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Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications

*Sarah Kamensky**

I. Introduction

The chief concerns in the health care system in the United States today are cost, quality, and access to care.¹ In an effort to improve our health care system, innovators have begun to develop technology and artificial intelligence to aid in reaching these goals.² In a health care setting, artificial intelligence can be used to improve the efficiency and quality of patient care, as well as advancing medical research.³ Today, approximately 86% of health care providers utilize at least one form of artificial intelligence in their practices. However, under traditional tort liability it remains unclear as to the possible legal implications and liability in the event of medical error involving artificial intelligence technology.⁴ The use of artificial intelligence technology in a medical setting will inevitably create risks since not all of the possible consequences of the use of the new technology are foreseeable.⁵ There is currently limited information as to legal implications for tort liability for error involving artificial intelligence in medical settings since both the

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¹ Concerns over improving the cost, quality, access, and choice of care are increasingly reflected in today's health care systems in the United States. Ongoing attempts to reform health care systems have focused on these concepts, while transforming health care delivery and payment systems with the aim of meeting these goals. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS, AND PROBLEMS* 1 (W. Acad. Publ'g, 8th ed. 2018); *see also How AI-based Systems Can Improve Medical Outcomes*, KNOWLEDGE@WHARTON (Dec. 12, 2018), <http://knowledge.wharton.upenn.edu/article/ai-based-systems-can-improve-medical-outcomes/>.

² Hannah R. Sullivan & Scott J. Schweikart, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?*, 21 *AMA J. ETHICS* 160, 160 (2019).

³ W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, 14 *SciTECHLAW* 10, 10 (2017).

⁴ Sullivan & Schweikart, *supra* note 2, at 160, 162, 164.

⁵ Chris Reed, *How Should we Regulate Artificial Intelligence?*, *ROYAL SOC'Y PUBL'G*, Apr. 29, 2018, at 1 <https://royalsocietypublishing.org/doi/pdf/10.1098/rsta.2017.0360>.

technology and usage are still developing themselves; however, traditional tort liability laws may be applicable.⁶

II. Overview

Today, highly intelligent machines and sophisticated robots are performing complex tasks that were once thought to only be within the exclusive ability of humans.⁷ This partnership of humans with technology is being realized in many tangible ways and is evident in health care settings today through the use of artificial intelligence technology in providing patient care.⁸ In general, artificial intelligence uses technology, along with programmed computer systems, to accomplish specific tasks by processing large amounts of data and recognizing patterns within the data.⁹ This form of technology makes it possible for machines to “learn from experience” so that they can perform human-like tasks.¹⁰ In a health care setting, artificial intelligence refers to the use of artificial intelligence technology and automated processes to diagnose and treat patients who require care.¹¹ Artificial intelligence relies on the power of predictive algorithms, which guide health care professionals in their practice of medicine.¹²

The mechanisms that give rise to the recommendations made by the predictive algorithms are currently undiscoverable and unknown due to the way that the algorithms calculate their

⁶ Sullivan & Schweikart, *supra* note 2, at 160 (explaining that given the limited information regarding tort liability involving artificial intelligence in medicine, traditional tort liability laws may be applicable. “Liability for medical errors falls under tort law. A tort is a civil claim in which a party requests damages for injuries caused by a harmful, wrongful act of another. Typical tort claims in the realm of medicine and health include medical malpractice (negligence), *respondeat superior* (vicarious liability), and products liability.”).

⁷ David C. Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence*, 89 WASH. L. REV. 117, 120 (2014).

⁸ *Id.* at 118.

⁹ Jim Goodnight, *Artificial Intelligence: What it is and why it matters*, SAS, https://www.sas.com/en_us/insights/analytics/what-is-artificial-intelligence.html (last visited Mar. 8, 2020).

¹⁰ *Id.*

¹¹ *Artificial Intelligence in Medicine*, MENDELEY (July 2, 2018), <https://www.mendeley.com/careers/article/artificial-intelligence-in-medicine/>.

¹² Sullivan & Schweikart, *supra* note 2, at 160.

“reasoning”.¹³ This is often referred to as “black-box” artificial intelligence.¹⁴ The “neural networks” behind the algorithms in black-box artificial intelligence are structured based on the human brain, so that the neural networks can self-teach, make decisions, and provide accurate responses.¹⁵ Despite the ability of this technology to provide accurate responses, and aid in improving the cost, access, and quality of patient care, the algorithms by which the technology operates have the potential to “become less intelligible to users and even the developers who originally programmed the technology.”¹⁶ This means that the artificial intelligence technology will not be able to demonstrate how it formed its conclusions.¹⁷ This can become problematic in a medical setting since artificial intelligence cannot explain its decision-making process in the same way that a physician or health care provider would.¹⁸ Even if the algorithm can give some explanation as to how the technology came to its conclusion, it will likely not have a useful meaning in medical terms.¹⁹ Additionally, the algorithms will become even more complex when more data is made available, which refines future predictions made by the algorithms, but also causes the algorithms to change over time.²⁰

¹³ *Id.*

¹⁴ *Id.*; see also W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 421 (2015).

¹⁵ Sullivan & Schweikart, *supra* note 2, at 160.

¹⁶ *Id.* at 160–61; see also Shailin Thomas, *Artificial Intelligence and Medical Liability (Part II)*, BILL HEALTH (Feb. 10, 2017), <http://blog.petrieflom.law.harvard.edu/2017/02/10/artificial-intelligence-and-medical-liability-part-ii/>.

¹⁷ Price, *supra* note 3.

¹⁸ *Id.* at 11.

¹⁹ *Id.* at 10 (explaining that either algorithms cannot explain their outcomes at all, or accurate explanations can be provided that will be useless in medical understanding. This field is referred to as “black-box medicine,” although it has also been referred to as “predictive analytics” or “AI in medicine” due to the inherent opacity of the technology. The inherent opacity of the algorithms may or may not be “augmented with deliberate secrecy” based on how the algorithms were developed and validated).

²⁰ *Id.*

III. Artificial Intelligence and Black-Box Medicine

Artificial intelligence technology in the form of “black-box” medicine is already being utilized in health care systems in many capacities, and has the potential to provide substantial benefits to patients.²¹ These automated processes not only aid in the diagnosis and treatment of patients, but also are gaining importance in the background processes that must take place in order for a patient to be properly treated.²² Arguments have been made that the use of these forms of technology allow tasks to be completed more quickly, while also allowing health care providers to treat patients more efficiently.²³

Artificial intelligence is currently being used to process and analyze patients’ test results, gather data through patient interviews, use data to determine appropriate diagnoses, and to present options for treatment methods while also monitoring patients after suitable treatments have been administered.²⁴ For example, a “decision support system” developed at the Laboratory of Computer Science at the Massachusetts General Hospital, DXplain, offers the health care provider a list of possible diagnoses after the symptoms are input in DXplain’s computer system.²⁵ DXplain

²¹ *Id.*; see also Price, *supra* note 14, at 421 (“Black box medicine, pursued by geneticists, personalized medicine advocates, and other health care innovators, already does and increasingly will use the combination of largescale high-quality datasets with sophisticated predictive algorithms to identify and use implicit, complex connections between multiple patient characteristics. A defining feature of black box medicine is that those algorithms are nontransparent — that is, the relationships they capture cannot be explicitly understood, and sometimes cannot even be explicitly stated. Note that this type of medicine is ‘black box’ to everyone by nature of its development; it is not ‘black box’ because its workings are deliberately hidden from view.”).

²² MENDELEY, *supra* note 11.

²³ *Id.* (“The potential for increased AI usage in medicine is not just in a reduction of manual tasks and the freeing up of physician’s time, increasing efficiency and productivity — it also presents the opportunity for us to move towards more ‘precision medicine.’”).

²⁴ *Id.*; see also Shailin Thomas, *Artificial Intelligence, Medical Malpractice, and the End of Defensive Medicine*, BILL HEALTH (Jan. 26, 2017), <http://blog.petrieflom.law.harvard.edu/2017/01/26/artificial-intelligence-medical-malpractice-and-the-end-of-defensive-medicine/>.

²⁵ *DXplain: Using Decision Support to Help Explain Clinical Manifestations of Disease*, MASS. GEN. HOSP. LAB. FOR COMPUT. SCI., <http://www.mghlcs.org/projects/dxplain/> (last updated 2017) (“The current DXplain knowledge base includes over 2400 diseases and over 5000 clinical findings (symptoms, signs, epidemiologic data and laboratory, endoscopic and radiologic findings). The average disease description includes 53 findings, with a range from 10 to over 100. Each disease/finding pair has two attributes describing the relationship: one representing the frequency with which the finding occurs in the disease and the other the degree to which the presence of the finding suggests consideration of the disease. There are over 230,000 individual data points in the knowledge base

uses appropriate data to determine diagnoses by using its knowledge base of diseases and clinical findings.²⁶ This is an example of “machine learning techniques”, a subset of artificial intelligence, that uses basic learning rules to find patterns in vast amounts of data.²⁷

With the rise of vast quantities of data combined with the need to have fast access to the data, medicine is now experiencing a need for technology and artificial intelligence containing machine learning techniques in order to reach the above mentioned goals of improving the cost, access, and quality of medical care.²⁸ DXplain is just one example of a machine learning technique currently used in medicine.²⁹ A laboratory information system, Germwatcher, is another machine learning technique currently used in medicine to “detect, track, and investigate infections in hospitalized patients.”³⁰

In addition to machine learning techniques, artificial intelligence is currently being used in medicine in other forms such as robotic systems.³¹ One of the more common robotic systems currently used in medicine is the da Vinci robotic surgical system.³² The robotic arms of the surgical system allow surgeons to perform precise movements that would not be possible with an entirely manual approach, thus allowing the quality of care in certain types of surgeries to be improved by utilizing the da Vinci robotic surgical system.³³

representing disease/finding relationships. In addition, each finding has an associated disease-independent term importance indicating how important it is to explain the presence of the finding.”).

²⁶ *Id.*

²⁷ Price, *supra* note 3.

²⁸ MENDELEY, *supra* note 11.

²⁹ MASS. GEN. HOSP. LAB. FOR COMPUT. SCI., *supra* note 25.

³⁰ MENDELEY, *supra* note 11.

³¹ *Id.*

³² *About da Vinci Systems*, INTUITIVE (2019), <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems> (“The da Vinci System is powered by robotic technology that allows the surgeon’s hand movements to be translated into smaller, precise movements of tiny instruments inside the patient’s body. One of the instruments is a laparoscope — a thin tube with a tiny camera and light at the end. The camera sends images to a video monitor in the operating room to guide doctors during surgery. The surgeon is 100% in control of the da Vinci System at all times. The da Vinci System has brought minimally invasive surgery to more than 3 million patients worldwide.”).

³³ *Id.*; *see also* MENDELEY, *supra* note 11.

As illustrated by these specific examples, artificial intelligence already does aid in improving the quality and access to health care, and has the potential to continue to provide significant developments in the field of medicine; however, this substantial potential comes with medical, technical, and legal challenges.³⁴ Artificial intelligence in medicine must be safe and effective, and the question becomes how to protect and provide recourse to patients while ensuring the efficient development and continuing use of artificial intelligence technology in medicine.³⁵

IV. Decision Making with Artificial Intelligence

Artificial intelligence and machine learning algorithms will continue to make significant impacts in decision-making processes, diagnoses, and the treatment of patients in health care systems.³⁶ The connections of these algorithms with patient data allow health care providers to “increase the precision and accuracy of their diagnoses and decisions” so that they are able to identify illness and treat patients with more exactness and accuracy than ever before.³⁷ According to Shailin Thomas in *Artificial Intelligence, Medical Malpractice, and the End of Defensive Medicine*, the introduction of artificial intelligence “to medical diagnosis and decision-making has the potential to greatly reduce the number of medical errors and misdiagnoses – and allow diagnosis based on physiological relationships we don’t even know exist.”³⁸ However, predictions based on the complex connections between a patient’s data and the recommended treatment are

³⁴ Price, *supra* note 3.

³⁵ *Id.*; see also Thomas, *supra* note 24.

³⁶ *Id.*

³⁷ Price, *supra* note 14 (explaining that this is also known as black-box medicine, “a version of personalized medicine in which researchers use sophisticated algorithms to examine huge troves of health data, finding complex, implicit relationships and making individualized assessments for patients. This new form of medicine offers potentially immense benefits but faces major hurdles both in development and in application [B]lack-box medicine also raises significant challenges with respect to privacy, regulation, and commercialization.”).

³⁸ Thomas, *supra* note 24.

often given with little to no explanation.³⁹ When such dependence in decision making is placed on an algorithm, potential malpractice claims become complicated due to the reliance on artificial intelligence and the lack of an explanation that it provides for its decisions.⁴⁰ When a physician pursues an improper diagnosis or treatment based on the reliance on artificial intelligence and machine learning algorithms, it becomes somewhat unclear who should be responsible when an error occurs.⁴¹

V. Current Tort Liability Laws Applied to Artificial Intelligence

Our current tort liability laws may not be sufficient to apply to medical error resulting from decisions made by artificial intelligence.⁴² The main source of concern in determining liability for these errors stems from the fact that we as humans cannot “see” the reasoning made by the artificial intelligence technology.⁴³ Questions then arise as to whether traditional products liability laws should apply, holding the manufacturer of the technology liable, or if the health care provider treating the patient by way of using artificial intelligence should be held liable for errors.⁴⁴

Typically, liability for medical errors falls under a negligence framework.⁴⁵ Tort liability law in general, including liability for medical errors, typically serves the purpose of compensating

³⁹ *Id.*

⁴⁰ Sullivan & Schweikart, *supra* note 2, at 160 (explaining that as capabilities of predictive algorithms improve, “machine learning will become an important element of physician practice and patient care. Implementation of artificial intelligence raises complex legal questions regarding health care professionals’ and technology manufacturers’ liability, particularly if they cannot explain recommendations generated by AI technology.”).

⁴¹ *Id.*

⁴² Vladeck, *supra* note 7, at 121.

⁴³ Vijay Pande, *Artificial Intelligence’s ‘Black Box’ Is Nothing to Fear*, N.Y. TIMES (Jan. 25, 2018), <https://www.nytimes.com/2018/01/25/opinion/artificial-intelligence-black-box.html> (clarifying that artificial intelligence cannot explain how it comes to its conclusions in the same way that a “human doctor would” when making a diagnosis. For example, when a physician makes a diagnosis, he or she will be capable of explaining how she reached that conclusion to the patient. If the same diagnosis were made using artificial intelligence, then it would be a diagnosis made with “a direct connection to the data” rather than “human intuition based on limited data.”).

⁴⁴ *Id.*

⁴⁵ *Id.*; *see also* Negligence, BLACK’S LAW DICTIONARY (10th ed. 2014) (defining negligence as “the failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation; any

injured parties and deterring unreasonably dangerous conduct.⁴⁶ Courts have typically enforced the standards of practice that the medical profession sets through tort lawsuits.⁴⁷ When there is a case involving medical error, physician liability is determined based on the notion of the physician as a trusted expert.⁴⁸ This means that the treating physician is entirely accountable for his or her decisions, and thus if the care provided is determined to be reckless or negligent, then the physician will be held responsible.⁴⁹

Standards also evolve over time based on advances in medical research and technology. In judicial determinations for tort claims involving medical error, expert testimony relating to customary practices in the specific field of medicine become important.⁵⁰ While these standards typically evolve through the practices of health care providers, the standard of care can also be influenced by practice guidelines set in place by professional medical organizations or legislative action.⁵¹ While artificial intelligence technology and machine learning algorithms currently used in medicine are continuously developing, standards of care involving artificial intelligence are still

conduct that falls below the legal standard established to protect others against unreasonable risk of harm, except for conduct that is intentionally, wantonly, or willfully disregarding of other's rights; the doing of what a reasonable and prudent person would not do under the particular circumstances, or the failure to do what such a person would do under the circumstances.”).

⁴⁶ B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPEDICS & RELATED RES., 339, 340 (2009).

⁴⁷ FURROW ET AL., *supra* note 1, at 218 (“Defendants trying to prove a standard of care normally present expert testimony describing the actual pattern of medical practice without any reference to the effectiveness of that practice. Courts have traditionally given professional medical standards conclusive weight so that the trier of fact is not allowed to reject the practice as improper.”); *see, e.g.*, *Doe v. Am. Red Cross Blood Serv.*, 377 S.E.2d 323, 328 (S.C. 1989) (concluding that a medical professional cannot be found liable as a matter of law if the plaintiff cannot demonstrate that the medical professional failed to conform to the generally recognized practices in his or her profession).

⁴⁸ Thomas, *supra* note 24.

⁴⁹ *Id.*

⁵⁰ Sullivan & Schweikart, *supra* note 2, at 160–61.

⁵¹ W. Nicholson Price II, *Medical Malpractice and Black Box Medicine*, at 9 (U. Mich. Pub. L. & Legal Theory Res. Paper Series, Paper No. 536, 2017).

evolving. Therefore, customs have not been established as they have been for more traditional medical techniques and practices.⁵²

Additionally, it becomes challenging to apply the current standards used to determine physician liability in cases of error involving artificial intelligence technology when the error has occurred due to the technology and not necessarily the physician.⁵³ The algorithms used in the artificial intelligence technology currently used in medicine are beginning to have higher accuracy rates than physicians.⁵⁴ Thus, it can become difficult to continue to solely hold the physician liable and to apply a traditional negligence framework to medical error involving artificial intelligence because the physician should not necessarily be blamed for following the algorithms and/or artificial intelligence technology.⁵⁵ However, the counterargument becomes that artificial intelligence technology that is used primarily as an aid to health care providers in decision-making allows the final decision in terms of diagnosis or treatment to always rest in the hands of the provider.⁵⁶ In these scenarios, traditional tort liability theories may be applicable since the decision making will arguably be primarily made by the provider and not the artificial intelligence technology.⁵⁷

VI. Applying Current Legal Doctrines to Artificial Intelligence

⁵² *Id.*

⁵³ Thomas, *supra* note 24 (explaining that if algorithms have “a higher accuracy rate than the average doctor — as many soon will — it seems wrong to continue to place blame on the physician. Going with the algorithm’s suggestion would always be statistically the best option — so it’s hard to argue that a physician would be negligent in following the algorithm, even if it turns out to be wrong and the doctor ends up harming a patient. As algorithms improve and doctors use them more for diagnosing and decision-making, the traditional malpractice notions of physician negligence and recklessness may become harder to apply.”).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Vladeck, *supra* note 7, at 121.

⁵⁷ *Id.*; see also Johan Ordish, *Legal liability for machine learning in healthcare*, PHG FOUND. (Aug. 2018) <https://www.phgfoundation.org/documents/briefing-note-legal-liability-for-machine-learning-in-healthcare.pdf> (“If a patient is harmed by a faulty diagnosis, the most obvious response is to sue the clinician, or most probably their employer. This remains true even where software may have contributed to this faulty diagnosis. This is because in many jurisdictions, the case law has developed in relation to software used to support rather than make clinical decisions.”).

Questions still surface when medical error arises due to malfunctions of the artificial intelligence technology.⁵⁸ Our current legal doctrines apply to the conduct of humans, so it is still unclear as to how the doctrines will apply to artificial intelligence technology if it is functioning in a more autonomous capacity or if the decision-making does not rest entirely in the hands of the medical provider.⁵⁹ Some argue that it is not entirely fair for providers to be solely held liable for errors or malfunctions of artificial intelligence technology and machine learning algorithms, especially when the technology is functioning by more autonomous means under the provider's supervision.⁶⁰ Hence, other types of tort liability theories could be applicable to artificial intelligence in medicine such as products liability and vicarious liability theories when a traditional negligence framework for physician liability and medical error may not apply.⁶¹

VII. Vicarious Liability and The Use of Artificial Intelligence

One possibility is the application of the doctrine of respondeat superior to place vicarious liability on the employer of the physician.⁶² If a physician is acting within the scope of his or her employment and simultaneously commits a negligent act involving the use of artificial intelligence technology or machine learning algorithms, then the employer of the physician can potentially be

⁵⁸ Price, *supra* note 14, at 441.

⁵⁹ Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 HARV. J.L. TECH. 889, 894 (2018).

⁶⁰ As Shailin Thomas describes in her article, there are emerging theories that if there is a decrease in associated malpractice liability with the use of artificial intelligence and machine learning algorithms, then doctors may also be able reduce the amount of defensive medicine that they currently practice, leading to reductions in cost in the provision of health care. Thomas, *supra* note 24 (explaining that it is hoped that “as these algorithms proliferate and improve, doctors will begin to rely on their superior accuracy and precision, and the associated decrease in malpractice liability will allow those doctors to forego ordering every conceivable test or treatment.”).

⁶¹ Bal, *supra* note 46, at 345.

⁶² *Id.*; see also *Sanchez v. Unified Sch. Dist.*, 339 P.3d 399, 407–08 (Kan. Ct. App. 2014) (“Under the doctrine of respondeat superior, an employer may be held liable to a third person for injuries caused by the negligence of an employee if the employee is acting within the scope of employment. An employer is generally relieved of liability under a theory of respondeat superior when a legal or factual determination has been made that the employee did not act negligently. Statutory immunity from liability granted by the legislature to an employee is personal to the employee and, in the absence of a clear legislative statement to the contrary, does not shield the employer from liability under a theory of respondeat superior.”).

held liable for their wrongdoing.⁶³ Under this theory, health care providers and hospitals may also be held negligent for failing to properly train and/or supervise employees in the use of the artificial intelligence technology if an error were to occur.⁶⁴ It has additionally been questioned whether health care providers and hospitals themselves must evaluate the quality of the artificial intelligence technology and machine learning algorithms before physicians use them in the course of treating their patients.⁶⁵ Courts have not addressed this issue yet, as the technology is still developing, and the information to make such a determination is largely unavailable at this time.⁶⁶ Currently, it is still unclear how courts will apply vicarious liability doctrines to the use of artificial intelligence in medicine.⁶⁷

VIII. Products Liability Laws Applied to Artificial Intelligence

Under current products liability laws, the manufacturers and creators of the artificial intelligence technology and machine learning algorithms that are currently being used in medicine

⁶³ *Id.*; see also *Far W. Fin. Corp. v. D & S Co.*, 760 P.2d 399, 410–11 (Cal. 1988) (“As a leading text on torts explains, the modern justification for vicarious liability closely parallels the justification for imposing liability on the nonnegligent manufacturer of a product: ‘What has emerged as the modern justification for vicarious liability is a rule of policy, a deliberate allocation of risk. The losses caused by the torts of employees, which as a practical matter are sure to occur in the conduct of the employer’s enterprise, are placed upon that enterprise itself, as a required cost of doing business. They are placed upon the employer because, having engaged in an enterprise, which will on the basis of all past experience involve harm to others through the torts of employees and sought to profit by it, it is just that he, rather than the innocent plaintiff, should bear them; and because he is better able to absorb them, and to distribute them, through prices, rates or liability insurance, to the public, and so to shift them to society, to the community at large.’” (citing PROSSER & KEETON ON TORTS § 69, p. 500 (5th ed. 1984))).

⁶⁴ Sullivan & Schweikart, *supra* note 2, at 162.

⁶⁵ Price, *supra* note 14, at 420, 430.

⁶⁶ *Id.* at 449 (explaining that even though the algorithms can potentially perform “the usual analyses more quickly and cheaply” than providers could without the use of the technology, “excessive caution” will likely still be used since courts have not tackled these issues of liability surrounding the use of artificial intelligence in medicine).

⁶⁷ *Id.* (clarifying that questions arise when determining what healthcare providers and healthcare institutions must do to fulfill their duties of care to patients in health care systems that use artificial intelligence technology and machine learning algorithms. Some of these questions include: “Must providers themselves evaluate the quality of black-box algorithms, based on procedural measures (validation undertaken, performance statistics, etc.) before relying on those algorithms in the course of providing care? And should healthcare institutions perform similar evaluations before implementing black-box software?” Currently, the information needed to make these types of evaluations and answer these questions is mostly unavailable).

may potentially be liable if an error involving the technology occurs.⁶⁸ Liability could exist based on the products liability principle that if the product, the artificial intelligence technology, causes harm, then that harm is implied proof of some defect within the technology.⁶⁹

The idea of imposing liability on the manufacturer is based on the reasoning that the creator must pay for any harm caused by the technology.⁷⁰ Arguably then, the creator is in the best place to develop the artificial intelligence technology so that it is safe and will prevent harm to users.⁷¹ The creator and/or manufacturer will also be in the best position to “absorb any economic losses stemming from the harm.”⁷² Medical devices and technology have at times been categorized by courts as “unavoidably unsafe products”, meaning that they are made in a way that makes them incapable of being completely safe.⁷³ A negligence standard will then be applied to a design that is considered defective under the products liability doctrines.⁷⁴ This negligence standard “focuses on the conduct of the manufacturer to use reasonable care to design...a product that is reasonably safe.”⁷⁵ The standard of “reasonable care” is then decided based on what the manufacturer knew or reasonably should have known at the time that the plaintiff was injured by the product.⁷⁶ Even

⁶⁸ Matthew O. Wagner, *You Can't Sue a Robot: Are Existing Tort Theories Ready for Artificial Intelligence?*, FROST BROWN TODD (Feb. 7, 2018), <https://www.frostbrowntodd.com/resources-you-cant-sue-a-robot-are-existing-tort-theories-ready-for-artificial-intelligence.html>.

⁶⁹ *Id.*

⁷⁰ *Payne v. Paugh*, 360 P.3d 39, 50 (Wash. App. Div. 1 2015).

⁷¹ *Id.*

⁷² Wagner, *supra* note 68.

⁷³ *Payne*, 360 P.3d at 50.

⁷⁴ *Id.*; *see also* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965) (describing the concept of an “unavoidably safe product,” such as a medical device or a prescription drug, for purposes of product liability law and establishes an exception to strict liability for unavoidably unsafe products).

⁷⁵ *Payne*, 360 P.3d at 53.

⁷⁶ *Id.* at 53–54 (determining whether a manufacturer has exercised reasonable care, the court in *Payne* instructed that the trier of fact must consider that a medical device manufacturer (1) “has a duty to use reasonable care to test, analyze, and inspect the products it sells, and is presumed to know what such tests would have revealed” and (2) “has a duty to use reasonable care to keep abreast scientific knowledge, discoveries, advances, and research in the field and is presumed to know what is imparted thereby.”); *see also* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965) (“[A] trier of fact must consider that a medical device manufacturer (1) has a duty to use reasonable care to test, analyze, and inspect the products it sells and is presumed to know what such tests would have revealed and (2) has a duty to use reasonable care to keep abreast scientific knowledge, discoveries, advances, and research in the field and is presumed to know what is imparted thereby.”).

though these standards have historically been applied by courts to medical devices, prescriptions, and their respective manufacturers, applications to artificial intelligence technology and the machine learning algorithms currently used in medicine are feasible.⁷⁷

Application of a products liability theory to artificial intelligence can be complicated. A designer of artificial intelligence technology cannot necessarily foresee how the technology will act once it is being used in a real world medical setting.⁷⁸ Therefore, it can be unfair to assign blame to one person whose work was far removed from the actual operation of the technology in a medical setting.⁷⁹ So many entities and individuals, such as designers, engineers, and developers, work together to create artificial intelligence technology and systems.⁸⁰ This makes it especially difficult to blame one individual.⁸¹ Moreover, arguments have been made that applying strict liability under traditional products liability doctrines will be too difficult since the algorithms in the artificial intelligence technology currently being used in medicine are characteristically imperfect.⁸² For example, an algorithm developed by researchers at Stanford has an accuracy rate

⁷⁷ Price, *supra* note 21, at 457; *see also* Price, *supra* note 3, at 11.

⁷⁸ Sullivan & Schweikart, *supra* note 2, at 162–63.

⁷⁹ *Id.* at 163.

⁸⁰ *Id.*; *see also* Wagner, *supra* note 68.

⁸¹ Sullivan & Schweikart, *supra* note 2, at 163; *see also* Wagner, *supra* note 68.

⁸² Thomas, *supra* note 16 (“Traditional products liability doctrine applies strict liability to most consumer products. If a can of soda explodes and injures someone, the company that produced it is liable, even if it didn’t do anything wrong in the manufacturing or distribution processes. Strict liability works well for most consumer products but would likely prove too burdensome for medical algorithms. This is because medical algorithms are inherently imperfect. No matter how good the algorithm is — or how much better it is than a human physician — it will occasionally be wrong. Even the best algorithms will give rise to potentially substantial liability some percentage of the time under a strict liability regime.”).

⁸³ *Id.* (referring to a research study performed by researchers at Stanford who “developed an algorithm that can diagnose melanomas as well as or better than expert dermatologists.” It is also important to note that the study claims that “as the algorithm improves, it could become an important part of identifying melanomas as early and often as possible.”); *see also* Andre Esteva et al., *Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks*, 542 NATURE INT’L J. SCI. 115, 115 (2017) (“Skin cancer, the most common human malignancy, is primarily diagnosed visually, beginning with an initial clinical screening and followed potentially by dermoscopic analysis, a biopsy and histopathological examination. Automated classification of skin lesions using images is a challenging task owing to the fine-grained variability in the appearance of the skin lesions. Deep convolutional neural networks (CNNs), show potential for general and highly variable tasks across many fine-grained object categories.”).

⁸⁴ *Id.*

of less than 75%.⁸³ Even though this technology will likely be of benefit to the medical community, it would impose liability each time a patient is inevitably misdiagnosed based on its accuracy rate under a strict liability theory.⁸⁴ Imposing strict liability in this example would not be beneficial since the production of this technology would likely slow down or cease completely if such sure and immediate liability was imminent.⁸⁵ This would be a setback for the medical community since the full potential of the use of artificial intelligence technology and machine learning algorithms would never be fully realized if development and production decreased or stopped due to fear of the imposition of liability.⁸⁶ This is why some argue that strict liability could be avoided altogether if an “unavoidably unsafe products” approach were to be applied, as previously mentioned.⁸⁷ However, questions then arise relating to the duty to warn under an unavoidably unsafe products approach.⁸⁸ Under this approach, a manufacturer would have to rely on a learned intermediary to warn the ultimate user of the manufacturer’s product.⁸⁹ For example,

⁸⁵ *Id.*

⁸⁶ Wagner, *supra* note 68.

⁸⁷ *Id.*

⁸⁸ Sullivan & Schweikart, *supra* note 2, at 162; *see also* Thomas, *supra* note 16.

⁸⁹ Sullivan & Schweikart, *supra* note 2, at 162; *see also* Conley v. Lift-All Co., No. 1:03-CV-1200-DFH-TAB, 2005 WL 1799505, at *9 (S.D. Ind. July 25, 2005) (considering RESTATEMENT (SECOND) OF TORTS § 388, cmt. n (AM. LAW INST. 2012), in determining whether a manufacturer has satisfied a duty to warn by relying on a learned intermediary. RESTATEMENT (SECOND) OF TORTS § 388, cmt. n (AM. LAW INST. 2012), considers the “likelihood or unlikelihood that harm will occur if the intermediary does not pass on the warning to the ultimate user, the trivial nature of the probable harm, the probability or improbability that the particular intermediary will not pass on the warning, and the ease or burden of the giving of the warning by the manufacturer to the ultimate user [In addition], the manufacturer’s reliance on the intermediary’s alleged sophistication may be more or less reasonable given the product’s nature, complexity and associated dangers, the likelihood that the intermediary will communicate warnings to the ultimate consumer, the dangers posed to the ultimate consumer by an inadequate or nonexistent warning, and the feasibility of requiring the manufacturer to directly warn the product’s ultimate consumers.”).

the manufacturer or developer of the artificial intelligence technology would need to rely on the health care provider to warn the patient of the potential risks associated with utilizing the technology.⁹⁰ Liability for pharmaceuticals and medical device manufacturers is often determined by utilizing this method, but it likely would not be as easily applied to the use of artificial intelligence technology in medicine.⁹¹ First, because of the way that the artificial intelligence technology is tested before use, all of the potential risks or complications that may arise from its usage will likely be discovered.⁹² This means that the probability of an unknown error occurring is not likely.⁹³ Second, since the algorithms are designed to be very accurate, an unavoidably unsafe products approach likely will not apply to the use of artificial intelligence in medicine in the same way that it applies to medical devices or pharmaceuticals.⁹⁴

IX. Summary

The use of artificial intelligence technology in a medical setting will unavoidably create risks because not all of the possible consequences of the use of the new technology are foreseeable.⁹⁵ As discussed, there is currently limited information as to legal implications for tort liability for error involving artificial intelligence in medical settings since the technology and usage are still developing themselves.⁹⁶ Current tort liability laws may be applicable, yet under traditional tort liability it remains somewhat unclear as to the possible legal implications in the event of medical error involving artificial intelligence technology and machine learning algorithms.⁹⁷

⁹⁰ *Id.*

⁹¹ Thomas, *supra* note 16.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Reed, *supra* note 5, at 1, 3; *see also* Price, *supra* note 3.

⁹⁶ Reed, *supra* note 5, at 1.

⁹⁷ Sullivan & Schweikart, *supra* note 2, at 162–63.

Some argue in favor of applying the traditional tort liability theories to artificial intelligence used in medicine since there is evidence of the “human hand” involved in machine-based decision making.⁹⁸ Under this theory, a human who helps to develop a piece of artificial intelligence technology or helps guide its decision making is potentially “responsible for wrongful acts – negligent or intentional – committed by, or involving, the machine.”⁹⁹ This reasoning is based upon the idea that artificial intelligence technology is not fully autonomous, so it cannot be considered a “legal person” that may be held accountable under tort law for errors.¹⁰⁰ The types of artificial intelligence used in medicine today fall within this category since the technology is not yet fully autonomous.¹⁰¹ For example, an app that may aid a physician in diagnosing a patient and the da Vinci Surgical System, previously mentioned, both function under human supervision and with the input of data by humans.¹⁰² Artificial intelligence currently used in medicine is not fully autonomous in the same way as artificial intelligence technology utilized by driver-less cars or fully independent drone aircrafts.¹⁰³ Therefore, it is feasible for current tort laws to be applied to the use of artificial intelligence and machine learning algorithms currently used in medicine since there is still evidence of the “human hand” in their usage.¹⁰⁴ Also, current products liability laws could potentially be applicable.¹⁰⁵

⁹⁸ Vladeck, *supra* note 7, at 120.

⁹⁹ *Id.* at 120–21.

¹⁰⁰ *Id.* at 121 (explaining that despite the sophistication of artificial intelligence technology and machines, they have no attribute of legal personhood. They are considered “agents or instruments of other entities that have legal capacity as individuals, corporations, or other legal ‘persons’ that may be held accountable under the law for their actions.”).

¹⁰¹ Monika Hengstler et al., *Applied Artificial Intelligence and Trust – The Case of Autonomous Vehicles and Medical Assistance Devices*, 105 TECH. FORECASTING SOC. CHANGE 105, 109 (2016).

¹⁰² MENDELEY, *supra* note 11; *see also About da Vinci Systems – Surgical robotics for minimally invasive surgery*, INTUITIVE, <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems> (last visited Mar. 8, 2020) (“The da Vinci Surgical System enables surgeons to perform operations through a few small incisions and features several key features, including . . . wristed instruments that bend and rotate far greater than the human hand.”).

¹⁰³ Hengstler et al., *supra* note 101, at 107.

¹⁰⁴ Vladeck, *supra* note 7, at 120, 146.

¹⁰⁵ *Id.* at 130.

However several counterarguments to this theory exist since some argue that it unfair to assign blame to those whose work was far removed from the actual use of the artificial intelligence technology.¹⁰⁶ Imposing strict liability arguably would not be beneficial since the production of the artificial intelligence technology would likely slow down or cease completely if such sure and immediate liability was imminent under current products liability and strict liability theories.¹⁰⁷ Many fear that this would be a setback for the medical community since the full potential of the use of artificial intelligence technology and machine learning algorithms would never be fully realized if development and production decreased or stopped due to fear of the imposition of liability.¹⁰⁸

X. Conclusion

Today, artificial intelligence and machine learning algorithms are being used in approximately 86% of health care providers' practices.¹⁰⁹ Innovators began to develop these forms of artificial intelligence technology in an effort to improve the efficiency and quality of patient care, as well as to improve the cost and access to care while at the same time advancing medical research.¹¹⁰ Artificial intelligence technology already does aid in improving the quality and access to health care and has the potential to continue to provide significant developments in the field of medicine; however, this substantial potential comes with medical, technical, and legal challenges.¹¹¹

¹⁰⁶ Sullivan & Schweikart, *supra* note 2, at 161, 163 (explaining that given the limited information regarding tort liability involving artificial intelligence in medicine, traditional tort liability laws may be applicable. "Liability for medical errors falls under tort law. A tort is a civil claim in which a party requests damages for injuries caused by a harmful, wrongful act of another. Typical tort claims in the realm of medicine and health include medical malpractice (negligence), *respondeat superior* (vicarious liability), and products liability.").

¹⁰⁷ *Id.*

¹⁰⁸ Thomas, *supra* note 16.

¹⁰⁹ Price, *supra* note 3.

¹¹⁰ Sullivan & Schweikart, *supra* note 2, at 160.

¹¹¹ Price, *supra* note 3.

Concerns arise when questioning how safe and effective artificial intelligence in medicine will be, and the issue then becomes how to protect and provide recourse to patients.¹¹² Current tort liability theories may be applicable, but information at this time is largely unavailable to make evaluations of how exactly how these theories will apply.¹¹³ Courts have also not yet addressed many of the issues surrounding liability and the usage of artificial intelligence technology and machine learning algorithms in medicine.¹¹⁴ In the future the goal will become ensuring the efficient development and continuing use of artificial intelligence technology in medicine, but these developments may change the way current laws are applied in the context of contemporary health care liability issues.¹¹⁵ As artificial intelligence technology continues to develop, courts will need to address these potential disputes surrounding the usage of artificial intelligence in medicine, and the need for the consideration of issues will likely grow in the future.¹¹⁶

¹¹² *Id.* at 11–12.

¹¹³ *Id.* at 12–13.

¹¹⁴ *Id.* at 12.

¹¹⁵ *Id.* at 13.

¹¹⁶ Price, *supra* note 3, at 12–13.