From Jeopardy! to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems

Jessica S. Allain
From Jeopardy! to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems

In the not so distant future, medical mysteries will crumble in the face of a more efficient, less dysfunctional Dr. House.\(^1\) Imagine that a patient walks into an emergency room with a wide spectrum of symptoms. Rather than subject the patient to an infinite battery of tests, the patient is sent to Watson, a medical supercomputer with borderline artificial intelligence.\(^2\) Watson analyzes the patient’s genome, reads the patient’s lifetime medical record, and searches through the entire body of medical knowledge, including the most cutting-edge research, to determine the likeliest diagnoses and most promising courses of treatment.\(^3\) In a matter of seconds, Watson compresses a process that normally takes an ordinary physician weeks to accomplish.\(^4\)

Copyright 2013, by JESSICA S. ALLAIN.


2. Watson is named after International Business Machines Corporation’s (IBM) founder, Thomas J. Watson. STEPHEN BAKER, FINAL JEOPARDY: MAN VS. MACHINE AND THE QUEST TO KNOW EVERYTHING 19 (2011). Although Watson currently lacks true artificial intelligence, his ability to learn by favoring more successful algorithms over less successful algorithms shows the rudimentary beginnings of artificial intelligence. Id. at 150. This Comment focuses on the issue of emerging artificial intelligence technologies in the healthcare industry.


Just down the hall in the Intensive Care Unit (ICU), another Watson station alerts the medical team that micro-changes in a patient’s biochemistry indicate that a secondary infection will likely present itself within a few days. Because Watson can monitor millions of data points and vital signs related to the patient by interfacing directly with medical monitoring equipment, the patient’s outcome can significantly improve with faster detection and treatment.\(^5\) In the clinic next door, a third Watson unit is working with a soldier thousands of miles away in war-torn Afghanistan.\(^6\) Watson can help lead less qualified healthcare professionals through specialized treatment, expanding the ability of limited military resources.

Although International Business Machines Corporation (IBM) developed Watson to play Jeopardy!, a healthcare team from Columbia University is currently repurposing “him” to diagnose patients, suggest treatments, and answer medical questions.\(^8\) Watson

\(^5\) Researchers have discussed the possibility of integrating Watson into other equipment to further his ability to gather information. *Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra* note 3, at 12:10–:51. Integrating Watson into electronic medical monitoring equipment is one possibility where this could be used.

\(^6\) Although researchers have not focused on Watson’s potential for telemedicine, this would be a natural development for IBM because it has a research department focused on expanding telemedicine services. *Focus on . . . Telemedicine, IBM* (last visited Mar. 8, 2013), http://domino.watson.ibm.com/odis/odis NSF/pages/focus.08.html. Researchers are planning to integrate Watson into other technologies to expand his ability. *Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra* note 3, at 12:10–:51, 15:53–16:55.

\(^7\) The ability to provide medical services from a distance will also be vital for recovery response to natural disasters or anywhere else with a shortage of healthcare providers. *See* Jonathan M. Teich, Michael M. Wagner, Colin F. Mackenzie & Klaus O. Schafer, *The Informatics Response in Disaster, Terrorism, and War*, 9 J. AM. MED. INFORMATICS ASSOC. 97, 101–04 (2002) (discussing the importance of telemedicine in disaster response and war).

\(^8\) IBM has a history of developing new technology around games. In 1997, IBM’s Deep Blue computer was the first computer system to beat a grand master at chess in IBM’s first “Grand Challenge.” *Baker, supra* note 2, at 20. IBM’s next grand challenge came when IBM developed Blue Gene, the world’s first supercomputer, designed to work on analyzing the human genome. *Id.* Watson represents the latest grand challenge. *Id.* Researchers chose to develop the system around Jeopardy! because of the advances that would be required in natural language processing and deep analytics. *Id.* When Watson competed on Jeopardy!, he defeated the two greatest Jeopardy! players of all time and won one million dollars. *IBM’s Watson Supercomputer Crowned Jeopardy King, BBC News* (Feb. 17, 2011), http://www.bbc.co.uk/news/technology-12491688. Darren Murph, *Columbia Doctors Turn to IBM’s Watson for Patient Diagnosis, Clairvoyance*, ENGADGET.COM (Mar. 24, 2011, 1:01 PM), http://www.engadget.com/2011/03/24/columbia-doctors-turn-to-ibms-watson-for-patient-diagnosis-cla/. For the sake of simplicity, Watson will be referred to as “he” throughout this
is 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 in less than three seconds.\(^9\) Initially, Watson will be able to answer physicians’ questions, to suggest diagnoses and treatments, and to give the physicians the probability of success and medical evidence supporting each option.\(^10\) Eventually, Watson may be able to interface directly with medical equipment and directly treat patients with much less physician interaction.\(^11\) Once Watson connects to the Internet, it is possible that he will be able to interface with a patient anywhere in the world, including underserved rural, prison, and refugee populations.\(^12\) Watson’s potential contributions to healthcare are astounding, but the potential complications that could arise when the law tries to respond to this new technology are equally staggering.

The law should encourage this innovative technology’s growth. Artificial intelligence systems like Watson can fill gaps that healthcare shortages cause and enhance the quality of care that patients receive.\(^13\) Creating a streamlined approach for assessing liability against artificial intelligence systems will encourage their use by clarifying unknown potential liabilities. By combining elements from medical malpractice, vicarious liability, products liability, and enterprise liability, the law can create a uniform approach for artificial intelligence systems, thereby eliminating any inequities that may arise from courts applying different theories of liability.

Comment. Moreover, Watson’s opponents consistently refer to the system as “he.” BAKER, supra note 2, at 131.


11. The Watson team regularly discusses how the system’s capabilities will grow as he integrates further into additional technology. Medical equipment is a natural extension. Id. at 12:10–:51, 15:53–16:55.


This Comment explores how the law should assess liability against artificial intelligence systems. Part I of this Comment discusses Watson, other areas of cutting-edge medical technology, and the law’s response to them. Part II analyzes current liability regimes—including medical malpractice, products liability, and vicarious liability—to determine how effectively these legal mechanisms can apply to artificial intelligence systems. Part II also explains why current liability regimes are inadequate. Finally, Part III proposes an integrated system for assessing liability against artificial intelligence systems based on enterprise liability.

I. EMERGING TECHNOLOGY IN ROBOTICS AND ARTIFICIAL INTELLIGENCE

Watson is one of many emerging medical technologies with the potential to change medical practice in the United States. The legal response to some of these technologies—particularly robotic surgery systems, cybermedicine, and telemedicine—is slowly developing.15 Because Watson shares many characteristics with these other forms of technology, courts will likely use jurisprudence based on these systems to analyze lawsuits involving Watson.16

A. Watson and the Next Frontier of Artificial Intelligence in Medicine

Over the last five years, approximately 25 researchers at IBM have been developing Watson—a super-computer capable of answering questions posed in natural language.17 Historically, natural language has been a computational limitation because of the naturally occurring ambiguities and complexities in human speech.18

---

14. Technically, Watson does not have true artificial intelligence. BAKER, supra note 2, at 150. However, he represents advancement in the field, particularly in computers capable of learning. Id. Further, he is a great model for starting the discussion about artificial intelligence and the law.

15. See infra Part I.B–C.


The IBM team developed Watson’s skills for Jeopardy! because the show’s questions require a full understanding of natural human speech—including nuances, regionalisms, and wordplay. Aside from his ability to understand questions, Watson can also answer them. As opposed to a search engine like Google, which looks for keywords to direct the user to websites and documents where the answer might be found, Watson is capable of actually understanding questions posed and giving the user the correct answer. This represents an extraordinary leap in artificial intelligence, deep analytics, and language processing.

Watson uses a four-step process to interpret and answer questions. First, Watson breaks down the question into its parts of speech to identify what kind of question is being asked and what the question is asking for. After determining the question type, Watson searches his database to come up with thousands of possible answers to all possible questions generated in the first step. Third, Watson goes through a process of hypothesis and evidence testing where he looks for negative and positive evidence for all potential answers generated in the previous step. Finally, Watson merges and ranks all potential answers by using his past experience at answering similar types of questions to create rankings and calculate the likelihood that the answers are correct. Watson does all of this in less than three seconds.

Watson is ideal for the healthcare industry for several reasons. First, there is simply too much information for a single doctor to constantly have at his fingertips, and the body of medical literature currently doubles every seven years. It is very difficult for
physicians to be aware of, let alone address, their own information gaps.\footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 28:49–29:20.} Furthermore, many doctors have a multitude of questions that cannot be answered easily and quickly after a full day of treating patients.\footnote{Id. at 17:00–:40.} Watson is capable of providing a simple and direct answer to a doctor’s complex medical question in seconds.\footnote{Id.} Second, the human body contains too many variables for humans to concurrently monitor.\footnote{Research suggests that human processing capacity may be limited to as little as four variables at any given time. Graeme S. Halford, Rosemary Baker, Julie E. McCredden & John D. Bain, How Many Variables Can Humans Process?, 16 PSYCHOL. SCI. 70, 75 (2005), available at http://www.psychologicalscience.org/pdf/ps/mind_variables.pdf.} Watson not only has the ability to monitor an individual’s health, but he can also individualize treatment based on the patient’s medical records.\footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 17:40–19:15.} Third, Watson can act as a decision support assistant and develop a better differential diagnosis.\footnote{Id. at 20:18–:46.} By calculating all the possible diagnoses and courses of treatment while also providing the evidence to the acting physician, Watson better enables the physician and patient to make informed decisions about medical care.\footnote{Perspectives on Watson: Healthcare, supra note 9, at 0:46–58, 1:44–2:10.} Watson can alleviate many sources of medical error by filling in informational gaps throughout treatment.\footnote{Video, Final Jeopardy! and the Future of Watson, at 3:13–4:35, IBM, http://www-07.ibm.com/innovation/in/watson/what-is-watson/the-future-of-watson.html (last visited Apr. 12, 2013), available at http://www.youtube.com/watch?v=II-M7O_bRNg.}

Watson does have limitations, however. He does not always realize when an answer is absurd or out of context.\footnote{Id.} For instance, he incorrectly answered, “What is Toronto?” to a question in the U.S. Cities category.\footnote{Id. at 28:49–29:20.} Further, Watson does not currently have the capacity to hear or see, although researchers will work on adding these features in the future.\footnote{Id. at 15:53–16:55.}

\begin{footnotesize}
\begin{enumerate}
\item \footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 28:49–29:20.}
\item \footnote{Id. at 17:00–:40.}
\item \footnote{Id.}
\item \footnote{Research suggests that human processing capacity may be limited to as little as four variables at any given time. Graeme S. Halford, Rosemary Baker, Julie E. McCredden & John D. Bain, How Many Variables Can Humans Process?, 16 PSYCHOL. SCI. 70, 75 (2005), available at http://www.psychologicalscience.org/pdf/ps/mind_variables.pdf.}
\item \footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 17:40–19:15.}
\item \footnote{Id. at 20:18–:46. Differential diagnosis is “the distinguishing of a disease or condition from others presenting with similar signs and symptoms.” Differential Diagnosis Definition, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/differential\%20diagnosis (last visited Mar. 8, 2013).}
\item \footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 17:40–19:15.}
\item \footnote{Id. at 28:49–29:20. Perspectives on Watson: Healthcare, supra note 9, at 0:46–58, 1:44–2:10.}
\item \footnote{Id.}
\item \footnote{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra note 3, at 15:53–16:55.}
\end{enumerate}
\end{footnotesize}
Jeopardy!, Watson used a database built by IBM rather than connecting to the Internet.\textsuperscript{41} Being linked into evidence-based treatment guidelines\textsuperscript{42} or Internet databases, such as Wolfram Alpha\textsuperscript{43} and PubMed,\textsuperscript{44} will expand Watson’s library of information. Researchers will continue working on Watson to increase his functionality in healthcare.\textsuperscript{45}

B. Robotic Surgical Systems

Watson is not the only emerging medical technology that could raise serious legal concerns. In recent years, various robotic surgery systems have gained popularity in the United States.\textsuperscript{46} The da Vinci and Zeus systems are composed of two robotic arms linked to a control panel by fiberoptic cable.\textsuperscript{47} The robotic arms are capable of extremely fine motor skills, and they allow more precision than traditional open surgery.\textsuperscript{48}

\textsuperscript{41} Watson’s developers did not think Jeopardy! would want Watson to have access to the Internet because other contestants on the show would not have such access. BAKER, supra note 2, at 30.

\textsuperscript{42} “[E]vidence-based medicine is the ‘conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.’” Nicolas P. Terry, An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation, 27 AM. J. L. & MED. 361, 385 (2001) (citation omitted). National standards for evidence-based guidelines can be found online through the National Guideline Clearing House, MedScape, AHRQ, organizations for medical specialties, and the U.S. National Library of Medicine Medline source. Id. at 386.

\textsuperscript{43} WolframAlpha is an Internet search engine that answers fact-based questions by computing the answer from structured data. Ian Paul, WolframAlpha Will Take Your Questions -- Any Questions, PCWORLD (Mar. 9, 2009, 7:36 AM), http://www.pcworld.com/article/160904/wolfram.html.


\textsuperscript{47} Id. While there are many similarities between the systems, there are a few differences. Id. The da Vinci system provides the surgeon with full stereoscopic vision, while the Zeus system is limited to a two-dimensional view. Id. Alternately, Zeus can respond to both voice commands and manual commands, while da Vinci is limited to manual commands alone. Id. at 498–99.

\textsuperscript{48} Id. at 498.
Rather than operate from the patient’s bedside, the surgeon manipulates the robot from a control panel as if playing a videogame.\textsuperscript{49} Commonly, the control panel and robot are in the same surgical suite, but they can also be thousands of miles apart.\textsuperscript{50} In fact, the first cybersurgery featured a physician in New York operating on a patient located in France.\textsuperscript{51}

Although there is little jurisprudence surrounding the Zeus and da Vinci systems, there has been at least one documented death resulting from the use of the da Vinci system.\textsuperscript{52} In 2002, a Florida man died after a botched kidney operation in which the surgeon used the da Vinci system.\textsuperscript{53} His family filed suit in state court, charging the hospital with negligence based on the surgeon’s lack of training and experience in operating the system.\textsuperscript{54} The case ultimately settled out of court,\textsuperscript{55} and courts have not yet addressed liability issues related to adequate training, mechanical malfunctions, and interruptions in communication between the consoles.

The legal issues that will persist with robotic surgical systems will likely bleed into the legal analysis of artificial intelligence systems in medicine. Although Watson currently lacks robotic components, any jurisprudence related to robotic surgical systems will likely serve as precedent for dealing with liability related to Watson. Watson is similar to the Zeus and da Vinci systems because he is highly advanced medical technology used by physicians to treat patients. Although both Watson and the robotic surgical systems depend on human interaction to treat patients, the interacting physician has no control over many aspects of these systems. Physicians have even less control over Watson, who works on his own and reports back to the physician, as opposed to the robotic systems, which depend completely on the physician to function. Because who should be held liable when injuries arise out

\textsuperscript{49} Id.
\textsuperscript{50} Id. at 498–99.
\textsuperscript{51} Id. at 499. \textit{Cybersurgery} is a surgical technique that allows a surgeon, using a telecommunication conduit connected to a robotic instrument, to operate on a remote patient. \textit{Id.}
\textsuperscript{53} Brink, \textit{supra} note 52; Good, \textit{supra} note 52.
\textsuperscript{54} Brink, \textit{supra} note 52; Good, \textit{supra} note 52.
of the use of robotic surgical systems is unclear, any decisions allocating responsibility and liability could be used to analyze cases arising out of Watson’s use.

C. Cybermedicine and Telemedicine

Watson’s use implicates legal issues surrounding telemedicine and cybermedicine. Being connected to the Internet could allow Watson to interact with physicians and patients anywhere in the world. Cybermedicine is generally defined as “the discipline of applying the Internet to medicine.” However, the term can encompass everything from pharmaceutical sales and email communications between doctors and patients to diagnosis and treatment via video chat. As more people rely on the Internet to interact with health care professionals, the legal regime for dealing with practicing medicine via cybermedicine becomes crucial.

Telemedicine is defined as the long-distance practice of medicine via telecommunications. Cybermedicine is merely an extension of telemedicine using the Internet. Telemedicine is becoming more prevalent in rural and prison populations. Many hospitals also use telemedicine to cover specialty areas, such as

58. A 2000 survey by the Pew Research Center’s Internet and American Life Project shows that a majority of Internet users have used the Internet to obtain health information, and the number of people using the Internet for health purposes has continuously increased. Solez & Katz, supra note 56, at 559.
59. Various definitions for telemedicine have been proposed. The World Health Organization defines telemedicine as

57. The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.
58. Herrmann, supra note 57, at 307 (alteration in original) (citation omitted). The American Medical Association defines telemedicine as “[m]edical practice across distance via telecommunications and interactive video technology.” Id. (citation omitted) (internal quotation marks omitted). Finally, the American Telemedicine Association defines telemedicine as “the use of medical information exchanged from one site to another via electronic communications to improve patients’ health status.” Id. (citation omitted) (internal quotation marks omitted).
60. Solez & Katz, supra note 56, at 557.
radiology, during evenings and weekends when those specialty services may be unavailable because fewer specialists are working. Thus, hospitals are already using telemedicine and cybermedicine to fill in the gaps in physician staffing. With worsening healthcare provider shortages expected after the enactment of the Patient Protection and Affordable Care Act (PPACA) in 2014, telemedicine and cybermedicine can be used to extend healthcare resources.

Although cybermedicine and telemedicine are becoming increasingly more common, serious legal issues remain unresolved with their use. Because telemedicine and cybermedicine create situations where doctors and patients are often in different states, if not different countries, questions arise regarding jurisdiction and licensing. Many states require physicians to be licensed in that state in order to practice medicine. A question arises as to where the medical practice actually occurs when the patient is in one state and the physician is in another. Many states have enacted statutes defining medical practice as occurring where the patient receives treatment, thus requiring the physician to be licensed in the patient’s state. These types of legal structures inhibit telemedicine by


64. Meghan Hamilton-Piercy, Cybersurgery: Why the United States Should Embrace This Emerging Technology, 7 J. HIGH TECH. L. 203, 214–18 (2007). The University of North Carolina (UNC) has entered into a contract with the University of Chile in which UNC will provide neonatal cardiac evaluations to Chilean newborns via telemedicine. This program expanded out of UNC’s initiative to provide cardiac evaluations to rural hospitals in North Carolina via telemedicine. Patricia C. Kuszler, Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability, 25 AM. J.L. & MED. 297, 303 (1999).

65. Hamilton-Piercy, supra note 64, at 214–15 & n.57.


67. Hamilton-Piercy, supra note 64, at 214–15 & n.57. For instance, Arkansas and Georgia both have statutes explaining that even in telemedicine situations, the
making interstate practice more difficult for physicians. Yet, several states have recognized the value of telemedicine and restructured their laws to encourage its use. Texas and several other states currently provide special-purpose licenses for out-of-state physicians practicing telemedicine. The special-purpose licensing process is quicker and less expensive while still ensuring that the treating physician is competent and qualified.

The legal response to telemedicine and cybermedicine is very important to artificial intelligence systems like Watson, who can make a global impact through telemedicine and cybermedicine. The Internet could give Watson the capacity to treat patients anywhere in the world, including patients in rural areas, war-torn areas, and areas

practice of medicine is considered to be within the state and the physician must be licensed in the state where the patient is treated. Id. ARK. CODE ANN. § 17-95-206 (Westlaw 2013) (“A physician who is physically located outside this state but who through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, including the performance or interpretation of an X-ray examination or the preparation or interpretation of pathological material that would affect the diagnosis or treatment of the patient, is engaged in the practice of medicine in this state for the purposes of this chapter and is subject to this chapter and to appropriate regulation by the Arkansas State Medical Board. This section does not apply to: (1) The acts of a medical specialist located in another jurisdiction who provides only episodic consultation services; (2) The acts of a physician located in another jurisdiction who is providing consultation services to a medical school; (3) Decisions regarding the denial or approval of coverage under any insurance or health maintenance organization plan; (4) A service to be performed which is not available in the state; (5) A physician physically seeing a patient in person in another jurisdiction; or (6) Other acts exempted by the board by regulation.”); GA. CODE ANN. § 43-34-31(a) (Westlaw 2013) (“A person who is physically located in another state or foreign country and who, through the use of any means, including electronic, radiographic, or other means of telecommunication, through which medical information or data are transmitted, performs an act that is part of a patient care service located in this state, including but not limited to the initiation of imaging procedures or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient is engaged in the practice of medicine in this state. Any person who performs such acts through such means shall be required to have a license to practice medicine in this state and shall be subject to regulation by the board. Any such out-of-state or foreign practitioner shall not have ultimate authority over the care or primary diagnosis of a patient who is located in this state.”).

68. Hamilton-Piercy, supra note 64, at 214–15.
69. Id.
70. Id. at 671 & n.105. Other states with similar special licensing procedures for telemedicine practitioners include Alabama, ALA. CODE § 34-24-500 (Westlaw 2013), and South Dakota, S.D. CODIFIED LAWS § 36-4-41 (Westlaw 2013). Id.
71. Id. See also 22 TEX. ADMIN. CODE § 174.3 (2013).
recovering from natural disasters. With healthcare shortages anticipated in the United States by 2014, Watson could become a vital tool in helping primary care providers expand their ability to provide services. States should continue to revise and lessen restrictions on telemedicine so that this technology can grow and fill many healthcare gaps, both in the United States and abroad. Aside from standard issues about licensing, it is unclear whether there will be some kind of medical licensing requirements for artificial intelligence systems, let alone for artificial intelligence systems practicing interstate medicine. If artificial intelligence specifications are held to a legal standard before being used in medical practice, it is left to be seen how these systems might be certified or to what standards they will be held.

Many questions remain regarding how courts will handle issues arising from emerging medical technology. Cases on robotic surgical systems, cybermedicine, and telemedicine can serve as precedent in dissecting questions that may arise from using Watson, but there are key differences between the technologies. Once courts begin to clarify the legal standards that will govern long-distance medicine and robotics, new issues will surface dealing with Watson’s rudimentary artificial intelligence.

II. THE CURRENT NATIONAL LEGAL LANDSCAPE AND POTENTIAL LIABILITY REGIMES APPLICABLE TO ARTIFICIAL INTELLIGENCE TECHNOLOGY

Courts and legislatures have developed many theories of recovery for injuries arising out of medical treatment. Medical malpractice generally applies to healthcare providers. Vicarious liability focuses on institutions that employ healthcare providers. Products liability attaches to defective equipment and medical devices that healthcare providers may use. Watson partially fits into all of these categories, but no single theory of recovery

72. See supra notes 6–7.
73. See supra note 13 (on anticipated healthcare shortages); supra note 63 (on how telemedicine can help healthcare shortage).
74. 1 THOMAS A. MOORE, MEDICAL MALPRACTICE: DISCOVERY AND TRIAL § 1:1 (2004); 1 STEVEN E. PEGALIS, AMERICAN LAW OF MEDICAL MALPRACTICE § 1:1 (2005), available at Westlaw.
76. AMERICAN LAW OF PRODUCTS LIABILITY § 1:1 (Westlaw 2013); 1 DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, MADDEN & OWEN ON PRODUCTS LIABILITY § 1:5 (3d ed. 2000).
A. Medical Malpractice

Medical malpractice is a subset of general negligence law, whereby the physician has a duty to the patient and breaches this duty by failing to act as a reasonably prudent physician. Medical malpractice is a subset of general negligence law, whereby the physician has a duty to the patient and breaches this duty by failing to act as a reasonably prudent physician. A provider–patient relationship is a prerequisite to a medical malpractice action. If that relationship exists, the next inquiry is whether the patient has consented to the particular treatment. If so, liability depends on whether the medical care is properly performed.

The standard medical malpractice action becomes far more complicated when an artificial intelligence system is injected into the physician–patient relationship. In a medical malpractice claim involving a treating physician’s consultation with another physician, the plaintiff can only establish liability against the other physician if sufficiently covers the liability questions that may arise from a computer system capable of practicing medicine.

77. MOORE, supra note 74; PEGALIS supra note 74, § 1:1, 1:3.
78. MOORE, supra note 74, § 2:1.1; Kuznar v. Raksha Corp., 750 N.W.2d 121, 128 (Mich. 2008) (holding that a pharmacist could not be held liable under medical malpractice because there was no physician–patient relationship); Oblachinski v. Reynolds, 706 S.E.2d 844, 846 (S.C. 2011) (holding that only a patient can bring a medical malpractice claim against a physician, as opposed to third parties affected indirectly); Estate of French v. Stratford House, 333 S.W.3d 546, 555 (Tenn. 2011) (holding that a physician–patient relationship is a prerequisite to a claim under the Tennessee Medical Malpractice Act).
79. Many medical malpractice actions arise from a lack of informed consent. MOORE, supra note 74, § 2:2.2. Originally, many medical malpractice claims were treated as battery claims, the medical treatment itself being an unwanted and offensive contact. Matthies v. Mastromonaco, D.O., 733 A.2d 456, 460 (N.J. 1999). These types of claims are now typically adjudicated on the basis of informed consent, i.e., whether the physician fully informed the patient of all aspects of the treatment prior to the patient consenting. Id. at 460–61.
80. MOORE, supra note 74, § 2:1.2; PEGALIS, supra note 74, § 1:1.
81. Some courts have held physicians liable under medical malpractice for using defective or malfunctioning equipment, but the defect or misuse generally must be blatant. S. Highlands Infirmary v. Camp, 180 So. 2d 904, 908 (Ala. 1965). In South Highlands Infirmary v. Camp, the court held that the defendant physician was not liable for using defective equipment because the defect was latent. Id. In dicta, the court suggested it would have found differently had the defect been patent. Id. In Mafhouz v. Xanar, a Louisiana appellate court held a physician liable for a defective laser that burned a patient because the doctor breached his duty to stop using the equipment when he started experiencing technical difficulties with the laser. Mahfouz v. Xanar, Inc., 646 So. 2d 1152, 1161 (La. Ct. App. 1995). Similarly, in Washington v. Washington Hospital Center, the United States Court of Appeals for the District of Columbia Circuit held a physician liable for misusing anesthesia equipment during surgery. Washington v. Washington Hosp. Ctr., 579 A.2d 177, 180 (D.C. 1990).
a physician–patient relationship existed between them.82 Without the physician–patient relationship, the consulting provider has no legal duty to the plaintiff.83

Because Watson is programmed to assume the role of a consulting physician, the question of his duty to patients is especially relevant to liability. Watson is vital to providing information to the treating physician but cannot yet take independent action in actually providing treatment.84 Current jurisprudence suggests that a consulting physician who does not interact with the patient has no duty to the patient.85 Because Watson will not interact with patients directly at first, there may be no duty to be breached as required for medical malpractice.

Watson could be considered analogous to a consulting physician. In Hill v. Kokosky, the treating physician contacted two other physicians by telephone for a consultation.86 The consulting physicians never interacted with the patient or saw her medical chart but merely gave informal medical advice to the treating physician.87 The court held that the consulting physicians did not establish a physician–patient relationship with the plaintiff and, therefore, owed no duty to her.88 Other courts have similarly held that consulting physicians who merely give advice, as opposed to orders or directions, without ever examining or talking to the patient, do not establish a physician–patient relationship giving rise to a cognizable medical malpractice claim.89

82. MOORE, supra note 74, § 2:1.1.
83. Id.
84. This situation will likely grow even more complicated if and when it becomes possible for Watson to interface directly with medical treatment and control life support equipment and the administration of medicine. See supra note 5.
85. See Irvin v. Smith, 31 P.3d 934, 941 (Kan. 2001) (determining that a consulting physician who only gives an informal opinion to a treating physician owes no duty to the patient); St. John v. Pope, 901 S.W.2d 420, 424 (Tex. 1995) (holding that a consulting physician who had recommended that the patient be transferred to a different facility for treatment and had not agreed to treat the patient did not owe the patient a duty).
87. Id.
88. Id. at 267.
89. See Jennings v. Badgett, 230 P.3d 861, 868 (Okla. 2010) (holding that “a telephone conversation between a non-treating physician and the treating physician concerning the patient, even when the treating physician relies on the non-treating physician’s opinion, without more, is insufficient to establish a physician-patient relationship”); Lopez v. Aziz, 852 S.W.2d 303, 306 (Tex. App. 1993) (holding that a single telephone conversation in which a treating physician sought advice from a colleague was insufficient to create a physician–patient relationship between the consulting physician and the patient); Schrader v.
If courts analogize Watson to a consulting physician, then he will owe no legal duty to a patient giving rise to a medical malpractice claim. This is likely because Watson can only recommend treatment to a physician after reading and analyzing patient records.90 If Watson evolves and obtains the ability to treat patients directly by interfacing with medical equipment, he will be much more intimately involved with the patient’s diagnosis and treatment than the consulting physician in Hill, who never interacted directly with the patient.91 Until that point, courts will likely have trouble finding that Watson has a duty to patients.

Many medical malpractice claims are based on a lack of informed consent.92 Watson as a consulting physician raises issues regarding informed consent because patients will have to be fully informed that the physician is using Watson as a diagnostic tool and that he is contributing to the medical diagnosis and treatment.93 Although the doctor is ultimately in charge of administering medical treatment, informed consent may require that a patient be fully informed of Watson’s results, including the options the physician

Kohout, 522 S.E.2d 19, 21 (Ga. Ct. App. 1999) (holding that numerous consultations between the patient’s psychologist and a colleague over a four-year period did not give rise to a physician–patient relationship between the consulting psychiatrist and the patient because the consultant never saw or examined the patient or her medical records and never had control over her medical treatment); Corbet v. McKinney, 980 S.W.2d 166, 170–71 (Mo. Ct. App. 1998) (holding that no physician–patient relationship exists “where the consult[ing] physician merely undertakes to advise the patient’s treating physician, has no explicit contractual obligation to the patient, treating physician, or treating hospital to provide care, and does not take actions which indicate knowing consent to treat a patient who has sought that treatment, such as by examining, diagnosing, treating, prescribing treatment for, or charging the patient”).

91. Hill, 463 N.W.2d at 266.
92. A medical malpractice action based on a lack of informed consent arises when a physician fails to inform the patient of all relevant information about a course of treatment, particularly the risks. MOORE, supra note 74, § 2:2.2. The modern medical malpractice action evolved from the historical notion that a physician committed a battery by touching a patient without consent. See supra note 79.
93. A physician is required to inform the patient of “alternatives to the proposed treatment or diagnosis and the reasonably foreseeable risks and benefits involved as would permit the patient to make a knowledgeable evaluation.” MOORE, supra note 74, § 2:2.2[A]. To meet this standard, physicians may be required to disclose that they are using Watson and to obtain the patient’s permission to use him.
chose not to pursue.\textsuperscript{94} This could lead to increased disagreement between physicians and patients about the best course of treatment.

Additionally, Watson’s involvement in a medical malpractice action could change the applicable standard of care to which physicians are held. Because Watson will be able to access an extraordinary amount of medical knowledge and evidence-based practice guidelines, situations in which the physician disagrees with Watson about the most appropriate course of treatment could arise.\textsuperscript{95} Watson will be able to use much more information than human physicians ever could. Physicians who use Watson may be held to a higher standard than physicians who do not because of their access to additional information. The rise of artificial intelligence could cause courts to lean more heavily on national standards, evidence-based treatment guidelines, and cutting-edge medicine to accommodate an enhanced standard of care.

Even if courts were to hold that medical malpractice was appropriate for suits dealing with Watson, whether artificial intelligence systems are even capable of committing negligent acts is unclear. By definition, breaching the physician–patient duty requires a physician to fail to act as a reasonably proficient physician.\textsuperscript{96} Because Watson runs on a carefully calculated system of algorithms, always calculating the risks and probabilities of various outcomes, Watson may not be programmed to breach any duty; his actions and decisions are inherently reasonable by necessity.\textsuperscript{97} As machines begin practicing medicine, the traditional medical malpractice action must evolve to accommodate the newest batch of stainless steel M.D.’s, as the traditional action built for human physicians seems to have inadequacies when applied to artificial intelligence systems.

\textbf{B. Vicarious Liability}

Vicarious liability is a liability regime whereby one individual can be held legally responsible for the acts of another.\textsuperscript{98} This arrangement is most commonly found in the employer–employee relationship in which an employer can be held liable for the

\begin{itemize}
  \item \textsuperscript{94} \textit{Id.}
  \item \textsuperscript{95} \textit{BAKER, supra} note 2, at 198.
  \item \textsuperscript{96} \textit{MOORE, supra note} 74, § 2:1.2.
  \item \textsuperscript{97} \textit{The Science Behind an Answer, supra} note 18, at 3:19–4:19; \textit{Experts and IBM Insiders Break Down Watson’s Jeopardy! Win, supra} note 3, at 6:55–7:05.
  \item \textsuperscript{98} \textit{JOHN M. CHURCH, WILLIAM R. CORBETT, THOMAS E. RICHARD & JOHN V. WHITE, TORT LAW: THE AMERICAN AND LOUISIANA PERSPECTIVES 515 (2008); RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIABILITY § 13 (2000); 65 C.J.S. NEGLIGENCE § 150 (2011).}
\end{itemize}
employee’s tortious conduct.99 Hospitals can be held vicariously liable for the acts of their employees, including physicians, who commit malpractice.100 Potentially, hospitals might also be vicariously liable for the actions of their artificial intelligence systems, like Watson.

Unlike what is normally the case, a hospital can be held vicariously liable for independent contractor physicians’ acts through apparent agency.101 Generally, employers are not liable for the actions of independent contractors because no employer–employee relationship exists.102 If it appears to a reasonable third party that the physician was providing services on behalf of the hospital or if the patient sought services from the hospital rather than the individual physician, then the hospital can be held vicariously liable under agency.103 In Clark v. Southview Hospital & Family Health Center, a young woman died due to negligent emergency medical care for an asthma attack.104 The Ohio Supreme Court held that the hospital was liable for an emergency room physician’s negligence, even though the doctor was technically an independent

100. PEGALIS, supra note 74, § 6:20.
101. Marjorie A. Shields, Annotation, Liability of Hospital or Sanitarium for Negligence of Independent Physician or Surgeon—Exception Where Physician Has Ostensible Agency or “Agency by Estoppel”, 64 A.L.R.6th 249, 249 (2011). Unless the hospital explicitly informs patients that the physicians are not hospital employees, patients may assume that they are. PEGALIS, supra note 74, § 6:21 (citing Mehlman v. Powell, 378 A.2d 1121 (Md. 1977)). See also Gilbert v. Sycamore Mun. Hosp., 622 N.E.2d 788, 793–94 (Ill. 1993) (holding a hospital liable for the negligent acts of an emergency room physician, who was not a hospital employee, because the public could reasonably assume that the physician was an agent of the hospital); Richmond Cnty. Hosp. Auth. v. Brown, 361 S.E.2d 164, 166–67 (Ga. 1987) (“Most modern hospitals hold themselves out to the public as providing many health related services including services of physicians. A patient is likely to look to the hospital, not just to a particular doctor he comes into contact with through the hospital... If [the plaintiff] can prove the hospital represented to [him] that its emergency room physicians were its employees and that he therefore justifiably relied on the skill of the doctors but suffered injury due to the legal insufficiency of their medical services, the hospital may be held liable therefor.” (citation omitted)).
104. Clark, 628 N.E.2d at 46.
In Clark, the court found that because the hospital represented to the public that the physicians worked for the hospital, the hospital was vicariously liable as an apparent agent.\(^{106}\)

The hospital’s own duty to supervise the quality of medical care administered in the facility is related to vicarious liability.\(^{107}\) This general duty further explains why courts can hold hospitals vicariously liable under a theory of ostensible agency.\(^{108}\) In Simmons v. Tuomey Regional Medical Center, the South Carolina Supreme Court found that the hospital owed an absolute, nondelegable duty to patients to provide competent services.\(^{109}\) Other courts have not followed this approach, however, by requiring that the hospital commit an overt act before the hospital may be held liable for medical treatment given at the facility.\(^{110}\)

Just as hospitals may be vicariously liable for a physician’s negligence, courts could likewise hold a hospital vicariously liable for injuries caused by its artificial intelligence systems. Whether the courts would view Watson as more of a physician or a Magnetic Resonance Imaging (MRI) machine is an unanswered but fundamental question. True vicarious liability will only attach if Watson is analogized to an employee.\(^{111}\) Because of his capability and role in the medical team, the courts may consider Watson more analogous to a physician rather than to equipment. In that case, hospitals could potentially be able to obtain separate insurance policies to cover the risk of Watson causing injury just like they

---

\(^{105}\) Id. at 54.

\(^{106}\) Id. at 53–54.

\(^{107}\) Shields, supra note 101, at 249; Kuszler, supra note 64, at 322 (citing Darling v. Charleston Cnty. Mem’l Hosp., 211 N.E.2d 253, 256 (Ill. 1965) (holding the defendant hospital liable for failing to supervise the quality of care that its physicians and nurses administered)).

\(^{108}\) PEGALIS, supra note 74, § 6:22.


\(^{110}\) See Bynum v. Magno, 125 F. Supp. 2d 1249, 1266 (D. Haw. 2000) (“Plaintiffs must show that the hospital actually did something to imply authority, not just that it failed to inform patients of a lack of authority. Moreover, Plaintiffs must demonstrate that they somehow relied on the representations of authority” in order for the hospital to be liable).

insure their healthcare provider employees. Because Watson cannot be held financially responsible for making restitution, hospitals will likely carry much of this burden if vicariously liable. Despite this potential burden, however, separate insurance policies and a streamlined liability standard will likely encourage hospitals to purchase and use artificial intelligence systems.

C. Products Liability and the Learned Intermediary Doctrine

Products liability defines the obligations associated with product distribution. A manufacturer or retailer can be liable for making or selling an unreasonably dangerous product. Most states have special statutes addressing products liability separately from basic actions for negligence. Some states hold product manufacturers and distributors to a strict liability standard, while other states hold them to a simple negligence standard.

In a products liability suit, the plaintiff has the burden of proving that the injury resulted from a product defect that rendered the product unreasonably dangerous and that the defect existed at the time the product left the manufacturer. There are a number of policy reasons behind allocating liability to the manufacturer, including reducing the total cost of accidents by deterring accident-causing activities and spreading the loss to more parties. Products liability actions achieve these goals and simultaneously uphold fundamental notions of fairness in adjudication.

Traditionally, hospitals and healthcare providers have been immune from products liability suits because the primary function

---

112. See PEGALIS, supra note 74, § 1:5.
113. AMERICAN LAW OF PRODUCTS LIABILITY, supra note 76, § 1:1; OWEN, MADDEN & DAVIS, supra note 76, § 1:5.
114. AMERICAN LAW OF PRODUCTS LIABILITY, supra note 76, § 1:1.
115. Louisiana also provides for the civilian contract remedy of redhibition: The action in redhibition is based upon the implied-in-law warranty against defects in the thing which would render it useless or inconvenient or, in other terminology, unfit for its intended use. A bad-faith seller, one who knows of the defect, or who declares it to have a quality it does not have, is liable for damages and reasonable attorney’s fees. WILLIAM E. CRAWFORD, TORT LAW § 16:10, in 12 LOUISIANA CIVIL LAW TREATISE 404 (2d ed. 2009). Redhibition differs from products liability in that redhibition covers damage to the thing itself, while products liability covers damage that the thing causes. Id. § 16:11, at 405–09. Plaintiffs can concurrently maintain products liability actions and redhibition actions. Id. § 16:11, at 407–08.
116. OWEN, MADDEN & DAVIS, supra note 76, § 1:5.
117. AMERICAN LAW OF PRODUCTS LIABILITY, supra note 76, § 1:4.
119. Id. at 118–19.
of healthcare providers is to provide services, not to sell goods.\textsuperscript{120} Although a hospital or physician may inadvertently provide goods to a patient when providing medical services, those goods are merely incidental.\textsuperscript{121} The \textit{services versus sales} distinction has been fundamental in protecting physicians and hospitals from products liability suits.\textsuperscript{122} Manufacturers of medical equipment and devices, however, can still be liable through products liability actions.\textsuperscript{123} Thus, “the cybersurgical robotic manufacturer must properly warn patients of potential danger of the instrument, properly design the instrument, and properly manufacture the instrument, if the manufacturer is to avoid liability in a lawsuit.”\textsuperscript{124}

The learned intermediary doctrine prevents plaintiffs from suing medical device manufacturers directly.\textsuperscript{125} Manufacturers have the duty to warn consumers of potential dangers inherent in a product’s natural use.\textsuperscript{126} In the case of medical devices, manufacturers have a

\begin{footnotesize}
\textsuperscript{120} Christopher L. Thompson, \textit{Imposing Strict Products Liability on Medical Care Providers}, 60 MO. L. REV. 711, 715–18 (1995) (citing Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 795 (N.Y. 1954) (holding that blood transfusions were services, not sales, and that the physician–patient relationship was to provide services, not goods)).

\textsuperscript{121} Thompson, supra note 120, at 717.


\textsuperscript{123} McLean, supra note 122, at 183.

\textsuperscript{124} Id.

\textsuperscript{125} \textit{Restatement (Second) of Torts} § 402A (1965); Ehls v. Shire Richwood, Inc., 367 F.3d 1013, 1019 (8th Cir. 2004) (holding that the learned intermediary doctrine prevented the plaintiff from suing the drug manufacturer); Vitanza v. Upjohn Co., 778 A.2d 829, 843 (Conn. 2001) (holding that the learned intermediary doctrine barred the plaintiff’s claim against the pharmaceutical manufacturer).

\textsuperscript{126} Gray v. Badger Mining Corp., 676 N.W.2d 268, 274 (Minn. 2004) (“In general, a supplier has a duty to warn end users of a dangerous product if it is reasonably foreseeable that an injury could occur in its use.” (citation omitted)); Crowston v. Goodyear Tire & Rubber Co., 521 N.W.2d 401 (N.D. 1994) (finding that manufacturers have a continuing duty to warn consumers about the dangers
duty to warn the treating physician of the product’s potential dangers.\textsuperscript{127} The physician becomes a learned intermediary between the manufacturer and the patient, eliminating any duty the manufacturer may have had directly to the patient.\textsuperscript{128} To qualify as a learned intermediary, the manufacturer must adequately warn the treating physician about the medical device’s risks.\textsuperscript{129} The physician, rather than the patient, is considered the end consumer of medical devices because the healthcare provider is in the best position to weigh the risks against the possible benefits of using the device.\textsuperscript{130} The learned intermediary doctrine results in the manufacturer having no duty to the patient.\textsuperscript{131}

Furthermore, because Watson is a computer system, only his hardware components will qualify as products in a products liability action.\textsuperscript{132} With a device as complicated as Watson, determining whether an injury caused by Watson’s diagnosis or treatment resulted from a defect in his software or his hardware may be difficult.\textsuperscript{133} Because software is generally not within the scope of products liability, such actions against Watson may be necessarily restricted to

---

\textsuperscript{127} Hamilton-Piercy, supra note 64, at 212. The learned intermediary doctrine was originally developed to apply to pharmaceuticals and was expanded to include medical devices. McLean, supra note 122, at 183–84.; Brooks v. Medtronic, Inc., 750 F.2d 1227, 1231 (4th Cir. 1984) (citations omitted).


\textsuperscript{129} Hamilton-Piercy, supra note 64, at 212; In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999) (finding that the physician being properly trained about the risks of a treatment is a requirement for the learned intermediary doctrine).

\textsuperscript{130} McLean, supra note 122, at 184; C.R. Ewell, Telemedicine: Overcoming Obstacles on the Road to Global Health Care, 12 CURRENTS: INT’L TRADE L.J., no. 2, 2003, at 68, 73.

\textsuperscript{131} Brown v. Drake-Willock Intl’l Ltd., 530 N.W.2d 510, 516 (Mich. 1995) (holding that the manufacturer had no duty to warn the patient); Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552 (E.D. Pa. 1990) (holding that prescription drug manufacturers had no duty to warn a patient of possible drug interactions and side effects); Humes v. Clinton, 792 P.2d 1032 (Kan. 1990) (holding that manufacturers of prescription drugs and interuterine device had no duty to directly warn patients of the dangerous side effects and risks of those products).


\textsuperscript{133} Id. at 128, 142.
blatant hardware failures. Trying to distinguish between hardware and software failures for such a complex system could be a formidable challenge for any court to assess.

This liability structure makes it challenging for patients to win products liability suits in medical device cases. Because hospitals and physicians provide services rather than goods, products liability does not apply to these entities. However, the learned intermediary doctrine prevents patients from seeking recovery from manufacturers directly. All that remains to the consumer is a medical malpractice action against the healthcare provider. The multitude of conflicting legal doctrines will make products liability claims against Watson unduly complex and difficult to address.

D. FDA and the Medical Device Regulatory Scheme

Congress enacted the Medical Device Amendments (MDA) of the Food, Drug, and Cosmetic Act in 1976. Under the MDA, the Food and Drug Administration (FDA) uses a system of classes to regulate medical devices. Classes range in dangerousness from Class I devices, the least dangerous, to Class III devices, the most dangerous. Class I devices include gloves and bedpans, which have a very low potential for causing harm and have the least stringent regulations, known as general controls. Class II devices include more sophisticated instruments with a higher possibility of causing harm, such as oxygen masks. They are subject to performance standards called special controls, in addition to general

134. Id. at 122. “Almost universally, judges have refused to apply strict products liability to software, usually by finding that software is not a ‘product.’” Id. at 128 (footnote omitted). A blatant hardware failure, for example, could include situations in which Watson catches fire and burns someone or in which Watson shuts down while monitoring and managing life support, resulting in the patient’s death.

135. Thompson, supra note 120, at 715–18.


137. There are also issues with federal preemption under the Food and Drug Administration (FDA) regulations, including the Medical Device Amendments (MDA). See infra Part II.D.


142. 21 U.S.C. § 360c.
Class III devices “‘present a potential unreasonable risk of illness or injury,’ or . . . are ‘purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.’”144

The FDA subjects Class III devices to stringent testing with the Pre-Market Approval (PMA) process, in which the FDA reviews all clinical and laboratory tests about the device’s safety and effectiveness.145 Manufacturers are required to report accidents related to the device’s use.146 However, medical devices can bypass the PMA process if they are substantially similar to a product on the market before the amendments were enacted.147 Currently, 98% of devices released to the market bypass the approval process through this exception.148

Where the MDA applies, it preempts some state law claims; however, whether the MDA preempts state products liability law is unclear.149 In Medtronic v. Lohr, the United States Supreme Court held that the MDA did not preempt the plaintiff’s claims because Florida’s products liability requirements were identical to the requirements under the act.150 The court further found that state statutes are only preempted when the FDA establishes “‘specific counterpart regulations or . . . other specific requirements applicable to a particular device.’”151

The Court reinforced this opinion in Riegel v. Medtronic, Inc., holding that the MDA does not preempt claims based on violations of FDA regulations.152 The Court relied on its rationale in Lohr, which declared that the MDA only preempts state requirements that differ from or add to the federal statute.153 Accordingly, the MDA does not preempt state statutes that are parallel to the federal requirements.154 Some lower courts have limited the Supreme

144. Medtronic, 518 U.S. at 477 (alteration in original) (citation omitted); 21 U.S.C. § 360c(a)(1)(C).
146. McLean, supra note 122, at 188.
147. Id. at 190; Medtronic, 518 U.S. at 477–78.
151. Id. at 498 (alteration in original) (quoting 21 CFR § 808.1(d) (1995)).
152. Riegel, 552 U.S. at 322–23.
153. Id.
154. Id. at 330.
Court’s holding in those cases. One district court refused to extend *Lohr* and *Riegel* to state statutes that only incidentally regulated medical devices, holding instead that the MDA preempts all state products liability claims, except those substantially identical or equivalent to the federal statutes.

Watson is not a typical medical device contemplated by the MDA, such as a pacemaker, heart valve, or cybersurgical instrument. Although Watson will diagnose and treat patients, he will not be surgically embedded into them. If Watson were classified under the MDA, it is unclear into which class he would fit. Because Watson currently only makes recommendations to the treating physician, he may not pose any more risk to a patient than a textbook or the Internet, which are clearly outside the scope of medical device regulation. However, Watson does make a clear impact on patients through his diagnosis and treatment recommendations, so he could be classified as a Class II or III device. FDA regulations emanating from the MDA preempt certain state law claims in some jurisdictions, further complicating any potential lawsuits involving Watson.

III. PROPOSAL: A STREAMLINED SYSTEM FOR ADDRESSING LIABILITY ISSUES OF ARTIFICIAL INTELLIGENCE ROBOTIC SYSTEMS IN MEDICINE

Our current legal regimes seem inadequate when applied to artificial intelligence. Medical malpractice does not perfectly apply to Watson because injecting an artificial intelligence system into the physician–patient relationship creates new questions of whether Watson can form a physician–patient relationship leading to an independent duty to the patient, whether the guidelines for informed consent and the standard of care will change to accommodate Watson, and how to properly assess causation and fault against Watson and his team of healthcare provider assistants. It is likewise unclear how vicarious liability may apply to the physicians who work

158. As Watson gains further capabilities, such as being directly linked into medical monitoring and life support equipment, it would likely become more sensible to classify him under the MDA, 21 U.S.C. § 360 (Westlaw 2013).
159. *See McLean, supra* note 122, at 188 (citing 29 U.S.C. § 360k (1994)).
160. *See supra* Part II.A.
with Watson and Watson’s owners.161 The dueling legal theories in products liability also do not provide a clear solution; patients have little recourse in actions surrounding medical devices.162 Federal law further complicates product liability actions involving medical devices by preempting many state law claims under the MDA.163

The law currently is a conglomeration of legal regimes that do not clearly apply to artificial intelligence systems. As a result, different courts could apply different theories to similar cases, leading to inconsistent results.164 A streamlined method for assessing liability against artificial intelligence systems will likely encourage this technology’s use. For instance, removing doubts about who will be liable and to what extent the responsible party will be financially responsible if these systems malfunction will likely encourage hospitals to adopt this emerging technology.165 Additionally, cases involving Watson will necessarily involve a team of supporting physicians. Distinguishing fault and causation between the actors for a traditional comparative fault analysis can be a very complex inquiry.166 A regime based on enterprise liability combining elements of medical malpractice, products liability, and vicarious liability will adequately address the legal challenges raised by Watson while ensuring fairness and consistency between courts.

One scholar suggests using an enterprise liability approach, which makes the business organization providing medical services

161. See supra Part II.B.
162. See supra Part II.C.
163. See supra Part II.D.
164. For an expression by the United States Supreme Court on the importance of consistency in the law, see Payne v. Tennessee, 501 U.S. 808, 827–28 (1991) ("Stare decisis is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process. . . . Considerations in favor of stare decisis are at their acme in cases involving property and contract rights, where reliance interests are involved." (citations omitted)).
the “exclusive bearer of liability for all medical negligence.” According to the traditional enterprise liability approach, fault and causation are analyzed against the team of actors, “the enterprise,” rather against the individuals that compose the team. No further analysis occurs on the relative fault of each individual actor. Once the enterprise’s fault is established, a single actor, generally the head of the enterprise, must make financial restitution. Although this approach would simplify the process and make plaintiffs getting adequate restitution easier, this approach places a disproportionate burden on the business organization and creates an economic disincentive for Watson’s use. Assessing all malpractice liability against Watson’s owners, whether a hospital, nursing home, or clinic, could bankrupt healthcare institutions and prevent Watson and other artificial intelligence technology from being used at all. This Comment proposes a system based on enterprise liability, but this proposal differs from other models because restitution will be equally shared among actors to better spread the risk of loss and reduce the economic disincentives associated with the traditional enterprise liability system. Because no current theory of liability clearly applies to lawsuits involving Watson, a new liability scheme based on enterprise liability is necessary to encourage artificial intelligence systems’ use in medicine.

167. McLean, supra note 122, at 205.
169. Id.
170. Id.
A. Paving the Way for the First Generation Watson System

The legislature should create a special cause of action for suing artificial intelligence systems. The first tier of this system should distinguish the cause of action. The statute should direct the court to determine initially the direct cause of the plaintiff’s injury. Based on this determination, the case will either proceed under products liability or medical malpractice.173 Forcing the case to proceed under a single theory will require the court to make an initial assessment of the direct cause of the plaintiff’s injury, and it will reduce the total number of lawsuits involving Watson.174

An action against an artificial intelligence system like Watson should entail one action with alternate theories of recovery. This statutory scheme for assessing liability should first address whether the case arises out of a defect in the system’s hardware.175 A panel of experts should examine the system to determine whether the injury’s source was a hardware failure. If the hardware failure is the injury’s cause-in-fact, the case should proceed against the manufacturer.176 If maintenance issues are implicated, the case may also proceed against Watson’s owner under a theory of contributory negligence or comparative fault.177 To spread the risk of loss, states should require manufacturers of artificial intelligence systems that

173. J.A. Jones Const. Co. v. Lehrer McGovern Bovis, Inc., 89 P.3d 1009, 1017 (Nev. 2004) (“A party may not assert contradictory theories of recovery such that the assertion of one theory will necessarily repudiate the other.”). But see Arter v. Spathas, 779 P.2d 1066, 1068–69 (Or. 1989) (“The doctrine of election between inconsistent remedies does not require an election until the matter has gone to judgment. . . . A party need only choose between or among inconsistent remedies, not inconsistent claims or theories of recovery.” (citations omitted)). Under this regime, plaintiffs would be free to plead both products liability and medical malpractice theories; however, for the sake of judicial efficiency, the court would make an initial inquiry into causation and proceed under the most appropriate theory.


175. Software is generally not within the scope of products liability because courts consistently hold that software is not a product. Childers, supra note 132, at 128 (2008).

176. AMERICAN LAW OF PRODUCTS LIABILITY, supra note 76, § 1:5; OWEN, MADDEN & DAVIS, supra note 76, § 1:5.

177. AMERICAN LAW OF PRODUCTS LIABILITY, supra note 76, § 39:2.
will be used to treat patients to develop a fund to pay claims resulting from products liability issues.

If no hardware is defective, the claim should instead proceed under the state’s medical malpractice regime against the hospital enterprise. In most projected situations, the enterprise would include Watson, his owner, and all the physicians that were part of the treatment plan that led to injury.\(^{178}\) To counteract any disincentives associated with Watson’s use, Watson should be protected like physicians under state medical malpractice regimes, including limits on liability, or “caps.”\(^{179}\) In many states, this would mean that any cap on medical malpractice should also limit Watson’s liability.\(^{180}\) Placing a disproportionate procedural burden on Watson results in new disincentives against his use.\(^{181}\) Equalizing the actors and providing Watson the same procedural protections given to other healthcare providers helps to counteract any disincentives that businesses may face while still providing avenues of recovery for plaintiffs.

Because Watson cannot own property and does not earn wages, the question of liability must be separated from the question of restitution.\(^{182}\) In a negligence analysis, courts first look to causation before assessing damages.\(^{183}\) The same approach should be used in lawsuits against Watson; however, fault and causation should be assessed against the enterprise rather than against the individual defendants.\(^{184}\) Separating fault between the physicians, Watson, and the hospital will be an incredibly fact-based, complex inquiry that may be unrealistic.\(^{185}\) Enterprise liability allows the courts to

---

178. McLean, supra note 46, at 496 (discussing traditional enterprise liability in which a hospital would be held liable for the negligence of all of the actors involved in medical care occurring under its auspices). As McLean points out, however, this creates disincentives, which is why this Comment suggests a modified form of enterprise liability.

179. See supra note 171 (discussing the economic forces on hospitals and general economic theory on disincentives).

180. For instance, the Louisiana Medical Malpractice Act places a $100,000 limit on each doctor’s liability. La. Rev. Stat. Ann. § 40:1299.42 (Supp. 2013). The plaintiff’s total recovery is capped at $500,000, with a special fund, the Patient’s Compensation Fund, paying the difference. Id.; id. § 40:1299.44.

181. See supra note 171 (discussing the economic forces on hospitals and general economic theory on disincentives).

182. Although this is a theoretical distinction in some sense, separating the cause of harm from the source of money that will pay for the harm clarifies the parties’ role in a suit against Watson. Because these suits will involve several third party defendants, including insurance companies, clarifying liability helps to simplify the proceedings.

183. Restatement (Second) of Torts §§ 328A, 328B, 328C, 328D (1965).

184. Tappan, supra note 168, at 1104.

185. Id.
analyze the team’s fault without breaking into the interrelated actions of the individual actors.\textsuperscript{186}

Even when courts determine that a physician committed malpractice, the doctor is generally not the party actually paying damages to the plaintiff.\textsuperscript{187} Insurance acts to better spread the risk of loss throughout society, reducing the economic impact of each individual judgment.\textsuperscript{188} Every practicing physician carries malpractice insurance to guard against the threat of lawsuits.\textsuperscript{189} Hospitals should be able to insure Watson against medical malpractice as physicians insure themselves. Hospitals should also be able to obtain enterprise liability insurance to protect them from being liable with the enterprise.\textsuperscript{190} Once fault is assessed against the enterprise, each actor, including Watson and the hospital, will be responsible for an equal share of restitution. In effect, each actor’s malpractice insurance will pay for part of the claim. Involving multiple policies and insurers helps reduce the economic impact of each individual lawsuit by further spreading the risk of loss.

By first separating the relevant causes of action, courts can reduce the total number of lawsuits involving Watson while focusing on the direct cause of the plaintiff’s injury.\textsuperscript{191} This also helps provide some insulation against liability for Watson’s owners by properly assessing responsibility against the manufacturer for hardware defects.\textsuperscript{192} Applying enterprise liability to the question of fault simplifies an impossibly complex analysis and provides plaintiffs a more direct route to recovery. Spreading liability for restitution equally among all actors in the enterprise could better reduce the economic impact of each lawsuit by further spreading the risk of loss among a greater number of parties. By reducing the economic impact of each lawsuit, this quasi-enterprise system reduces any disincentives the medical community may have against purchasing and using Watson and other artificial intelligence systems.

\begin{footnotesize}
\begin{enumerate}
\item 186. \textit{Id.}
\item 187. Pegalis, \textit{supra} note 74, § 1.5.
\item 188. \textit{Id.}
\item 189. \textit{Id.}
\item 190. McLean, \textit{supra} note 122, at 205.
\item 191. \textit{See supra} note 173 (discussing the pleading of multiple causes of action); \textit{supra} note 174 (discussing judicial efficiency).
\item 192. \textit{See supra} Part II.C.
\end{enumerate}
\end{footnotesize}
First-generation Watson systems will be limited to interacting with physicians and helping them with diagnosis and treatment.\textsuperscript{193} If IBM integrates Watson into electronic medical equipment, then Watson could one day directly treat patients. Watson would be similar to a very complex pacemaker, monitoring the patient and administering treatment as necessary. Once artificial intelligence systems make this leap into medicine, states will be required to revisit their legal regimes to reassess liability constructs.

The law should treat true artificial intelligence systems as quasi-juridical persons.\textsuperscript{194} Artificial intelligence systems with the capacity to learn and change over time are inherently independent.\textsuperscript{195} Further, artificial intelligence systems make autonomous decisions and can take action at their own initiative.\textsuperscript{196} Although Watson will likely always have an owner, the law should recognize that the owner could never assert full control over the system and that the system changes from the time it is first created and purchased.\textsuperscript{197} Once Watson evolves into a sentient system with true artificial intelligence, the law should recognize Watson as an autonomous decision maker.

Labeling artificial intelligence systems as quasi-juridical persons would endow Watson with some rights and duties, specifically the capacity to be sued as an independent entity.\textsuperscript{198} Because Watson is not capable of filing or answering lawsuits, the hospital or business that owns Watson will have to act on his behalf, as the board of directors does for a corporation.\textsuperscript{199} Allowing Watson to be sued directly clarifies legal proceedings by allowing plaintiffs to focus the lawsuit more narrowly to the potentially responsible parties.\textsuperscript{200}

\textsuperscript{193} See supra Part I.A.

\textsuperscript{194} Wein, supra note 99, at 107.


\textsuperscript{196} Moravec, supra note 195; Miyake, supra note 195.

\textsuperscript{197} Moravec, supra note 195; Miyake, supra note 195.

\textsuperscript{198} For example, these rights and duties would include freedom of expression, the right to due process, and protection from unreasonable searches and seizures. Wein, supra note 99, at 107–09.


\textsuperscript{200} Wein, supra note 99, at 114.
The law will have to decide whether Watson can breach duties. Because current medical malpractice schemes present issues when applied to artificial intelligence systems like Watson, the law should proactively accept that Watson does have a duty to patients that could be breached. Before claims could be brought against Watson in court, a medical review panel should review Watson’s reports and evidence to determine if this was a reasonable course of treatment from the perspective of a human physician. Holding Watson to the same standard as other doctors will better protect patients who are injured, rather than categorically reasoning that computers cannot make mistakes or commit negligent acts.

Because he is a quasi-juridical person, courts should treat Watson the same as any other physician. Any recovery would be subject to the same state limitations that apply to other physicians and would be paid from the mandatory malpractice insurance policy that is paid by Watson’s owner. As the law begins to shape around rudimentary artificial intelligence systems like the first-generation Watson, new laws and precedent will be created to lay the groundwork for more advanced future systems. Whether artificial intelligence systems will ever achieve more legal autonomy will greatly depend on what legislatures and courts do with the present systems.

CONCLUSION

The law can either support and promote technological innovation or impede it. Current liability regimes are not easily applicable to artificial intelligence systems. To encourage the use of artificial intelligence in healthcare, a new legal action based on enterprise liability should be created to encompass the relevant aspects of medical malpractice, products liability, and vicarious liability. Artificial intelligence will be challenging for courts to analyze on first impression, and putting a legal construct in place before artificial intelligence becomes pervasive in healthcare will likely incentivize the growth of this powerful technology.

Jessica S. Allain∗