THE MEDICAL AND LEGAL IMPLICATIONS OF ARTIFICIAL INTELLIGENCE IN HEALTH CARE – AN AREA OF UNSETTLED LAW

By: Samuel D. Hodge, Jr.[*]

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[*] Samuel D. Hodge, Jr. is a professor at Temple University where he teaches law and anatomy. He is also a mediator and neutral arbitrator for The Dispute Resolution Institute in Philadelphia. Professor Hodge has authored more than 145 articles, over 500 non-referred publications and ten books. He is also a national public speaker and has spoken at hundreds of Continuing Legal or Medical Education courses.

*AI is not going to replace physicians, but physicians who use AI
are going to replace physicians who don't, and that may be the
cautionary tale*
---Dr. Keith Horvath [1]

[1]   James "Jim" Corrigan returned home following a stressful day at
work with a headache that only increased in intensity as time elapsed.[2] He
laid down, but the room started to spin and his vision blurred. Sensing that
something was wrong, he went to the emergency room and was greeted by
a waiting area filled with others seeking medical attention. Jim was
summoned by a nurse who asked various questions that she read from a
screen. His answers produced a computer response indicating that he may
be having a stroke and needed a computerized tomography (CT) scan. The
patient was immediately transported to radiology, and the CT scan was
performed. Twenty seconds later, a computer indicated that Jim had an
ischemic stroke and notified the attending physician that the patient needed
a tissue plasminogen activator to dissolve the blood clot and restore blood
flow to the brain.[3] The appropriate action was initiated, and the patient made
a prompt and successful recovery.

[2]   This scenario is not a script from a science fiction movie, but rather
a representation of how the use of artificial intelligence (AI) is advancing
medical care. Through the use of technology similar to that which is used

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[1] Carla Garnett, *Former NIH'er Horvath Explains Why Machines Won't Replace
Doctors*, NIH RECORD, https://nihrecord.nih.gov/2020/09/18/former-niher-horvath-
explains-why-machines-wont-replace-doctors [https://perma.cc/GD58-RPVY].

[2] This is a fictitious case.

[3] Inga Shugalo, *How Artificial Intelligence Can Predict and Detect Stroke*, IMAGING
TECH. NEWS (May 17, 2019), https://www.itnonline.com/article/how-artificial-
intelligence-can-predict-and-detect-stroke [https://perma.cc/7JCS-BGE9].

in self-driving cars,[4] artificial intelligence powers health care software that diagnoses a wide range of medical problems, from diabetic retinopathy to skin cancer.[5]

I. BACKGROUND

[3]   More than 145 million emergency room (hereinafter "ER") visits occur annually in the United States.[6] It is becoming increasingly common for ER facilities to treat older patients and patients in need of urgent care, yet these facilities are suffering from a shortage of available physicians.[7] At the same time, health care is expanding, requiring more expensive technical tools amid an unsustainable upward trend in costs and expenditures.[8] A partial solution to these challenges may be available from a creative resource: artificial intelligence. These "smart apps" and tools can lower ER patient loads "while increasing diagnostic speed, precision and accuracy."[9] It is highly unlikely that healthcare providers will be digitally displaced, but

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[4] *Artificial intelligence speeds emergency room care*, UCI HEALTH (Oct. 25, 2018), https://www.ucihealth.org/blog/2018/10/artificial-intelligence-emergency-room [https://perma.cc/7W3W-78XM].

[5] Shugalo, *supra* note 3; *see Saving sight: Using AI to diagnose diabetic eye disease*, EUREKALERT! (Jan. 8, 2019), https://www.eurekalert.org/news-releases/584252 [https://perma.cc/2GAL-RYZE].

[6] Diku Mandavia, *The AI Revolution Is Coming in Emergency Care*, U.S. NEWS & WORLD REP. (Jan. 13, 2020, 8:00 AM), https://www.usnews.com/news/healthcare-of-tomorrow/articles/2020-01-13/commentary-the-ai-revolution-is-coming-in-emergency-care [https://perma.cc/2BN4-JVG7].

[7] *Id.*

[8] *Id.*

[9] *Id.*

AI will gradually ease the day-to-day weariness, lethargy, and delay of reviewing patient charts.[10] It will also allow physicians to concentrate on the most challenging matters.[11]

[4]   Health care providers are increasingly relying on artificial intelligence to serve the medical needs of their patients. In fact, "approximately 86% of health care providers utilize at least one form of artificial intelligence in their practices."[12] However, such uses generate risk since not all conceivable outcomes utilizing this technology are foreseeable.[13] Unfortunately, the implications for tort liability are unsettled since both the technology and its deployment are still developing.[14] This article will provide a historical background of artificial intelligence, list its uses in health care, and conclude with a discussion of the unique legal issues presented by the application of artificial intelligence in medicine.

II. ARTIFICIAL INTELLIGENCE

[5]   Artificial intelligence refers to hardware and software applications that permit computers "to determine relationships between datasets and apply the learned relationships in a predictive fashion."[15] The technology is

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[10] *See* Bruce I. Reiner & Elizabeth Krupinski, *The Insidious Problem of Fatigue in Medical Imaging Practice,* 25 J. DIGIT. IMAGING 3, 3–6 (2012).

[11] Mandavia*, supra* note 6.

[12] Sarah Kamensky, *Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications*, 21 DEPAUL J. HEALTH CARE L. 1, 1 (2020).

[13] *Id.*

[14] *Id*. at 1–2.

[15] Supratik K. Moulik et al., *Applications of Artificial Intelligence in the Emergency Department*, 27 EMERGENCY RADIOLOGY 355, 358 (2020).

modeled after the brain's neural network.[16] It employs many kinds of data such as "algorithms, pattern matching, rules, deep learning and cognitive computing" to discover how to comprehend the information.[17] This process is similar to that employed by the lawyer who handles several whiplash claims, developing intuition and comprehension applicable to like cases in the future.[18] Following six decades of development, AI[19] applications have become pervasive in all walks of life.[20] This growth has caused "both excitement and trepidation" concerning its possible influences in most undertakings.[21] AI has been labeled the "fourth industrial revolution" with life-changing repercussions.[22] It is commonly recognized as "a field of study that combines computer science, engineering and related disciplines

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[16] *See id.*

[17] *What is artificial intelligence in medicine?*, IBM, https://www.ibm.com/uk-en/watson-health/learn/artificial-intelligence-medicine [https://perma.cc/747Y-RS5J].

[18] *See* Moulik et al., *supra* note 15 (describing analogous process used by a medical trainee).

[19] *Difference between Artificial intelligence and Machine learning*, JAVA T POINT, https://www.javatpoint.com/difference-between-artificial-intelligence-and-machine-learning [https://perma.cc/3GJA-VGEE] (explaining that artificial intelligence allows a machine to mimic human behavior whereas machine learning is a subdivision of AI which permits a device to automatically learn from prior information without specific programming).

[20] Jason D. Morgenstern et al., *"AI's Gonna Have an Impact on Everything in Society, so It Has to Have an Impact on Public Health": A Fundamental Qualitative Descriptive Study of the Implications of Artificial Intelligence for Public Health*, 21 BMC PUB. HEALTH, no. 40, 2 (2021).

[21] *Id.*

[22] Kathleen Murphy et al., *Artificial Intelligence for Good Health: A Scoping Review of the Ethics Literature*, 22 BMC MED. ETHICS, no. 14, 1 (2021) (quoting Klaus Schwab, Founder and Executive Chairman, World Economic Forum).

to build machines capable of behaviour that would be said to require intelligence were it to be observed in humans."[23]

A. How It Works

[6]   AI is a subset of computer technology that attempts to comprehend and formulate aptitude, usually as software programs.[24] Many elements impact the ability of AI to function and complete its tasks.[25] The software must gather the background information about a problem "through sensors or human input."[26] That data is then matched to the accumulated information, and the software interprets the background information based on the previously accumulated information.[27] The software considers many possible outcomes, and "predicts which action will be most successful based on the collected information."[28] While this approach generates useful information, it is limited by the confines of the imputed data.[29]

[7]   These systems perform functions previously believed to require human intelligence. They can handle uncertainty, "learning from experience; making predictions; interpreting language in a complex,

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[23] *Id*.

[24] Kun-Hsing Yu et al., *Artificial Intelligence in Healthcare*, 2 NATURE BIOMED. ENG'G 719, 719 (2018).

[25] *Id.*

[26] Tom Harris & Chris Pollette, *How Robots Work*, HOWSTUFFWORKS (Jan. 10, 2022), https://science.howstuffworks.com/robot.htm [https://perma.cc/Q4NQ-6SGJ].

[27] *Id.*

[28] *Id.*

[29] *Id.*

contextual manner."[30] Some schemes, known as neural networks, are even designed to replicate the human brain but at a much faster pace.[31] These developing types of artificial intelligence can function on a scale that far surpasses our intellectual abilities, releasing untold possibilities to make use of vast collections of data.[32]

[8]   Several tech giants are developing artificial intelligence applications, such as Apple, Amazon, Microsoft, and Facebook.[33] For instance, IBM has expended very substantial sums of money to foster the growth of artificial reasoning "to health care, retail, banking, and insurance."[34] The firm dubbed its creation "IBM Watson."[35] As a mechanism to attract publicity to its new creation, the company allowed the device to participate in the television show Jeopardy.[36] Much to everyone's surprise, Watson defeated two of the show's prior champions, demonstrating the computer's intellectual acumen.[37]

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[30] Elizabeth Merritt, *Artificial Intelligence The Rise Of The Intelligent Machine*, AM. ALL. MUSEUMS (May 1, 2017), https://www.aam-us.org/2017/05/01/artificial-intelligence-the-rise-of-the-intelligent-machine/ [https://perma.cc/3DNF-B667].

[31] *Id.*

[32] *Id.*

[33] Wayne Duggan, *Artificial Intelligence Stocks: The 10 Best AI Companies*, U.S. NEWS & WORLD REP. (Mar. 9, 2022), https://money.usnews.com/investing/stock-market-news/slideshows/artificial-intelligence-stocks-the-10-best-ai-companies [https://perma.cc/RS5M-GPE5].

[34] Merritt, *supra* note 30.

[35] *Id.*

[36] *Id.*

[37] *Id.*

B. Current Uses

[9]   Artificial intelligence has many applications that influence our daily activities.[38] Navigation apps like Google Maps employ the technology to evaluate traffic movement and provide road navigation cues for drivers.[39] Snapchat and Facebook use AI in their facial recognition technology to identify faces and apply filters to consumer pictures.[40] Digital devices, such as Siri, Alexa, and Google Assistant, can understand human voice directives and take the appropriate action, like turning on the light or raising the temperature.[41] AI has even entered the world of self-driving automobiles by allowing driverless cars to travel to specific locations without human assistance.[42]

[10]   These vehicles are guided by an array of information collected by image recognition technology, coupled with artificial intelligence, to operate motor vehicles independently.[43] Self-driving cars depend upon

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[38] *10 Examples Of Artificial Intelligence In Our Everyday Lives*, LUCIDPIX, https://www.lucidpix.com/10-examples-of-artificial-intelligence-in-our-everyday-lives/ [https://perma.cc/NW8L-54X8]; *see* Khari Johnson, *How Google Maps uses machine learning to predict bus traffic delays in real time*, VENTUREBEAT (June 27, 2019, 1:00 PM), https://venturebeat.com/2019/06/27/how-google-maps-uses-machine-learning-to-predict-bus-traffic-delays-in-real-time/ [https://perma.cc/95ET-U27A].

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] Ben Lutkevich, *self–driving car (autonomous car or driverless car)*, TECHTARGET (Oct. 2019), https://searchenterpriseai.techtarget.com/definition/driverless-car [https://perma.cc/3242-8X6P].

[43] *Id.*

hardware and software to operate without a user's input.[44] The hardware gathers the data; the software systematizes and assembles it.[45] On the software side, the imputed information is usually managed through machine learning algorithms or complex codes assembled using real-world situations.[46] This computer learning is at the forefront of self-driving technology.[47] While this innovation is exciting, it creates an array of novel legal questions that will take years to resolve.

III. ARTIFICIAL INTELLIGENCE IN HEALTHCARE

[11]   Society's "new medical superstar doesn't wear a stethoscope or wield a scalpel."[48] Rather, it is software guided by artificial intelligence that can detect critical health issues much faster than its human counterpart.[49] After many years of research and development, AI and machine learning have finally yielded significant advancements in the practice of medicine.[50] Between 2017 and 2019, the Food and Drug Administration (FDA) approved more than forty devices premised upon "algorithms for clinical

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[44] *Id.*

[45] *Id.*

[46] Lutkevich, *supra* note 42.

[47] Trevor English, *How Do Self-Driving Cars Work?*, INTERESTING ENG'G (Jan. 11, 2020), https://interestingengineering.com/how-do-self-driving-cars-work [https://perma.cc/EUP7-33TL].

[48] UCI HEALTH, *supra* note 4.

[49] *Id.*

[50] George Maliha et al., *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629, 629 (2021).

use."[51] These applications involve improved methods for discovering abnormalities during procedures such as "radiographs, electrocardiograms, or biopsies."[52] "From diagnosing patients to policing drug theft in hospitals, AI has crept into nearly every facet of the health-care system, eclipsing the use of machine intelligence in other industries."[53]

[12]   Artificial intelligence-driven technologies are quickly developing and providing answers in the field of clinical medicine. Scientists forecast that by the year 2030, "AI may affect up to 14% of global domestic product with half of this effect coming from improvements in productivity," and the health care industry will likely be a priority for its implementation.[54] Indeed, "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.'"[55] AI is currently being used to diagnose conditions such as heart arrhythmias, low blood sugar, tissue pathologies, and abnormalities visible on diagnostic imaging.[56]

[13]   Technological advancements permit the creation of a new field in medical care: augmented reality (AR). AR[57] assists the surgeon in planning

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[51] *Id.* at 630.

[52] *Id*.

[53] Sharna Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 1, 4 (2020) (quoting Meryl Kornfield, Staff Writer for *The Washington Post*).

[54] Frank Griffin, *Artificial Intelligence and Liability in Health Care*, 31 HEALTH MATRIX 65, 67 (2021) (quoting Robert Challen et. al.).

[55] *Id.* (quoting the US. Food and Drug Admin.).

[56] Giovanni Briganti & Olivier Le Moine, *Artificial Intelligence in Medicine: Today and Tomorrow*, 7 FRONTIERS MED., 1, 2–3 (2020).

an operation and resultant treatment and "helps explain complex medical situations to patients and their relatives."[58] This technique involves the employment of innovative technologies to improve clinical medicine.[59] Augmented reality systems incorporate digital information into the patient's real-world setting.[60] This technique provides a fresh approach for treatment and instruction in medicine.[61]

[14]   The inception of artificial intelligence in medicine is more than 70 years old.[62] However, various restrictions in early applications prohibited extensive approval and use in treatment.[63] This roadblock was solved at the turn of the twenty-first century with "the advent of deep learning,"[64] which

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[57] Adam Hayes, *Augmented Reality*, INVESTOPEDIA (Dec. 2, 2020), https://www.investopedia.com/terms/a/augmented-reality.asp [https://perma.cc/3CZ4-S2CA] (explaining that augmented reality is an amplified form of the physical world that is obtained through the employment of digital elements produced by technology).

[58] Martin Eckert et al., *Augmented Reality in Medicine: Systematic and Bibliographic Review*, 7 JMIR MHEALTH & UHEALTH, at 604, 604 (2019).

[59] *Id.* at 2.

[60] *Id.* at 2–3.

[61] *Id.* at 2.

[62] Vivek Kaul et al., *History of Artificial Intelligence in Medicine*, 92 GASTROINTESTINAL ENDOSCOPY 807, 807–809 (2020).

[63] *Id.* at 807.

[64] *Id.*; *see* Jason Brownlee, *What Is Deep Learning?*, MACH. LEARNING MASTERY (Aug. 14, 2020), https://machinelearningmastery.com/what-is-deep-learning/ [https://perma.cc/FF7K-EV3R] (stating that deep learning is a subset of machine learning with algorithms inspired by brain function).

overcame a number of these limitations.[65] Artificial intelligence is now "capable of analyzing complex algorithms and self-learning."[66] Society is undertaking a new frontier in which technology "can be applied to clinical practice through risk assessment models, improving diagnostic accuracy, and workflow efficiency."[67] The use of machine and deep learning in healthcare has dramatically increased.[68] This development has produced "opportunities for personalized medicine rather than algorithm–only–based medicine."[69] The applications are unlimited. AI's abilities "can be used for diagnosis of diseases, predication of therapeutic response, and potentially preventative medicine in the future."[70]

A. Developments In Medicine

[15]   Physicians have grappled with the challenge of properly "balancing the exorbitant amount of patient information with diagnosing disease accurately," and that struggle has been aggravated by "an overall shortage of clinical support."[71] However, the growth of AI in medicine allows health care providers to diagnose and treat diseases from a new platform.[72] For

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[65] Kaul et al., *supra* note 62, at 807.

[66] *Id.*

[67] *Id.*

[68] *See id.*

[69] *Id.*

[70] Kaul et al., *supra* note 62, at 807.

[71] Talya Van Embden, *Paging Dr. Robot: Applying an Outdated, Regulated Scheme to Robotic Medicine*, 43 NOVA L. REV. 387, 398 (2019).

[72] *Id.*

instance, virtual medical devices "can readily diagnose and track a patient's health without a doctor present, . . . [and] algorithms . . . can accelerate and assist in drug development," and robots can be used in "biologicals, genomics, and surgical care."[73]

[16]   IBM became the true pioneer in using computers in the medical field by creating "the first system to truly understand questions posed in natural language and to tap into the entire body of medical knowledge and personal records of a patient to develop a diagnosis or treatment plan" within a few seconds.[74] This system can respond to questions posed by health care providers, recommend diagnoses and treatment plans, and forecast the likelihood of success and medical evidence behind each treatment recommendation.[75] This type of AI is well suited for the medical profession because there is simply too much information for a doctor to have instantly available at any given time. To make matters even more challenging, consider that "the body of medical literature currently doubles every seven years."[76] A physician cannot be expected to recognize every new development without hesitation.[77] However, these AI-based systems are programmed to offer an answer to a doctor's medical questions in seconds.[78] The human body has countless variables for health care providers to

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[73] *Id.*

[74] Jessica S. Allain, *From Jeopardy! To Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems*, 73 LA. L. REV. 1049, 1050–51 (2013).

[75] *Id.* at 1051.

[76] *Id.* at 1053.

[77] *See id.* at 1053–54.

[78] *Id.* at 1054.

concurrently observe.[79] AI software is able to oversee an individual's health and can prescribe a personalized treatment plan founded upon the person's medical records.[80]

[17]   Additionally, in this country alone, it is estimated that there are between 210,000 and 400,000 deaths annually attributable to medical errors.[81] The fact that medical mistakes cause many deaths compels the use of AI in medicine. These deaths are primarily caused by improper diagnoses and improper treatment.[82] AI technology can assist in lowering patient deaths attributable to medical mistakes.[83]

[18]   Errors made during surgery also present a significant issue. A Mayo Clinic study published in 2017 reported that "8.9% of surgeons reported making a medical error in the preceding three months."[84] Supervised or autonomous operations could shrink this troubling statistic.[85] The American Medical Association (AMA) recognized the importance of artificial intelligence in medicine and issued a policy statement on augmented

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[79] Allain, *supra* note 74, at 1054.

[80] *Id.*

[81] Tokio Matsuzaki, *Ethical Issues of Artificial Intelligence in Medicine*, 55 CAL. W.L. REV. 255, 257 (2018).

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] *Id.*

intelligence.[86] The AMA articulates that its goal is to "[l]everage ongoing engagement in digital health and other priority areas for improving patient outcomes and physician professional satisfaction to help set priorities for health care AI."[87] The AMA targets opportunities to incorporate physicians' viewpoints into the enhancement, design, validation, and employment of health care AI,[88] and wants to assist in the design and evaluation of AI by focusing on the best practices, especially for physicians and others on the health care team.[89]

B. Specific Applications

[19]   Medical applications of artificial intelligence can be divided into two categories: virtual and physical.[90] The virtual application "includes informatics approaches from deep learning information management to control of health management systems, including electronic health records, and active guidance of physicians in their treatment decisions."[91] The physical subset involves robots which help with surgeries, intelligent prostheses for disabled individuals, and elderly care.[92] Computers acquire

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[86] AM. MED. ASS'N, AUGMENTED INTEL. IN HEALTH CARE 1, 1 (2019), https://www.ama-assn.org/system/files/2019-08/ai-2018-board-policy-summary.pdf [https://perma.cc/AB6T-953B].

[87] *Id.*

[88] *Id.*

[89] *Id*.

[90] Pavel Hamet & Johanne Tremblay, *Artificial Intelligence in Medicine*, 69 METABOLISM CLINICAL & EXPERIMENTAL S36, S37 (2017).

[91] *Id.* at S36.

[92] *Id.*

the ability to diagnose a patient through two methods: flowcharts or databases.[93] The flowchart-based method involves a host of questions asked by the physician, answers to which the computer synthesizes to reach an impression based upon the symptoms displayed.[94] The flowchart-based method necessitates supplying a large quantity of information into machine-based cloud networks containing the diverse assortment of symptoms and diseases encountered by physicians.[95] This process suffers from a major limitation: the computer can only process the indications observed by the physician during the doctor/patient examination.[96]

[20]   Alternatively, the database method applies the advantages of pattern recognition, where the computer is taught to recognize constellations of symptoms through recurring algorithms.[97] Google's artificial brain project demonstrates this learning process.[98] The Google system taught itself to identify cats by viewing millions of YouTube videos; accuracy increased as the computer observed more videos.[99] Following several days of this viewing and synthesizing, the system could identify an image of a feline with 75% reliability.[100]

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[93] Amisha et al., *Overview of Artificial Intelligence in Medicine*, 8 J. FAM. MED. & PRIMARY CARE 2328, 2328 (2019).

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *Id.* at 2329.

[98] Amisha et al., *supra* note 93, at 2329.

[99] *Id.*

[100] *Id.*

[21]   One of the most well-known medical applications of artificial intelligence is robotic surgery. This form of high-tech surgery permits a physician to undertake a host of intricate operations with greater accuracy and manipulation than is available through traditional methods.[101] These robotic units are usually equipped with a camera and mechanical arms that wield surgical tools. The physician operates the device while sitting at a specially designed table.[102] The console is equipped with an enlarged, 3-D view of the operating room.[103] Common robotic surgeries include gynecologic procedures, prostate surgery, and head and neck operations.[104]

[22]   AI-based algorithms are transforming the way robotic surgery is performed. Using deep machine learning data, the system can appreciate and predict the actions and routines of a physician during a procedure and transform them into instructions for the robot to undertake.[105] This form of artificial intelligence accumulates information by watching physicians perform repeated operations.[106] Coupled with the ability to remember the actions of a surgeon, AI helps these robots with deduction and

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[101] *Robotic surgery*, MAYO CLINIC (Mar. 26, 2021), https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974 [https://perma.cc/FZJ8-WS67].

[102] *Id.*

[103] *Id.*

[104] *Robotic Surgery*, SANFORD HEALTH, https://www.sanfordhealth.org/medical-services/surgery/robotic-surgery [https://perma.cc/Y22A-QWMQ].

[105] Madhu Prasad, *AI-Enabled Robotic Surgery: How Collaborative Robots Are Assisting Surgeons*, FAR NORTH (Oct. 18, 2020), https://www.farnorthsurgery.com/blog/aienabled-robotic-surgery-how-collaborative-robots-are-assisting-surgeons [https://perma.cc/EFP9-UGJN].

[106] *Id.*

implementation of cognitive actions like decision making, problem solving, and speech recognition.[107]

[23]   AI-based algorithms also aid in analyzing scans, detecting cancer, and expediting instrument positioning.[108] For example, guided by artificial intelligence, the device can automatically remove the deep roots of hair during a hair transplant and properly place them onto a person's scalp, with the desired force and speed.[109] AI even allows a cardiac surgeon to make small incisions between the ribs during heart surgery, whereas traditional heart operations would require the breastbone to be split.[110]

C. Use in Emergency Medicine

[24]   Overcrowding of the emergency department (ED) has been labeled "the biggest impediment to the delivery of timely and adequate emergency care' worldwide."[111] This congestion impedes the ability to obtain emergency attention in the form of ambulance rerouting, increased delays, and increased likelihood of those who are ill departing the facility without getting much-needed medical attention.[112] Artificial intelligence can substantially influence ED personnel and the larger arena of medical

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[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] Prasad, *supra* note 105.

[111] Clare Allison Parker et al., *Predicting Hospital Admission at the Emergency Department Triage: A Novel Prediction Model*, 37 AM. J. EMERGENCY MED. 1498, 1498 (2019) (quoting Daniel Fatovich).

[112] *Id.*

diagnostics.[113] This department can uniquely benefit from AI because of the software's capacity to forecast a patient's prognosis during triage and its elasticity in evaluating multiple patient comorbidities.[114]

[25]   However, the ED nonetheless faces unique challenges. The sheer amount of ED patients requires physicians to treat multiple people concurrently, many of whom are suffering from life-threatening conditions. This requires quick access to patient and clinical information for essential acute decision making.[115] Unfortunately, patients are screened in the ED with limited available data, and doctors find themselves weighing the odds for risk stratification and decision making.[116] To make matters worse, an article published in the Annals of Emergency Medicine reported that less than two thirds of emergency medicine doctors are actually trained in emergency medicine, especially in rural areas.[117]

1. Triage

[26]   Triage stems from the French term "trier" and was coined during Napoleon's reign, referring to care for the volume of injured soldiers seen

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[113] Mandavia, *supra* note 6.

[114] Abirami Kirubarajan et al., *Artificial Intelligence in Emergency Medicine: A Scoping Review*, 1 J. AM. COLL. EMERGENCY PHYSICIANS OPEN 1691, 1692 (2020).

[115] Rourke M. Yeakley & Mayur Saxena, *How could artificial intelligence benefit emergency medicine?*, AI MED (Sept. 3, 2018), https://ai-med.io/ai-med-news/artificial-intelligence-emergency-medicine/ [https://perma.cc/QC7L-RCGF].

[116] *See id.*

[117] *Id.*

by a small cadre of overwhelmed physicians.[118] In modern-day medicine, triage is "the ultimate in front line medical care, providing both the medical practitioner and patient with the coordinates they need to ensure that care is provided to the right person, on time."[119] Triage seeks to target those who need priority care by allocating a specific urgency level based on a patient's current condition and necessity for care.[120] Time is of the essence in the emergency room, so it is critical to properly categorize patients at this stage, since improper triage can result in devastating harm, and even death.[121]

[27]   AI has surfaced as a critical instrument for emergency department triage.[122] The technology supports highly complex algorithms, going beyond simple collections of data. [123] Rather, it combines deep learning, neural networks, and machine learning. The software creates algorithms that can identify the various levels of patient triage so that health care workers can ensure that patients receive the proper care.[124] AI technology could also help to analyze the myriad of information provided,

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[118] Mara Geller, *Emergency Room Triage With AI*, AIDOC (June 16, 2020), https://www.aidoc.com/blog/emergency-room-triage-with-ai/ [https://perma.cc/AWL5-XXDL].

[119] *Id.*

[120] Marta Fernandes et al., *Risk of Mortality and Cardiopulmonary Arrest in Critical Patients Presenting to the Emergency Department Using Machine Learning and Natural Language Processing*, PLOS ONE, at 1 (Apr. 2, 2020), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0230876 [https://perma.cc/5FED-R4VE].

[121] *Id.*

[122] Geller, *supra* note 118.

[123] *Id.*

[124] *Id.*

including "the age and sex of the patient, presenting history, complaints, vital signs, what was the mode of transport . . . [and] past medical history."[125] These systems assist the medical staff in correctly classifying patients so that those most in need of medical care are seen first.[126]

2. Emergency Radiology

[28]   The employment of artificial intelligence in emergency radiology can be of great benefit, because it can help make better choices involving the need for medical imaging and selection of imaging modality founded upon an examination of the patient's records.[127] As noted by Dr. Agrawal, when speaking about the use of AI in emergency radiology, "AI enabled algorithms could play a huge role in reducing radiation doses of CT examinations or reducing scan time for MRI, by using various enhancement and post-processing techniques."[128]

[29]   Diagnostic imaging can also be time sensitive.[129] Traditionally, radiologists learn to examine films for the discovery, classification, and

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[125] Artificial Intelligence in Emergency Radiology, TELERAD TECH & IMAGE CORE LAB (Dec. 28, 2018), https://www.teleradtech.com/artificial-intelligence-in-emergency-radiology) [https://perma.cc/7SD5-MWZX] ("A Report, based on the Keynote Speech delivered By Dr. Anjali Agrawal, Head, Teleradiology Solutions, Delhi Operations @ Artificial Intelligence in Radiology 2018 Symposium, November 10, 2018").

[126] Geller, *supra* note 118.

[127] TELERAD TECH & IMAGE CORE LAB, *supra* note 125.

[128] *Id.*

[129] Kamil Zelenák et al., *How to Improve the Management of Acute Ischemic Stroke by Modern Technologies, Artificial Intelligence, and New Treatment Methods*, 11 LIFE 488 (2021).

monitoring of illnesses.[130] Recently, AI has demonstrated noteworthy innovation in image recognition responsibilities. For example, correct stroke supervision requires specific findings on diagnostic imaging. Innovative uses of "automated methods for stroke imaging evaluation is therefore required."[131] AI has shown remarkable improvement in the ability to detect an abnormality in diagnostic studies.[132]

[30]   Much of the time spent in performing a CT scan is devoted to patient positioning.[133] Indeed, poor-quality images can result in the improper reading of the films and poor replication of the studies.[134] The ability to rapidly reconstitute the images through AI technology utilization could reduce the scan time, minimize contrast utilization, and offer either improved film quality of the MRI or decrease the amount of contrast needed in CT scans.[135] AI-created software fosters enhanced techniques, including the autonomous evaluation of brain function in terms of brain abnormities such as cerebral bleeding, blockages, or tissue death.[136]

3. Other Uses in the Emergency Department

[31]   The wait time in an ED can be critical to a patient's prognosis, yet the CDC estimates that only 35% of those who go to an ED are seen in less

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[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] Zelenák et al., *supra* note 129.

[135] *Id.*

[136] *Id.*

than fifteen minutes from when they arrive.[137] The longer a patient waits to be seen at an ED, the higher the death rate.[138] Emergency medicine is also undoubtedly very demanding and challenging; life and death decisions must be made quickly and decisively.[139] Such an exacting environment increases the chance that a mistake is made at some point.[140] AI-assisted care utilizes data-driven decision making to help provide critical care patient assessments and assist in determining which tests to order while the individual is in the ED and which patients can be treated on a non-emergency basis.[141]

[32]   Research demonstrates that the majority of AI uses in the emergency department focus on prediction.[142] Studies show that AI technology is superior to traditional determination-making instruments and scoring methods.[143] For instance, AI has proven superior in forecasting the death rates from pneumonia and in ascertaining the danger from fainting.[144] A possible reason for this superior outcome is AI's capacity to consider many variables at the same time.[145]

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[137] Yeakley & Saxena, *supra* note 115.

[138] *Id.*

[139] *Id.*

[140] *See id.*

[141] *Id.*

[142] Kirubarajan et al., *supra* note 114, at n.26–27.

[143] *Id*.

[144] *Id.*

[145] *Id.*

IV. LIMITATIONS OF ARTIFICIAL INTELLIGENCE IN MEDICINE

[33]   Artificial intelligence has made great strides in medicine, but human observation is still mandatory.[146] Some patients are hesitant to abide by the advice generated by artificial intelligence even when it exceeds physician recommendations.[147] They assume that their medical situation is unique and cannot be properly evaluated by artificial intelligence.[148] Research demonstrates that when medical advice was presented by AI rather than by a practitioner, patients were less likely to follow those recommendations, and wanted to pay less money for that service.[149] They also preferred having a physician perform the services even if it produced a greater chance of a misdiagnosis or an adverse operative result.[150]

[34]   Additional criticism includes the argument that surgical robots "operate logically, as opposed to empathetically."[151] Health care providers are often asked to provide explanations that can help with a medical

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[146] *Pros & Cons of Artificial Intelligence in Medicine*, DREXEL UNIV. (July 21, 2021), https://drexel.edu/cci/stories/artificial-intelligence-in-medicine-pros-and-cons/ [https://perma.cc/E85Z-URL7]; Dave Muoio, *Clinical AI's limitations: Some are short-term, others are unavoidable*, MOBIHEALTHNEWS (May 14, 2020, 2:56 PM), https://www.mobihealthnews.com/news/clinical-ais-limitations-some-are-short-term-others-are-unavoidable [https://perma.cc/8XPQ-EWQL].

[147] Chiara Longoni & Carey K. Morewedge, *AI Can Outperform Doctors. So Why Don't Patients Trust It?*, HARV. BUS. REV. (Oct. 30, 2019), https://hbr.org/2019/10/ai-can-outperform-doctors-so-why-dont-patients-trust-it [https://perma.cc/5VVK-3PPN].

[148] *Id.*

[149] *Id.*

[150] *Id.*

[151] DREXEL UNIV., *supra* note 146.

impression or prevent medical complications.[152] While an AI algorithm may be able to assign a patient to a specific rehabilitation facility or nursing home, the system may not take a patient's limited financial resources or other individual preferences into consideration.[153]

[35]   Some claim that AI's limited capacity to perceive a patient's full medical picture may result in "cold and harsh decisions that devalue human life."[154] This weakness lead critics to assert that AI is unable to supersede human judgment because medical decisions may require a solution other than the most rational answer to untangle a complicated problem.[155]

V. THE FOOD AND DRUG ADMINISTRATION'S APPROVAL PROCESS

[36]   The Food and Drug Administration (FDA) safeguards public health by "ensuring the safety, efficacy, and security of human . . . drugs, biological products, and medical devices."[156] It is also accountable for approving advancements which make medical products more operational and cost-efficient, while guaranteeing that society acquires precise, science-based information that promotes general health.[157] An important consideration in the FDA regulatory process is "whether an AI system is a

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[152] *See id.*

[153] *Id.*

[154] Jason Chung & Amanda Zink, *Hey Watson - Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine*, 11 ASIA PACIFIC J. HEALTH L. & ETHICS 51, 57 (2018).

[155] *Id.*

[156] *What We Do*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do [https://perma.cc/3B2R-QKJR].

[157] *Id.*

medical device or a medical service or procedure."[158] This determination is essential since the FDA regulates items that are medical devices, while the states supervise the practice of medicine.[159]

[37]   Premarket approval (PMA) is the FDA's way of providing for a regulatory review to assess the safety and usefulness of Class III medical devices.[160] These items refer to those products that promote or maintain life, are of considerable value in avoiding the diminution of a person's health, or which demonstrate a possible threat of illness or injury.[161] The agency also inspects and approves changes in medical tools, "including software as a medical device, depending on the significance or risk posed to patients of that modification."[162] Artificial intelligence in medicine is defined by the FDA as "the science and engineering of making intelligent machines."[163] "This AI software can, for example, help health care providers diagnose diseases, monitor patients' health, or assist with rote functions such as

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[158] Gary E. Marchant & Lucille M. Tournas, *AI Health Care Liability: From Research Trials to Court Trials*, J. HEALTH & LIFE SCIS. L., Feb. 2019, at 23, 32.

[159] *Id.*

[160] *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma [https://perma.cc/5CXS-5ZLJ].

[161] *Id.*

[162] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN. (Sept. 22, 2022), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation [https://perma.cc/Y4X8-8MJG].

[163] *Id.*

scheduling patients." [164] The agency's standard prototype of a medical device regulation was not intended for all artificial intelligence and machine learning technologies.[165] Based upon the FDA's existing protocol for software alterations, the agency expects that numerous artificial intelligence and machine learning software device modifications may require premarket approval.[166]

[38]   The regulatory environment for AI technology is complicated. The FDA oversees some AI-designed products employed in medicine, and the regulatory agency has a vital role in ensuring the safety and usefulness of those commodities within its ambit.[167] To this end, the FDA is tasked with confirming the safety of various AI-based medical items.[168] This means that it examines software based on its intended use and the degree of error-associated risk to patients.[169] The FDA will treat AI software as a medical device if its aim is to "treat, diagnose, cure, mitigate, or prevent disease or other conditions."[170] An applied example is a computer program that helps

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[164] *How FDA Regulates Artificial Intelligence in Medical Products*, PEW CHARITABLE TRUSTS (Aug. 5, 2021)*, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products [https://perma.cc/AC22-4D96].

[165] *Id.*

[166] U.S. FOOD & DRUG ADMIN., *supra* note 162.

[167] *Id.*

[168] *Id.*

[169] *Id.*

[170] PEW CHARITABLE TRUSTS, *supra* note 164.

a medical provider discover and diagnose a stroke by examining MRI films.[171]

[39]   A medical device driven by AI software must undergo an FDA analysis founded upon its risk classification.[172] These devices can be broken down into three categories. A Class I device possesses very little risk to the user, such as a scanning thermometer that detects and displays a person's body temperature. These items are exempt from the FDA approval process.[173] The risk presented by a Class II device demonstrates a "moderate to high risk [to patients if it is inaccurate]."[174] This classification encompasses items such as syringes, contact lenses, and pregnancy test kits.[175] The majority of Class II devices are subject to a premarket 510(k) review, which requires the manufacturer to show that its technology is substantially the same as a product already being used for "the same intended use and technological characteristics."[176] Class III is reserved for those devices that present the highest risk to a patient if the device were to be inaccurate. These consist of "products that are life-supporting, life-sustaining, or substantially important in preventing impairment of human health."[177] An example of a Class III device is a breast implant or artificial

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[171] *Id.*

[172] *Id.*

[173] *Id.*

[174] *Id.*

[175] *How To Classify Your Medical Device For FDA Approval*, ARENA, https://www. arenasolutions.com/resources/articles/how-to-classify-your-medical-device-for-fda-approval/ [https://perma.cc/UY3V-9N4W].

[176] PEW CHARITABLE TRUSTS, *supra* note 164.

[177] *Id.*

hip.[178] These technologies must apply for premarket approval and provide results from clinical studies.[179]

[40]   A database search reveals that over 220 AI medical devices have gained FDA approval.[180] According to one study, a little more than half of those AI technologies were approved for radiology use, followed by 13% for general hospital utilization, 10% pertained to cardiovascular applications, 8% were neurological devices, 5% pertained to ophthalmic units, and 4% were pathological devices.[181] Other medical specialty applications involve gastroenterology, urology, clinical chemistry, anesthesiology, microbiology, obstetrics, gynecology, dental, and hematology.[182]

[41]   The FDA recently enhanced its efforts to supervise the administration of AI medical software.[183] In January 2021, the agency announced its Artificial Intelligence/Machine Learning-Based

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[178] *What's the Difference Between the FDA Medical Device Classes?*, BMP MEDICAL, https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-2/ [https://perma.cc/9VXC-YR3K].

[179] Jill Jin, *FDA Authorization of Medical Devices*, JAMA (Jan. 29, 2014), https://jamanetwork.com/journals/jama/fullarticle/1817798 [https://perma.cc/7YHM-L57F].

[180] Urs J. Muehlematter et al., *Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–2020): A Comparative Analysis*, 3 LANCET DIGIT. HEALTH e195, e200 (2021).

[181] *Id.* at e198.

[182] *Id.*

[183] *Id.*

Software as a Medical Device Action Plan,[184] a scheme that describes the FDA's future regulatory oversight. The plan provides an all-encompassing approach based on total product lifecycle management, seeking to improve capabilities benchmarks, in turn improving patient care by ensuring proper software functionality.[185] This undertaking fosters the progress of sound machine learning practices to appraise and enhance learning algorithms; to promote a patient-centered method, "including device transparency to users; [d]eveloping methods to evaluate and improve machine learning algorithms; and [a]dvancing real-world performance monitoring pilots."[186] It is too early to determine the effectiveness of this new action plan on the development and use of AI technologies in medicine. There are too many questions about what this new scheme will involve, the number of AI entities that will be covered, and the FDA's power to police businesses in addition to devices.[187]

[42]   The bottom line is that there are numerous unanswered questions about how this government agency will handle AI health technologies. The solution to these issues may have a significant impact on liability for the use of artificial intelligence.[188] As a caveat, if an AI device ends up being classified as a medical device, this designation may prevent a product

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[184] Jessica Kent, *FDA Evaluations of Medical AI Devices Show Limitations*, XTELLIGENT HEALTHCARE MEDIA (Apr. 8, 2021), https://healthitanalytics.com/news/fda-evaluations-of-medical-ai-devices-show-limitations [https://perma.cc/N7ET-8LYF].

[185] *FDA Releases Artificial Intelligence/Machine Learning Action Plan*, U.S. FOOD & DRUG ADMIN. (Jan. 12, 2021), https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan [https://perma.cc/4N8R-RXHB].

[186] *Id.*

[187] Marchant & Tournas, *supra* note 158, at 33.

[188] *See id.*

liability claim on the state level.[189] Conversely, if the AI technology is considered a medical device controlled by different means "such as Section 501(k) clearance, then no preemption will apply but the regulatory classification will suggest that product liability is the appropriate tort theory if the system causes injury."[190] However, a FDA finding that the AI technology is not a medical device, excepting it from FDA regulation, could suggest that medical malpractice is the proper course of action.[191]

VI. LEGAL ISSUES RAISED BY ARTIFICIAL INTELLIGENCE IN MEDICINE

[43]   The luster of AI in medicine becomes somewhat diminished when one considers the legal implications involving the technology when something goes wrong.[192] The employment of AI in medicine will generate tort consequences because of the inability to forecast all liability scenarios.[193] For instance, if a health care provider uses AI to formulate a medical impression of a patient and that conclusion is ultimately incorrect, it is uncertain who should be liable and to what extent.[194] As with most advancements, the law lags behind in addressing the issues presented by this developing technology.[195] Little guidance exists on how the tort system will respond to these quickly changing medical systems and the duty of

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[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] Kamensky, *supra* note 12.

[193] *Id.*

[194] *Id.*

[195] *Id.*

care.[196] Complicating matters, the technology and its usages are not yet fully understood.[197] These advancements mean that health care providers will be unable to depend upon accepted medical practice, but will be required to repeatedly research and follow the most recent developments to ascertain the best practices and safest treatment plan.[198]

[44]   Our tort system is based upon concepts of agency, control, and foreseeability.[199] After all, an entity able to foresee the result should be answerable to pay an aggrieved party the appropriate amount to compensate for that injury.[200] A diagnosis founded upon AI technology offers an array of issues that are difficult to remedy through present concepts of responsibility.[201] For instance, how do you assign liability involving a "black box" diagnosis?[202] Many entities end up being involved in the decision-making process from the manufacturer of the system to the doctor who relied upon the information produced by the AI technology. This allocation of responsibility among the stakeholders when no one entity is

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[196] Marchant & Tournas, *supra* note 158, at 35.

[197] Kamensky, *supra* note 12.

[198] Marchant & Tournas, *supra* note 158, at 34.

[199] *See* Kyle T. Jorstad, *Intersection of Artificial Intelligence and Medicine: Tort Liability in The Technological Age*, 3 J. MED. A.I. 1, 10 (2020).

[200] *Id.* at 10–11.

[201] *Id.* at 15.

[202] *Id.*; *see also* Richard Harris, *How Can Doctors Be Sure A Self-Taught Computer Is Making the Right Diagnosis?*, NPR (Apr. 1, 2019, 6:14 AM), https://www.npr.org/sections/health-shots/2019/04/01/708085617/how-can-doctors-be-sure-a-self-taught-computer-is-making-the-right-diagnosis [https://perma.cc/L34A-JM4V] (explaining that the term "black box diagnosis" is used because the scientists don't understand how AI makes it decision).

solely responsible for the diagnosis muddles judicial resolution. It is also hard to determine breaches of the duty of care given untested AI software.[203] For instance, a black box will provide a diagnosis, but it does not explain how it arrived at that impression.[204] Existing tort law can be employed to resolve some of these issues, but not to the level of certainty desired by the judiciary, which seeks clearly established measures for assessing liability and apportioning responsibility.[205]

[45]   The primary reason for apprehension in assigning responsibility for medical errors arises when no one can "'see' the reasoning made by the artificial intelligence technology."[206] This inability raises concerns about whether standard products liability principles should be used, finding that the technology manufacturer is responsible, or if the physician managing the patient through AI technology should be liable.[207] The question of liability is further blurred because AI is associated with the health care provider as an aspect of patient care. From this perspective, it is just an instrument to help the doctor render care to the patient.[208] One must also keep in mind that the pace of AI deployment in medicine is accelerating

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[203] Jorstad, *supra* note 199, at 15.

[204] *Cf. id.* at 16 ("Comparing the machine's gross accuracy in all previous similar cases will yield a measure of whether the [] diagnosis was reasonable compared to similarly situated patients.").

[205] *Id.*

[206] Kamensky, *supra* note 12.

[207] *Id.*

[208] Scott J. Schweikart, *Who Will Be Liable for Medical Malpractice in the Future? How the Use of Artificial Intelligence in Medicine Will Shape Medical Tort Law*, 22 MINN. J. L. SCI. & TECH. 1, 5 (2021).

very quickly, such that "what might be malpractice if relied on today may be negligent to not use tomorrow."[209]

[46]   An important case involving the evolving standard of care in medical malpractice is *Burton v. Brooklyn Doctors Hospital*.[210] In that case, the court determined that the traditional standard of care for providing oxygen to premature infants was no longer consistent with new evidence about the treatment plan.[211] The plaintiff demonstrated that prolonged liberal exposure to concentrated oxygen causes blindness in infants.[212] As the court noted, "the conventional medical wisdom at the time believed that increased oxygen was essential to the survival of premature babies."[213] However, "the [defendants] cannot avail themselves of the shield of acceptable medical practice when a number of studies, including their own, had already indicated that increased oxygen was both unnecessary and dangerous."[214] So, because of the constantly changing advancements involving AI technology in medicine, physicians can no longer depend upon accepted medical practice, but instead must be vigilant in tracking current changes to ascertain the preeminent and soundest treatment option.[215]

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[209] Marchant & Tournas, *supra* note 158, at 34.

[210] *Id.* at 35 (quoting Burton v. Brooklyn Doctors Hospital, 452 N.Y.S.2d 875 (N.Y. 1982)).

[211] *See* Burton v. Brooklyn Doctors Hospital, 452 N.Y.S.2d 875, 880 (N.Y. 1982).

[212] *Id.* at 879.

[213] *Id.* at 880.

[214] Marchant & Tournas, *supra* note 158, at 35.

[215] *See id.*

A. Products Liability

[47]   Artificial intelligence is a game-changing development that can dramatically affect the practice of medicine, but it also has risks. AI-based systems are not perfect and will occasionally provide incorrect information.[216] While some of these mistakes may be harmless, others could injure a patient. What is the liability if an AI algorithm makes an incorrect diagnosis that causes an injury? How should the fault be apportioned? These questions require an analysis of the laws of products liability and artificial intelligence.[217]

[48]   Injuries sustained because of defective or unreasonably dangerous products are commonplace.[218] The law of products liability involves the responsibility of a manufacturer, distributor, or seller of a defective product. In other words, liability attaches to all those in the chain of distribution.[219] This means that a product must meet the ordinary expectations of the consumer.[220] This requirement is breached when the item has an unforeseen flaw or danger.[221] However, no products liability law exists on the federal

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[216] John Villasenor, *Product liability as a way to address AI harms*, BROOKINGS (Oct. 31, 2019), https://www.brookings.edu/research/products-liability-law-as-a-way-to-address-ai-harms/ [https://perma.cc/3386-R2CU].

[217] *See id.*

[218] *See generally id.* (discussing the positives and negatives of AI and how it can be both dangerous and defective).

[219] *What is Product Liability?,* FINDLAW (Jul. 2, 2019), https://www.findlaw.com/injury/product-liability/what-is-product-liability.html#:~:text=Product%20liability%20refers%20to%20a,are%20in%20the%20distribution%20chain [https://perma.cc/H7CC-6SRM].

[220] *Id.*

[221] *Id.*

level. Instead, it is a creature of state law, and theories of liability sound in negligence, strict liability, or breach of warranty.[222] Regardless of the theory, a claimant must prove the item that caused the injury was defective at the time it left the hands of the seller, and that the defect caused the injury.[223]

1. Theories of Liability in Products Cases

[49]   Medical device suppliers and manufacturers are an obvious target for injured claimants.[224] The characteristic claim is that of a patient who is injured by a defect in a medical device.[225] Several theories of products liability arise: design defect, manufacturing defect, and marketing defect.[226] A manufacturing defect can surface when the product fails to adhere to the manufacturer's specifications and causes harm.[227] Design defects occur when a product is in a "defective condition unreasonably dangerous to the user or consumer "[228] or "foreseeable risks of harm posed by the product

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[222] *Id.*

[223] *See id.*

[224] *See generally* David Goguen, *Product Liability Claims Involving Medical Devices*, NOLO, https://www.nolo.com/legal-encyclopedia/product-liability-claims-medical-devices-29684.html [https://perma.cc/BJW7-BYTN] (discussing medical device product liability).

[225] Sara E. Dyson, *Medical Device Software & Products Liability: An Overview (Part I)*, MEDTECH INTEL. (Sept. 15, 2017), https://www.medtechintelligence.com/feature_article/medical-device-software-products-liability-overview-part/ [https://perma.cc/T38N-7K6Y].

[226] FINDLAW, *supra* note 219.

[227] Chung & Zink, *supra* note 154, at 68.

[228] RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).

could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor."[229] A failure to warn theory may surface when the seller fails to give proper warnings to the consumer of the risks intrinsic in the product or to issue instructions for safe use of the technology.[230] For instance, suppose an AI-enabled system is employed to detect abnormalities on MRI films automatically and is advertised to physicians as a way to improve their productivity in analyzing MRI images. This system has no problem interpreting high-resolution images.[231] However, the system is unable to adequately interpret films of lesser quality.[232] If the system's seller does not disclose this limitation to the user, an improper diagnosis may be generated, leading to a products liability claim for both negligence and failure to warn.[233]

[50]   The manufacturers of medical-focused AI technologies and machine learning algorithms may be sued under a products liability theory "if an error involving the technology occurs."[234] Counsel may assert responsibility premised upon the concept that AI caused the injury, and the harm is implicit evidence of a flaw within that technology.[235] After all, AI should have limitations placed on its ability to cause harm, and the manufacturer is best able to undertake the financial responsibility resulting from such

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[229] RESTATEMENT (THIRD) OF TORTS § 2 (AM. L. INST. 1998).

[230] *Id.*

[231] *Id.*

[232] Villasenor, *supra* note 216.

[233] *Id.*

[234] Kamensky, *supra* note 12, at 12.

[235] *Id.*

injury.[236] As noted in *O'Neil v. Crane Co*., "[A] manufacturer is liable in strict liability for the dangerous components of its products, and for dangerous products with which its product will necessarily be used."[237] This risk-shifting responsibility was created to guarantee that the manufacturer that placed the technology into the market assumes the expense of the injuries caused by its defective product instead of leaving the cost to the injured claimant who cannot protect himself.[238]

[51]   As previously noted, applying products liability law to AI in a medical setting is a complex task. A creator of AI technology cannot always predict how the device will perform once it is employed in the field.[239] Therefore, one might argue that it is unjust to assign responsibility to an entity whose efforts were detached from the actual use of the technology.[240] In this regard, the courts are not eager to expand products liability to cover software designers, and they are even more recalcitrant in the framework of health care software.[241] Nevertheless, some scholars assert that products liability law should apply to software-related injuries.[242] In this thought process, the sellers of software would bear liability for all damages caused

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[236] *Id.*

[237] O'Neil v. Crane Co., 266 P.3d 987, 994 (Cal. 2012).

[238] Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 901 (Cal. 1963).

[239] Kamensky, *supra* note 12, at 13.

[240] *Id.*

[241] *Id.*

[242] RANDOLPH A. MILLER & SARAH M. MILLER, CLINICAL DECISION SUPPORT: THE ROAD AHEAD, 425–26 (Robert A. Greenes ed., 2007).

by the product's failure, despite the use of reasonable care when the product was crafted.[243]

[52]   An unanswered question is whether health care facilities using the software should also be strictly liable.[244] In an AI setting, a products liability claim would most likely be premised upon a design defect, as opposed to a manufacturing or warning defects theory.[245] Software is reproduced more effortlessly than tangible goods, making it improbable that the software a buyer obtains would contain features different from the master copy.[246] Therefore, manufacturing deficiency assertions are misplaced.[247] Likewise, issues stemming from the software itself are doubtful to be of the type for which a warning would have permitted the consumer to avoid potential injury. Instead, the calculable harm from the use of the software is usually associated with design defects, such as programming mistakes or inaccuracies that pertain to how the software is generated in the first place and how it operates.[248]

2. Defenses

[53]   There are various defenses a manufacturer or seller of AI medical technology can assert to a products liability claim, such as that the item was not defective when sold or the physician misused it. One such defense is

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[243] *Id.*

[244] *Id.* at 426.

[245] *Id.*

[246] *Id.*

[247] MILLER & MILLER, *supra* note 242, at 426.

[248] *Id.*

that the algorithm was not faulty, but rather if a defect existed in the product, it was introduced after the device or software was released to the buyer.[249] After all, algorithms are not unchanging items—they evolve.[250] The software is created to accommodate additional data after its issuance to enhance its functionality.[251] For instance, a physician might use patient or hospital records to supplement the software's database. Therefore, the seller would not know the specifics of these additional records or how the algorithm developed following its use by the health care facility.[252] Blame may also be cast against the user. For instance, an automobile operator who causes an accident by speeding cannot blame the seller for the incident. Likewise, the user of an AI system who employs it improperly should assume liability for the subsequent harm.[253]

[54]   There is also the issue of whether software can be the focus of a products liability claim. One may argue that software is more comparable to a service instead of a tangible item. This makes it dissimilar to the broad classification of material goods which may generate products liability claims.[254] Instead, they resemble a category that courts have classically found to not be products under a strict liability theory.[255] Alternatively, the

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[249] Villasenor, *supra* note 216.

[250] Saurabh Jha, *Can you sue an algorithm for malpractice? It depends*, STAT (Mar. 9, 2020), https://www.statnews.com/2020/03/09/can-you-sue-artificial-intelligence-algorithm-for-malpractice [https://perma.cc/3QJT-CARY].

[251] Villasenor, *supra* note 216.

[252] *See id.* (claiming that AI companies may argue that the data users add to the AI system may result in unforeseeable and harmful consequences to the algorithm).

[253] *Id.*

[254] Dyson, *supra* note 225.

[255] *Id.*

software is an integral part of tangible goods or sufficiently like a tangible item. In that case, the law of products liability is applicable.[256] Courts differ when interpreting these positions, resulting in unsettled precedent.[257]

[55]   Even if the claimant sued the designer or manufacturer of the AI technology claiming that it qualified as a medical device, the learned intermediary doctrine would be asserted.[258] Under this defense, the physician serves as a "learned intermediary" between the manufacturer and the ultimate user.[259] The seller fulfills its duty to warn by giving adequate notice to the physician.[260] In other words, the doctor must assess the risks and advantages of a device for a specific patient.[261] Courts recognize the doctrine as reasonable because it is impracticable for a manufacturer to warn each patient.[262] Enforcing an obligation on sellers to directly caution patients would intrude on the doctor-patient relationship.[263] Medical software is considered "technology that helps healthcare providers make decisions by providing them with information or analysis."[264] Therefore, the

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[256] *Id.*

[257] *Id.*

[258] Chung & Zink, *supra* note 154, at 71.

[259] Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1190 (D.N.M. 2008).

[260] *Id.* at 1190–91.

[261] Chung & Zink, *supra* note 154, at 71.

[262] *Id.*

[263] *Rimbert*, 577 F. Supp. 2d at 1190–91.

[264] Jorstad, *supra* note 199, at 15 (quoting W. Nicholson Price II).

learned intermediary doctrine places medical assessments squarely within the province of health care providers using the product.[265]

[56]   *Taylor v. Intuitive Surgical, Inc.*, provides an interesting limitation to the learned intermediary doctrine.[266] This matter involved a robotic device that the FDA approved for use in laparoscopic surgeries.[267] The hospital at issue purchased the device for use by its surgeons in performing prostatectomies.[268] The defendant provided a user's manual to any physician using the robot, which noted the device should not be used to perform prostate removal surgery on obese patients or those who had previously undergone an operation involving the lower abdomen.[269]

[57]   Despite these warnings, a surgeon performed a prostatectomy on the plaintiff, who was severely overweight and had a history of prior lower abdominal operations.[270] During the surgery, the plaintiff experienced complications that contributed to his death four years later.[271] Suit was filed by the estate against the manufacturer, hospital, and surgical practice.[272] However, after all other defendants settled their portions of the claim, the suit continued against the only remaining defendant: the manufacturer of

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[265] *Id.*

[266] Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 517 (Wash. 2017).

[267] *Id.* at 520.

[268] *Id.* at 520.

[269] *Id.* at 520–21.

[270] *Id.* at 521.

[271] Taylor, 389 P.3d at 521 ("Roughly four years after the surgery, Taylor passed away.").

[272] *Id.*

the device.[273] The court granted summary judgment in favor of the manufacturer on each of the plaintiff's claims, except for a claim brought pursuant to the Washington product liability act for failure to warn.[274] The jury returned a verdict in favor of the defendant, finding that the manufacturer was "not negligent in providing warnings or instructions" to the doctor who performed the robotic prostatectomy on the plaintiff.[275]

[58]   The Washington Supreme Court reversed this decision and found that the manufacturer had a duty to warn the hospital of the product's dangers when it purchased the unit.[276] That duty was not fulfilled by warning the physicians who use the device.[277] Under the traditional learned intermediary doctrine, the court explained, manufacturers of medical products can fulfill their duty to inform patients of the risks of their products by issuing the appropriate warnings to the physicians who use the device.[278] Thus, the creator's duty to warn a patient is transferred to the physician, who is better suited to warn the patient based upon her knowledge of both the product and patient.[279] However, the court held that the manufacturer also has a separate and independent duty to warn the purchaser of the product's risks.[280] "While a physician is the gatekeeper between the

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[273] *Id.*

[274] *Id.*

[275] *Id.* at 521–22.

[276] *Taylor*, 389 P.3d at 522, 530.

[277] *Id.* at 522.

[278] *Id.* at 524.

[279] *See id.* at 524–25 (quoting Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978)).

[280] *Id.* at 524.

manufacturer and the unwarned patient, a physician is not a gatekeeper between the manufacturer and the unwarned *hospital*."[281] Therefore, hospitals have a separate obligation to make sure a device is safe to use.[282] Doctors do not serve as intermediaries to caution the hospital of the risk of the device, so nothing about the learned intermediary doctrine is applicable when a manufacturer fails to warn a hospital of its product's risks.[283]

[59]   Another defense asserted by manufacturers or sellers is that the software is not within the ambit of a products liability claim.[284] By definition, products liability claims are only appropriate where the item is a "product" and not a service.[285] Whether the software is a product is a disputed question.[286] Most courts have determined that software is not a "product" under the law of strict liability.[287] The Restatement (Third) Torts defines the term as "tangible personal property distributed commercially for

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[281] *Taylor*, 389 P.3d at 525 (quoting Taylor v. Intuitive Surgical, Inc., 355 P.3d 309, 318 (Wash. Ct. App. 2015) (Worswick, J., dissenting in part)).

[282] *Id.* at 525.

[283] *Id.*

[284] Chung & Zink, *supra* note 154, at 71.

[285] *Id.*

[286] David Polin, *Proof of Manufacturer's Liability for Defective Software,* 68 AM. JURIS. PROOF FACTS 3d 333, 347 (2002).

[287] Kenneth Ross, *Technology Developments and the Risk of Product Liability*, IN COMPLIANCE (Oct. 31, 2019), https://incompliancemag.com/article/technology-developments-and-the-risk-of-product-liability/ [https://perma.cc/FCW9-9G55].

use or consumption."[288] The Uniform Computer Information Transactions Act also notes that software is not a product.[289]

[60]   A different barrier to the applicability of products liability law is the commonly shared perception that it is almost impossible to ensure that software is error-free.[290] Strict liability was initially considered as liability without fault.[291] However, in application, it has assimilated many of the principles of negligence.[292] Therefore, even when confronted with a product's defect, courts are reluctant to find responsibility where the product could not be made flawlessly.[293]

[61]   An important case in which the court considered whether software is a product is *Rodgers v. Christie.*[294] In this case, the Third Circuit Court of Appeals determined that an algorithm is not a product for purposes of products liability.[295] This case adds another possible option for a party when defending itself against a claim involving defective AI technology. The matter involved a man murdered by an individual who had been granted pretrial release by a New Jersey state court days before the homicide.[296] A

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[288] RESTATEMENT (THIRD) TORTS: PRODUCTS LIABILITY § 19(a) (AM. L. INST. 1998).

[289] Polin, *supra* note 286.

[290] *Id.*

[291] *Id.*

[292] *Id.*

[293] *Id.*

[294] Rodgers v. Christie, 795 F. App'x 878, 878–79 (3rd Cir. 2020).

[295] *Id.* at 879.

[296] *Id.* at 878.

strict liability claim was advanced against the entity in charge of the Public Safety Assessment (PSA), a multifactor risk evaluation model that was part of the state's pretrial release program.[297] The trial court dismissed the lawsuit, determining that the PSA was not a "product" under New Jersey's law.[298] This ruling was upheld on appeal.[299] The court found that the multifactor risk assessment model did not fit within the definition of a product for two reasons. First, the system was not disseminated commercially.[300] Instead, it was created to be employed by pretrial services programs.[301] More importantly, the PSA was neither "tangible personal property" nor tenuously "analogous to" it.[302] Instead, it is an "algorithm" or "formula" that assesses various elements to predict a defendant's risk of fleeing or jeopardizing the community.[303] As the lower court documented, "information, guidance, ideas, and recommendations" do not fall within the definition of a product under the Third Restatement.[304] The court justified this ruling as a definitional issue, and remained cautious not to implicate First Amendment concerns by widening strict liability to the spreading of ideas.[305]

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[297] *Id.* at 878–79.

[298] *Id.* at 879.

[299] *Rodgers*, 795 F. App'x at 879.

[300] *Id.*

[301] *Id.*

[302] *Id.* at 880.

[303] *Id.*

[304] *Rodgers*, 795 F. App'x at 880.

[305] *Id.*

B. Medical Malpractice and Artificial Intelligence

[62]   Medical malpractice is "any act or omission by a physician during treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury to the patient."[306] This cause of action is a subcategory of tort law that applies to professional negligence.[307] Negligence is a legal term of art that describes any action that falls below the standard of a "reasonable person" in the same circumstances.[308] A reasonable person is a fiction crafted so that the legal system can have a standard of conduct by which to determine what an individual in a like position would do, or not do, to safeguard others from a foreseeable risk of harm.[309] In the medical malpractice context, this standard means that the injured patient must show that the health care provider acted negligently in providing care and that such negligence caused an injury.[310] Four elements must be proven to show negligence: (1) a professional duty owed to the patient; (2) breach of such duty; (3) the injury was the proximate cause of the harm; and (4) damages arose from that conduct.[311] Monetary compensation will consist of economic and noneconomic losses, such as pain and suffering.[312]

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[306] B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPAEDIC & RELATED RSCH. 339, 340 (2009).

[307] *Id.*

[308] *Id.*

[309] *Id.*

[310] *Id.*

[311] Bal, *supra* note 306 at 339.

[312] *Id.*

[63]   An important issue that arises when tort law is applied to AI is the issue of who controls the application and how the technology is created.[313] These considerations may affect liability throughout a wide range of different entities and impact the success and appropriate operation of implemented AI systems.[314] However, in the framework of "black-box AI,"[315] the advice or impression given by the AI system may not have been foreseeable by the user or manufacturer.[316] Given this lack of foreseeability, it is unclear whether the user or manufacturer can be liable for the advice or impression.[317]

[64]   Applying tort law to AI is also tricky because "[c]ourts have traditionally deemed it impossible for machines to have legal liability as they are not persons."[318] Possible defendants in a medical malpractice context include the hospital, physician, AI developer, and manufacturer. However, assigning responsibility among these entities may be difficult.[319] Perhaps AI should only be viewed as a device to make the physician more

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[313] Schweikart, *supra* note 208, at 4.

[314] *Id.* at 8.

[315] Ivy Wigmore, *black box AI*, WHATIS.COM (Aug. 2019), https://whatis.techtarget.com/definition/black-box-AI [https://perma.cc/S6M6-AKZ9] ("Black-box AI is any artificial intelligence system whose inputs and operations are not visible to the user or another interested party.").

[316] *Id.*

[317] Schweikart, *supra* note 208, at 12.

[318] *Id.* at 11 (quoting Jason Chung and Amanda Zink).

[319] *Id.*

proficient.[320] That way, doctors retain the primary duty of ensuring that their patients are properly treated and managed. Doctors should not be released from this liability by using artificial intelligence to help with their tasks.[321]

[65]   According to a study of potential jurors, health care providers remain liable for medical malpractice, but those who follow the advice presented by AI may be found less liable than one might assume.[322] Research revealed that those surveyed used two different components to judge a doctor's use of medical AI systems: (1) whether the care rendered was standard, and (2) whether the doctor followed the recommendations made by AI.[323] Those surveyed viewed physicians who accepted a standard AI suggestion more positively than those who disregarded it.[324] However, if a doctor received non-standard AI advice, the health care professional was not judged "safer from liability by rejecting it."[325]

[66]   A fundamental challenge involving AI is establishing liability when an error and injury happens from a malpractice viewpoint. For instance,

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[320] ESBO LTD, *Medical Malpractice And Artificial Intelligence: Can You Sue An AI For Malpractice?*, MEDGADGET (June 16, 2020), https://www.medgadget.com/2020/06/bmedical-malpractice-and-artificial-intelligence-can-you-sue-an-ai-for-malpractice.html [https://perma.cc/XHR2-4QWE].

[321] *Id.*

[322] *Study offers data related to physicians' potential liability to use AI in personalized medicine*, NEWS MED. LIFE SCI. (Jan. 11, 2021), https://www.news-medical.net/news/20210111/Study-offers-data-related-to-physicians-potential-liability-to-use-AI-in-personalized-medicine.aspx [https://perma.cc/BX9F-WF73].

[323] *Id.*

[324] *Id.*

[325] *Id.*

what occurs when the AI software recommends one course of action, but the doctor considers another avenue more beneficial based upon personal experience?[326] What is the outcome when the software suggests a course of treatment which the physician follows, but the treatment plan is wrong, and the patient is harmed? These are complex issues because it is often problematic to ascertain how the AI made its decision.[327]

[67]   The standard of care for most doctors is that of a reasonably competent physician.[328] In other words, the doctor must use a reasonable degree of care and skill.[329] In matters where a physician should have used new technology—such as artificial intelligence—complicated issues arise, including whether the use of the new technology or the failure to use it qualifies as negligence.[330] Use of a novel system may also generate claims that the physician who used the technology was not yet sufficiently familiar with its nuances, leading to misuse.[331] The courts understand that technology changes and the general standard of care for professions and trades may also change.[332]

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[326] Schweikart, *supra* note 208, at 4.

[327] *Id.* at 4–5.

[328] *Id*. at 13.

[329] *Id.*

[330] A. Michael Froomkin et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning*, 61 ARIZ. L. REV. 33, 51 (2019).

[331] *Id.*

[332] *Id.*

[68]   Another consideration pertinent to ascertaining reasonable care is the special knowledge or skills a defendant possesses.[333] As noted in the Restatement (Second) of Torts:

> The standard of the reasonable man requires only a minimum of attention, perception, memory, knowledge, intelligence, and judgement in order to recognize the existence of the risk. If the actor has in fact more than the minimum of these qualities, he is required to exercise the superior qualities that he has in a manner reasonable under the circumstances. The standard becomes, in other words, that of a reasonable man with such superior attributes.[334]

This duty of care requires those with special training and experience to be held to a standard of conduct corresponding to those qualities.[335] It is this concept of unique learning and skill which gives life to the law of professional negligence.[336]

[69]   AI may change the applicable standard of care concerning a treating physician. AI-based systems can access and possess a vast amount of medical information, including evidence-based practice guidelines.[337] Physicians who use AI software may be held to a higher standard of care than those who do not because of the availability of additional data.[338] These

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[333] WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 161–66 (4th ed. 1971).

[334] RESTATEMENT (SECOND) OF TORTS § 289 cmt. m (AM. L. INST. 1965).

[335] *Id.*

[336] Morrison v. MacNamara, 407 A.2d. 555, 560 (D.C. 1979).

[337] Allain, *supra* note 74, at 1064.

[338] *Id.*

software systems could cause the courts to rely more heavily on national standards, evidence-based treatment standards, and advanced medicine to impose an elevated standard of care.[339] Courts are also unwilling to dismiss a malpractice claim because of a manufacturer or system technician's error.[340]

[70]   On the other hand, a health care provider who, in good faith, relies on an artificial intelligence system to formulate a treatment recommendation may still face responsibility if the measures the doctor used fell below the standard of care.[341] Physicians have an independent duty to utilize the proper standard of care, irrespective of the AI algorithm output.[342] For example, courts have permitted malpractice claims to proceed against physicians who provided literature containing errors to patients[343] or when a doctor acted in reliance on an intake form that failed to contain a complete history of illness.[344] Most courts have also been reluctant to use medical guidelines as unambiguous evidence of the duty of care and have demanded a more customized determination in such matters.[345] This duty of care issue has caused one physician to exclaim that existing malpractice

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[339] *Id.*

[340] Schweikart, *supra* note 208, at 12–14.

[341] Maliha et al., *supra* note 50.

[342] *Id.*

[343] *See* Smith v. Linn, 563 A.2d 123 (Pa. Super. Ct. 1989) ("[N]o appellate court in any jurisdiction has held a book to be a product for purposes of section 402A; in fact, two courts have expressly refused to hold that a publication is a product.").

[344] Maliha et al., *supra* note 50.

[345] *Id.*

law "incentivizes physicians to minimize the potential value of AI."[346] He went on to note that the best method for doctors to use AI systems to avoid litigation is as a "confirmatory tool to support existing decision-making processes, rather than as a source of ways to improve care."[347]

C. Direct Liability

[71]   Hospitals can be found responsible through direct negligence.[348] It is foreseeable that institutions providing medical care may be exposed to greater liability because of AI-enabled systems.[349] Most physicians working in a hospital, regardless of their status, will not have the financial resources to purchase these systems.[350] Instead, the medical facility will purchase, install, teach, and operate the AI system that the physician utilizes, thereby exposing the hospital to liability when something goes wrong.[351] For example, a medical facility will be responsible for its negligence in not correctly caring for or servicing an AI device.[352] In *Payas v. Adventist Health System/Sunbelt, Inc.*, the court found that a hospital may be liable

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[346] Griffin, *supra* note 54, at 99 (quoting W. Nicholson Price II).

[347] *Id.*

[348] *See* Barkes v. Richer Park Hosp., Inc., 328 S.W.3d 829, 835 (Tenn. 2010) (noting that a patient may have a negligence action "against hospitals that have failed to exercise reasonable care in discharging duties owed directly to patients").

[349] Marchant & Tournas, *supra* note 158, at 37.

[350] *Id.*

[351] *Id.*

[352] Griffin, *supra* note 54, at 102.

for its "failure to properly maintain and operate the surgical robot and to properly train its staff on the proper use of the surgical robot."[353]

[72]   An issue that the courts have not yet addressed is whether the facility must independently assess the quality of the artificial intelligence processes and machine learning algorithms before doctors use them in treating their patients.[354] Some legal scholars have opined that liability may attach for not sufficiently vetting machine learning of AI before its clinical implementation.[355] This result would not be surprising because hospitals already owe a duty to provide safe equipment and facilities.[356] Likewise, a hospital will have liability in allowing an improperly trained physician to use an AI system.[357] As the court noted in *Aldoroty v. HCA Health Services of Kansas, Inc.*, "[u]nder the corporate negligence theory, a hospital has an independent duty to its patients to ensure their health by not entrusting the work of health care to an independent contractor/physician who is not competent and careful."[358]

D. Vicarious Liability

[73]   A medical facility may also be held "vicariously" liable for the negligent conduct of an employee or affiliate. [359] Vicarious

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[353] Payas v. Adventist Health Sys./Sunbelt, Inc., 238 So. 3d 887, 893 (Fla. Dist. Ct. App. 2018).

[354] Kamensky, *supra* note 12, at 11.

[355] *Id.*

[356] Maliha et. al., *supra* note 50, at 632.

[357] *Id.*

[358] Aldoroty v. HCA Health Servs. Kan., Inc., 962 P.2d 501, 511 (Kan. 1998).

[359] Griffin, *supra* note 54, at 103.

liability means an entity is responsible for the negligence of another.[360] When a hospital's employee commits malpractice and harms a patient, the hospital may be held responsible under the doctrine of "respondeat superior."[361] Under this theory, an employer may be held liable for the negligent acts of its employee, as long as the worker was acting within the scope of the employment when the negligent act was committed.[362] This form of liability is important because it helps guarantee there will be a financially responsible entity to compensate an injured claimant.[363]

[74]   Courts have liberally applied vicarious liability to find an employer liable even when the worker is not a direct employee.[364] For example, one court applied the concepts of apparent or ostensible authority to find liability against a hospital even when the physician was an independent contractor.[365] Apparent authority occurs as the result of a principal representing, through expression or action, to a third party that another is her agent.[366] This display may be made directly to the third person or to the

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[360] *Medical Malpractice: Who Can Be Sued?* FINDLAW (Oct. 2, 2019), https://www.findlaw.com/injury/medical-malpractice/medical-malpractice-who-can-be-sued-.html [https://perma.cc/WS2Y-8DYK].

[361] *Id.*

[362] *Id.*

[363] *Id.*

[364] Maliha et. al., *supra* note 50, at 633.

[365] Adam Alstott, *Hospital Liability for Negligence of Independent Contractor Physicians Under Principles of Apparent Agency*, 25 J. LEG. MED. 485, 490 (2004) (discussing the Texas Supreme Court's holding in Baptist Mem. Hosp. Sys. v. Sampson, 969 S.W.2d 945, 948 (Tex. 1998)).

[366] *Id.* at 487–88.

community by signs or advertising.[367] However, apparent authority can only be established to the extent that it is reasonable for the third party to think the agent is empowered to act. [368] As the court stated, ostensible agency is premised upon Section 429 of the Restatement (Second) of Torts, which notes:

> One who employs an independent contractor to perform services for another which are accepted in the reasonable belief that the services are being rendered by the employer or by his servants, is subject to liability for physical harm caused by the negligence of the contractor in supplying such services, to the same extent as though the employer were supplying them himself or by his servants.[369]

[75]   For example, suppose a hospital hires outside contractors to staff its emergency room and a patient is brought to the emergency room in critical condition. The physician utilizes an AI program to make a diagnosis but enters incorrect data, causing the patient to suffer an adverse consequence. Despite the physician's status as an independent contractor, the hospital may be liable for the physician's actions. Where a medical facility holds itself out as offering a service, it has a contract with a physician to provide that service, and the patient uses the facility without regard to the identity of a specific doctor—depending upon the hospital to deliver the appropriate

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[367] *Ostensible Agency (Apparent Agency) in Medical Malpractice*, MAPLES, NIX & DIESSELHORST (Apr. 2, 2013), https://www.oklahomainjurylaw.com/blog/2013/04/ostensible-agency-apparent-agency-in-medical-malpractice/ [https://perma.cc/SC8J-NG2X].

[368] *Id.*; *see also* Jansen v. Packaging Corp. Am., 123 F.3d 490, 500 (7th Cir. 1997).

[369] Green v. Pa. Hosp., 123 A.3d 310, 317 (Pa. 2015) (quoting RESTATEMENT (SECOND) OF TORTS § 429 (AM. L. INST. 1965).

treatment—the law of respondeat superior is applicable.[370] Therefore, the hospital is vicariously responsible for harm resulting from the negligence of that physician.[371]

[76]   Separately, respondeat superior requires determining whether an AI system or algorithm itself can be an agent or employee of the medical facility to impute responsibility to the principal.[372] This is a difficult question to answer because respondeat superior is premised upon an agency theory that the hospital has some control or power over the agent.[373] The problem is that AI usually functions autonomously.[374] If a judicial determination is made that AI is completely autonomous, then finding a medical facility vicariously liable for the harm resulting from the employment of AI will be difficult because the autonomous artificial intelligence or algorithm is functionally independent of the principal's control.[375]

E. Informed Consent

[77]   Several questions arise involving informed consent and artificial intelligence. First, does the informed consent law require physicians to inform their patients that AI or machine learning will be employed to assist in treatment decisions? Second, assuming that such disclosure is necessary,

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[370] *Id.* at 321.

[371] *Id.*

[372] Schweikart, *supra* note 208, at 16.

[373] *Id.*

[374] *Id.*

[375] *Id.*

how much specificity must the doctor provide about the recommendations made by the technology and the system itself?[376] Informed consent is based upon the belief that the patient's right of self-decision is premised upon the duty to reveal.[377] That right can be adequately exercised only if the patient acquires enough information to make an intelligent choice.[378] Therefore, the test for ascertaining whether a specific danger must be disclosed is the danger's materiality to the patient's choice: all risks that could potentially influence the patient's decision must be disclosed.[379] To protect the patient's interest in making her own treatment decision, the law must establish the benchmark for proper disclosure.[380] These considerations inspired the American Medical Association to recognize informed consent as "a basic social policy" necessary to permit patients to make their own decisions even if the doctor disagrees with that process.[381]

[78]   The test for determining whether there is a need to disclose that AI was used in forming a diagnosis is "what a reasonable patient would find material."[382] However, there is no clear answer to this determination. One

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[376] I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, 108 GEO. L.J. 1425, 1441 (2020).

[377] Samuel D. Hodge & Maria Zambrano Steinhaus, *The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated*, 71 ARK. L. REV. 727, 731 (2019).

[378] Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir. 1972).

[379] Hodge & Steinhaus, *supra* note 377.

[380] *Id.*

[381] TOM L. BEAUCHAMP & RUTH R. FADEN, A HISTORY AND THEORY OF INFORMED CONSENT 96 (1986).

[382] Cohen, *supra* note 376, at 1443.

possibility is to treat AI or the algorithm as another "member of the care team."[383] In that case, the physician may be required to provide the patient with information about *the technology's* expertise.[384] This disclosure could include a discussion about whether the FDA or another regulator reviewed the algorithm or AI about false positives and negatives.[385] Physicians could even be mandated to describe how they use a given AI-based system and how much they do or do not comprehend the system's results given limited understanding of how it reaches those results.[386] Because of uncertainty on disclosure, physicians may wish to err on the side of caution by discussing the use of AI in the decision making process and by obtaining the patient's consent to use AI. After all, the patient should retain the power to accept or reject a treatment plan suggested in whole or in part by an algorithm or AI system. This would provide the patient with the option of seeking a second opinion or a different physician.[387]

[79]   Courts may analogize an AI system to a consulting physician. In that event, a patient would have to be informed that the doctor is using artificial intelligence to render an opinion.[388] While the physician bears the responsibility of directing the medical care, informed consent may mandate that a patient be fully informed of the conclusions reached by the AI, including the choices the doctor did not select to pursue.[389] This discussion

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[383] *Id.* at 1447.

[384] *Id.*

[385] *Id.*

[386] *Id.*

[387] Cohen, *supra* note 376, at 1462.

[388] Allain, *supra* note 74, at 1063.

[389] *Id.* at 1063–64.

could result in additional disagreements between the patient and physician over the best treatment plan.[390]

F. Breach of Warranty

[80]   An aggrieved party may argue that artificial intelligence gives rise to a breach of warranty. These types of claims are usually regulated by statute and consist of an express warranty, the implied warranty of merchantability, and the implied warranty of fitness for a particular purpose.[391] If the plaintiff can overcome the initial hurdle of proving that the technology is a product and not a service, the claimant must then demonstrate that (1) the product was purchased from the defendant; (2) the seller provided an express warranty, or one was implied by operation of law; (3) the seller breached the warranty because the item did not perform as warranted; and (4) the plaintiff was injured.[392] It is unlikely for a patient to succeed on a breach of warranty in a medical device setting because it is typically the medical provider, and not the patient, that purchased the system. However, as AI systems become more commonplace in society, these devices may be marketed openly to consumers and utilized in at-home settings.[393] This idea is not farfetched. Currently, examples of home medical devices include glucose meters, ventilators, infusion pumps, sleep

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[390] *Id.* at 1064.

[391] Joe Fornadel & Wes Moran, *Predicting Liability Risks Based on the Existing Regulatory and Legal Framework*, FOR DEF., Sept. 2020, at 48, 51.

[392] *Id.* at 52.

[393] *Id.*

apnea machines, and home dialysis equipment.[394]

[81]   Robotic surgery provides an example of the creation of a warranty. Hospitals usually consider robotic surgeries superior to traditional operations and advertise the availability of robotic surgery to patients at their institutions.[395] This "perceived superiority" causes patients to select robotic surgeries over traditional procedures.[396] Indeed, patients tend to believe that robotic surgery is safer and results in fewer complications.[397] A warranty may arise by an affirmation of fact or a promise made by a seller which relates to the product.[398] The language forming a warranty does not need to contain special phrases or formal terms such as 'guarantee' or 'warranty.'[399]   In   fact,   an   advertisement   may create an express warranty in certain situations.[400] The hospital's promotion of an AI system as a superior product may create a cause of action for breach of warranty.[401] For instance, in *Darringer v. Intuitive Surgical, Inc.*, the plaintiff suffered complications after undergoing surgery using a Da Vinci

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[394] *Home Medical Devices Market: Growing Demand for Homecare Medical Devices due to Increasing Geriatric Population*, BIOSPACE (June 3, 2021), https://www.biospace.com/article/home-medical-devices-market-growing-demand-for-homecare-medical-devices-due-to-increasing-geriatric-population/ [https://perma.cc/QEN5-88AB].

[395] Rebotix Repair LLC v. Intuitive Surgical, No. 8:20-cv-2274-VMC-TGW, 2021 U.S. Dist. LEXIS 67039, at *1, *4 (M.D. Fla. Mar. 8, 2021).

[396] *Id.*

[397] *Id.* at *16–17.

[398] *See* U.C.C. § 2-313 (AM. L. INST. & UNIF. L. COMM'N 2002).

[399] Overstreet v. Norden Lab'ys, Inc., 669 F.2d 1286, 1290 (6th Cir. 1982).

[400] *Id.* at 1291.

[401] *Id.* at 1288.

Robot.[402] The manufacturer of the system promoted the device to hospitals and more generally on websites, asserting that it was safe and better than other surgical approaches.[403] The plaintiff was to have a laparoscopic procedure to repair a kidney.[404] The surgeon gave him information and materials promoting the employment of the Da Vinci Robot prepared by the unit's manufacturer.[405] The patient's doctor informed him that by selecting the Da Vinci Robot, he would heal faster, have an improved outcome, and endure less pain.[406] A lawsuit was filed because of complications stemming from the surgery, and it was asserted that the manufacturer's advertising and promotional information "did not accurately reflect the serious and potentially fatal side effects" of the artificial intelligence.[407]

VII. CONCLUSION

[82]   AI has been labeled the "fourth industrial revolution" with transformative worldwide implications.[408] Stripped of its scientific-fictional façade, AI is merely a subdivision of computer science that tries to comprehend and create intelligent entities, generally represented as

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[402] Darringer v. Intuitive Surgical, Inc., No. 5:15-cv-00300-RMW, 2015 U.S. Dist. LEXIS 101230, at *1, *3 (N.D. Cal. Aug. 3, 2015).

[403] *Id.* at *1–*2.

[404] *Id.* at *2

[405] *Id.*

[406] *See id.*; Griffin, *supra* note 54, at 103.

[407] *Darringer*, 2015 U.S. Dist. LEXIS 101230, at *3 (With robotic surgery, the physician still operates the computer assisted system).

[408] Murphy et al., *supra* note 22.

software programs.[409] The technology has undoubtedly fostered significant advancements in medicine.[410] Healthcare providers will not be digitally displaced, but AI will gradually replace the day-to-day weariness, lethargy, and delay of reviewing patient charts.[411] It will also allow physicians to concentrate on the complicated, challenging matters, rather than dull administrative tasks.[412]

[83]   The use of AI in medicine will inexorably generate risk since evidently not all results are foreseeable.[413] At present, there is little precedent on how the tort system will react to these quickly changing medical technologies and standards of care.[414] The situation is further exacerbated because the technology and usages are still developing.[415] These advancements mean that health care providers will be unable to depend on "accepted medical practice," but will be required to repeatedly research and follow the most recent developments to ascertain the best practices and safest treatment plan.[416] A diagnosis based on AI may lead to a host of complications that will prove challenging to address through present concepts of responsibility.[417]

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[409] Yu et al., *supra* note 24, at 719.

[410] *Id.*

[411] *See* Reiner & Krupinski, *supra* note 10.

[412] *See* Kamensky, *supra* note 12, at 4.

[413] *Id.* at 1.

[414] Marchant & Tournas, *supra* note 158, at 26.

[415] Kamensky, *supra* note 12, at 1–2.

[416] Marchant & Tournas, *supra* note 158, at 35.

[417] *Id.* at 23.

[84]   Issues of liability likewise obscure malpractice standards.[418] It is possible to classify liability based on three categories in which the law interacts with AI and machine learning. The first is AI as a medical device. This approach would subject AI-based technologies to the same sorts of products liability claims to which other medical devices are exposed. The second is AI as information. In this classification, the courts would view AI-based technologies purely as information. Liability would rest entirely with the physician who chooses to rely or not rely on the technology. For example, if a doctor proceeds based on incorrect information from a book, the patient cannot successfully sue the author of the text. Similarly, if a physician acts on incorrect information provided by AI, the patient should not be able to sue the programmer. Finally, AI may be viewed as an artificial person. Here, AI-based technologies would be employees or independent contractors of the owning physician or medical facility, and their masters could be vicariously liable for their torts.

[85]   Nevertheless, judicial resolution is wanting with so much uncertainty surrounding the liability questions.[419] It is also hard to determine breaches of the duty of care given untested AI software.[420] Current legal principles consider some of these issues, but not to the extent needed for the courts to have clear criteria for assessing liability and apportioning blame.[421] Whether the theories of liability and standards of care will follow traditional theories of responsibility remains to be seen. It will take years before the legal landscape is settled, and even then, jurisdictions will differ in how they apply the law.

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[418] *Id.* at 25.

[419] *See id.* at 35–36.

[420] *See id.* at 38–40.

[421] Marchant & Tournas, *supra* note 158, at 36–37.