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Artificial Intelligence and Liability in Health Care

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ARTIFICIAL INTELLIGENCE AND LIABILITY IN HEALTH CARE

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ABSTRACT

Artificial intelligence (AI) is revolutionizing medical care. Patients with problems ranging from Alzheimer's disease to heart attacks to sepsis to diabetic eye problems are potentially benefiting from the inclusion of AI in their medical care. AI is likely to play an ever-expanding role in health care liability in the future. AI-enabled electronic health records are already playing an increasing role in medical malpractice cases. AI-enabled surgical robot lawsuits are also on the rise. Understanding the liability implications of AI in the health care system will help facilitate its incorporation and maximize the potential patient benefits. This paper discusses the unique legal implications of medical AI in existing products liability, medical malpractice, and other law.

CONTENTS

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INTRODUCTION

Robots armed with artificial intelligence (AI) will replace doctors by 2035, according to at least one "legendary Silicon Valley investor," and in some cases, AI is already better than human doctors.[1] Today, for example, AI can (1) "look at brain scans of people who are exhibiting memory loss and tell who will go on to develop full-blown Alzheimer's disease and who won't,"[2] (2) allow hospitals "to predict the likelihood of a cardiac arrest in 70 percent of occasions, five minutes before the event occurs,"[3] and (3) save lives and speed hospital discharge by improving treatment for "a deadly blood infection called sepsis."[4]

1. Bob Kocher & Zeke Emanuel, *Will Robots Replace Drs.?*, THE BROOKINGS INST. (Mar. 5, 2019), https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/03/05/will-robots-replace-doctors/ [https://perma.cc/5VT2-R2QW] (discussing, for example, a study showing that "an artificial intelligence (AI) system was equal or better than radiologists at reading mammograms for high risk cancer lesions needing surgery[,]" that "computers are similar to ophthalmologists at examining retinal images of diabetics[,]" and that "computer-controlled robots performed intestinal surgery successfully on a pig[]" with "much better" sutures than human surgeons).

2. Daisy Yuhas, *Doctors have trouble diagnosing Alzheimer's. AI doesn't*, NBC NEWS (Oct. 30, 2017), https://www.nbcnews.com/mach/science/doctors-have-trouble-diagnosing-alzheimer-s-ai-doesn-t-ncna815561 [https://perma.cc/6DJU-8S4B].

3. David Shimabukuro, et al., *Effect of machine learning-based severe sepsis prediction algorithm on patient survival and hospital length of stay: A randomised clinical trial,* 4 BMJ OPEN RESP. RES. 1 (2017), https://bmjopenrespres.bmj.com/content/4/1/e000234 [https://perma.cc/R54D-8QV4]. Sony Salzman, *How hospitals are using AI to save their sickest patients and curb alarm fatigue*, NBC NEWS (July 27, 2019, 6:24 AM), https://www.nbcnews.com/mach/science/how-hospitals-are-using-ai-save-their-sickest-patients-curb-ncna1032861 [https://perma.cc/V9K5-C33K].

4. *Id.* (noting that in a 2016 study at the University of San Francisco, the "death rate fell more than 12 percent" after the AI system was implemented "meaning patients whose treatment involved the [AI] system were 58 percent less likely to die in the ICU." Further, the system sped patients' recoveries with AI monitored patients being "discharged from the hospital an average of three days earlier than those who were not."); Shimabukuro, *supra* note 3, at 1.

AI is being incorporated into health care worldwide.[5] By 2030, researchers predict that AI may affect up to 14% of global domestic product with half of this effect coming from improvements in productivity.[6] AI will transform healthcare by "deriving new and important insights from the vast amount of data generated during the delivery of health care every day."[7] AI can quickly and cost-effectively analyze previously unscalable data sets (like electronic health record data, medical images, laboratory results, prescriptions, and demographics) "to make predictions and recommend interventions" in patient care.[8] The United States "is investing heavily in developing AI" as evidenced by the recent executive order from the White House establishing the "American AI Initiative" to promote education and apprenticeships in U.S. schools to support "the industries of the future like . . . algorithms for disease diagnosis."[9]

However, "AI is only as good as the humans programming it and the system in which it operates."[10] Generally speaking, AI is defined as computer technology designed to perform tasks like, or better than, humans.[11] AI mimics human intelligence using computer algorithms

5. Thomas Maddox et al., *Questions for A.I. in Health Care*, 321 JAMA 31, 31 (2018) (stating, "Artificial intelligence (AI) is gaining high visibility in the realm of health care innovation.").

6. Robert Challen et al., *Artificial Intelligence, Bias and Clinical Safety*, 28 BMJ QUAL. SAF. 231, 231 (2019).

7. U.S. FOOD AND DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) 2 (2019), https://www.fda.gov/media/122535/download [https://perma.cc/DE9P-C7XX].

8. Kocher & Emanuel, *supra* note 1.

9. Greg Kuhnen & Andrew Rebhan, *Doctors beware: A robot doctor just matched humans' diagnostic performance,* ADVISORY BOARD, https://www.advisory.com/daily-briefing/2019/02/13/ai-diagnosis [https://perma.cc/9Q45-UM8A].

10. Kocher & Emanuel, *supra* note 1.

11. Maddox et al., *supra* note 5 at E1; PRAC. L. INTELL. PROP. & TECH., PRACTICE NOTE: ARTIFICIAL INTELLIGENCE KEY LEGAL ISSUES: OVERVIEW (2021), Westlaw w-018-1743, at 2 [hereinafter *AI Key Legal Issues*] (stating that AI "generally refers to computer technology with the ability to simulate human intelligence" by analyzing and learning from data "to reach conclusions about it, find patterns, and predict future behavior" leading to adaptations that help perform tasks better over time); Sonoo Israni and Abraham Verghese, *Humanizing Artificial Intelligence*, 321 JAMA 29, 29 (2019); Pavel Hamet & Johanne Tremblay, *Artificial Intelligence in Medicine,* 69 METABOLISM 536, 536 (2017) ("Artificial Intelligence (AI) is a general term that implies the use of a computer to model intelligent behavior with minimal human intervention" and "AI is generally accepted as having started with the invention of robots," and "The term [AI] is applicable to a broad range of

that learn from existing data by incorporating statistics and mathematics on a larger scale than generally possible for humans.[12] An algorithm is simply sets of computer software code with instructions for the computer to perform certain tasks like recognizing patterns, reaching a conclusion, or predicting future behavior.[13]

AI often involves humans "relinquishing control and entrusting artificial intelligence to perform dangerous and complicated tasks"—like driving an autonomous car or performing a complex surgical maneuver.[14] Examples of AI already being employed in health care include broadly (1) *virtual uses* relying heavily on informatics like *machine learning* (including artificial neural networks like those used in image recognition technology and electronic health record algorithms to improve diagnostic accuracy and clinical decision support), and (2) *physical uses* like *robotics* employing machine perception/motion manipulations.[15] While there are other AI applications in use in health care, this paper will focus on *machine learning* and on *robotics* as representations of the *virtual and physical branches* of AI generally being used in medicine.

AI is important in emerging medical law because new technologies are one of the biggest drivers of liability risk.[16] The American Medical Association (AMA) passed its first policy recommendations for AI in June 2018.[17] One AMA board member noted that AI combined with monitoring by "irreplaceable human clinician[s] can advance the delivery of [health] care in a way that outperforms what either can do alone," but added that "challenges in the design, evaluation and

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items in medicine such as robotics, medical diagnosis, medical statistics, and human biology—up to and including today's 'omics'.").

12. Maddox et al., *supra* note 5; *AI Key Legal Issues*, *supra* note 11; *see also* STEFAN A. MALLEN & THOMAS H. CASE, DESIGNING AN EFFECTIVE PRODS. LIAB. COMPLIANCE PROGRAM § 1:39 NEED FOR STANDARDS IN INDUS. USING A.I. (2018–19), Westlaw.

13. *AI Key Legal Issues*, *supra* note 11, at 2 (defining algorithms as "sets of code with instructions to perform specific tasks").

14. Madeline Roe, *Who's Driving That Car?: An Analysis of Regulatory and Potential Liability Frameworks for Driverless Cars,* 60 B.C. L. REV. 317, 337 (2019).

15. *AI Key Legal Issues*, *supra* note 11, at 3 ("Machine learning . . . is AI that learns from its past performance . . . .").

16. Gerke et al., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare,* ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295 (June 26, 2020).

17. Press Release, Am. Med. Assn., AMA passes first policy recommendation on augmented intelligence (June 14, 2018) [hereinafter *AMA Policy*], https://www.ama-assn.org/press-center/press-releases/ama-passes-first-policy-recommendations-augmented-intelligence [https://perma.cc/F9CR-HENC].

implementation" must be addressed.[18] The AMA's policy recognizes the potential legal issues—including liability risks—associated with the rapid proliferation of AI use and pledges that the AMA will "[*e*]*xplore the legal implications* of health care AI."[19]

As recognized by the AMA, AI is likely to play a significant role in health care liability cases in the future. Understanding the liability implications of AI in health care is necessary to help facilitate its incorporation into the health care system.[20] This paper provides an overview of the unique legal liability issues related to AI use in health care.

I. AI IN HEALTH CARE

AI is being rapidly incorporated into health care. Healthcare AI projects "attracted more investment than AI projects within any other sector of the global economy."[21] Currently, "one-third of hospitals and imaging centers report using artificial intelligence . . . to aid tasks associated with patient care imaging or business operations."[22] The two main branches of AI applications in medicine are *physical* and *virtual*.[23] The physical branch includes surgical robots, which will be one focus of this article.[24] "The virtual branch includes informatics approaches from deep learning information to control of health management systems, including electronic health records, and active guidance of physicians in their treatment decisions" (i.e., clinical decision support systems).[25]

A. Surgical Robots

Surgical robots assist surgeons during surgical procedures in ways that are "revolutioniz[ing]" medical care "by allowing surgeons to be less invasive, work in smaller areas, and be more precise than when

18. *Id.*

19. *Id.* (emphasis added).

20. Challen et al., *supra* note 6 (stating that AI's "clinical value has not yet been realised, hindered partly by . . . increasing concerns about the . . . medico-legal impact.").

21. Varun H. Buch, Irfan Ahmed & Mahiben Maruthappu, *Artificial Intelligence in Medicine: Current Trends and Future Possibilities*, 68 BRIT. J. GEN. PRAC. 143, 143 (2018).

22. Jessica Kent, *One Third of Orgs Use A.I. in Med. Imaging*, Health IT Analytics (Jan. 28, 2020), https://healthitanalytics.com/news/one-third-of-orgs-use-artificial-intelligence-in-medical-imaging [https://perma.cc/8DED-SQSH].

23. Hamet & Tremblay, *supra* note 11, at 537.

24. *Id.* at 539.

25. *Id.* at 536.

performing the same surgery by hand."[26] "Minimally invasive surgery" has been facilitated by surgical robots because the robots help surgeons navigate around vital structures with less surgical dissection by creating "safe zones" in the surgical field, by automating some functions like shutoff of potentially dangerous surgical equipment as it nears vital structures, and by helping the surgeon "see" where the instrument is in space without requiring actual visual observation of the surgical instrument.[27]

Robots guide the surgeon in three-dimensional space by tracking the movements of the instruments during the procedure using sensors (e.g., optical or electromagnetic)[28] in the operating room.[29] The computer and robot alert the surgeon to the precise location and orientation in space of the surgical instruments, which can provide vital feedback regarding danger to surrounding structures and appropriate placement and orientation of medical implants and devices.[30]

Many surgical robots use "haptics"—e.g., increased resistance to movement at the borders of safe zones—to give the surgeon feedback during surgery.[31] If the surgeon using the robotic device deviates outside the safe zone created by the preoperative surgical planning, the robot provides haptic feedback to the surgeon in the form of tactile, auditory, or visual alerts that warn the surgeon to the possibility of error.[32] Such robots define haptic boundaries for the surgical instruments that constrain cutting tools within a specific working field, thereby preventing injuries outside that field.[33] Safety factors, such as push back, are used when a haptic boundary is approached and shutting down the surgical instrument may be employed when a haptic boundary

26. Roe, *supra* note 14, at 328; *see also Robotic Surgery*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974 [https://perma.cc/G6KG-MNPJ].

27. Martin Roche, *Robotic-Assisted Knee Arthroplasty, in* 5 ORTHOPAEDIC KNOWLEDGE UPDATE: HIP AND KNEE RECONSTRUCTION 163, 163–65 (Michael A. Mont & Michael Tanzer eds., 2017).

28. *See id.* at 165–66.

29. *Id.* at 167.

30. *Id.* at 165.

31. Bradford S. Waddell & Douglas E. Padgett, *Computer Navigation and Robotics in Total Hip Arthoplasty, in* 5 ORTHOPAEDIC KNOWLEDGE UPDATE: HIP AND KNEE RECONSTRUCTION 423, 427 (Michael A. Mont & Michael Tanzer eds., 2017).

32. *Id.* ("Passive, or haptic, systems require surgical guidance: if deviation beyond the boundaries created by the surgical plan occurs, tactile, auditory, or visual feedback alerts the surgeon to the possibility of error. Haptic systems allow the surgeon to 'drive' the robot, thereby allowing surgeons to retain some element of control.").

33. Roche, *supra* note 27, at 165.

is breached.[34] Haptic feedback allows the surgeon to perform the procedure without having to directly expose the surrounding tissues for visualization, leading to smaller incisions and less unnecessary dissection.[35] For example, robot-assisted, minimally invasive orthopedic surgery often "combines three-dimensional preoperative planning with a precisely guided bone resection and implant placement."[36]

Theoretically, robots can also be used to automate procedures such that "[c]utting tools and instruments . . . controlled by the robotic arm, with no need for surgeon control."[37] However, fully-automated robotic invasive surgical procedures (i.e., "active" robotics) are not currently being performed in the U.S.[38] Systems in use are either "semi-active" such that the robot functions to augment the surgeon by controlling surgical maneuvers by guiding and physically constraining the surgeon within three-dimensional space or are "passive" such that the robot positions the instrument but does not manipulate the patient or constrain the surgeon.[39]

According to a recent report, the top five robotic surgery systems are (1) da Vinci by Intuitive Surgical, (2) Ion by Intuitive Surgical, (3) Mako by Stryker, (4) NAVIO by Smith Nephew, and (5) Monarch by Auris Health.[40] The first robotic surgery device to obtain FDA clearance for general laparoscopic surgeries was the da Vinci Surgical System by Intuitive Surgical.[41] Surgical instruments and a camera are controlled by the surgeon who operates using the "Surgeon Console."[42] Using the da Vinci system, surgeons can perform operations using minimally invasive techniques that previously required more extensive surgeries.[43] Da Vinci is used in around 1,700 hospitals internationally, has been used on more than 775,000 patients, and is now used in approximately three fourths of U.S. prostate cancer operations.[44] In addition, the

34. *Id.*

35. *Id.*

36. Waddell & Padgett, *supra* note 31, at 427.

37. *Id.*

38. Roche, *supra* note 27, at 165.

39. *Id.*

40. Jack Carfagno, *Top 5 Robotic Surgery Systems*, DOCWIRE NEWS (May 15, 2019), https://www.docwirenews.com/future-of-medicine/top-5-robotic-surgery-systems/ [https://perma.cc/49ZW-FSUA]

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

system is often used in "minimally invasive cardiac, colorectal, gynecology, head and neck, thoracic, urology, and general surgeries."[45]

Intuitive Surgical also has a robotic surgical system designed to allow surgeons to perform lung biopsies using minimally invasive techniques with a robotic catheter.[46] The device, called Ion, was cleared by the FDA's 510(k) pathway in February 2019.[47] Another lung device, the Monarch System bronchoscopic device by Auris Health, uses a "video game-like controller" during the procedure which the surgeon uses to "navigate a flexible robotic endoscope throughout the branches of the lungs."[48] The Monarch System offers the surgeon continuous bronchoscopic vision, computer assisted guidance, and precise instrument control; it was cleared via the FDA's 510(k) pathway in March 2018.[49]

Robotics are being used extensively in orthopedic surgery as well.[50] Mako Surgical Corporation created the Mako System to allow individualized positioning and minimally invasive approaches to partial knee replacement, as well as total hip and knee replacement surgeries.[51] The Mako System uses preoperative CT scans to "generate a 3D model of the patient's bone structure," which is used to assist surgeons with optimal implant placement for that particular patient.[52] Stryker, a large orthopedic device manufacturer, purchased Mako Surgical Corporation for $1.65 billion, highlighting the money and focus on robotics in orthopedics.[53] Another big orthopedic company, Smith Nephew, has its own robotic system called the NAVIO Surgical System to assist with total knee replacement surgery.[54] The NAVIO system relies upon intraoperative bone mapping to generate a 3D model of the patient's bone structure and was approved by the FDA via the 510(k) pathway in April 2018.[55] The bone model is then used "by the surgeon to virtually position the implant and balance tissues" before cutting the bone.[56] A robotically-assisted hand tool is used by the surgeon to guide

45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. *Id.*
50. *See* Carfagno, *supra* note 40.
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.*

the instruments during the procedure based upon the individualized bone mapping model.[57]

B. Machine Learning

Machine learning (ML) enables computers to "receive data and learn for themselves" from "examples rather than a list of instructions."[58] ML uses statistical methods that incorporate algorithms to mimic human thought, "allowing computers to make predictions from large amounts of patient data, by learning their own associations" within the data.[59] Using big health care data, "machine learning can create algorithms that perform on par with human physicians."[60] ML can "account for often unexpected predictor variables and interactions and can facilitate recognition of predictors not previously described in the literature" and not previously recognized by human researchers.[61]

ML comes in a spectrum that varies by the amount of human oversight with some ML including more human specification of the predictive algorithm's properties while other ML requires less human involvement such that the computer is allowed to learn the algorithm's properties by analyzing data.[62] For instance, at one end of the spectrum, human statisticians and clinical experts decide "which variables to include in the model, the relationship between the dependent and independent variables, and variable transformations and interactions."[63] When there is more human involvement, the algorithm is lower on the machine learning spectrum.[64]

Deep learning is the most advanced part of the "machine learning spectrum."[65] Deep learning "refers to a set of highly intensive computational models"[66] that "allow an algorithm to program itself by learning from a large set of examples that demonstrate the desired

57. *Id.*

58. *Using AI for social good*, GOOGLE AI, https://ai.google/education/social-good-guide/ [https://perma.cc/49A4-7DMD] (last visited Jan. 14, 2021).

59. Challen et al., *supra* note 6, at 231.

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

61. Ravi B. Parikh, et al., *Machine Learning Approaches to Predict 6-Month Mortality Among Patients with Cancer*, 10 JAMA NETWORK OPEN 1, 8 (2019).

62. Beam & Kohane, *supra* note 60, at 1317–18.

63. *Id.* at 1317.

64. *Id.* at 1317–18.

65. *Id.* at 1317.

66. Ricardo Miotto et al., *Deep Learning for Healthcare: Rev., Opportunities & Challenges*, 19 BRIEFINGS IN BIOINFORMATICS 1236, 1241 (2018).

behavior, removing the need [for humans] to specify rules explicitly."[67] When fewer assumptions are imposed by humans on the algorithm, deep learning is approached, and the computer acts more autonomously in decision-making.[68] "Deep learning" has been used by technology companies like Google and Facebook to analyze "big data" to "predict how individuals search the internet, where they travel, what they like to purchase, what is their favorite food, and who are their potential friends." [69]

The "intellectual roots of 'deep learning'" were planted in the 1940s and 1950s with the development of "artificial neural network algorithms" based loosely "on the way in which the brain's web of neurons adaptively becomes rewired in response to external stimuli to perform learning and pattern recognition."[70] Deep learning models involve "stunningly complex networks of artificial neurons" in multiple layers of neural networks performing "highly intensive computational models" designed to produce increasingly accurate models from raw data.[71] Deep learning can revolutionize health care by allowing doctors to identify which patients may develop particular diseases, to identify "which patients need to be seen more frequently," to identify which patients need to be "treated more aggressively," and to determine the most appropriate specific treatments ("i.e., precision medicine").[72]

Two examples where deep learning is being applied today are medical image analysis and clinical decision support.

1. Medical Image Analysis

Medical images contain a large amount of complex data. Deep learning is being applied to medical images and diagnosis in ways that facilitate physicians' decision-making process by providing support in

67. Varun Gulshan et al., *Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs*, 22 JAMA 2402, 2402 (2016).

68. Beam & Kohane, *supra* note 60, at 1317.

69. Tien Yin Wong & Neil M. Bressler., *Artificial Intelligence With Deep Learning Technology Looks Into Diabetic Retinopathy Screening,* 316 JAMA 2366, 2366 (2016).

70. Andrew L. Beam & Isaac S. Kohane, *Translating Artificial Intelligence Into Clinical Care*, 316 JAMA 2368, 2368 (2016) (internal quotation marks omitted); *see also* Lawrence Carin & Michael Pencina, *On Deep Learning for Medical Image Analysis*, 320 JAMA 1192, 1192 (2018) ("Successful neural networks for such tasks [as identifying natural images of everyday life, classifying retinal pathology, selecting cellular elements on pathological slides, and correctly identifying the spatial orientation of chest radiographs] are typically composed of multiple analysis layers; the term *deep learning* is also (synonymously) used to describe this class of neural networks.").

71. Beam & Kohane, *supra* note 60; Miotto, *supra* note 66.

72. Wong, *supra* note 69, at 2366.

analyzing complex data sets like (1) clinical images, (2) radiology images, and (3) pathology slides.

Deep learning is being applied to clinical image analysis. In one example, researchers demonstrated "a deep learning algorithm capable of detecting diabetic retinopathy . . . from retinal photographs at a sensitivity equal to or greater than that of ophthalmologists."[73] The algorithm learned "the diagnosis procedure directly from the raw pixels of the images with no human intervention outside of a team of ophthalmologists who annotated each image with the correct diagnosis."[74] In another example, the photographs of skin lesions were being analyzed by AI to diagnose skin cancers.[75] Using this technology, theoretically, a layperson could take the photograph and allow the computer to review the image and report the diagnosis.

Similarly, deep learning is being used to analyze complex radiology images and is being used for "diagnostic decision support . . . using algorithms that learn to classify from training examples (i.e., supervised learning)."[76] A radiologist "typically views 4000 images in a CT scan of multiple body parts ("pan scan")" in polytrauma patients.[77] Searching for a hidden fracture in a pan scan can be like "searching for needles in haystacks" leading to visual fatigue, which may make radiologists more likely to fail.[78]

In contrast, deep learning learns as it analyzes more images and has a "boundless capacity for learning."[79] Watson—IBM's prototype for AI—"can identify pulmonary embolism on CT and detect abnormal wall motion on echocardiography."[80] With over 30 billion images available to analyze, Watson "may become the equivalent of a general radiologist with super-specialist skills in every domain."[81] For example, AI algorithms "can look at brain scans of people who are exhibiting memory loss and tell who will go on to develop full-blown Alzheimer's disease and who won't," which scientists believe will "accelerate the discovery of therapies" to treat Alzheimer's disease by identifying "participants for drug or lifestyle interventions at the earliest stages of dementia."[82]

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73. Beam & Kohane, *supra* note 60, at 1317.

74. *Id.*

75. Challen et al., *supra* note 6.

76. *Id.*

77. Saurabh Jha and Eric Topol, *Adapting to A.I.: Radiologists and Pathologists as Info. Specialists*, 316 JAMA 2353, 2353 (2016).

78. *Id.*

79. *Id.*

80. *Id.*

81. *Id.*

82. Yuhas, *supra* note 2.

Likewise, deep learning can be used in pathology. Deep learning can be applied to "whole-slide pathology images" potentially improving diagnostic accuracy and efficiency. [83] For example, for breast cancer lymph node slides, "some deep learning algorithms achieved better diagnostic performance than a panel of 11 pathologists."[84] The deep learning algorithm produced results "comparable with an expert pathologist interpreting whole-slide images without time constraints."[85] The usefulness in a clinical setting of this approach is being evaluated. [86] Another study showed that AI "could predict the grade and stage of lung cancer" with "superior accuracy" compared to human pathologists.[87]

2. Clinical Decision Support

AI-enabled clinical decision support (CDS) systems are being used by physicians to interpret large amounts of data in patients' medical records—like laboratory results, imaging studies, radiology reports, EKGs, fitness tracker data, genetic testing, family history, medications, hospital admission history, and countless other data points.[88] Computerized alerts provided by CDS systems inside the patients' electronic medical records (EMR) are already in widespread use and offer health care providers "targeted and timely information that can improve clinical decisions"[89] and "reduce clinical error."[90] EMR-incorporated CDS systems generally "sit quietly in the background of the hospital's computer systems, diligently tracking vital sign monitors and then sending doctors a text message or other notification at the first sign of trouble."[91] EMR-based CDS systems are having significant "impact providing guidance on safe prescription of medicines, guideline

83. Babak Ehteshami Bejnordi, et al., *Diagnostic Assessment of Deep Learning Algorithms for Detection of Lymph Node Metastases in Women with Breast Cancer*, 318 JAMA 2199, 2199 (2017).

84. *Id.*

85. *Id.*

86. Li-Qiang Zhou et al., *Lymph Node Metastasis Prediction from Primary Breast Cancer US Images Using Deep Learning*, 294 RADIOLOGY 19, 19 (2020) ("Using US images from patients with primary breast cancer, deep learning models can effectively predict clinically negative axillary lymph node metastasis.").

87. Jha, *supra* note 77, at 2354.

88. Beam & Kohane, *supra* note 60, at 1318.

89. Milena Gianfrancesco et al., *Potential Biasesin Machine Learning Algorithms Using Electronic Health Record Data*, 11 JAMA INTERNAL MED. 1544, 1545 (2019).

90. Challen et al., *supra* note 6 (noting that CDS systems usually reduce clinical error).

91. Salzman, *supra* note 3; Shimabukuro, *supra* note 3, at 1.

adherence, [and] simple risk screening . . . ."[92] In addition, CDS systems "are being developed to provide other kinds of decision support, such as providing risk predictions (eg, for sepsis) based on a multitude of complex factors, or tailoring specific types of therapy to individuals."[93]

For example, CDS systems can be used to individualize dosing of medication and radiation treatments. Some systems try approaches to "personalized treatment problems such as optimizing a heparin loading regime to maximize time spent within the therapeutic range or targeting blood glucose control in septic patients to minimize mortality."[94] Similarly, for radiation dosing, "[s]ystems . . . can analyze CT scans of a patient with cancer and by combining this data with learning from previous patients, provide a radiation treatment recommendation, tailored to that patient which aims to minimize damage to nearby organs."[95]

CDS systems can also use predictions to save lives by improving physician decision-making. For example, AI is allowing hospitals to "predict the likelihood of a cardiac arrest in 70 percent of occasions, five minutes before the event occurs."[96] In addition, use of an AI-enabled EKG machine resulted in more rapid identification of patients with a difficult-to-identify heart condition.[97] Similarly, AI is saving lives by improving treatment for "a deadly blood infection called sepsis"[98] and to predict "impending sepsis from a set of clinical observations and test results."[99] In fact, in a 2016 study at the University of San Francisco, the "death rate fell more than 12 percent" after the AI system was implemented, "meaning patients whose treatment involved the [AI] system were 58 percent less likely to die in the ICU."[100] Further, the system sped patients' recoveries with AI-monitored patients being

92. Challen et al., *supra* note 6.

93. *Id.*

94. *Id.* at 231–32.

95. *Id.* at 231.

96. Salzman, *supra* note 3; Shimabukuro, *supra* note 3, at 1.

97. Zachi Attia, et al., *An Artificial Intelligence Enabled ECG Algorithm for the Identification of Patients with Atrial Fibrillation During Sinus Rhythm: A Retrospective Analysis of Outcome Prediction*, 394 LANCET 861, 861 (2019) (noting, "An AI-enabled ECG acquired during normal sinus rhythm permits identification at point of care of individuals with atrial fibrillation" using a 10 second test and reporting 83% accuracy).

98. Salzman, *supra* note 3; Shimabukuro, *supra* note 3, at 1.

99. Challen et al., *supra* note 6.

100. Salzman, *supra* note 3; Shimabukuro, *supra* note 3, at 1.

"discharged from the hospital an average of three days earlier than those who were not" AI-monitored.[101]

AI can also simplify life for health care providers in ways that improve patient outcomes. For example, AI is being used in intensive care units (ICUs) to make "life . . . less chaotic for doctors and nurses" by decreasing the number of false positive alarms associated with simple vital sign monitors, which can create "alarm fatigue" for health care workers leading them to ignore the alarms or even turn them off.[102] For example, in traditional ICUs, nurses "respond to an alarm every 90 seconds" with two out of three of those alarms being false positives—meaning they "don't signal real danger."[103] The FDA estimated that "alarm-related problems contributed to more than 500 patient deaths from 2005 to 2008."[104] AI alarm systems are better because AI "is often able to predict problems hours in advance," so that "doctors and nurses get a calm, text message warning rather than having to respond to an urgent alarm signaling that a patient is already in trouble."[105]

II. THEORIES OF LIABILITY FOR AI IN MEDICINE

Currently, there is minimal case law regarding AI liability in medicine.[106] Legal liability frameworks under products liability law, medical malpractice law, and ordinary negligence are likely to be applied to AI liability with some novel twists discussed below.[107]

A. Products Liability

Traditional products liability law has generally provided the framework to hold the "seller, manufacturer, distributor, or any other party in the distribution chain" liable for physical injury or damage caused by machines or tools, regardless of whether the product acts

101. Salzman, *supra* note 3; Shimabukuro, *supra* note 3, at 1.

102. Salzman, *supra* note 3 (describing "alarm fatigue" as doctors and nurses turning off or tuning out ICU alarms, which traditionally occur at a rate of every 90 seconds with two thirds being false alarms).

103. *Id.*

104. *Id.*

105. *Id.*

106. W. Nicholson Price et al., *Potential Liability for Physicians Using Artificial Intelligence*, 322 JAMA 1765, 1765 (2019)(noting, "there is essentially no case law on liability involving medical AI.").

107. Roe, *supra* note 14, at 328–40 (observing that in the realm of surgical robots, "claims against the surgeons, the manufacturers of the robot, and the hospitals where the surgeries are performed" have been filed mostly using theories of medical malpractice, products liability, and ordinary negligence).

autonomously or is assisted by a human.[108] For example, products liability law has been applied to AI-like products such as autopilot in airplanes and automated vehicle controls like cruise control and automatic parking.[109] The Restatements, and consequently many states, say that a "product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings."[110] Each of these categories of product defect present some unique issues when applied to AI.

1. Design Defect

Design defect claims have been common in the few surgical robot claims available for review[111] and are likely to be common in other medical AI claims. According to the Restatements, "a product is defective in design when the *foreseeable risks* of harm posed by the product could have been reduced or avoided by the adoption of a *reasonable alternative design* . . . and the omission of the alternative design renders the product *not reasonably safe*."[112] There are several ways that AI might include the elements of (1) foreseeable risks, (2) reasonable alternative design, and (3) not reasonably safe.

Note that a design defect claim "is a strict liability claim, and therefore, the plaintiff [is] required to prove that the manufacturer proximately caused the malfunction that led to the injuries," which requires "the plaintiff to prove that the machine, rather than the doctor, caused the injury."[113] Causation is a difficult part of design defect claims for AI due to the complex way that "artificial intelligence and human oversight are intertwined," and this issue is further discussed under medical malpractice below.[114]

a. Foreseeable Risks

AI algorithms include some unique foreseeable risks. For a product to be defective, the risks must be foreseeable such that, "[o]nce the plaintiff establishes that the product was put to a reasonably foreseeable use, physical risks of injury are generally known or

108. Karni A. Chagal-Feferkorn, *Am I an Algorithm or a Product? When Products Liability Should Apply to Algorithmic Decision-Makers*, 30 STAN. L. & POL'Y REV. 61, 62–63 (2019).

109. *Id.* at 63.

110. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998).

111. Roe, *supra* note 14, at 328–40 (reporting "[b]oth product liability and design defect claims are also common in surgical robot litigation").

112. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998) (emphasis added).

113. Roe, *supra* note 14, at 332.

114. *Id.*

reasonably knowable by experts in the field."[115] Common knowledge that is attributable to experts in the field is imputable to manufacturers of AI.[116] AI includes foreseeable risks common to many other types of products like malfunction, user error, normal wear and tear, among other things, which are likely to present similar issues and have similar liability profiles to non-AI products and therefore, are not discussed here. Some unique foreseeable risks discussed here associated with AI include bad data, discrimination, corruption, and others.

i. Bad Data

AI's deep learning depends upon quality data, with some experts noting "there is nothing more critical than the data."[117] Large amounts of data are involved in health care interactions. If the AI uses bad data to generate models, it "can be amplified into worse models" than non-AI models.[118] The AMA's AI policy includes priorities of transparency and reproducibility,[119] which are reliant upon having good data. Factors involving data that can cause flaws in deep learning outcomes include (1) data volume, (2) data quality, (3) temporality, (4) domain complexity, and (5) interpretability.

First, data volume is required. In health care "the number of patients is usually limited in a practical clinical scenario."[120] In order to meet its goal of accuracy and improved outcomes, a "huge amount of data" is required; "while there are no hard guidelines about the minimum number of training documents, a general rule of thumb is to have at least about 10 [times] the number of samples as parameters in the network."[121] So in domains where a "huge amount of data can be easily collected," like image or speech recognition, deep learning can be

115. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §2 cmt. m (1998).

116. *See* A.G.S., Annotation, *Duty of manufacturer or seller to warn of latent dangers incident to article as a class, as distinguished from duty with respect to defects in particular article*, 86 A.L.R. 947 (originally published in 1933); RESTATEMENT (THIRD) OF AGENCY § 5.03 (AM. L. INST. 2006); RESTATEMENT (SECOND) OF AGENCY § 272 (AM. L. INST. 1958); RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. m (AM. L. INST. 1998); Curtis, Collins & Holbrook Co. v. United States, 262 U.S. 215, 222 (1923) ("The general rule is that a principal is charged with the knowledge of the agent acquired by the agent in the course of the principal's business.").

117. Abraham Verghese et al., *What This Computer Needs is a Physician: Humanism and Artificial Intelligence,* 319 JAMA 19, 19 (2018).

118. *Id.*

119. *AMA Policy*, *supra* note 17.

120. Miotto, *supra* note 66, at 1242

121. *Id.* at 1241.

very successful.[122] In clinical decision-making from EMRs, "understanding diseases and their variability is much more complicated" than image or speech recognition, and the "amount of medical data that is needed to train an effective and robust deep learning model would be much more comparing with other media."[123]

Second, data quality is required, and health care data are not typically as "clean and well-structured" as data in other domains. Because "health care data are highly heterogeneous, ambiguous, noisy, and incomplete," data quality must be questioned and considered in training a good deep learning model, which leads to special challenges considering "data sparsity, redundancy, and missing values."[124]

Third, temporality of data is important. Deep learning models often "assume static vector-based inputs" that do not adapt to changes over time; this can be problematic in medicine where "diseases are always progressing and changing over time."[125] Fourth, data complexity is important. In health care, "diseases are highly heterogenous and for most diseases there is still no complete knowledge on their causes and how they progress."[126] Fifth, interpretability is important. To convince medical professionals regarding "the actions recommended from the predictive system (e.g., prescription of a specific medication, potential high risk of developing a certain disease)," deep learning models will need to be transparent and not an opaque black box—which is different than many domains.[127]

The maxim of "garbage in, garbage out" is especially important when applying AI models to health care data, and special care must be taken to ensure that the data upon which AI models are based is good.[128]

ii. Discrimination

Theoretically, AI systems "make objective decisions and do not have the same subjective biases that influence human decision making."[129] However, in reality, "AI systems are subject to many of the same biases" as human decision-making because AI is often trained using imperfect data sets.[130] "[W]ithout proper awareness and control [AI] systems can amplify biases and unfairness that already exists

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.* at 1242.

126. *Id.*

127. *Id.*

128. Beam & Kohane, *supra* note 60, at 1318.

129. Tom Lawry et al., *Realizing the Potential for AI in Precision Health*, 13 THE SCITECH LAW. 22, 24 (2017).

130. *Id.*

within datasets—or can 'learn' biases" during the process of machine learning.[131] The AMA AI policy includes avoiding bias and avoiding exacerbation of disparities for vulnerable populations among its priorities for AI systems.[132]

There are numerous ways bias can be introduced by AI. First, AI biases can result from "under-representation" in datasets of some populations that may "hide population differences in disease risk or treatment efficacy."[133] In one example, researchers "found that cardiomyopathy genetic tests were better able to identify pathogenic variants in white patients than patients of other ethnicities."[134]

Second, "nonrepresentative data collection" can result in bias.[135] For example, data sets gathered from apps and wearables "may skew toward socioeconomically advantaged populations with greater access to connected devices and cloud services."[136] Likewise, expensive genetic testing results in datasets that are skewed toward richer consumers.[137] The location of the dataset can also contribute to bias and nonrepresentative data collection. For example, data collected from EMRs comes from health systems that have implemented such EMR systems, which may lead to underrepresentation of "the uninsured and underinsured and those without consistent access to quality health care (such as some patients in rural areas).[138] Further, EMR data can introduce bias when it is collected for patient care and billing instead of for research because important "clinical contextual information" can be missing.[139]

Third, care must be taken to make sure AI is not applied unfairly. For example, if a machine learning system is used to predict 6 to 12 month mortality rates to help physicians with prognostic projections regarding hospice care, it should not be used to "withhold treatment from patients with a higher mortality risk."[140]

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131. *Id.*

132. *AMA Policy*, *supra* note 17.

133. Lawry et al., *supra* note 129.

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*; "Clinical context" means interpreting data in the context of the patient's other symptoms. Doctors must look at patients holistically, i.e., look at the whole patient. AI may just look at data points and make a mistake where it fails to consider the whole clinical picture. *See also* Section III.A.1.b.

140. *Id.* at 25.

Fourth, an AI system can reflect the biases of its developers and users.[141] Therefore, diversity in developers, users, teams, health care professionals, and medical experts is necessary to avoid bias and discrimination.[142] In addition, AI scientists "must continue to develop analytical techniques to detect and address unfairness in AI-driven technologies."[143]

iii. Corruption and Industry-Led Bias

AI raises the possibility of "abhorrent" corruption filtering into clinical decision support tools, as shown by a recent $145 million settlement with the DOJ by an EMR vendor in the "first ever criminal action against an EHR vendor."[144] Pharmaceutical companies and other medical supply vendors may gain access to clinical decision support tools and use those tools to direct doctors to prescribe their products.

For example, in January 2020, an EMR vendor paid the DOJ $145 million to settle criminal and civil investigations related to its admission that it "solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications" by manipulating its EMR software.[145] According to the DOJ, the EMR company, Practice Fusion, "extracted unlawful kickbacks from pharmaceutical companies in exchange for implementing clinical decision support (CDS) alerts in its EHR software designed to increase prescriptions for their drug products."[146] According to the DOJ, the EMR company—"in exchange for 'sponsorship' payments"—allowed pharmaceutical companies to "participate in designing the CDS alert, including selecting the guidelines used to develop the alerts, setting the criteria that would determine when a health care provider received an alert, and in some cases, even drafting the language used in the alert itself"; this was done

141. *Id.* at 24.

142. *Id.* at 25.

143. *Id.*

144. Press Release, Department of Justice, Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations (Jan. 27, 2020), available at https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0 [https://perma.cc/DN2L-NHCM] [hereinafter DOJ].

145. *Id.* (further explaining that Practice Fusion "executed a deferred prosecution agreement and agreed to pay over $26 million in criminal fines and forfeiture," and it also agreed to pay "$118.6 million to the federal government and states to resolve allegations that it accepted kickbacks from the opioid company and other pharmaceutical companies.").

146. *Id.* ("In discussions with pharmaceutical companies, Practice Fusion touted the anticipated financial benefit to the pharmaceutical companies from increased sales of pharmaceutical products that would result from the CDS alerts.").

"in ways aimed at increasing the sales of the companies' products" and "did not always reflect accepted medical standards."[147] For example, the criminal information detailed by the DOJ alleged that "Practice Fusion solicited a payment of nearly $1 million from the opioid company to create a CDS alert that would cause doctors to prescribe more extended release opioids" and "touted that it would result in a favorable return on investment for the opioid company based on doctors prescribing more opioids."[148]

The Assistant Inspector General noted, "'As new technologies continue to develop and evolve, so too do new and innovative fraud schemes.'"[149] Civil claims could follow for patients injured by criminal activity, and companies could be liable for failing to prevent criminal activity during development of their products. Liability could be present for doctors who failed to recognize deviations from clinical practice guidelines and for hospitals that did not adequately investigate potential fraud under liability theories mentioned elsewhere in this paper.

iv. Other Unique Foreseeable Risks

AI's complex and rapidly developing applications create innumerable foreseeable risks beyond the scope of this paper that will become apparent as AI continues to be implemented in the medical field. The AMA Policy foreshadows a few potential risks that will be briefly mentioned here.[150] For example, the AMA Policy states that the AMA will help "integrate the perspective of practicing physicians into the development, design, validation and implementation of health care AI" and sets a priority of "best practices in user-centered design."[151] The AMA states that "a major source of dissatisfaction in physicians' professional lives" is physicians' "frustrations with electronic health records . . . especially usability issues."[152] If AI developers fail to adequately consider the end user, then foreseeable risks are present that are unique to the health care environment.[153] Physicians are commonly known to be extremely busy with limited time to address complex patient issues, so AI that hinders the flow of care, disrupts physicians' workflow, or distracts physician decision-making foreseeably causes patient harm.[154] Therefore, AI developers who fail to consider end-user

147. *Id.*

148. *Id.*

149. *Id.*

150. *See AMA Policy*, *supra* note 17.

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

issues may face liability for design defects where injury may have been prevented by making the device more user-centric.

Other foreseeable risks include inadequate end-user training, loss of patient privacy, inadequate security to protect patient data, and other risks.

b. Reasonable Alternative Designs

Another factor in determining whether a product is defective is whether adopting a *reasonable alternative design* (RAD) could have reduced the risk of harm.[155] The possibilities for AI RAD are many.

First, RAD options may include devices without AI. A human-only interaction may be better than an AI-facilitated interaction in some situations. Often, human "clinicians make assumptions and care choices that are not neatly documented as structured data" and often rely on clinical "intuition" developed from human experiences.[156] "[D]octors make decisions on more than just the data available in a patient's chart,"[157] which leads some to describe medicine as both an "art" and a science.[158] In other words, "clinical judgment is not well represented by data" in medicine.[159] For example, AI may fail to recognize context of data. Context of data is important, and machines may have problems with data taken out of context where the machine fails to recognize artifacts.[160] In one example, AI missed context in evaluating the risk of death from pneumonia at the University of Pittsburg Medical Center (UPMC) when AI determined that the risk of death was lower in pneumonia patients over 100 years of age and in patients with asthma arriving at the emergency department.[161] The AI algorithm "correctly analyzed the underlying data" but failed to understand the context that "their risk was so high that the emergency department staff gave these patients antibiotics before they were even registered into the electronic medical record," which made the time stamps for the "lifesaving antibiotics" inaccurate.[162] If the AI predictions had been taken out of context, then pneumonia patients over 100 years of age and those with

155. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998).

156. Kocher & Emanuel, *supra* note 1.

157. Kuhnen & Rebhan, *supra* note 9.

158. *The "Art" and "Science" of Medicine*, 184 JAMA 142, 142 (1963), https://jamanetwork.com/journals/jama/article-abstract/664090.

159. Kocher & Emanuel, *supra* note 1.

160. Verghese et al., *supra* note 117, at 19 ("For example, a model might classify patients with a history of asthma who present with pneumonia as having a lower risk of mortality than those with pneumonia alone, not registering the context that this is an artifact of clinicians admitting and treating such patients earlier and more aggressively.").

161. Kocher & Emanuel, *supra* note 1.

162. *Id.*

asthma could have been treated less aggressively—leading to likely deaths and additional harm to these high-risk populations.[163]

Sometimes AI can interfere with important human components of medicine—like touch, compassion, and empathy—that many recognize as part of the art of medicine. Illness is more than just a physical or biological experience.[164] The doctor-patient relationship includes elements like touch, compassion, empathy, context, and other human elements that AI alone cannot provide.[165] The "placebo effect" has been found across medical fields, from surgery, to back pain treatments, to medications suggesting that the mind can play an important part in illness not represented by data on the patient's chart.[166] Medicine is not purely a science that can be managed with statistics, mathematics, and computer algorithms, and overreliance on AI may lead to harm in instances when human compassion, human touch, or human interpretation of data context is necessary. For example, when a robot recently delivered the news to a patient and his family that he would die soon from cancer, news outlets, the family, and experts were all aghast.[167] "[A] tall machine on wheels . . . rolled into the [patient's] room [in the hospital]" with "a screen streaming a live video of a doctor wearing a headset [attached]."[168] The doctor delivered the news of the poor CT scan results and recommended morphine to keep the patient comfortable, while the robot stood on the side of the patient's bad ear where he barely seemed to understand.[169] The patient died within 48 hours.[170] The patient's daughter said, "'It should have been a

163. *Id.*

164. DEREK BOLTON & GRANT GILLETT, THE BIOPSYCHOSOCIAL MODEL OF HEALTH AND DISEASE: NEW PHILOSOPHICAL AND SCIENTIFIC DEVELOPMENTS (2019), NCBI Bookshelf.

165. *See* Caitlin Kelly, *The Importance of Medical Touch*, N.Y. TIMES (Oct. 8, 2018), https://www.nytimes.com/2018/10/08/well/live/the-importance-of-medical-touch.html [https://perma.cc/AW9J-BURX];
Michael M. Patterson, *Touch: Vital to Patient-Physician Relationships*, 112 J. OF THE AM. OSTEOPATHIC ASS'N 485, 485 (2012).

166. *See The Power of the Placebo Effect*, HARVARD HEALTH PUBL'G (Aug. 9, 2019), https://www.health.harvard.edu/mental-health/the-power-of-the-placebo-effect [https://perma.cc/SF38-XPS7].

167. 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 [https://perma.cc/6WQ8-87VN] (The 78 year old man was told by a "videoconference" robot with a live doctor on the video screen that he would die soon from cancer).

168. *Id.*

169. *Id.*

170. *Id.*

human' . . . 'It should've been a doctor who came up to his bedside.'"[171] In evaluating the incident, the AMA president said, "'We should all remember the power of touch—simple human contact—can communicate caring better than words'."[172] One medical ethicist noted, "technology may not be sensitive enough to pick up nuanced social cues, like body language and tone of voice, in an emotionally charged moment."[173]

However, for many AI systems, the argument that humans alone are better as a RAD will likely fail because even when AI systems have notable issues, they still often outperform humans alone. For example, in total hip replacement surgery, there is a notable learning curve for surgeons placing the acetabular cup, with surgeons obtaining better positioning after their first 50 cases.[174] However, even the first 50 placements are better than for non-AI navigated hips.[175]

Second, for RAD options, choosing a different data set, a modified software design, different clinical practice guidelines, or some other technological changes based on expert testimony are likely to be more fruitful for plaintiffs in most instances than suggesting eliminating the AI altogether. For example, RADs for surgical robots might include using different sensory techniques for sensors in the rooms (e.g., optical vs. electromagnetic). Simplified navigational procedures may also be a RAD proposal where robotic computer navigation is associated with significant learning curves for surgeons.[176]

Third, user-interface modifications to make the human/AI interaction better will be an obvious point for RAD consideration. The AMA policy emphasizes the importance of "best practices in user-centered design" and the need for companies to "integrate the perspective of practicing physicians into the development, design, validation and implementation of health care AI."[177] When companies fail to do so, they open themselves up to RAD arguments. Based upon the AMA's mention of physicians' "frustrations with electronic health records (EHRs), especially usability issues," as a "major source of dissatisfaction" among doctors, this area of design may be a particularly

171. *Id.*

172. *Id.*

173. *Id.*

174. Waddell & Padgett, *supra* note 31, at 425.

175. *Id.*

176. *See* Frank Griffin, *The Trouble with the Curve: Manufacturer and Surgeon Liability for "Learning Curves" Associated with Unreliably-Screened Implantable Medical Devices*, 69 ARK. L. REV. 755, 757 (2016) (describing surgeon learning curves associated with new medical devices).

177. *AMA Policy*, *supra* note 17.

ripe point to target faulty AI in design defect claims.[178] One example of a case where a RAD could include some user interface change involved a May 2009 article entitled "Nearly Killed by E-Records Data Model."[179] The article described the experience of an ICU patient who was "nearly killed" because of an EMR system "that did not allow doctors and nurses to access critical medical information or obtain medication from the pharmacy in a timely fashion."[180] A RAD here might simply be a more user-friendly interface. The possibilities for RAD are endless for AI and will continue to evolve over time.

c. Not Reasonably Safe

In Restatement jurisdictions, the jury must find that the device at issue in the trial is "not reasonably safe."[181] Other states have adopted modifications of the Restatement language, using phrases like "unreasonably dangerous."[182] If the state uses the "Consumer Expectations Test," generally the device sold "must be dangerous to an extent beyond that which would be expected by the ordinary consumer."[183] Reasonableness is also often analyzed using risk-utility balancing as described by Judge Learned Hand in *United States v. Carroll Towing Co.*[184] Other reasonableness factors, like those identified by Professor John Wade, are used by some jurisdictions in risk-utility evaluations.[185]

178. *Id.*

179. Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Records Systems*, 24 BERKELEY TECH. L. J. 1523, 1526-27 (2009). Tony Collins, *"Nearly Killed" by e-records data model*, COMPUTERWEEKLY.COM, (May 21, 2009 9:13), http://www.computerweekly.com/Articles/2009/05/21/236128/nearly-killed-by-e-records-data-model.htm [https://perma.cc/N962-XD2R].

180. Hoffman & Podgurski, *supra* note 179, at 1527.

181. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998).

182. RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965) (Comment i defines "unreasonably dangerous" as "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it"). *See, e.g.*, Horst v. Deere & Co., 752 N.W.2d 406, 410 (Wis. Ct. App. 2008), *aff'd*, 769 N.W.2d 536 (Wis. 2009) (applying the "unreasonably dangerous" standard to products liability law).

183. David Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence*, 89 WASH. L. REV. 117, 134–35 (2014) (noting that if the state uses the consumer expectations test it may define an "unreasonably dangerous" product as one with a defect that makes the product "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it").

184. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998); United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

185. John W. Wade, *On The nature of Strict Tort Liability for Products,* 44 MISS. L.J. 825, 837–38 (1973).

AI will likely shift the definition of "reasonableness." For instance, in the case of an AI system, the focus will be on whether the AI system performed as well as it should, not whether it performed as safely as a reasonable human-alone system.[186] Ironically, a 1966 court recognized the issue well before AI was in common use in discussing liability standards:

> A human being, no matter how efficient, is *not a mechanical robot and does not possess the ability of a radar machine to discover danger before it becomes manifest.* Some *allowances*, however slight, *must be made for human frailties* and for reaction, and if any allowance whatever is made for the fact that a human being must require a fraction of a second for reaction and cannot respond with the mechanical speed and accuracy such as is found in modern mechanical devices . . . [187]

The Louisiana court foreshadows the argument that a "mechanical robot" may be held to a higher standard.[188] Today, the court will not ask whether the AI performed as well as a reasonable human; instead, the question will be whether the AI performed as well as it was supposed to perform based on the performance of other AI systems and the performance specifications of the manufacturer.[189]

AI systems may also be unreasonably dangerous when the human-user interface is too difficult or when the systems do not make allowances for the humanness of their users. EMRs may be particularly susceptible to this argument. For example, one EMR vendor faced a class-action lawsuit alleging software defects that threatened patient safety and that also entangled hospitals that adopted the EMR; the class-action complaint was *led by a patient's estate who died of cancer allegedly because "'he was unable to determine reliably when his first symptoms of cancer appeared [as] his medical records failed to accurately display his medical history on progress notes.'"*[190] *The*

186. Vladeck, *supra* note 183, at 132 (noting that the court in a driverless car case will "likely ask whether the car involved in the accident performed up to the standards achievable by the majority of other driver-less cars, as well as the performance specification set by the car's manufacturer" and not whether it performed up to the standards of human drivers).

187. *Id.* at 131 (emphasis added).

188. *Id.*

189. *Id.* at 132.

190. *Lawsuit Claims EHR Dangerous to Patients, Could Affect Hospitals*, RELIAS MEDIA (Apr. 1, 2018), https://www.reliasmedia.com/articles/142432-lawsuit-claims-ehr-dangerous-to-patients-could-affect-hospitals [https://perma.cc/994J-5DP6]. Complaint at 16, Tot v. eClincal Works, LLC, No. 17-8938 (S.D.N.Y. 2017), https://s3.amazonaws.com/assets.fiercemarkets.net/public/004-

complaint also alleged that the software failed to "reliably record diagnostic imaging orders," provided "insufficient audit logs," had "issues with data portability," and was not compliant with criteria required for certification.[191]

Unfriendly EMR user-interfaces can create a good argument for unreasonable dangerousness. One observer noted, "most EMRs serve their frontline users quite poorly."[192] "The redundancy of the notes, the burden of alerts, and the overflowing inbox has led to the '4000 keystrokes a day' problem' and has contributed to, and perhaps even accelerated, physician reports of symptoms of burnout."[193] When doctors spend all of their time on computers, patient care suffers.[194]

EMRs may provide significant opportunities for "unreasonably dangerous" arguments. For example, in one medical malpractice case, the physician allegedly did not have adequate space to document the patient's symptoms, which allegedly led to the mismanagement of the patient's condition resulting in a heart problem.[195] In another case, a patient's diagnosis of and treatment for cancer was allegedly delayed for years because the EHR system used by the provider referred the physician to outdated imaging.[196] Each of these issues might provide a foundation for a plaintiff to argue that the EMR was "unreasonably dangerous" in a design defect claim.

EHR-related risks are due to system technology and design issues or due to user-related issues.[197] According to one study, the top system technology and design issues include (1) electronic systems/technology

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Healthcare/external_Q42017/eclinicalworks_classaction.pdf [https://perma.cc/92TV-N3UN].

191. RELIAS MEDIA, *supra* note 189.

192. Verghese et al., *supra* note 117, at 19.

193. *Id.*

194. *See id* ("The unanticipated consequences include the loss of important social rituals (between physicians and between physicians and nurses and other health care workers) around the chart rack and in the radiology suite, where all specialties converged to discuss patients.").

195. Penny Greenberg & Gretchen Ruoff, *Malpractice Risks Associated with Electronic Health Records*, CRICO (June 13, 2017), https://www.rmf.harvard.edu/Clinician-Resources/Article/2017/Malpractice-Risks-Associated-with-Electronic-Health-Records [https://perma.cc/Y5YZ-E75J].

196. Vera Lúcia Raposo, *Electronic Health Records: Is it a Risk Worth Taking in Healthcare Delivery?*, 11 GMS HEALTH TECH. ASSESSMENT 1, 2 (2015); *see also* Hoffman & Podgurski, *supra* note 179, at 1525–26 (listing benefits of EHRs).

197. Darrell Ranum, *Electronic Health Records Continue to Lead to Medical Malpractice Suits*, DOCTORS COMPANY (Aug. 2019), https://www.thedoctors.com/articles/electronic-health-records-continue-to-lead-to-medical-malpractice-suits/ [https://perma.cc/TE6W-MZMV].

failure in 12% of EMR-related claims from 2010 to 2018, (2) lack of, or failure of, EMR alerts or alarms in 7% of claims, (3) fragmented record in 6% of claims, (4) failure/lack of electronic routing of data in 5% of claims, (5) insufficient scope/area for documentation in EMR in 4% of claims, (6) lack of integration/incompatible systems in 2% of claims, and (7) other issues in 14% of claims.[198] Only one claim in this study involved failure to ensure information security.[199]

Expert testimony will be required for most "unreasonably dangerous" AI arguments. [200] The AI industry will have an overwhelming advantage of access to AI experts, much like that described for orthopedic devices.[201] Under Federal Rule of Evidence 702, the trial court serves as a "gatekeeper" to prevent unreliable and irrelevant scientific testimony from entering the courtroom.[202] Four nonexclusive factors are to be used by trial courts to determine the reliability of expert testimony, including: "'(1) whether the 'scientific knowledge . . . can be (and has been) tested'; (2) whether 'the theory or technique has been subjected to peer review and publication'; (3) 'the known or potential rate of error'; and (4) 'general acceptance.'"[203] Importantly, AI manufacturers will have decisive advantages in all four of those factors. First, the AI companies will likely be the ones doing the scientific testing, which may bias research outcomes. Second, peer review and publication will likely be performed by AI scientists working for companies, again introducing bias. Third, any known or potential error rate will likely be discovered by AI companies, which may limit disclosure. Fourth, general acceptance will be up to AI scientists working for AI companies, which may limit the field of witnesses willing to testify on behalf of injured plaintiffs.

2. Manufacturing Defect

According to the Restatements, "a product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation

198. *Id.*

199. *Id.*

200. Roe, *supra* note 14, at 330, 339.

201. *See* Frank Griffin, *Prejudicial Interpretation of Expert Reliability on the 'Cutting Edge' Enables the Orthopedic Implant Industry's Bodily Eminent Domain Claim*, 18 MINN. J. L. SCI. & TECH. 207, 237–38 (2017).

202. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 145–47 (1999).

203. Martinez v. United States, No. 1:16-cv-01556-LJO-SKO, 2019 WL 266213, at *7 (E.D. Cal. Jan. 18, 2019) (noting, "*Daubert* makes clear that the factors it mentions do *not* constitute a definitive checklist or test. (emphasis in the original) (citation and internal quotation marks omitted)").

and marketing of the product."[204] Strict liability typically applies.[205] "Generally, to establish a claim for strict liability, 'a plaintiff must demonstrate, *inter alia,* that the product was defective, that the defect caused the plaintiff's injury, and the defect existed at the time the product left the manufacturer's control.'"[206] The Restatement (Second) of Torts says that liability "applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller."[207]

One example of an alleged AI manufacturing defect involved the da Vinci robot, which the plaintiff alleged had "microcracking" allowing "electricity to escape in the form of sparks" from monopolar curved scissors dubbed "Hot Shears" resulting in "internal burns to [the plaintiff's] rectum" during a robotically-assisted prostatectomy.[208] Expert testimony is almost always required to establish claims for strict products liability.[209] A court in a prior case had found that "the da Vinci robot is a complex machine, one in which a juror would require the assistance of expert testimony in order to reasonably determine if the robot had a defect;" [210] thus, the court decided that the operative report of the surgeon describing the "narrative of the robot failing to function properly" was not adequate because the surgeon did "not opine that the robot ha[d] a defect."[211] The court also noted that the surgeon may have "used that same da Vinci robot in dozens of previous operations without any trouble," seeming to imply that this might show it was not defective.[212] Without expert testimony, summary judgment was granted for the defendant.[213]

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204. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998).

205. *Id.*

206. Mracek v. Bryn Mawr Hosp., 363 F. App'x 925, 926 (3d Cir. 2010) (citation omitted).

207. RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965); Mracek v. Bryn Mawr Hosp., 610 F. Supp. 2d 401, 404 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010) (citation omitted) (In states where the Restatement (Second) of Torts §402A has been adopted, "§ 402A 'imposes strict liability in tort not only for injuries caused by the defective manufacture of products, but also for injuries caused by defects in their design.'").

208. Pohly v. Intuitive Surgical, Inc., No. 15-CV-04113-MEJ, 2017 WL 900760, at *1 (N.D. Cal. Mar. 7, 2017).

209. *See, e.g., Bryn Mawr Hosp.*, 610 F. Supp. 2d at 404 (noting that without an expert report, the plaintiff failed to establish a claim for strict liability).

210. *Id.* at 405.

211. *Id.* at 405–06.

212. *Id.* at 406.

213. *Id.* at 406–07.

Manufacturing defects for AI are likely to be treated similarly to other manufacturing defects, and therefore, are not covered extensively here.

3. Failure to Warn

According to the Restatements, "a product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller . . . and the omission of the instructions or warnings renders the product not reasonably safe."[214]

Some argue that some AI products are "unavoidably unsafe" under the Restatements.[215] For example, the Washington Supreme Court considered the da Vinci robot as "unavoidably unsafe" and held that the manufacturer of the da Vinci system failed to fulfill its duty to warn the hospital and surgeon about the robot.[216] An unavoidably unsafe

214. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998).

215. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

216. Taylor v. Intuitive Surgical, Inc., 187 Wash.2d 743, 769 (2017) (noting that an exception to strict liability for products liability is provided by comment k for unavoidably unsafe products only when the manufacturer provides adequate warning of the unavoidably unsafe nature of their product); Comment k states:

> Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

product is "one that is unable to be made safe for its intended and ordinary use" and therefore, carries with it a duty to warn the users of the product.[217] A manufacturer may qualify for an exception to strict liability under comment k only if it provides proper warnings and marketing to the end user.[218]

In the Washington da Vinci case, the patient's intraoperative complication was a laceration of the rectal wall caused by the surgical robot that required the doctor to convert the operation to an open procedure and bring in another surgeon to repair the rectal tear.[219] The patient ultimately died four years later, after suffering through numerous subsequent complications allegedly related to the rectal tear including incontinence, the need for a colostomy bag, respiratory failure requiring a ventilator, kidney failure, infection, neuromuscular damage causing difficulty with walking, among others.[220]

The Washington State Supreme Court created "an unexpected shift in the law with regards to the standard that applies to medical device manufacturers' duty to warn"[221] when it held "that device manufacturers are indeed liable for ensuring that their product is safely adopted by its users."[222] The decision has major implications for hospitals, surgeons, and physician leadership and "seem[s] to destroy the learned intermediary doctrine."[223] Washington became "the first state to impose a duty on medical device manufacturers to warn hospitals" about surgical robots.[224]

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

217. Roe, *supra* note 14, at 340.

218. *Taylor*, 187 Wash.2d at 743.

219. *Id.* at 750.

220. *Id.*

221. Catherine Mullaley, *Washington Supreme Court Holds That Medical Device Manufacturers Have A Duty to Warn Hospitals—Taylor v. Intuitive Surgical, Inc.*, 43 AM. J. L. & MED. 165, 168 (2017).

222. Jason Pradarelli, et al., *Who is Responsible for the Safe Introduction of New Surgical Technology? An Important Legal Precedent from the Da Vinci Surgical System Trials*, 152 JAMA 717, 717 (2017).

223. Mullaley, *supra* note 221, at 168.

224. Nathan Reeves, *Medical Device Manufactures' Duty to Warn Expands*, MED. DEVICE BLOG (Apr. 4, 2017), http://knobbemedical.com/medicaldeviceblog/article/washington-state-supreme-court-modifies-duty-warn-device-manufacturers/ [https://perma.cc/AQM4-7HKL]. Roe, *supra* note 14, at 328–40 (observing that the Washington Supreme Court held the manufacturer liable even though the surgeon (1) was performing his first unproctored da Vinci prostatectomy, (2) performed the procedure on the patient whose level of obesity was clearly outside the recommended parameters provided by the manufacturer, (3) performed the procedure in a surgical position not recommended by the manufacturer (i.e., the patient was not in the Trendelenberg position), and (4) performed the surgery on the patient who had undergone previous

AI is associated with a learning curve.[225] For example, in total hip replacement surgery, the learning curve for robot-assisted navigation results in notable improvements in acetabular cup placement after 50 cases.[226] Reducing learning curves and preparing hospitals and surgeons to safely use AI devices falls at least partially to the manufacturer. At least one company is using virtual reality training to train surgeons. Smith and Nephew, an orthopedic device maker, "recently collaborated with Osso VR, a surgical training company, to create a module for the NAVIO Surgical System."[227] The NAVIO training module "is designed to be used by practicing surgeons and residents who are learning the robotics-assisted procedure and involves clinically supported virtual reality (VR) simulations of the procedure."[228] As companies institute these types of training, some type of similar VR training may become a "reasonable" expectation in products liability cases, effectively raising the standard of care for companies and surgeons alike—so that by the time a surgeon performs their first robotic surgery on a patient, a significant amount of VR training may become the norm. By requiring the doctor who is using new AI to participate in learning activities before clinical use, the companies may help satisfy their duty to warn under products liability law.

B. Medical Malpractice

AI adds an additional layer of complexity (e.g., adding superseding causes and mitigation of damages) to medical malpractice cases, with minimal current law available to help with the evaluation.[229] Generally, physicians "must provide care at the level of a competent physician within the same specialty, taking into account available resources."[230] In applying AI in health care, the "key step [is] separating prediction from action and recommendation" with the machine making the prediction and the human deciding upon recommendations and actions.[231] One observer noted, "Proper interpretation and use of computerized data will depend as much on wise doctors as any other

lower abdominal surgeries—again against the recommendations of the company).

225. *See* Claudia Perlich, *Learning Curves in Machine Learning*, ENCYCLOPEDIA OF MACH. LEARNING (2011), https://www.tcs.com/blogs/human-learning-curve-for-artificial-intelligence [https://perma.cc/Y999-HQHK].

226. Waddell & Padgett, *supra* note 31, at 425.

227. Carfagno, *supra* note 40.

228. *Id.*

229. Price et al., *supra* note 106, at 1765 (noting, "there is essentially no case law on liability involving medical AI."); Roe, *supra* note 14, at 330.

230. Price et al., *supra* note 106, at 1765.

231. Verghese et al., *supra* note 117, at 19.

source of data in the past."[232] Medical malpractice elements include duty, breach, causation and damages. AI can have unique effects on each of these elements.

1. Duty and Breach

Physicians have a duty to provide the human interface for AI so that data are interpreted properly and so that recommendations make clinical sense. EMRs and their clinical decision support (CDS) tools are adding "an army of new liability risks" which physicians must now navigate because EMRs have been ubiquitously adopted by "almost all health care entities."[233] In alleged malpractice cases, "more discoverable evidence" is available than ever before because EMRs increase the amount of documentation of clinical decisions.[234] Doctors have a duty to make sure that the EMR data relied upon for clinical decisions is correct and evaluated. EMRs tempt doctors "to copy and paste patient information and data" instead of adding new information, which may "perpetuat[e] . . . prior inaccuracies" and lead to missing new information or information that has changed.[235] Email and telecommunication encounters with patients are "multiplying the number of patient encounters manifold" and may lead to a concomitant increase in malpractice claims; these encounters may also "heighten the risk if medical advice is offered without a recorded physical examination and a comprehensive investigation of patients complaints."[236] The physician's duty does not change just because the communication is electronic.

In addition, AI has the ability to deliver "information overload" that "may lead to physicians missing important clinical information amid the noise and chaos."[237] The physician has a duty to navigate this information overload with expertise.[238] Improved access to patients' clinical information via EMRs will likely create additional legal duties to act upon that information.[239] The physician may also have a duty to use health information exchanges "to search the extensive data generated by health care providers" as EMR systems become more

232. *Id.*

233. Zachary Paterick et al., *Medical Liability in the Electronic Medical Records Era*, 31 BAYLOR U. MED. CTR. PROC. 558, 558 (2018).

234. *Id.* (observing, "Clinical decisions are extensively documented, creating more discoverable evidence including metadata.").

235. *Id.*

236. *Id.* at 559.

237. *Id.*

238. *Id.* at 558.

239. *Id.* at 559 (stating, ""Better access to clinical information through EMRs may create legal duties to act on the information.").

interconnected.[240] In addition, with increasing development of health information exchanges, physicians could be subject to a legal duty to review outside records for which they have not previously been held responsible—again changing the standard of care.[241] Given that most physicians only have 15-20 minutes to "take a history, examine a patient, and review the EMR" and given the large amount of extraneous information contained in today's electronic health records, with records often being hundreds or even thousands of pages, required review of all of this information as part of the standard of care may often be unreasonable.[242]

Therefore, unsurprisingly, EMRs are playing an increasing role in medical malpractice lawsuits, with claims involving EMRs *tripling* from 2010 to 2018.[243] Overall, however, EMR-related cases were only 1.1 percent of claims closed since 2010 in one study.[244] But as adoption continues at an almost-universal level, these cases are likely to increase in frequency. In one example, a physician gave the patient a morphine dose over 10 times the dosage intended by clicking the wrong selection on the EHR's drop down menu, which only offered either 15 or 200 milligram dosages.[245]

EMRs are usually deemed contributing factors in medical malpractice claims rather than the primary cause. [246] In one study, EMR-related factors that contributed to patient harm included user error in 17%, incorrect information in the record in 16%, copy/paste errors in 14%, "conversion issues (hybrid paper & electronic records)" in 13%, and system/software design issues in 12%.[247] User-related errors include copy and paste errors where users copy and paste redundant, outdated, or erroneous information, propagating it throughout the patient's chart, often making it difficult for physicians and nurses to

240. *Id.*

241. *Id.* at 560.

242. *Id.*

243. Ranum, *supra* note 197 ("The Doctors Company's analysis of claims in which EHRs contributed to injury show a total of 216 claims closed from 2010 to 2018. The pace of these claims grew, from a low of seven cases in 2010 to an average of 22.5 cases per year in 2017 and 2018.").

244. *Id.* ("The Doctors Company's analysis of claims in which EHRs contributed to injury show a total of 216 claims closed from 2010 to 2018. The pace of these claims grew, from a low of seven cases in 2010 to an average of 22.5 cases per year in 2017 and 2018.").

245. *Id.*

246. *Id.*

247. Greenberg & Ruoff, *supra* note 195 (focusing on concerns raised by unintended consequences of HIT).

sort through the chart to make good decisions and can lead to patient injury.[248]

In medical malpractice cases, physicians breach their legal duties when they fail to meet the standard of care, which means that physicians are generally "held to a standard of learning and skill normally possessed by such specialists in the same or similar locality under similar circumstances" or some similar standard dependent upon state law.[249] The legal standard of care is not fixed and is constantly evolving.[250] The standard of care is almost always a "matter peculiarly within the knowledge of experts," so expert testimony is usually required to establish the relevant standard of care.[251] As one physician commentator noted, "sooner rather than later," with AI entering medical practice, "physicians need to know how law will assign liability for injuries that arise from interaction between algorithms and practitioners."[252]

AI will rapidly influence the standard of care.[253] As noted earlier, AI can currently (1) "look at brain scans of people who are exhibiting memory loss and tell who will go on to develop full-blown Alzheimer's disease and who won't,"[254] (2) allow hospitals "to predict the likelihood of a cardiac arrest in 70 percent of occasions, five minutes before the event occurs,"[255] and (3) save lives and speed hospital discharge by improving treatment for "a deadly blood infection called sepsis."[256] At some point, as each of these technologies become more widely available, each may become a part of the "standard of care" for treating patients

248. Sue Bowman, *Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications*, PERSP. HEALTH INFO. MGMT. 1,4 (Fall 2013) (calling attention to safety hazards of EHRs).

249. Martinez v. United States, No. 1:16-cv-01556-LJO-SKO, 2019 WL 266213, at *5 (E.D. Cal. Jan. 18, 2019).

250. Price et al., *supra* note 106, at 1765 (pointing out, "The legal standard of care is key to liability for medical AI, but it is not forever fixed. Over time, the standard of care may shift.").

251. Martinez v. United States, No. 1:16-cv-01556-LJO-SKO, 2019 WL 266213, at *5 (E.D. Cal. Jan. 18, 2019) (citation omitted); *see also* Paterick et al., *supra* note 233, at 560.

252. Price et al., *supra* note 106, at 1766.

253. *Id.*

254. Yuhas, *supra* note 2.

255. Salzman, *supra* note 3; Shimabukuro et al., *supra* note 3, at 1.

256. Salzman, *supra* note 3 (In fact, in a 2016 study at the University of San Francisco, the "death rate fell more than 12 percent" after the AI system was implemented "meaning patients whose treatment involved the [AI] system were 58 percent less likely to die in the ICU." Further, the system sped patients' recoveries with AI monitored patients being "discharged from the hospital an average of three days earlier than those who were not."); Shimabukuro et al., *supra* note 3, at 1.

with the respective issues. Early adapters risk stepping outside the "standard of care" when other doctors are reluctant to embrace new AI-powered technologies, whereas late adapters also risk violating the standard of care if they fail to adopt beneficial AI that most other doctors have already accepted. One physician observer noted that current medical malpractice law "incentivizes physicians to minimize the potential value of AI,"[257] saying that the safest way for physicians to use AI to avoid liability is as a "confirmatory tool to support existing decision-making processes, rather than as a source of ways to improve care."[258] However, where AI use becomes mainstream, reluctant physicians could end up on the wrong side of the standard of care for widely adopted, clearly beneficial AI because "the failure to adopt and use electronic technologies may establish a deviation from the standard of care."[259]

EMR and other AI clinical decision support systems "may reshape medical liability by shifting the standard of care."[260] Doctors who decide to vary treatment from AI-powered "clinical decision support guidelines may represent a risk for malpractice liability based on a violation of new standards of care."[261] Departure from the recommendations of an EMR or other clinical decision support system could be used as evidence of medical malpractice as a departure from the standard of care.[262] Similarly, physicians could be protected from liability by following AI recommendations—even if those recommendations are incorrect.[263] If the doctor supersedes or overrides the EMR's default, the physician may need to be prepared to defend that decision in court.[264] If juries rely too much on these EMR defaults, erroneous liability may be assigned.[265]

Surgical robots also change the standard of care. Surgeons who adopt robotic techniques early risk violating the standard of care if robot-less surgeries clearly outperform robot-assisted procedures. Similarly, surgeons who fail to adopt robotic techniques may violate the standard of care once the robotic systems become widely accepted and have better outcomes than non-robotic techniques.

Mitigation of damages caused by the robot and competent use of AI are part of the standard of care. Surgeons do relinquish some control

257. Price et al., *supra* note 106, at 1765.

258. *Id.*

259. Paterick et al., *supra* note 233, at 559.

260. *Id.* at 560.

261. *Id.* at 559; Price et al., *supra* note 106, at 1766.

262. Paterick et al., *supra* note 233, at 559.

263. Price et al., *supra* note 106 (reviewing eight possible scenarios).

264. Paterick et al., *supra* note 233, at 560.

265. *Id.*

during robotic surgery but maintain control over the robots and are responsible for mitigating any damages a robot may cause during surgery.[266] For example, in a case involving the Da Vinci system, the expert opined that "generally accepted standards [require] the operating surgeon to identify [a puncture caused by the robot] and correct[] this issue prior to completion of the surgery."[267]

Surgeons must also maintain their surgical skills in traditional techniques to mitigate damages when robots and computerized options inevitably and foreseeably fail. This can be problematic when surgeons are trained to only perform procedures using robot-assisted techniques. For example, in a recent case, the da Vinci robot displayed multiple "error" messages and neither the surgical team nor the company representative was able to make the robot functional, so the surgeon had to use "laparoscopic equipment instead of the robot for the remainder of the surgery."[268] The patient suffered complications after the robot malfunctioned that he alleged were due to the robot malfunction and surgeon error.[269] When a robot fails, a surgeon must have maintained the skills necessary to finish the procedure without the robot, which can become problematic if the surgeon has rarely, if ever, performed the procedure without the robot. At some point, the standard of care might become to abort the procedure until the robot is repaired rather than risk complications by performing the procedure in a way in which they are only vaguely familiar.

2. Causation

As human and AI interactions are intertwined, proving causation can become difficult for plaintiffs. In medical malpractice cases, "causation must be proven within a reasonable medical probability based upon competent expert testimony" or a similar state law standard.[270] Causation must also be proven in products liability cases. Specifically, in one surgical robot case, the "plaintiff was required to prove that the manufacturer proximately caused the malfunction that led to the injuries," and thus, "prove that the machine, rather than the doctor, caused the injury."[271] The plaintiff's failure to prove proximate

266. Roe, *supra* note 14, at 330.

267. Martinez v. United States, No. 1:16-cv-01556-LJO-SKO, 2019 WL 266213, at *3 (E.D. Cal. Jan. 18, 2019).

268. Mracek v. Bryn Mawr Hosp., 363 F. App'x 925, 926 (3d Cir. 2010).

269. *Id.* ("One week later, Mracek suffered a gross hematuria and was hospitalized. He now has erectile dysfunction, which he had not suffered from prior to the surgery, and has severe groin pain.").

270. Martinez v. United States, No. 1:16-cv-01556-LJO-SKO, 2019 WL 266213, at *5 (E.D. Cal. Jan. 18, 2019).

271. Roe, *supra* note 14, at 332.

causation by the manufacturer led to dismissal of the case.[272] In a medical malpractice case, the opposite would be true; for example, the plaintiff would have to show that the doctor, and not the machine, caused the damage. In AI cases, the intricate relationship between human and machine exacerbate "the difficulty of proving causation, especially when artificial intelligence and human oversight are intertwined."[273] The entanglement of human versus machine liability can "make a technical, factual determination of who [the doctor or the AI device] was responsible" difficult for a jury and will require expert testimony.[274]

3. Damages

AI opens up the possibility of new types of damages in medicine. For example, AI-enabled EMRs can provide patients and doctors with the opportunity for "early advance care planning conversations,"[275] and eventually, failure to have these conversations may make physicians liable for the consequences of patients dying without planning. Doctors and patients have traditionally dealt with "[p]rognostic uncertainty and optimism bias" that often leads "patients and clinicians to overestimate life expectancy, which can delay important conversations."[276] In cancer care, one of the key reasons for this deficiency is that "oncology clinicians cannot accurately identify patients at risk of short-term mortality using existing tools."[277] Therefore, "most patients with cancer die without a documented conversation about their treatment goals and end-of-life preferences and without the support of hospice care."[278]

Today, however, AI-enabled EMRs can be used to "accurately identify patients at high risk of short-term mortality in general medicine settings,"[279] which may give patients the opportunity for end-of-life planning that previously may not have been possible. Today, "oncology specific ML algorithms can accurately predict short-term mortality among patients starting chemotherapy."[280] In a recent study, "ML models based on structured EHR data accurately predicted the short-term mortality risk of individuals with cancer from oncology

272. *Id.*

273. *Id.*

274. *Id.* at 339.

275. Parikh et al., *supra* note 61, at 2.

276. *Id.*

277. *Id.*

278. *Id.*

279. *Id.*

280. *Id.*

practices."[281] These tools "could be very useful in aiding clinicians' risk assessments for patients with cancer as well as serving as a point-of-care prompt to consider discussions about goals and end-of-life preferences."[282] Clinicians agreed that "most patients flagged . . . were appropriate for a timely conversation about goals and end-of-life preferences" suggesting that "ML tools hold promise for integration into clinical workflows to ensure that patients with cancer have timely conversations about their goals and values."[283]

At some point, failure to provide these end-of-life discussions could lead to damages for which physicians could become liable. As AI proliferates throughout medicine, more novel damage theories will likely become evident.

C. Other Liability Theories

Other theories of liability are likely to include ordinary negligence and breach of warranty. However, AI-related issues are likely to be largely similar to law in other areas for these theories, so they are only mentioned briefly here.

1. Negligence by the Owner of the AI

The hospital or other owner of the AI system will have liability for ordinary negligence for issues related to the proper care and maintenance of the AI equipment.[284] For example, in a recent case involving the Mako total knee robot, the plaintiff alleged that the hospital "failed in its duty owed plaintiff as the owner and custodian responsible for ensuring the 'proper care, maintenance and performance of' the Mako system."[285]

Hospitals could also be liable for negligence for adopting impractical and overly burdensome AI EMR systems. EMRs are creating liability issues by compromising patient safety due to something one author termed "death by a thousand clicks."[286] Physicians are being overloaded with the task of creating and interpreting the EMR with "many doctors

281. *Id.* at 7.

282. *Id.* at 8.

283. *Id.* at 9.

284. *See, e.g.*, Moll v. Intuitive Surgical, Inc., No. 13-6086, 2014 WL 1389652, at *1 (E.D. La. Apr. 1, 2014) (suing Ochsner hospital under negligence theories for "injuries sustained as the result of robot-assisted laparoscopic hysterectomy.").

285. Porter v. Stryker Corp., No. CV 6:19-0265, 2019 WL 3801635, at *1 (W.D. La. Aug. 12, 2019).

286. Fred Schulte and Erika Frye, *Death by a thousand clicks: Where electronic health records went wrong,* HEALTH LEADERS (Mar. 18, 2019), https://www.healthleadersmedia.com/innovation/death-thousand-clicks-where-electronic-health-records-went-wrong [https://perma.cc/7VYG-QEF9].

say[ing] they spend half their day or more clicking pulldown menus and typing rather than interacting with patients."[287] When hospitals implement new EMR systems without adequate physician input and training, foreseeable injuries may occur for which the hospital could be liable under ordinary negligence theories. In addition, the hospital can be liable for the doctor's mistakes using its AI system under vicarious liability theories even if the doctor is an independent contractor.[288]

In some cases, AI can even endanger hospital employees. For example, one nurse recently filed a lawsuit including claims of negligence and loss of consortium for a "traumatic brain injury" allegedly suffered during her employment by a hospital when, "while assisting during a surgery, [she] fell over a stool when the robotic arm of a 'da Vinci Surgical System' . . . 'moved rapidly and unpredictably toward her causing her to step back to avoid coming in contact with it.'"[289]

2. Breach of Warranty

Plaintiffs may allege breach of express and implied warranty.[290] One approach taken by a plaintiff in a robot case involved alleging that the manufacturer's "advertising and promotional materials 'did not accurately reflect the serious and potentially fatal side effects'" of the AI.[291] In another case, the doctors informed the patient that they would use the da Vinci robot to minimize the chance of erectile dysfunction associated with radical prostatectomy.[292] The patient had allegedly expressed concern over the potential complication and otherwise may not have consented to the procedure without the robot, which may help form the foundation for a case.[293] The same standards that apply from

287. *Id.*

288. Roe, *supra* note 14, at 332 (noting "[i]n addition to products liability, the use of surgical robots also raises the question of vicarious liability").

289. Patrico v. BJC Health Sys., No. 4:19-CV-01665-SNLJ, 2019 WL 3947781, at *1 (E.D. Mo. Aug. 21, 2019).

290. *See, e.g.*, Reece v. Intuitive Surgical, Inc., 63 F. Supp. 3d 1337 (N.D. Ala. 2014) (alleging breach of express and implied warranty, among other claims).

291. Darringer v. Intuitive Surgical, Inc., No. 5:15-CV-00300-RMW, 2015 WL 4623935, at *1 (N.D. Cal. Aug. 3, 2015).

292. Mracek v. Bryn Mawr Hosp., 610 F. Supp. 2d 401, 402 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010) (noting that the doctor "informed [the plaintiff] that the da Vinci surgical robot ("robot") would be used for the radical prostatectomy, so as to minimize the risk of erectile dysfunction.").

293. *Id.*

§402A of the Restatement (Second) of Torts apply to breach of warranty that apply to strict liability.[294]

3. AI as a "Person"

Some futurists argue that "machines capable of independent initiative and of making their own plans . . . are perhaps more appropriately viewed as persons than machines," and therefore, should be subject to liability themselves.[295] If machines are viewed as legal persons, then the machine itself could be held liable and be required to keep adequate insurance.[296] However, as long as the machine can be linked to a person or recognized legal entity, current product liability, negligence, and medical malpractice laws are likely to suffice—so legal recognition of machines as persons seems to be speculative and probably unnecessary at this time.

CONCLUSION

Artificial intelligence is revolutionizing medical care while simultaneously creating novel liability issues for providers and manufacturers. By mimicking human intelligence using computer algorithms that can learn from vast amounts of data, AI has the potential to outperform human physicians. Virtual systems like EMR and other clinical decision support systems augmented by AI are already ubiquitous in health care systems. Physical systems like AI-enabled robots are becoming more common in surgical procedures ranging from total knee replacements to radical prostatectomies. AI is showing promise to improve the care of patients with many different types of diseases noted throughout this paper from Alzheimer's disease to heart attacks to sepsis, among others.

New technologies like AI are important drivers of liability risk. In order to maximize the potential of AI, liability risks need to be defined so that all parties understand their responsibilities and the legal implications when technology inevitably causes harm. 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. In products liability law, the usual risks for design defects are present similar to other medical products. Uniquely foreseeable AI-specific design risks include data flaws, discrimination and bias, corruption and industry influence, user-interface issues, privacy compromise, and security issues, among others that will develop as AI use increases.

294. *See id.* at 407.

295. Vladeck, *supra* note 183, at 122.

296. *Id.* at 129.

Human touch, compassion, clinical intuition, and empathy are important components of medical care that have led many to describe medicine as an "art" as well as a science, so there will likely remain many instances in which predominantly human medical care will outperform AI-dominated care. However, AI is likely to play an increasing role in medical decision-making going forward.

For many types of medical issues, new measures for when an AI product is "not reasonably safe" will arise, and AI will likely be held to a higher standard than humans alone as AI systems will be compared to other AI systems and to manufacturer performance standards. Expert testimony will be especially important in AI cases and will likely represent a considerable barrier for many plaintiffs, as experts may be scarce or unwilling to testify against their potential employers. AI manufacturing defect liability will likely mirror that of other medical devices. "Failure to warn" defects in AI cases will likely be based in failure to train the end users, overpromising results, overly-steep learning curves. At least one court has already concluded that an AI system was "unavoidably unsafe." Causation issues will play a role in outcomes as juries will have to decide whether the physician or the AI manufacturer was responsible for the plaintiff's injury.

AI also affects medical malpractice liability by adding a complex layer of issues like superseding causes and mitigation of damages. Wise doctors will remain as important as ever in applying AI to medicine in ways to maximize benefits to patients. AI will create new duties for physicians to adopt and properly use AI as new technologies become the prevailing standard of care. AI will move the standard of care in medical malpractice cases with both early and late adapters potentially facing liability issues.

AI will create new liability risks for doctors as it leads to more discoverable evidence and the potential for information errors related to the overwhelming amount of data, as well as the mixture of erroneous/old data with correct/current information (e.g., copy and paste errors) in medical records. EMR involvement in medical malpractice cases tripled over the past decade and is likely to continue to climb as EMR adoption becomes universal.

Doctors' decisions to either follow or go against AI predictions will have legal consequences. Doctors who are trained on AI and never learn to practice without it may have difficulties when computers fail, which could lead to liability issues if the doctor is not prepared to complete a surgery, for instance, without a robot. Causation issues will likely play a large role because it will be hard for juries to dissect liability when physician responsibilities are so intertwined with AI systems. Again, expert testimony will be key. AI also may create new areas of liability where, for example, AI may allow doctors to warn patients prior to bad events, so that patients can be better prepared for illness or end of life, and failure to provide this information may lead to new areas of damages (e.g., similar to loss of chance theories).

Other liability frameworks will also play a more conventional role in AI-related claims, like ordinary negligence for maintenance and repair of AI or breach of warranty claims. Current liability frameworks are likely to suffice for AI systems in medicine, so it is unlikely that AI will rise to the level of personhood in the law of liability. All parties involved have unique responsibilities in dealing with AI. Manufacturers must ensure data is good, algorithms valid, and systems nondiscriminatory, in addition to ensuring the usual care in manufacturing to avoid defect. Manufacturers must also make sure the AI is not a black box and that end users are aware of its limitations and potential flaws, as well as ensuring that the users are properly trained to use their AI. Hospitals must properly maintain their AI and make sure their employees are properly trained in its use. Doctors must be the human interface between the technology and the patient by analyzing context for AI outputs and continuing to provide the human elements (e.g., compassion, empathy, clinical intuition) of good medical practice. As outlined in this paper, existing legal frameworks should provide the parties involved with AI's proliferation reasonable ability to anticipate liability issues so that AI continues to rapidly revolutionize medical care.