See Maliha et al., *supra* note 19, at 630 (“Physicians, health systems, and algorithm designers are subject to different, overlapping theories of liability for AI/ML systems.”).

371. See *supra* notes 85–86 and accompanying text (AI failure to understand causation).

372. See Rachum-Twaig, *supra* note 17, at 1169–71 (suggesting duties to monitor and related duties to warn and patch).

373. See Maliha et al., *supra* note 19, at 640–41 (“[B]inding regulatory actions by the FDA and other agencies can directly affect the liability system.”).

374. See *id.* (suggesting FDA regulations might “work to ensure that AI/ML training populations are representative of patient populations, akin to guidance requiring clinical trials to enroll participants from groups that have been underrepresented in biomedical research studies, including racial minorities and older adults.”).

375. See sources cited *supra* note 211 (discussing healthcare organization liability).

patient making the hospital vicariously liable for injuries caused by incorrect treatment recommendation if it fell below the standard of care applicable to the Autonomous AI Physician.³⁷⁶

The Human Provider(s). A human healthcare provider who implemented the treatment recommendation might be directly liable if they knew or should have known that the treatment recommendation was wrong.³⁷⁷ For example, if they failed to look at the patient's age prior to prescribing a medication that was contraindicated by age or ignored an age-related warning from the AI.

The Autonomous AI Physician. The Autonomous AI Physician might be liable for medical malpractice if the treatment recommendation fell below the applicable standard of care in such a way that was not caused by the bad training data.³⁷⁸ For example, if the treatment recommendation would have been faulty regardless of the age of the patient, then the AI might be liable.

B. Missed Specialist Diagnosis in General Practice

This scenario illustrates potential liability for IDx-DR, an Autonomous AI Physician designed to provide an ophthalmologic diagnosis of diabetic retinopathy for general practitioners, when the AI misses a diagnosis.³⁷⁹ The injury-causing action/output is the missed diagnosis. An analysis of liability for involved parties under the control framework proceeds as follows:

The Creator(s). Assuming there are no identifiable design defects with the Autonomous AI Physician, that the AI was approved for market use, and the creators had no knowledge that the AI presented an unreasonable risk of missing a diagnosis in the particular facts of this case, the AI's algorithmic decision-making which resulted in a missed diagnosis is an unpredictable medical error.³⁸⁰ In this case, the creators would not be liable.

The Human General Practitioner. In this case, the Autonomous AI Physician used by a human general practitioner in private practice to provide a specialist diagnosis outside of the human physician's area of specialty might not be considered an apparent agent of the human physician who the patient knows or should know has a limited area of expertise.³⁸¹ Given the patient's lack of medical training, the general practitioner should have a duty to advise patients that the Autonomous AI Physician is providing a service outside of the treating (human) physician's area of medical expertise and the risks and benefits associated with using the AI and obtain consent for the AI's use.³⁸² Assuming

376. PEGALIS., *supra* note 214, § 6:20.

377. Lopez v. Ledesma, 505 P.3d 212, 214, 219 (Cal. 2022).

378. Barfield, *supra* note 142, at 196.

379. See Food & Drug Admin, *supra* note 1 (FDA approval of IDx-DR).

380. See *supra* Section II.A.1 (examining control by the AI creators).

381. General practitioners are generally not held the same standards of care as specialists. See McPhee v. Reichel, 461 F.2d 947, 951 (3d Cir. 1972) (finding that a defendant who is a specialist should be held to a higher degree of care than a general practitioner).

382. Jerald J. Director, Annotation, *Malpractice: Physician's Failure to Advise Patient to Consult Specialist or One Qualified in a Method of Treatment Which Physician is Not Qualified to Give*, 35 A.L.R.3d 349 § 10 ("[A]s a part of the requirements which the law exacts of general practitioners of medicine and surgery,

the human physician obtained informed consent, implemented the Autonomous AI Physician in accordance with its authorized market use, and did not know or should have known that the AI missed a diagnosis, the human practitioner should not be liable for the AI's missed diagnosis.³⁸³ Avoiding liability in such a scenario is important for the human practitioner, who is subject to malpractice reporting in the National Practitioner Database.

The Autonomous AI Physician. The Autonomous AI Physician will bear liability in this case if the missed diagnosis falls below the applicable standard of care because the AI's autonomous decision making caused the medical error.³⁸⁴ For example, if expert testimony, using one or more of the methods for determining the standard of care above, establishes that the patient data received by the AI should have led to a correct diagnosis.

C. *Incorrect Prognosis for Oncology Patient*

In this scenario, the Autonomous AI Physician uses algorithmic decision making to analyze correct patient data and renders an incorrect prognosis for a cancer patient in a hospital.³⁸⁵ Relying on this prognosis, a human physician implements the wrong treatment plan. The injury-causing action/output is the prognosis. An analysis of liability for involved parties under the control framework proceeds as follows:

The Creator(s). Assuming there are no identifiable design defects with the Autonomous AI Physician, that the AI was approved for market use, and the creators had no knowledge that the AI presented an unreasonable risk of rendering a wrong prognosis in the particular facts of this case, the AI's algorithmic decision-making which resulted in an incorrect prognosis is an unpredictable medical error.³⁸⁶ In this case, the creators would not be liable.

The Healthcare Organization. The Autonomous AI Physician would be an apparent agent of the hospital providing in-patient oncology services to the patient and would be liable for injuries caused by the incorrect prognosis if such error fell below the standard of care applicable to the Autonomous AI

or other schools of healing, if, in the exercise of the care and skill demanded by those requirements, such a practitioner discovers, or should know or discover, that the patient's ailment is beyond his knowledge or technical skill, or ability or capacity to treat with a likelihood of reasonable success, he is under a duty to disclose the situation to his patient, or advise him of the necessity of other or different treatment.").

383. See *Est. of Tranor v. Bloomsburg Hosp.*, 60 F. Supp. 2d 412, 415–16 (M.D. Pa. 1999) ("[I]f a treating physician reasonably should be expected to realize that a specialist's care is inadequate, based on the standard of care of a general practitioner, then the general practitioner may be liable for failing to take appropriate steps. Conversely, if the general practitioner does not realize that the specialist's care is inadequate, he or she is not necessarily liable, but may be liable if a general practitioner (under the same standard) should have recognized the inadequacy and taken appropriate steps.").

384. Currently, IDx-DR's creators assume liability for injuries caused by the AI's medical negligence. *A Second Opinion with Dr. Michael Abramoff*, A SECOND OPINION (March 30, 2020), <https://asecondopinionpodcast.com/a-second-opinion-with-dr-michael-abramoff>. While creators may continue to assume liability for malpractice by Autonomous AI Physicians that they create, the malpractice itself should still be determined pursuant to uniform liability rules regardless of whether the creator or hospital ultimately ensures damage caused by that malpractice.

385. TAULLI, *supra* note 80, at 86–87.

386. See *supra* Section II.A.1 (examining control by the AI creators).

Physician.³⁸⁷ The hospital may also face liability for any organizational negligence associated with the implementation of the AI in clinical practice.

The Human Provider. The human physician who relied on the Autonomous AI Physician's prognosis to implement an incorrect treatment plan would not be directly liable if the physician (1) did not know and should not have reasonably known that the prognosis was incorrect and (2) the treatment plan prescribed met the standard of care for a cancer patient with the AI's prognosis.³⁸⁸ If the human physician faces vicarious or joint liability because of the AI's medical error, their ability to seek indemnity from the Autonomous AI Physician could result in payment from the hospital's rather than the physician's insurance.³⁸⁹

The Autonomous AI Physician. The Autonomous AI Physician will bear liability in this case if the incorrect prognosis falls below the applicable standard of care because the AI used autonomous decision making to render a prognosis.

D. *Erroneous Medication Order Administered by Hospital Nurse*

In this scenario, a hospital nurse relies upon the Autonomous AI Physician's erroneous medication order to administer medication to a patient. The injury-causing action/output is the medication order. An analysis of liability for involved parties under the control framework proceeds as follows:

The Creator(s). Assuming there are no identifiable design defects with the Autonomous AI Physician, that the AI was approved for market use, and the creators had no knowledge that the AI presented an unreasonable risk of ordering the wrong medication in the particular facts of this case, the AI's algorithmic decision-making which resulted in a wrong medication order is an unpredictable medical error.³⁹⁰ In this case, the creators would not be liable.

The Healthcare Organization. The Autonomous AI Physician would be an apparent agent of the hospital providing in-patient treatment to the patient resulting in vicarious liability for the hospital.³⁹¹ The hospital may also face direct liability for any organizational negligence associated with the implementation of the AI in clinical practice.³⁹² For example, organizational negligence might stem from the hospital's failure to provide training to nurses interacting with the AI or to implement procedures designed to mitigate risks associated with the AI's medication orders if those failures fall below the organizational standard of care.³⁹³

The Human Provider. The human nurse who relied on the Autonomous AI Physician's erroneous medication order to administer medication to the patient would not be directly liable if the nurse did not know and should not have

387. See Huberman, *supra* note 17, at 279–283 (discussing theory of legal agency for autonomous agents).

388. Lopez v. Ledesma, 505 P.3d 212, 214, 219 (Cal. 2022).

389. See Allain, *supra* note 318, at 1067 (“Because Watson cannot be held financially responsible for making restitution, hospitals will likely carry much of this burden if vicariously liable.”).

390. See *supra* Section II.A.1 (examining control by the AI creators).

391. PEGALIS, *supra* note 214, § 6:20.

392. See sources cited *supra* note 211 (discussing direct liability for hospitals).

393. *Id.*

reasonably known that the medication order was erroneous.³⁹⁴ This can include a requirement that the nurse follow organizational procedures designed to prevent the administration of erroneous medication ordered by the AI. Failure to comply with the relevant procedures could result in negligence for the nurse if compliance would have prevented the erroneous medication administration.³⁹⁵

The Autonomous AI Physician. The Autonomous AI Physician will bear liability in this case because the AI's autonomous algorithmic decision making caused it to provide an erroneous medication order.

E. Component Malfunction Burns Patient

In this scenario, a physical component of an Autonomous AI Physician overheats and burns a patient. The injury-causing action/output is the physical component malfunction. An analysis of liability for involved parties under the control framework proceeds as follows:

The Creator(s). The creator(s) who manufactured the AI will likely face a products liability claim based on the component malfunction.³⁹⁶ In this case, claims for defective design and manufacture will result in strict liability.³⁹⁷

The Healthcare Organization. Although the Autonomous AI Physician might be considered an apparent agent of the healthcare organization, the risk of burn to the patient resulting from a malfunctioning part of the robot might fall outside of the scope of risks covered by the agency relationship.³⁹⁸ Unless the hospital knew or should have known of this risk to patients when it implemented the robot into clinical practice, it might not be liable for this injury.³⁹⁹

The Autonomous AI Physician. The Autonomous AI Physician would not be liable because the injury resulted from a machine-based quality of the AI as opposed to the AI's autonomous decision making.⁴⁰⁰

F. Incorrect Data Input Results in Misdiagnosis

In this scenario, the Autonomous AI Physician, relying on incorrect data provided by a human provider or the patient, misdiagnoses a hospital patient. The injury-causing action/output is the misdiagnosis. An analysis of liability for involved parties under the control framework proceeds as follows:

The Creator(s). Assuming there are no identifiable design defects with the Autonomous AI Physician, that the AI was approved for market use, and the creators had no knowledge that the AI presented an unreasonable risk of rendering a misdiagnosis in the particular facts of this case, the AI's algorithmic

394. See Barfield, *supra* note 144, at 199 (identifying case law where employer was not liable for employees' injuries as the employer did not know of dangerous conditions where the accident occurred).

395. *Id.*

396. See *supra* Section II.A.1 (examining control by AI creators).

397. Red Hill Hosiery Mill, Inc. v. Magnetek, Inc., 530 S.E.2d 321, 327 (N.C. App. 2000).

398. PEGALIS, *supra* note 214, § 6:20.

399. See *id.*

400. Food & Drug Admin., *supra* note 1.

decision-making which resulted in a misdiagnosis is an unpredictable medical error. In this case, the creators would not be liable.

The Healthcare Organization. The Autonomous AI Physician would be an apparent agent of the hospital providing in-patient treatment to the patient and would be vicariously liable for injuries caused by erroneous diagnosis if such error fell below the standard of care applicable to the Autonomous AI Physician.⁴⁰¹ The hospital may also face direct liability for any organizational negligence associated with the implementation of the AI in clinical practice.⁴⁰²

The Human Provider(s). The human provider who provided the incorrect data to the Autonomous AI Physician would be liable if the incorrect data was a cause of the misdiagnosis.⁴⁰³ A human healthcare provider who provided (or failed to provide) treatment based on the misdiagnosis would be liable if they knew or should have known that the diagnosis was wrong.⁴⁰⁴

The Patient. If the patient provided incorrect data to the Autonomous AI Physician, they could be contributorily negligent if the incorrect data was a cause of the misdiagnosis.⁴⁰⁵

The Autonomous AI Physician. The Autonomous AI Physician could be liable for medical malpractice if the AI's algorithmic decision making caused or contributed to misdiagnosis if the misdiagnosis fell below the applicable standard of care considering the provision of incorrect data.⁴⁰⁶ In the likely case of multiple tortfeasors, the AI could claim defenses of comparative fault and contributory negligence and/or assert actions for indemnity and contribution.⁴⁰⁷

G. *Inability to Touch Results in Missed Diagnosis*

In this scenario, the Autonomous AI Physician is used to evaluate a patient's complaint of periodic itching on his scalp, neck, and ears that his regular human providers determined was unrelated to his hospital admission for pneumonia. After interviewing the patient, observing his neck, head, and ears using computer vision, reviewing his medical records, and reviewing a large database of medical literature, the Autonomous AI Physician misses a diagnosis of actinic keratoses, which later develops into skin cancer. The injury-causing action/output is the missed diagnosis. An analysis of liability for involved parties under the control framework proceeds as follows:

Creator(s). The creator(s) who trained the AI during its development as a medical product, could face a products liability claim if they failed to warn users of the AI's limited ability to make diagnosis that require palpation of the skin.⁴⁰⁸

401. PEGALIS, *supra* note 214, § 6:20.

402. *Id.*

403. *See supra* Section II.A.3 (examining control by individual healthcare providers).

404. *Id.*

405. *See generally* Caroll J. Miller, Annotation, *Patient's Failure to Reveal Medical History to Physician as Contributory Negligence or Assumption of Risk in Defense of Malpractice Action*, 33 A.L.R.4th 790 (discussing patients' contributory negligence).

406. Barfield, *supra* note 142, at 196.

407. PEGALIS, *supra* note 214, § 6:20.

408. *See* Rachum-Twaig, *supra* note 17, at 1169–71 (suggesting duties to monitor and related duties to warn and patch).

Depending on the nature and delivery of information provided about the AI's limitations and whether that information complied with FDA regulations for such medical devices, the creator may face liability for failure to warn or may be entitled to immunity for complying with the applicable regulations.⁴⁰⁹ Another potential basis for liability for the creator could be based on product or manufacturing defect associated with safety feature that was designed to alert providers of diagnosis that require further patient examination via human touch if the AI failed to alert the human provider.⁴¹⁰

The Healthcare Organization. The healthcare organization that employed the AI might have direct organizational liability for failing to have procedures in place to ensure that the Autonomous AI Physician is only used in clinical situations when it is competent to provide a diagnosis or that provide sufficient oversight in clinical situations when the AI's competency is limited.⁴¹¹ The Autonomous AI Physician would also be an apparent agent of the hospital providing in-patient treatment to the patient making the hospital vicariously liable for injuries caused by missed diagnosis if it fell below the standard of care applicable to the Autonomous AI Physician.⁴¹²

The Human Provider(s). A human healthcare provider who relied on the AI's diagnosis might be directly liable if they knew or should have known that the diagnosis was wrong.⁴¹³ For example, if they ignored an alert from the AI suggesting that its diagnosis be confirmed by a human who can examine the patient using physical palpation.

The Autonomous AI Physician. The Autonomous AI Physician might not be liable in this scenario because the applicable standard of care for an autonomous AI physician might be lower than that of a human physician who is capable of physical touch.⁴¹⁴ Assuming the AI involved is not capable of touch, if the actinic keratoses was not visible and the other information given to the AI did not indicate actinic keratoses as a reasonable diagnosis, the AI might not have breached the applicable standard of care. This is true even if a human physician with all the same information about the patient would have breached the standard of care applicable to their own practice of medicine.⁴¹⁵

CONCLUSION

Applying the control framework set forth in this Article fills the liability gap illustrated by the scenario proposed in the introduction because it allows the Autonomous AI Physician to be directly liable for the harm to the oncology

409. See Maliha et al., *supra* note 19, at 640–41 (“[B]inding regulatory actions by the FDA and other agencies can directly affect the liability system.”).

410. *Id.*

411. See *Darling v. Charleston Cmty. Mem'l Hosp.*, 211 N.E.2d 253, 256 (Ill. 1965) (illustrating an example with a human counterpart).

412. *Id.*

413. See *supra* Section II.C (discussing reasonable standards of care).

414. See Abhimanyu S. Ahuja, *The Impact of Artificial Intelligence in Medicine on the Future Role of the Physician*, NAT'L LIBR. OF MED., Oct. 4, 2019, at 13–14 (discussing the impact of AI on physicians and noting “physicians are still needed for traditional physical exams . . .”).

415. *Id.*

patient caused by the AI's incorrect prediction. Although this scenario assumed no fault by the AI's creators, the healthcare organization, or the human oncologist, medical liability litigation is typically more dynamic and involves a variety of parties and legal theories, all of which can be situated with the control framework.⁴¹⁶ In addition to eliminating the liability gap for medical injuries caused by the AI's autonomous medical decision making, the control framework also results in a fair distribution of risks stemming from the Autonomous AI Physician's "practice of medicine" under existing tort law doctrine.⁴¹⁷ As a result, the control framework helps pave the way for a legally responsible and societally beneficial Autonomous AI Physician without requiring significant structural changes to liability law.⁴¹⁸

To continue this path, there must be ongoing interdisciplinary collaboration to identify, address, and propose solutions for legal, ethical, and technical concerns that arise with current use and ongoing development of the Autonomous AI Physician. Additionally, as demonstrated by the EU's proposed AI Act, these concerns are not only interdisciplinary, but international.⁴¹⁹ As a result, continued collaboration across disciplines and borders is required to answer difficult legal questions relating to legal standards of care applicable to both humans and AI in medicine, bias and discrimination in the development and use of medical AI, governance of cross-border e-health interactions, health data privacy, and the overall role of law in the ongoing risk-benefit analysis of AI in healthcare.⁴²⁰

416. Chung & Zink *supra* note 4, at 18–19.

417. *Id.*

418. *See supra* Part II (articulating the control framework).

419. *See* The AI Act, *The Artificial Intelligence Act*, <https://artificialintelligenceact.eu> (“[T]he EU AI Act could become a global standard.”); Alex Engler, *The EU AI Act Will Have Global Impact, But a Limited Brussels Effect*, BROOKINGS (June 8, 2022), <https://www.brookings.edu/research/the-eu-ai-act-will-have-global-impact-but-a-limited-brussels-effect> (“[T]he extraterritorial scope is limited to products sold to the EU, yet there is still a high likelihood that this leads to international conformity”).

420. Engler, *supra* note 420.