

BLACK BOX, WHITE COAT: ACCOUNTABILITY FOR ARTIFICIAL INTELLIGENCE IN MEDICAL MALPRACTICE LAW

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Artificial Intelligence (AI) is revolutionizing the way the United States approaches healthcare. In a monumental push to integrate this technology, healthcare facilities are implementing AI everywhere from patient appointment portals to operating rooms. AI falls somewhere between serving as a physician's new tool and functioning as a collaborative partner, making it a welcome advancement to many. However, AI's implementation has not been flawless—the use of AI has resulted in misdiagnoses and surgical errors, leading to serious injuries and the death of patients. There is no federal guidance formally determining who will be liable for injuries caused by AI. Thus, healthcare professionals who use AI in practice face a new wave of potential liability from medical malpractice lawsuits. Correctly allocating liability requires a carefully calibrated legal framework that ensures accountability without overreach. Because the federal government appears inclined either to adopt an incomprehensive regime or to preempt state regulation entirely, an exhaustive framework that meaningfully addresses AI's role in medical malpractice litigation must be crafted on the state level.

This Note argues that the Colorado legislature should enact regulations that accommodate the various types of AI used in the healthcare industry. Automated AI systems should be treated as products, and failure to warn product liability principles should apply. Physicians using such systems should be classified as deployers of “high-risk AI systems” and granted a rebuttable presumption of reasonableness if they meet specific disclosure requirements to their patients. Autonomous AI systems warrant a two-step inquiry to allocate liability in a principled and equitable manner. Such an inquiry would examine (1) whether the alleged

* This article is dedicated to my brother, Mitchell Hymowitz, M.D., who inspires me every day. I am especially thankful to my family and mentors, whose steadfast support made this work possible.

harm resulted from the AI system’s independent decision-making and, if so, (2) identify which actor—the physician, the hospital, or the developer—exerted the most significant influence over that decision. Under this framework, hospitals that fail to adequately assess AI systems or properly train their staff, as well as AI developers whose programming or design flaws contribute to patient harm, could be subject to medical malpractice liability arising from AI use.

This Note highlights the risks of holding physicians overly liable without such legal protections, arguing that increased physician liability could discourage AI adoption despite its potential to reduce provider burnout and improve care delivery. To avoid unjust outcomes, a nuanced framework that acknowledges the differences between types of artificial intelligence and focuses on shared liability is recommended to balance innovation with accountability.

INTRODUCTION.....	300
I. COLORADO MEDICAL MALPRACTICE LAW AND THE TYPES OF AI IN HEALTHCARE	302
A. <i>Medical Malpractice Law in Colorado</i>	302
B. <i>Types of AI in Healthcare</i>	307
II. WHY STATE LEGISLATION IS IMPERATIVE FOR CHANGE.....	310
III. THE DRAWBACKS OF AI IN HEALTHCARE AND THE ISSUE OF ALLOCATING LIABILITY	312
IV. AI AND PRODUCTS LIABILITY.....	316
V. THE STANDARD THAT DOCTORS SHOULD RECEIVE	322
CONCLUSION.....	327

INTRODUCTION

After years of development and anticipation, AI and machine learning (ML) are finally making significant strides in healthcare. AI “refers to the use of technologies to build machines and computers that have the ability to mimic cognitive functions associated with human intelligence[.]”¹ AI is not a system in and of itself, but rather a suite of technologies integrated into a system that enable it to reason, learn, and act to solve complex problems.² ML is a subset of AI that uses algorithms to analyze data, learn

1. Google Cloud, *Artificial Intelligence (AI) vs. Machine Learning (ML)*, <https://cloud.google.com/learn/artificial-intelligence-vs-machine-learning> [https://perma.cc/EZ2V-6BFG].

2. *Id.*

from insights, and improve over time with exposure to data.³ Put simply, “ML is an application of AI that allows machines to extract knowledge from data and learn from it autonomously.”⁴ Systems that use machine learning AI are referred to as AI/ML systems.⁵ Over the past decade, the number of medical devices with AI or ML technology has risen sharply.⁶ As of July 29, 2025, the Food and Drug Administration (FDA) has authorized 1,250 AI or ML-enabled devices.⁷ These devices include virtual assistant chatbots, wearable monitoring devices, predictive analytic models, personalized treatment regimens, and automated appointment systems.⁸ With these devices, AI/ML are improving the quality of care and fostering a more interactive dynamic between patients and healthcare providers.⁹ What’s more, many of these devices can enhance the detection of potential disease from image-based sources such as radiographs, electrocardiograms, and biopsies.¹⁰ The FDA has also approved AI/ML predictive algorithms for clinical use, some of which have demonstrated performance surpassing that of human physicians.¹¹ Despite their great potential, AI/ML systems have faced criticism for inconsistent performance, particularly with minority populations, raising concerns about equitable outcomes and algorithmic reliability.¹² Furthermore, inaccuracies in AI/ML systems can lead to poor clinical decisions and harmful patient outcomes, presenting important questions about liability for harm.¹³ The way liability is allocated affects patients’ ability to seek redress and the widespread adoption of innovative technologies.

3. Cole Stryker & Eda Kavlakoglu, *What is artificial intelligence (AI)?*, IBM, <https://www.ibm.com/think/topics/artificial-intelligence> [https://perma.cc/U76P-GYGA].

4. Google Cloud, *supra* note 1.

5. Deb Richardson, *What is AI/ML and why does it matter to your business?*, Red Hat Blog (Nov. 11, 2022), <https://www.redhat.com/en/blog/what-aiml-and-why-does-it-matter-your-business> [https://perma.cc/2MPC-E72Q].

6. Elise Reuter & Jasmine Ye Han, *The Number of AI Medical Devices has Spiked in the Past Decade*, MEDTECH DIVE (Oct. 9, 2024), <https://www.medtechdive.com/news/fda-ai-medical-devices-growth/728975/> [https://perma.cc/DH43-5X33].

7. Bertalan Mesko, *The Current State Of Over 1250 FDA-Approved, AI-Based Medical Devices*, MEDICAL FUTURIST (July 29, 2025), <https://medicalfuturist.com/the-current-state-of-fda-approved-ai-based-medical-devices/> [https://perma.cc/E4YQ-CXKM].

8. Yu-Hao Li et al., *Innovation and Challenges of Artificial Intelligence Technology in Personalized Healthcare*, 14 SCI. REP. 1, 1 (2024).

9. *Id.*

10. Maliha et al., *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629, 630 (2021).

11. *Id.*

12. Shehu Mohammed & Neha Malhotra, *Ethical and Regulatory Challenges in Machine Learning-Based Healthcare Systems: A Review of Implementation Barriers and Future Directions*, 5 BENCHCOUNCIL TRANSACTIONS ON BENCHMARKS, STANDARDS & EVALUATIONS 1, 4 (2025).

13. *Id.* at 5.

Heightened liability risks for healthcare professionals could deter the integration of potentially beneficial algorithms into clinical practice.¹⁴

Currently, physicians, healthcare institutions, and AI developers face distinct yet overlapping liability standards when a patient is injured. Physicians and hospitals may be held liable under medical malpractice and other negligence-based claims, but are generally not subject to product liability suits.¹⁵ AI developers are likely to face both negligence claims and product liability suits.¹⁶ While case law on physician use of AI/ML is not yet well developed, several existing cases suggest that physicians are most likely to bear the burden of errors resulting from AI/ML output.¹⁷ For example, many courts have been unwilling to treat clinical guidelines as definitive proof of the standard of care and have instead required a more individualized determination based on each case, thereby subjecting physicians to heightened scrutiny.¹⁸ Other “courts are disinclined to excuse malpractice based on errors by system technicians or manufacturers.”¹⁹ This leaves doctors who rely in good faith on AI/ML systems open to liability for a patient’s injury. Without an improved standard, doctors are at risk of being unfairly held liable for errors attributable to AI.²⁰

I. COLORADO MEDICAL MALPRACTICE LAW AND THE TYPES OF AI IN HEALTHCARE

A. Medical Malpractice Law in Colorado

In Colorado, medical malpractice is a type of negligence action originating in English common law that has been shaped and refined through rulings in state courts.²¹ Just as in other negligence actions, a medical malpractice plaintiff must show that the defendant had a legal duty of care, there was a breach of that duty,

14. Tom Lawton, et al., *Clinicians Risk Becoming ‘Liability Sinks’ for Artificial Intelligence*, 11 FUTURE HEALTHCARE J. 1, 1 (2024).

15. Maliha et al., *supra* note 10, at 630.

16. Gregory Smith et al., *Liability for Harms from AI Systems*, RAND (Nov. 20, 2024), https://www.rand.org/pubs/research_reports/RRA3243-4.html [https://perma.cc/C32Q-ET6Z].

17. Kyle Jorstad, *Intersection of Artificial Intelligence and Medicine: Tort Liability in the Technological Age*, 3 J. MED. ARTIF. INTELL. 1, 1 (2020).

18. *See, e.g.*, *Quigley v. Jobe*, 851 P.2d 236, 238 (Colo. App. 1992) (holding clinical practice guidelines did not serve as evidence of the standard of care).

19. Maliha et al., *supra* note 10, at 632.

20. Mohammed & Malhotra, *supra* note 12, at 3 (noting that “no uniform AI liability framework in the healthcare space” currently exists).

21. *Day v. Johnson*, 255 P.3d 1064, 1068 (Colo. 2011) (citing *Greenberg v. Perkins*, 845 P.2d 530 (Colo. 1993)); *see* Colo. Jury Instr., Civ. 15:3 (3d ed. 2023) [hereinafter CJI-Civ.].

the plaintiff suffered an injury, and the defendant's breach caused the plaintiff's injury.²² "A nonspecialist physician must act consistently with the standards required of the medical profession in the community where he or she practices."²³ A nonspecialist physician's conduct is measured against that of other "physicians practicing in the same field of practice in the same or similar locality."²⁴ A physician who represents themselves as a specialist in a particular medical field must exercise the level of care and skill that a reasonably careful physician practicing in that specialty, or possessing comparable specialized expertise, would exercise under similar circumstances.²⁵ "[T]o establish causation under Colorado law, a plaintiff must show either that (1) but for the defendant's alleged negligence, the claimed injury would not have occurred, or (2) the defendant's alleged negligence was a necessary component of a causal set that would have caused the injury."²⁶

Concerns about liability for a patient's injury often center on physician malpractice. However, physicians operate within a broader healthcare ecosystem that includes hospitals. Notably, vicarious liability under *respondeat superior* does not apply to hospitals. "Respondeat superior embodies the general rule that an employer is responsible for the negligent acts or omissions of its employees."²⁷ Under this doctrine, an employer is liable for any employee's negligent acts or omissions performed within the scope of employment.²⁸ The existence of an employer-employee relationship primarily hinges on whether the employer possesses the "right of control" over the employee.²⁹ The right of control refers to the employer's ability to direct the manner in which the employee performs their work.³⁰ The inquiry centers on whether the employer has the authority to manage how the employee completes daily tasks.³¹ Although it may seem that hospitals would meet this standard, the corporate practice of medicine doctrine (CPMD) holds otherwise. The CPMD is a common law principle stating that

22. See *Day*, 255 P.3d at 1068–69.

23. *Jordan v. Bogner*, 844 P.2d 644, 666–67 (Colo. 1993); see *Larson v. Lindahl*, 450 P.2d 77, 78 (Colo. 1968); see also CJI-Civ. 15:2 (a "nonspecialist" physician is a member of the healing arts, which includes dentists, chiropractors, and surgeons).

24. CJI-Civ. 15:2.

25. See *Short v. Kinkade*, 684 P.2d 210 (Colo. App. 1983); CJI-Civ. 15:3 (15:2 includes the "locality rule" for physicians, while 15:3 does not since "specialists" are presumed to operate on a national standard of care).

26. *Reigel v. SavaSeniorCare L.L.C.*, 292 P.3d 977, 987 (Colo. App. 2011); *Kaiser Found. Health Plan of Colo. v. Sharp*, 741 P.2d 714, 719 (Colo. 1987).

27. Russell G. Thornton, *Responsibility for the Acts of Others*, 23 BAYLOR U. MED. CTR. PROC. 313, 314 (2010).

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

corporations, as non-human entities, cannot perform medical procedures or hold medical licenses.³² The doctrine holds that health care is intended to be provided by individuals licensed to practice medicine, not by institutions.³³ Accordingly, institutions such as hospitals or other medical facilities are prohibited from interfering with a physician's independent medical judgment. Thus, the CPMD acts as a shield, preventing hospitals from being held liable for doctors' actions under respondeat superior.³⁴ The CPMD is not all-encompassing; for example, it does not prevent hospitals from being held vicariously liable for the negligence of other employees, such as nurses.³⁵ Nonetheless, doctors arguably bear more than their fair share of responsibility due to the CPMD.

This is best illustrated by the "captain of the ship" doctrine, under which physicians are liable for hospital employees in the operating room. This doctrine holds a surgeon vicariously liable for the negligence of hospital staff acting under their control and supervision during an operation.³⁶ A licensed physician is considered a principal or "master" while providing medical services within a hospital rather than an agent or "servant."³⁷ Therefore, hospital personnel assisting under the physician's direction are treated as "borrowed servants," and the physician bears liability for their negligent acts.³⁸

Courts and commentators have argued that policy considerations provide a strong rationale for prohibiting respondeat superior in the medical context. Courts maintain that the Colorado Health Authority Act, Colo. Rev. Stat. § 25-29-101 (2005) et seq.—read in conjunction with Colo. Rev. Stat. § 25-3-103.7(3)—expresses a clear intent by the Colorado legislature to preclude hospitals from interfering with the independent professional judgment of their employees.³⁹ The rationale behind the legislature's decision is likely that doctors must make independent decisions, and reporting to a hospital as their employer would contradict that goal. As a matter of public policy, doctors must take responsibility for their actions and remain accountable to their patients.

32. *Estate of Harper v. Denver Health & Hosp. Auth.*, 140 P.3d 273, 275 (Colo. App. 2006).

33. *Id.* at 277.

34. *Hall v. Frankel*, 190 P.3d 852, 861 (Colo. App. 2008) (discussing policy considerations underlying prohibition); *Villalpando v. Denver Health & Hosp. Auth.*, 181 P.3d 357 (Colo. App. 2007).

35. *Nieto v. State*, 952 P.2d 834, 840–41 (Colo. App. 1997).

36. *Ochoa v. Vered*, 212 P.3d 963, 966 (Colo. App. 2009) (citing *Beadles v. Metayka*, 311 P.2d 711, 713–14 (Colo. 1957)).

37. *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1283 (Colo. App. 2010).

38. *Id.*

39. *See Hall*, 190 P.3d. at 861.

Despite the policy reasons for holding doctors liable, Colorado medical malpractice law, as it is, imposes financial and psychological burdens on medical professionals. Although case law on physician use of AI/ML is in its infancy, existing cases suggest that doctors will ultimately bear the burden of errors resulting from AI/ML output.⁴⁰ For instance, courts across the United States have allowed malpractice claims to proceed against doctors in cases where there were mistakes in medical literature given to patients or when a practitioner relied on an intake form that did not ask for a complete history.⁴¹ Courts have also been reluctant to allow physicians to offset their liability when a pharmaceutical company did not adequately warn of a therapy's adverse effects.⁴² Likewise, many courts are reluctant to excuse malpractice based on errors by system technicians or manufacturers.⁴³

It should go without saying that doctors who deviate from the standard of care and harm their patients should be held responsible. However, healthcare professionals, especially specialists and surgeons, routinely operate under high-stress conditions and face life-or-death situations. After years of schooling, hundreds of thousands of dollars in debt, and countless hours serving their community, many doctors fear being sued for something they may not have had complete control over.⁴⁴ Litigation can derail doctors' lives and compromise their ability to perform optimally.⁴⁵ Doctors facing malpractice suits may reduce the number of patients they see or leave their practices, limiting patient access to quality care.⁴⁶

40. Jorstad, *supra* note 17, at 15.

41. Maliha et al., *supra* note 10, at 632 (citing *Roman v. City of New York*, 442 N.Y.S. 945 (Sup. Ct. 1981) and *Appleby v. Miller*, 554 N.E.2d 773 (Ill. App. Ct. 1990)).

42. *Id.* (citing *Ross v. Jacobs*, 684 P.2d 1211 (Okla. App. Ct. 1984) and *Bristol-Myers v. Gonzales*, 561 S.W.2d 801 (Tex. 1978)).

43. *Id.* (citing *Toth v. Community Hosp. at Glen Cove*, 292 N.Y.S.2d 440 (1968) and *Sander v. Geib, Elston, Frost Pro. Ass'n*, 506 N.W.2d 107 (S.D. 1993)).

44. See Melanie Hanson, *Average Medical School Debt*, EDUC. DATA INITIATIVE (Sept. 14, 2025), <https://educationdata.org/average-medical-school-debt> [https://perma.cc/D5WX-BSMA]; Robert Pearl, *If AI Harms A Patient, Who Gets Sued?*, FORBES (May 6, 2024, 5:30 AM EDT), <https://www.forbes.com/sites/robertpearl/2024/05/06/if-ai-harms-a-patient-who-gets-sued/> [https://perma.cc/8KCV-UGXW].

45. Tom Lawton et al., *supra* note 14, at 2 ("Clinicians can become 'second victims' and suffer serious mental health consequences after such an incident, including depression, anxiety, PTSD, and even suicide.").

46. See R. Madan et al., *Consequences of Medical Negligence and Litigations On Health Care Providers – A Narrative Review*, 66 INDIAN J. PSYCH. 317 (2024); see also Daniel Payne, *Who pays when AI steers your doctor wrong?*, POLITICO (Mar. 24, 2024, 7:00 AM EDT), <https://www.politico.com/news/2024/03/24/who-pays-when-your-doctors-ai-goes-rogue-00148447> [https://perma.cc/8KCV-UGXW] (noting upward trends in insurance premiums could have implications for where doctors choose to practice and what specialties they pick).

To provide a complete picture of Colorado medical malpractice law, it is important to note the protections in place for physicians. The Colorado Health Care Availability Act (HCAA), C.R.S. §13-64-101 to 503 (2025), limits “[t]he total amount recoverable for all damages” in a medical malpractice case against healthcare professionals and institutions.⁴⁷ Before 2025, the HCAA had capped damages at \$1 million, with a hard cap on non-economic damages at \$300,000.⁴⁸ Thus, all doctors received up to \$1 million in insurance coverage.⁴⁹ In June 2024, the non-economic damages cap was raised and will incrementally increase through 2029, at which point it will reach \$875,000.⁵⁰ Because of the HCAA, the problems doctors realistically face after being sued are higher insurance premiums and difficulty obtaining insurance coverage.⁵¹ The law, however, is not unalterable. On November 24, 2025, the Colorado Supreme Court concluded in *Banner Health v. Gresser* that when a plaintiff establishes good cause to exceed the HCAA damage caps, the jury may retain its authority to determine the amount of damages.⁵² Accordingly, in that case, the Court affirmed a jury’s finding of Banner Health’s negligence and its award of \$27,647,274.23 in economic damages to the plaintiff.⁵³ The *Gresser* decision will likely remove some of the HCAA’s protection against extreme jury verdicts above \$1 million.⁵⁴

On balance, the threat of financial loss, the increased price of insurance, and the extreme stress of malpractice suits may deter doctors from wanting to use AI at all.⁵⁵ The threat of liability has not previously warranted a reevaluation of the law, but the rise of artificial intelligence adds a new layer of complexity. The integration of AI will likely introduce a new source of error that, yet

47. C.R.S. § 13-64-302(1)(b) (2024).

48. C.R.S. § 13-64-302(1)(b)–(c) (2024).

49. *Colorado Medical Malpractice Insurance*, GALLAGHER HEALTHCARE, <https://www.gallaghermalpractice.com/state-resources/colorado-medical-malpractice-insurance/> [https://perma.cc/F7ZY-R5AK].

50. Christopher Ryan Jones, *Colorado’s Evolving Malpractice Damages Framework: Legislative Increases and Supreme Court Guidance*, GORDON REES SCULLY MANSUKHANI (Dec. 2025), <https://www.grsm.com/insight/colorados-evolving-malpractice-damages-framework-legislative-increases-and-supreme-court-guidance/> [https://perma.cc/VNR9-MCJB].

51. *How Much Does Medical Malpractice Insurance Cost?*, GALLAGHER HEALTHCARE (Mar. 19, 2020), <https://www.gallaghermalpractice.com/blog/post/how-much-does-medical-malpractice-insurance-cost> [https://perma.cc/Q3R9-EL8E].

52. *Banner Health v. Gresser*, 579 P.3d 882 (Colo. 2025).

53. *Id.*

54. Jones, *supra* note 50.

55. *Malpractice Concerns Impact Physician Decisions to Consult AI*, JOHN HOPKINS CAREY BUS. SCH. (June 15, 2023), <https://carey.jhu.edu/articles/research/malpractice-concerns-physician-consult-ai> [https://perma.cc/M5F5-7F4D].

again, will fall on doctors' shoulders. Basic principles of fairness compel a change in the law.

B. Types of AI in Healthcare

To set the stage for discussing the challenges in governing AI, it is essential to understand what it is, what it encompasses, and how the subcategories of AI work together in the healthcare industry. Broadly speaking, artificial intelligence is an umbrella term encompassing a wide range of approaches and algorithms.⁵⁶ The term refers to the general ability of computers to emulate human thought by performing tasks in real-world environments.⁵⁷ There are many subfields of AI, each with unique capabilities and a distinct impact in the area where it's used.⁵⁸ This Note will discuss five AI systems that are most relevant to medical malpractice law: Machine Learning, Rule-based Expert Systems, Natural Language Processing, Robotic Process Automation, and Physical Robots. Their applications in the medical field are diagnosis and treatment, patient engagement and adherence, and administrative improvement.

Machine Learning (ML) is a subcategory of AI that refers to the technologies and algorithms that equip systems with the capability to learn autonomously from past data.⁵⁹ Specifically, ML AI uses self-learning algorithms to analyze large data sets to detect patterns and make predictions without explicit programming.⁶⁰ Traditional ML is based on an underlying "neural network" comprising one or two computational layers.⁶¹ These layers provide the baseline information from which the ML/AI derives its knowledge.⁶² ML/AI can vary in complexity, ranging from simple models to "deep learning" models with hundreds of thousands of computational layers.⁶³ ML/AI can analyze medical images, including X-rays, CT scans, MRIs, and pathology slides.⁶⁴ This speeds up interpretation, enhances early disease detection, and

56. Google Cloud, *supra* note 1.

57. *Master of Science in Artificial Intelligence (AI)*, Columbia Eng., <https://ai.engineering.columbia.edu/ai-vs-machine-learning/> [<https://perma.cc/957G-L2U5>]; see *What is artificial intelligence (AI)?*, ISO, <https://www.iso.org/artificial-intelligence/what-is-ai> [<https://perma.cc/4VNC-EUE2>].

58. Google Cloud, *supra* note 1.

59. *Id.*

60. Andrew Zellers, *The Benefits of AI in Healthcare With Examples*, CHARTREQUEST (June 8, 2023), <https://chartrequest.com/benefits-of-ai-in-healthcare-2023/> [<https://perma.cc/9RA3-G3HX>].

61. See Dave Bergmann, *What is deep learning?*, IBM, <https://www.ibm.com/topics/deep-learning> [<https://perma.cc/NNR5-YFZE>].

62. *Id.*

63. *Id.*

64. *Id.*

improves diagnosis accuracy.⁶⁵ ML/AI can also analyze patients' health records, genetic history, lifestyle factors, and clinical notes to predict risk factors and disease progression, leading to more personalized treatment plans.⁶⁶

Another subfield of AI is Natural Language Processing (NLP). NLP “enables computers and digital devices to recognize, understand and generate text and speech by combining computational linguistics—the rule-based modeling of human language—together with statistical modeling, machine learning and deep learning.”⁶⁷ Essentially, NLP enables computers to understand and process human language, either written or spoken, and synthesize vast amounts of information.⁶⁸ NLP and ML often work together—ML provides the basis for NLP's understanding of human language while NLP contextualizes data inputs.⁶⁹ However, they are not the same. For instance, ML models may receive inputs from developers or independently draw on multiple databases, whereas NLP tools receive inputs directly from users.⁷⁰ Nonetheless, using this technology, healthcare professionals can aggregate data for research, clinical decision support systems, and quality improvement initiatives without manually scouring through medical records and clinical notes.⁷¹

Next, a Rules-Based Expert System is a more foundational type of AI that uses pre-established rules and knowledge bases to emulate human decision-making.⁷² This system is automated rather than autonomous, meaning it is mechanically controlled and can be programmed to execute tasks.⁷³ It expedites workflow by

65. *Id.*

66. Zellers, *supra* note 60.

67. Cole Stryker & Jim Holdsworth, *What is NLP (Natural Language Processing)?*, IBM, <https://www.ibm.com/topics/natural-language-processing> [<https://perma.cc/3MCT-33E8>].

68. Stephanie Overby, *Artificial intelligence (AI) vs. natural language processing (NLP): What are the differences?*, ENTERPRISERS PROJECT (Feb. 26, 2020), <https://enterprisersproject.com/article/2020/2/artificial-intelligence-ai-vs-natural-language-processing-nlp-differences/> [<https://perma.cc/U8JS-GTBM>].

69. *Machine Learning vs. NLP: What's the Difference?*, SALESFORCE, <https://www.salesforce.com/artificial-intelligence/machine-learning-vs-nlp/> [<https://perma.cc/Q6CR-E2JK>].

70. *Id.*

71. *NLP in Medical Record Review*, TREND HEALTH PARTNERS (Oct. 6, 2023), <https://trendhealthpartners.com/nlp-in-medical-record-review/> [<https://perma.cc/5FCB-SLC7>].

72. Maeve Sentner, *Rule-based AI: the backbone of automation*, TELNYX (2025), <https://telnyx.com/learn-ai/rule-based-ai> [<https://perma.cc/35LU-TTNU>].

73. *Automation vs. AI: Meaning, Differences, and Real World Uses*, COURSERA, (Apr. 18, 2026), <https://www.coursera.org/articles/automation-vs-ai> [<https://perma.cc/ZM9W-ZGP5>]; *Automated Robots vs Autonomous Robots*, ROBOTS DONE RIGHT, <https://robotsdoneright.com/Articles/automated-robots-vs-autonomous-robots.html> [<https://perma.cc/Z7W3-GCZ9>].

compiling patients' symptoms, medical history, and test results to develop rules.⁷⁴ The system also can be used to diagnose diseases and provide treatment recommendations.⁷⁵ Significantly, this system "cannot adapt or improve based on experience, unlike machine learning systems that can learn and optimize over time."⁷⁶ Because this system is rule-based, it may struggle with novel or complex scenarios beyond its established rules.⁷⁷ Handling contradictory information is challenging for this type of AI, which can lead to errors.

Another automated process, Robotic Process Automation (RPA), is a form of business process automation where users provide instructions for the system to execute.⁷⁸ RPA automates repetitive and rule-based administrative tasks, which improves operational efficiency.⁷⁹ RPA systems can mimic human-computer interactions and precisely execute tasks at a high volume and speed.⁸⁰ This capability frees up human resources for more critical tasks while expediting insurance claim submissions, reimbursement processes, and appointment scheduling.⁸¹

The practical integration of these AI subcategories is evident in AI-enhanced robotics, a domain that encompasses both automated and autonomous systems. Some robots operate autonomously, using AI applications such as ML, deep learning, and NLP to carry out specialized tasks with minimal human oversight.⁸² In healthcare, robots are already assisting in surgical procedures at varying levels of autonomy.⁸³ "AI modeling is allowing surgeons to have advanced intraoperative metrics such as force and tactile measurements, enhanced detection of positive surgical margins, and even allowing for the complete automation of certain steps in surgical procedures."⁸⁴ Embedded AI algorithms enable these robotic systems to analyze real-time data, offer surgical guidance, and enhance clinical decision-making.⁸⁵

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. Kevin Casey, *How to explain robotic process automation (RPA) in plain english*, ENTER. PROJECT (July 30, 2020), <https://enterpriseproject.com/article/2019/5/rpa-robotic-process-automation-how-explain> [<https://perma.cc/7ZZG-WKZP>].

79. Zellers, *supra* note 60.

80. *Id.*

81. *Id.*

82. *The Molex Robotics Report: How Robotics Will Empower Human Potential*, MOLEX (2024), <https://www.molex.com/en-us/trends-insights/next-generation-connectivity-innovation/robotics-report> [<https://perma.cc/NE8F-JJPM>].

83. J. Everett Knudsen et al., *Clinical Applications of Artificial Intelligence in Robotic Surgery*, 18 J. ROBOT. SURG. 102, 102 (2024).

84. *Id.*

85. Zellers, *supra* note 60.

By contrast, automated robots are designed to perform repetitive tasks by following predefined instructions, requiring little to no direct, real-time human intervention.⁸⁶ This form of robotic automation is also reshaping healthcare.⁸⁷ For example, in the pharmaceutical industry, “robotic dispensing systems ... have streamlined the prescription-filling process by automating tasks such as counting, labeling, and dispensing medications.”⁸⁸ A robotic dispensing system in Japan was found to have reduced dispensing errors from 0.204 percent to 0.044 percent and unprevented errors from 0.015 percent to 0.002 percent after its introduction.⁸⁹

These innovations have undeniably revolutionized the healthcare industry. As AI becomes increasingly prevalent, it holds the potential to improve accuracy, reliability, and efficiency. Nevertheless, the incorporation of AI into medical practice is not without risk and may produce serious negative consequences.

II. WHY STATE LEGISLATION IS IMPERATIVE FOR CHANGE

While international bodies, such as the European Union, have long advocated limits on AI, the United States has primarily allowed the industry to regulate itself.⁹⁰ This hands-off approach stems in part from the fact that many federally elected officials often lack sufficient expertise in the intersection of computer science and law, and Congress has been notoriously averse to imposing sweeping limitations on technology companies.⁹¹

Although federal action has been slow, there have been incremental steps. In 2022, the White House created a “Blueprint for an AI Bill of Rights,” which offered high-level guidance in designing, deploying, and using automated systems to prioritize civil rights and democratic values.⁹² Federal agencies have issued

86. Jason Axelrod, *What is the Difference Between AI and Automation?*, LEAPWORK (Apr. 8, 2026), <https://www.leapwork.com/blog/ai-and-automation-what-is-the-difference> [https://perma.cc/3U4Y-SVA6].

87. *The Future of Robotics in Healthcare*, JOHNS HOPKINS ENG. FOR PRO. (May 14, 2025), <https://ep.jhu.edu/news/robots-making-a-difference-in-healthcare/> [https://perma.cc/3AJR-TQ2X].

88. *Id.*

89. *Id.*; Tomoki Takase et al., *Evaluating the Safety and Efficiency of Robotic Dispensing Systems*, 8 J. PHARM. HEALTH CARE & SCI. 24, at 1, 5 (2022).

90. Sara Helene Shanti et al., *AI In Healthcare: Cautions And Considerations Of A Healthcare Revolution*, MONDAQ (June 21, 2023), <https://www.mondaq.com/unitedstates/healthcare/1332290/ai-in-healthcare-cautions-and-considerations-of-a-healthcare-revolution> [https://perma.cc/8LPW-XZ4J].

91. Maya Kornberg, *Congress is Woefully Unprepared to Regulate Tech*, BRENNAN CTR. FOR JUST. (July 5, 2023), <https://www.brennancenter.org/our-work/analysis-opinion/congress-woefully-unprepared-regulate-tech> [https://perma.cc/4X4P-PXJR].

92. OFF. SCI. & TECH. POL’Y, *Blueprint for an AI Bill of Rights* (2022), <https://bidenwhitehouse.archives.gov/ostp/ai-bill-of-rights/> [https://perma.cc/48BX-P78L].

similarly broad guidance, and Congress has begun educating itself through hearings with stakeholders and technology executives.⁹³ Additionally, during the Biden administration, Congress created a bipartisan AI task force and introduced a wide variety of proposed legislation.⁹⁴ These efforts, however, fell short of firmly establishing the clear, standardized safeguards urgently needed to guide responsible AI development.⁹⁵ In the absence of comprehensive federal legislation, states such as New York, Illinois, and Colorado enacted their own AI-related laws.⁹⁶

Against this backdrop of expanding state involvement, the federal government's attitude toward state regulation of AI shifted in 2025. In drafting President Trump's One Big Beautiful Bill Act, federal lawmakers made an ambitious attempt to prevent nearly all state and local regulation of AI.⁹⁷ One version of the One Big Beautiful Bill Act contained a provision preventing states and localities from enforcing, for ten years, "any law or regulation ... limiting, restricting, or otherwise regulating artificial intelligence models, artificial intelligence systems, or automated decision systems entered into interstate commerce."⁹⁸ The moratorium was ultimately stripped from the bill for lack of majority support.⁹⁹ Still, the attempt to strip states and localities of the right to regulate AI suggests an emerging federal ambition to centralize AI governance.¹⁰⁰

"Advocates of a federal-first approach to AI regulation ... argue that a ban on state-by-state laws is necessary to avoid an unwieldy patchwork of legislation that would harm American AI companies, particularly startups."¹⁰¹ Advocates of state regulation agree that

93. *Id.*

94. *Id.*; LAURIE A. HARRIS, CONG. RSCH. SERV., R46795, ARTIFICIAL INTELLIGENCE: BACKGROUND, SELECTED ISSUES, AND POLICY CONSIDERATIONS 22 (May 19, 2021), <https://www.congress.gov/crs-product/R46795> [<https://perma.cc/7USC-CMCH>].

95. See Aaron Klein et al., *1 year later, how has the White House AI Executive Order delivered on its promises?*, BROOKINGS (Nov. 4, 2024), <https://www.brookings.edu/articles/one-year-later-how-has-the-white-house-ai-executive-order-delivered-on-its-promises/> [<https://perma.cc/SBA4-DSY6>] ("Without legislative action, the safety measures risk becoming outdated or insufficient as AI technology continues to evolve rapidly.").

96. Guy Brenner & Jonathan Slowik, *'Big Beautiful Bill' Leaves AI Regulation to States and Localities ... For Now*, PROSKAUER (July 8, 2025), <https://www.lawandtheworkplace.com/2025/07/big-beautiful-bill-leaves-ai-regulation-to-states-and-localities-for-now/> [<https://perma.cc/KGM8-5WWP>].

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. Jared Perlo, *Trump administration drafts an executive order to challenge state AI laws*, NBC NEWS (Nov. 19, 2025, 18:07 MST), <https://www.nbcnews.com/politics/trump-administration/trump-administration-executive-order-regulating-state-ai-laws-rcna244890> [<https://perma.cc/R6EW-D8CJ>].

they would prefer federal regulation that allows states and localities to regulate AI, but a “piecemeal approach is preferable to lackluster action at the federal level.”¹⁰² De facto legal frameworks for AI will likely continue to emerge outside the United States, shaping domestic standard practices in the absence of more comprehensive U.S. federal guidance.¹⁰³ Although AI has legislators’ attention, and future federal regulation is ultimately expected, states like Colorado have a tremendous opportunity to lead in this arena. Passing more nuanced legislation that addresses AI’s impact on specific industries, namely, the healthcare industry, will likely influence the direction of national policy.

III. THE DRAWBACKS OF AI IN HEALTHCARE AND THE ISSUE OF ALLOCATING LIABILITY

Healthcare leaders, including the American Medical Association (AMA), have maintained that doctors should never rely entirely on AI and must always pair its use with their personal judgment. “Whatever the future of health care looks like, patients need to know there is a human being on the other end helping guide their course of care,” said AMA President Jesse M. Ehrenfeld, MD, MPH. “That’s essential.”¹⁰⁴ Dr. Ehrenfeld, an anesthesiologist who co-chairs the Association for the Advancement of Medical Instrumentation’s AI committee, has also publicly stated that “[s]teps should be taken to ensure that these systems are not overriding clinical judgment and do not eliminate human review of individual circumstances ... [Clinical] decisions influenced by AI must be made with specified human intervention points during the decision-making process.”¹⁰⁵

Despite this standard, it will likely become commonplace for doctors to use AI daily, and the technology will influence decisions made in practice. After all, using AI systems for specific, well-defined decisions will likely be justified in the minds of physicians if strong clinical evidence shows that the system performs the task more efficiently than a human.¹⁰⁶ Once AI technologies are fully integrated into doctors’ daily practice, assigning responsibility for medical errors will become more complex. The critical question is:

102. *Id.*

103. Shanti et al., *supra* note 90.

104. Andis Robeznieks, *Big majority of doctors see upsides to using health care AI*, AM. MED. ASS’N (Jan. 12, 2024), <https://www.ama-assn.org/practice-management/digital-health/big-majority-doctors-see-upsides-using-health-care-ai> [<https://perma.cc/FDX4-DP7Y>].

105. *Id.*

106. Ciro Mennella et al., *Ethical and Regulatory Challenges of AI Technologies in Healthcare: A Narrative Review*, 10 HELIYON 1, 15 (2024).

Who will be held responsible when AI contributes to a patient's injury? Significant challenges that complicate the liability analysis include: (1) the "control problem"; (2) "disagreement between equals"; and (3) "traceability of harm."

The "control problem" is the concern that doctors may not fully understand how AI algorithms reach their conclusions, potentially leading to an inability to interpret and implement AI-generated recommendations appropriately. "AI-driven systems can operate independently and evolve in ways the developer may assert are unpredictable."¹⁰⁷ No one has complete control over the output because AI systems rely on human input, their history of interactions, discretionary functions, and their capacity to uncover implicit intricacies.¹⁰⁸ "Before, a doctor could see when their scalpel needed to be sharpened ... Now for all [intents and] purposes doctors are working off of an invisible scaffold with invisible tools."¹⁰⁹ Some analysts have asserted that "AI is only as good as the information and values of the programmers who design it, and their biases can ultimately lead to both flaws in the technology and amplified biases in the real world."¹¹⁰ Algorithmic bias may result in predicting a greater likelihood of disease based on gender or race when those are not actually causal factors.¹¹¹ Moreover, doctors may grow to rely on erroneous software recommendations without realizing it. This has already materialized in cases such as *Sampson v. HeartWise Health Systems Corporation*.¹¹² In this 2023 case, physicians followed the output of a software program for cardiac health screening that wrongly classified a young adult with a family history of congenital heart defects as "normal."¹¹³ The patient died weeks later.¹¹⁴ The case was allowed to proceed to trial on the allegation that the physicians should have scrutinized the erroneous software recommendation or, if they had not, should have independently reached the right decision.¹¹⁵ The court ultimately dismissed the negligence claim because the AI developer's licensing

107. *Id.* at 14.

108. *See id.*

109. *Hard Choices: AI in Health Care*, YALE MED. MAG., Mar. 24, 2021, at 1, 4 [hereinafter *Hard Choices*].

110. Harris, *supra* note 94, at 39–40.

111. Thomas Davenport & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 94, 97 (2019).

112. *See* *Sampson v. HeartWise Health Sys. Corp.*, 386 So.3d 411 (Ala. 2023); Michelle M. Mello & Neel Guha, *Understanding Liability Risk from Healthcare AI*, STANFORD INST. HUMAN-CENTERED A.I. 1, 3 (Feb. 8, 2024), <https://hai.stanford.edu/policy/policy-brief-understanding-liability-risk-healthcare-ai> [https://perma.cc/66R8-MB9P].

113. *Id.*

114. *Id.*

115. *Id.*

agreement gave doctors final decision-making authority, and the developer was not technically a “healthcare provider” under state law.¹¹⁶ This emerging case law signals a future in which liability varies depending on private contracts and jurisdictional differences—one in which physicians can be held liable for unintentional, nearly unforeseeable errors.¹¹⁷

Another problem that complicates the liability analysis arises when there is a “disagreement between equals.” When two “experts”—the doctor and the AI—disagree, there is no feasible method for harmonizing decisions or discussing differences of opinion.¹¹⁸ Some may advocate prioritizing AI’s recommendations because they reflect a wide range of data points from the training data.¹¹⁹ However, one wonders whether a physician’s consistent agreement with AI recommendations might undermine the physician’s professional authority and dilute their sense of accountability. At the same time, routinely deferring to AI could introduce errors stemming from embedded bias or the system’s inability to fully assess a patient’s circumstances. Conversely, if a physician habitually disregards the AI’s guidance, the technology offers little meaningful added value. There is no answer to what doctors should be consistently advised to do. This is especially troublesome in “such a litigious country as the United States, where lawyers will have audit trails and other evidence proving what the machine proposed versus what the doctor did. Most experts think this issue will almost inevitably fuel a proliferation of legal battles.”¹²⁰

Lastly, the “traceability of harm,” or lack thereof, poses a challenge. Doctors routinely use non-AI technologies to diagnose and treat their patients. Errors from technologies such as X-rays, MRI machines, and complex computer software are easily traceable to the doctor, especially if the doctor has received the requisite training in the machine’s application.¹²¹ In contrast, AI technology is implemented by numerous agents. It has many points of input, which can lead to “incomplete identification of the harm and its root causes, unaddressed harm, and potential erosion of societal trust in

116. *Id.*

117. *Id.*

118. Mennella et al., *supra* note 106, at 15.

119. Nicol Turner Lee et al., *Algorithmic bias detection and mitigation: Best practices and policies to reduce consumer harms*, BROOKINGS (May 22, 2019), <https://www.brookings.edu/articles/algorithmic-bias-detection-and-mitigation-best-practices-and-policies-to-reduce-consumer-harms/> [<https://perma.cc/BTM9-8L8S>].

120. *Hard Choices*, *supra* note 109.

121. Mennella et al., *supra* note 106, at 14.

such technologies when it appears that neither developers nor users can be held accountable.”¹²²

Furthermore, the AI developer, the hospital, and the physician may *all* play a role in a medical error, complicating efforts to assign responsibility.¹²³ For example, in *Sergeant v. Orthopedic Associates Medical Clinic*, doctors, a technician, and the clinic were all sued after a human error during a reprogramming of an infusion pump caused a lethal morphine dosing.¹²⁴ In other cases, developers have been targeted “for defects in manufacturing, design, and warnings, though plaintiffs often fail to meet the court’s demand that they identify specific design flaws rather than point to the software failure itself as a defect.”¹²⁵ Despite these examples, the lack of legislation governing responsibility allocation often leaves patients without effective recourse, frequently leading them to sue multiple parties. The lack of clarity also puts doctors at greater risk of medical malpractice suits, even when their fault is uncertain.

Numerous factors tip the scales against placing the bulk of responsibility on physicians.¹²⁶ From a high-level perspective, the argument can be made that physicians do not truly have a choice about whether to use AI in practice. The World Health Organization (WHO) has acknowledged the essential role of technology in integrating long-term healthcare services into patients’ everyday lives.¹²⁷ “Technology is considered vital in achieving universal health coverage for all age groups by promoting cost-effective integration and service delivery.”¹²⁸ Advances in technology, especially in AI and robotics, are increasingly being utilized and encouraged to support healthcare research and practice.¹²⁹ Hospitals are keen to integrate new and helpful AI technology; thus, they appear to have the authority to manage how employees complete daily tasks.¹³⁰ Doctors who work in hospitals may have little say in whether they work with this new “partner.”

122. *Id.*

123. See Davenport & Kalakota, *supra* note 111.

124. Mello & Guha, *supra* note 112, at 4.

125. *Sergeant v. Orthopedic Assoc. Med. Clinic* (2006); see Mello & Guha, *supra* note 112, at 4.

126. Mennella et al., *supra* note 106, at 14.

127. *Id.* at 1.

128. *Id.*

129. *Id.*

130. *The Future According to Mayo Clinic: How AI is Transforming the Hospital*, CB INSIGHTS, <https://businessdevelopment.mayoclinic.org/wp-content/uploads/2024/11/The-future-according-to-Mayo-Clinic-How-AI-is-transforming-the-hospital-CB-Insights.pdf> [<https://perma.cc/7XXF-3FUS>] (stating that Mayo Clinic’s investment activity and development of new partnerships have focused on AI, suggesting that “AI is shaping the hospitals of the future”).

This may call for a reevaluation of liability under the CPOM doctrine. In addition, under the existing CPOM doctrine, generative AI models are limited or even prohibited in some states.¹³¹ The doctrine directly conflicts with the use of generative AI in healthcare, as technology is a non-human entity that cannot perform medical actions or hold a medical license. Therefore, applying traditional medical malpractice liability to doctors is illogical. These considerations necessitate that the Colorado legislature establish a new standard for medical malpractice lawsuits involving AI.

IV. AI AND PRODUCTS LIABILITY

There is little case law on AI-related liability in healthcare. AI technologies are still relatively new, and few personal injury claims have led to judicial opinions.¹³² The standard elements of a negligence action—that the defendant owed the plaintiff a duty of care, the defendant’s actions fell below the standard of care, and that this breach of duty caused the plaintiff an injury—become significantly more complex when dealing with AI. Courts have yet to decide how to treat AI in a medical malpractice action. There is an ongoing debate about whether AI will be treated as a person, a product, a tool, or a combination of these.¹³³

Throughout history, the legal definition of “personhood” has evolved, and there has never been a singular, unchanging standard for who qualifies as a person under U.S. law.¹³⁴ Personhood is a flexible concept. Society is now approaching a pivotal moment when we must grapple with legal and ethical questions about how to classify and treat an advanced form of intelligence that cannot easily be dismissed as occupying a lower rung on the cognitive hierarchy.¹³⁵ Still, most would argue that personhood requires sentience, a quality AI does not possess, even as it surpasses human capabilities in certain domains.¹³⁶ Furthermore, granting AI legal personhood would create significant hurdles to plaintiffs’ recovery,

131. Shanti et al., *supra* note 90.

132. Mello & Guha, *supra* note 112, at 2.

133. See Thomas Frey, *The Person in the Machine: Why AI Personhood Rights Are Inevitable (And Arriving Sooner Than You Think)*, FUTURIST SPEAKER (Feb. 11, 2026), <https://futuristspeaker.com/artificial-intelligence/the-person-in-the-machine-why-ai-rights-are-inevitable-and-arriving-sooner-than-you-think/> [https://perma.cc/WT5Q-R7PN]; Frank Young, *AI as a Product: The Next Frontier in Product Liability Law*, U. ILL. CHI. (Oct. 13, 2025), <https://library.law.uic.edu/news-stories/ai-as-a-product-the-next-frontier-in-product-liability-law/> [https://perma.cc/BX47-6NMC].

134. Katherine B. Forrest, *The Ethics and Challenges of Legal Personhood for AI*, 133 YALE L.J. F. 1175 (2024).

135. See *id.* at 1176.

136. See *id.*

leaving them without a clear avenue to seek justice or compensation for harm caused by AI systems. Thus, while the idea of AI as a person raises intriguing philosophical and legal debates, it is improbable that AI will ever be held personally liable, as it fundamentally lacks the essential characteristics of personhood.¹³⁷ It is more likely that AI will be treated as a tool with human-like attributes rather than as an entity entitled to the rights and responsibilities of personhood.

It is more practical to view AI as a tool or product, but applying product liability principles to AI poses challenges. “The intangible and opaque nature of software and AI models poses significant challenges for holding software developers liable according to traditional rules governing product liability.”¹³⁸ In Colorado, product liability actions are based on either negligence or strict liability.¹³⁹ Medical product liability cases sit at the crossroads of medical malpractice and product liability law, addressing situations in which healthcare providers depend on medical products for diagnosis and treatment.¹⁴⁰ The distinction between these legal claims hinges on the cause of the harm. Errors by doctors in the placement, use, monitoring, or communication of medical devices constitute medical malpractice.¹⁴¹ Conversely, if a medical product malfunctions and directly causes patient harm, the responsibility typically lies with the product’s manufacturer or seller under product liability law.¹⁴²

Importantly, courts rarely let doctors escape liability when a product they use fails, recognizing that “ordinarily, a manufacturer has a duty to warn all foreseeable ultimate users of dangers inherent in its products.”¹⁴³ However, under the learned intermediary doctrine, physicians are trained to assess the risks and benefits of drugs administered to patients, and a warning is deemed adequate when it explains to the physician the risk the plaintiff asserts is associated with the drug.¹⁴⁴ Courts have

137. See Nancy S. Jecker, *What is ‘personhood’? The ethics question that needs a closer look in abortion debates*, CONVERSATION (May 13, 2022, 8:14 AM EDT) <https://theconversation.com/what-is-personhood-the-ethics-question-that-needs-a-closer-look-in-abortion-debates-182745> [<https://perma.cc/9MUB-TYVN>].

138. Mello & Guha, *supra* note 112, at 1.

139. See *Product Liability Claims and You: A Quick Reference*, BACHUS & SCHANKER <https://www.coloradolaw.net/practice-area/product-liability/product-liability-claims/> [<https://perma.cc/DY2T-EELQ>].

140. See *Medical Product Liability*, LEVENTHAL PUGA BRALEY, <https://www.leventhal-law.com/medical-malpractice/medical-product-liability.html> [<https://perma.cc/A3RQ-B4T4>].

141. *Id.*

142. *Id.*

143. *O’Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281 (Colo. App. 2010) (discussing the learned intermediary doctrine).

144. *Id.*

maintained that “[i]t is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment.”¹⁴⁵ Accordingly, if a patient receives substandard care because a drugmaker fails to adequately warn about its risks, the physician is unlikely to escape liability.¹⁴⁶ In some cases, doctors followed allegedly errant software suggestions for which drugs to prescribe and how to treat patients, which plaintiffs claimed caused them harm, and courts still heard the cases “despite doctors’ efforts to blame the tool.”¹⁴⁷

Product liability law is intended to hold manufacturers, sellers, and others in a product’s distribution chain responsible for damages if the product causes harm to the end consumer. Historically, software has largely been exempted from product liability, and some courts have hesitated to classify AI as a product.¹⁴⁸ However, this Note argues that courts face challenges in classifying AI as a product because they fail to differentiate between automated and autonomous AI. Additionally, judges’ difficulty in applying product liability principles stems from an overemphasis on manufacturing and design defects and the allowance of the learned intermediary doctrine, which functions as an escape hatch for those who make products for patients. To ensure the liability analysis is both coherent and effective in holding the appropriate parties accountable, the focus should shift to a framework grounded in a revised version of warning defect/failure to warn liability.

Three types of defects give rise to a product liability lawsuit: design defects, manufacturing defects, and warning defects.¹⁴⁹ Although laws vary by jurisdiction, a design defect means the product’s design is inherently defective, making it dangerous to consumers.¹⁵⁰ Design defect liability is a complex and often subjective area of law, frequently requiring expert testimony to determine whether a product could have been designed more safely.¹⁵¹ Currently, states that have commented on this issue require patients suing a manufacturer to demonstrate that a safer, reasonable alternative design was available and that the injury was

145. *Id.* (quoting *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992)).

146. Payne, *supra* note 46.

147. *Id.*

148. See Young, *supra* note 133.

149. *Types of Products Liability Legal Claims*, JUSTIA (Oct. 2025), <https://www.justia.com/products-liability/types-of-products-liability-claims/> [https://perma.cc/U357-RGRA].

150. *Design Defect*, LEGAL INFO. INST. CORNELL L. SCH., https://www.law.cornell.edu/wex/design_defect [https://perma.cc/2CCW-D9GM].

151. *Artificial Intelligence & Product Liability*, MCCARTER & ENGLISH (Aug. 20, 2024), <https://www.mccarter.com/insights/artificial-intelligence-product-liability/> [https://perma.cc/MN9H-UYHA].

foreseeable.¹⁵² These requirements are challenging to meet because plaintiffs have limited access to the inner workings, or “black box,” of AI systems.¹⁵³ As AI emerges as a relatively new product component, it is developed, marketed, and adopted amid ongoing discovery of its capabilities and limitations. Questions remain unanswered, such as: Should a deep neural network be considered inherently dangerous by design? Specifically, is its internal behavior—how it functions through a conventional step transformation process—so uncontrollable that it becomes unreasonably or inherently dangerous, or at least unsuitable for certain applications? Without clear answers, categorizing an AI system’s errors as design defects remains difficult. This uncertainty raises the question of whether an adverse outcome from an AI component might be more appropriately classified as a manufacturing defect rather than a design defect.

A manufacturing defect occurs when a product departs from its intended design and becomes more dangerous than consumers expect.¹⁵⁴ Manufacturing defects occur in only some products due to a manufacturing mistake. In Colorado, the manufacturer or seller is strictly liable for damages caused by a manufacturing defect, meaning they are liable to the customer even if they were not necessarily negligent.¹⁵⁵ Mitigating manufacturing defects for AI is intrinsically challenging, especially when companies use third-party AI systems.¹⁵⁶ Unlike tangible products like X-ray machines or Boyle’s machines, it is not possible to inspect AI for conformity with its design specifications.¹⁵⁷

Accordingly, if AI is to be designated as a product, allocating liability based on a failure to warn is the least problematic. A failure to warn defect arises when a product is designed correctly but lacks appropriate instructions or warnings.¹⁵⁸ This lack of warnings makes the product unreasonably dangerous to its consumers. The opaque nature of AI technology makes it more appropriate to shift the analytical focus away from manufacturing or design defects and toward failure to warn theories. Although the learned intermediary doctrine has held doctors liable for instances that are arguably the

152. JUSTIA, *supra* note 149 (discussing the alternative design test).

153. See Jorstad, *supra* note 17, at 15.

154. *Manufacturing Defect*, LEGAL INFO. INST. CORNELL L. SCH., https://www.law.cornell.edu/wex/manufacturing_defect [<https://perma.cc/4UDN-KSGH>].

155. *Product Liability Lawsuits in Colorado*, ENJURIS, <https://www.enjuris.com/colorado/product-liability/> [<https://perma.cc/3PJS-U8PK>].

156. MCCARTER & ENGLISH, *supra* note 151.

157. *Id.*

158. ENJURIS, *supra* note 155.

fault of AI developers, recent legislative developments in Colorado support stronger disclosure requirements for developers.

On May 17, 2024, Colorado became the first state to enact broad AI legislation when Governor Jared Polis signed the Consumer Protections for Artificial Intelligence Act (Colorado AI Act), into law.¹⁵⁹ The Act took effect on February 1, 2026, and broadly establishes disclosure requirements for certain uses of generative AI.¹⁶⁰ “The new law is notable not just as a ‘first’ in AI regulation in the United States, but also in its level of complexity: it establishes a range of detailed obligations for AI developers and deployers.”¹⁶¹ Under the Act, a high-risk AI system is defined to include “any [AI] system that, when deployed, makes, or is a substantial factor in making, a consequential decision.”¹⁶² The law further defines “consequential decision” to have a “material legal or similarly significant effect on the provision or denial to any consumer of, or the cost or terms of” a defined category of opportunities and services.¹⁶³ Healthcare is one of these defined services.¹⁶⁴ The Act places a duty of reasonable care on developers of high-risk AI systems to protect consumers from known or reasonably foreseeable risks of “algorithmic discrimination” arising from high-risk AI systems.¹⁶⁵ Algorithmic discrimination is defined as:

any condition in which the use of an artificial intelligence system results in an unlawful differential treatment or impact that disfavors an individual or group of individuals based on their actual or perceived age, color, disability, ethnicity, genetic information, limited proficiency in the English language, national origin, race, religion, reproductive health, sex, veteran status, or other classification protected under the laws of [Colorado] or federal law.¹⁶⁶

159. Duane C. Pozza et al., *Colorado Enacts Landmark AI Legislation*, WILEY (May 20, 2024), <https://www.wiley.law/alert-Colorado-Enacts-Landmark-AI-Legislation> [https://perma.cc/8TP7-DXKZ].

160. *Id.*; Michael J. Laszlo, *Colorado’s AI law delayed until June 2026: What the latest setback means for businesses*, CLARK HILL (Aug. 28, 2025), <https://www.clarkhill.com/news-events/news/colorados-ai-law-delayed-until-june-2026-what-the-latest-setback-means-for-businesses/> [https://perma.cc/7RLB-GEDF].

161. Pozza et al., *supra* note 159.

162. Consumer Protections for Artificial Intelligence, COLO. REV. STAT. § 6-1-1701 (2024) [hereinafter Colorado AI Act].

163. *Id.* § 6-1-1701(3).

164. *Id.*

165. Pozza et al., *supra* note 159.

166. Colorado AI Act, § 6-1-1701(1)(a).

Most important to our discussion, the law creates a “rebuttable presumption of reasonableness” for developers and deployers who meet specific requirements.¹⁶⁷

A presumption of law is a “rule of law which declares that one fact is presumed to exist if another fact or set of facts is proved.”¹⁶⁸ Presumptions function as formalized heuristics, or intellectual shortcuts—if a factfinder finds A and B, it must find C unless D, where C is the presumed fact and D is the rebuttal.¹⁶⁹ In practice, a presumption shifts the burden of proof from the party satisfying the presumption to the opposing party and can be incorporated into a rule of procedure to formalize which party bears that burden.¹⁷⁰ A *rebuttable* presumption specifically allows the opposing party to present contrary evidence to shift the burden back to the original party.¹⁷¹

To ensure developers and deployers of high-risk AI deserve this heightened standard of proof, the Colorado AI Act requires them to implement safety precautions and provide disclosures to deployers and consumers.¹⁷² AI developers must implement a comprehensive risk management policy aligned with guidelines such as the National Institute of Standards and Technology (NIST) AI Risk Management Framework, conduct impact assessments for high-risk AI systems, and ensure consumer rights and transparency in decision-making.¹⁷³ For consequential decisions, developers and deployers must notify consumers when a high-risk AI system is involved, explain the nature of the system and decision, and provide opt-out rights under the Colorado Privacy Act.¹⁷⁴ In adverse cases, deployers must disclose the reasons for their decisions, offer opportunities to correct data, and where feasible, provide appeals with human review.¹⁷⁵ Additionally, deployers must publish a website statement detailing their use of high-risk AI systems, efforts to prevent algorithmic discrimination, and data practices. And they are required to notify the Attorney General within 90 days if algorithmic discrimination is discovered.¹⁷⁶

167. *Id.* § 6-1-1702(1).

168. David Kaiser, *Presumptions of Law and of Fact*, 38 MARQ. L. REV. 253, 253 (1955).

169. Aaron Sontz, *A Presumption Like No Other*, PITTSBURGH CRIM. LEGAL DEF., <https://www.pittsburghcriminallegaldefense.com/blog/a-presumption-like-no-other> [https://perma.cc/46FJ-T8ND].

170. Kaiser, *supra* note 168, at 254–55; see CJI-Civ. 3:5 (2026).

171. COLO. R. EVID. 301; Kaiser, *supra* note 168, at 257.

172. Colorado AI Act, § 6-1-1704 (2024).

173. Pozza et al., *supra* note 159.

174. *Id.*; Colorado Privacy Act, COLO. REV. STAT. § 6-1-1301 (2021).

175. *Id.*

176. *Id.*

V. THE STANDARD THAT DOCTORS SHOULD RECEIVE

Traditional product liability theories can be applied to automated AI systems, particularly given how these systems operate and the Colorado AI Act's allocation of responsibility to developers and deployers. The source code that runs automated AI systems “does not differ from one computer to another,” reinforcing the notion that their functionality is analogous to tangible personal property.¹⁷⁷ Accordingly, automated AI systems can properly be classified as products or tools for purposes of product liability analysis.¹⁷⁸ When doctors employ automated technologies such as Rule-Based Expert Systems, Robotic Process Automation, or Physical Robots, they should be considered similar to deployers of high-risk AI systems. In that capacity, physicians should be held to standards comparable to manufacturers in warning-based product liability claims. If physicians comply with disclosure requirements comparable to those in the Colorado AI Act—such as notifying patients when a high-risk AI system is used and explaining the system's role in decision-making—they should benefit from a rebuttable presumption that their disclosures were reasonable.

Moreover, efforts by AI developers to disclaim liability for downstream harms should not automatically insulate them from responsibility. The Supreme Court's reasoning in *Air & Liquid Systems Corp. v. DeVries* illustrates how existing warning defect principles can accommodate post-sale duties in appropriate circumstances.¹⁷⁹ In *DeVries*, a manufacturer produced a “bare metal” turbine that was safe when it left the factory.¹⁸⁰ After the sale, another company added asbestos-containing gaskets.¹⁸¹ Workers exposed to the asbestos later sued the original turbine manufacturer, alleging a failure to warn.¹⁸² The central issue was whether a product manufacturer could be held liable for harms caused by hazardous components added by a third party after the product had entered the marketplace.¹⁸³ A majority of the Court

177. Catherine Sharkey, *Products Liability for Artificial Intelligence*, LAWFARE (Sept. 25, 2024, 8:01 AM), <https://www.lawfaremedia.org/article/products-liability-for-artificial-intelligence> [https://perma.cc/84XC-27ND].

178. See *Garcia v. Character Tech., Inc.*, 785 F. Supp. 3d 1157, 1189 (M.D. Fla. 2025) (holding that an AI chatbot app was a product for the purposes of product liability claims revolving around app defects); see also *In re Soc. Media Adolescent Addiction/Pers. Injury Prods. Liab. Litig.*, 702 F. Supp. 3d 809 (N.D. Cal. 2023) (holding that the alleged defects, including ephemeral content and algorithm design, were sufficiently analogous to tangible products to be deemed products).

179. *Air & Liquid Sys. Corp. v. DeVries*, 586 U.S. 446 (2019).

180. *Id.* at 458.

181. *Id.* at 449.

182. *Id.* at 446.

183. *Id.*

said yes.¹⁸⁴ Manufacturers' responsibilities do not necessarily end at the point of sale, and a seller may have a post-sale duty to warn when it knows or reasonably should know that its product poses a substantial risk of harm.¹⁸⁵ This decision underscores the flexibility of modern products liability law. Although this decision was in the maritime tort context, the principles could, in theory, apply to the proper tort rule.

Consistent with *DeVries*, AI manufacturers should be required to warn of newly discovered dangers and be held liable for failing to do so. Given the complexity of AI systems and the layered nature of required disclosures, the learned intermediary doctrine should be employed less frequently. This framework more effectively allocates responsibility between developers and physicians while accounting for evolving technological risks.

A different standard is needed for autonomous AI. Autonomous AI, like ML/AI, presents unique challenges that do not fit neatly within the automated AI framework. Autonomous AI makes decisions independently and learns from its environment. As a result, ML/AI-generated harms arise from its independent judgment and human influence rather than intrinsic design. When a doctor's interaction with an ML/AI system causes an injury, courts should adopt a two-step inquiry to allocate liability that better addresses the problems of control, disagreement between equals, and traceability of harm. The inquiry would be applied after a patient is injured and decides to sue their treating physician for medical malpractice.

The inquiry would involve two steps:

- (1) Courts must first determine if the doctor's independent judgment caused the harm. If the harm is a result of the doctor's independent judgment, then the doctor should be held to a traditional reasonableness standard.
- (2) If the harm is a result of the AI's independent judgment, courts should evaluate various factors to identify the human actor who had the most significant influence on the AI's decision—whether that be the AI's developer, the hospital, or the doctor.

This approach aims to reasonably attribute liability while accounting for ML/AI's inherent autonomy.

Step 1:

To decide the first question, the court must determine if the patient's harm stemmed directly from the doctor's judgment. This

184. *Id.* at 457.

185. *Id.* at 457; RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 10.

situation could occur if the doctor unreasonably disregards the AI's care recommendation, leading to patient injury, or if the doctor carelessly misinterprets the AI's guidance. In such cases, it would be logical to evaluate the physician under the traditional medical malpractice standard of reasonableness based on the accepted standard of care.

When conducting this analysis, courts must consider the likelihood that blame will be placed on physicians when working with AI. A study published in the *Journal of Nuclear Medicine* explored potential jurors' assessments of physician liability when AI is involved in medical decision-making.¹⁸⁶ The study utilized an online experiment with a nationally representative sample of 2,000 U.S. adults.¹⁸⁷ Participants were presented with one of four scenarios where an AI system offered a treatment recommendation to a physician.¹⁸⁸ These scenarios varied in whether the AI recommended standard or nonstandard care, and whether the physician accepted or rejected the recommendation.¹⁸⁹ In all cases, the physician's decision resulted in patient harm.¹⁹⁰ Participants were then asked to assess the physician's liability.¹⁹¹

The study found that when AI recommended standard care, physicians could mitigate their liability risk by following the AI's recommendation.¹⁹² However, if the AI suggested nonstandard care, a doctor who rejected that advice and provided standard care was not afforded the same liability protection.¹⁹³ These findings align with the notion that medical negligence standards are grounded in judgments about what constitutes common or customary care. Furthermore, the results are consistent with prior research showing that lay perceptions of reasonableness are influenced by what is perceived as typical or standard practice.¹⁹⁴

As AI becomes more widespread in medicine, the study predicts that doctors' incentive to follow ML/AI recommendations for standard care will grow stronger. This effect is expected to apply both to negligence standards emphasizing custom and those expressed in broader terms of reasonableness. Ultimately, the findings support applying a traditional reasonableness standard to physicians when a patient's injury is not directly attributable to

186. Kevin Tobia et al., *When Does Physician Use of AI Increase Liability?*, 62 J. NUCL. MED. 17, 17 (2021).

187. *Id.*

188. *Id.* at 18.

189. *Id.*

190. *Id.*

191. *Id.*

192. *Id.* at 19.

193. *Id.*

194. *Id.* at 20.

autonomous AI. Jurors are equipped to evaluate the reasonableness of the physician's actions in these scenarios. However, it would be wise for judges to give instructions acknowledging the inherent disadvantage to doctors when making judgment calls based on AI's recommendations.

Step 2:

If the harm resulted from the AI's independent judgment, and not the doctor's, then the court should move on to the second step of the inquiry. This analysis deviates most from the existing medical malpractice framework by aiming to determine which entity is responsible for harm caused by AI. If the court decides that the harm resulted from the AI's independent judgment and the doctor had the most significant influence over how the AI's output was used, the doctor should be afforded a rebuttable presumption of reasonableness, like the standard applied when using automated AI. Physicians, as intermediaries between patients and high-risk AI systems, play a role analogous to that of deployers, bridging the gap between the technology and its practical application.

Failing to adopt a rebuttable presumption of reasonableness risks the emergence of a legal framework akin to the "captain of the ship" doctrine for AI, where AI systems might be treated as "borrowed servants." Under this framework, a doctor could be held liable for patient harm even if their acceptance of the AI's recommendation was objectively reasonable. Given the complexity and opaque "black box" nature of autonomous AI systems, such an approach would impose an unfair burden on physicians, holding them accountable for decisions shaped by technologies they cannot fully comprehend.

In a departure from current law, plaintiffs should also be eligible to recover from hospitals. Courts should be able to decide that the hospital where the injury occurred is responsible for harm caused by AI. The push for hospitals to make their services more efficient is stronger than ever since the COVID-19 pandemic.¹⁹⁵ The rising demand for surgeries, telehealth, and expedited care has led groups such as the American Hospital Association to publish guidelines and advice for "smart hospitals" integrating AI on a large scale.¹⁹⁶ Hospital acquisitions of physician practices have increased

195. Jasiya Fairiz Raisa et al., *Transition Toward Healthcare 5.0: Impact of COVID-19 in the Healthcare Industry*, 11 INFO. & COMM'NS TECH. EXPRESS 371 (2025).

196. See also *The Smart Hospital Journey*, AM. HOSP. ASS'N (2023), <https://www.aha.org/sponsored-executive-dialogues/2023-09-08-/smart-hospital-journey> [https://perma.cc/F8GQ-5JC4].

in all regions since the start of 2022.¹⁹⁷ Additionally, continuing a decade-long trend away from private practice, nearly four out of five physicians (77.6 percent of all physicians) are now employees of hospitals, health systems, and other corporate entities.¹⁹⁸ More doctors are under the control of hospitals than ever before.¹⁹⁹

The purpose of the Corporate Practice of Medicine Doctrine is to prevent hospitals from interfering with their employees' independent professional judgment.²⁰⁰ However, imagine that a hospital implements a policy that virtually dictates how a doctor should work with autonomous AI or that the hospital insufficiently vets the technology before clinical implementation. In line with the legislature's intent to preclude hospitals from dictating how doctors treat their patients, the doctrine of respondeat superior should be incorporated into the medical malpractice analysis.²⁰¹ Hospitals already have a well-established duty to provide safe equipment and facilities and to train their employees to use this equipment adequately.²⁰² Thus, evidence of poor implementation, training, or vetting of an autonomous AI system should fit squarely in a respondeat superior analysis. Given hospitals' significant influence on both doctors and patients in the implementation of AI, it would be unfair to exclude them from the liability analysis.

Finally, the responsibility for a flawed decision by autonomous AI could lie with its developer. Errors in the AI's algorithms could stem from programming mistakes, such as developer bias, miscalculations, or oversight.²⁰³ In such instances, courts should hold AI developers accountable under a negligence theory. While a doctor may have directly interacted with the technology, liability

197. Jesse L. Popover et al., *Physician Employment in America: Private Practices Dominate Despite Increased Hospital Employment*, 29 J. SOC'Y LAPAROENDOSCOPIC SURGEONS 1 (2025).

198. Dave Muoio, *Nearly 80% of docs employed by hospitals, corporate entities in continued shift away from independent practice*, FIERCE HEALTHCARE (Apr. 12, 2024, 7:55 AM), <https://www.fiercehealthcare.com/providers/more-and-more-physicians-are-working-under-hospitals-corporate-entities-report-finds> [https://perma.cc/7KET-GEHC].

199. Georgia Garvey, *Smaller share of doctors in private practice than ever before*, AM. MED. ASS'N (June 24, 2025), <https://www.ama-assn.org/practice-management/private-practices/smaller-share-doctors-private-practice-ever> [https://perma.cc/69GE-FDZF].

200. Hall v. Frankel, 190 P.3d 852, 861 (Colo. App. 2008).

201. Maliha et al., *supra* note 10, at 632 ("Some legal experts have suggested that a similar liability may extend to health systems that insufficiently vet an AI /ML system prior to clinical implementation.").

202. O.S.H.A., *Worker Safety in Hospitals: Education and Training*, <https://www.osha.gov/hospitals/education-training> [https://perma.cc/Q7DM-XNBD].

203. See Juan D. Ramirez, *When AI Makes a Mistake, Who's Responsible?*, BUILT IN (Sept. 5, 2023), <https://builtin.com/artificial-intelligence/responsibility-for-AI-mistakes> [https://perma.cc/FET4-GSUK].

should rest with the AI developer when the error originates from its design or programming.

CONCLUSION

Moving forward, courts and policymakers must design a liability system that balances accountability, promotes safe AI integration, and avoids undue burdens on physicians. A traditional products liability or medical malpractice framework is inadequate for analyzing injury claims stemming from AI use, and guesswork will not suffice. Although the legal system moves more slowly than the worlds of technology and healthcare, it cannot remain static in the face of such innovation. The evolving nature of AI and the uncertainty surrounding it offer a unique opportunity for Colorado to craft a liability framework that supports medical advancement, provides patients with effective recourse, and protects physicians. To maximize the benefits of such innovation, the legal system must strike a balance that fosters progress, ensures safety, and protects the well-being of physicians upon whom patients depend.