# PREDICTING THE FUTURE OF PREDICTIVE ANALYTICS: IMPOSING LIABILITY ON AI TECHNOLOGY IN HEALTHCARE

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## I. Introduction

Technological advancement over the last two decades has propelled modern western society into something out of a science fiction novel. Increasingly, Artificial Intelligence (AI) has developed the capacity to potentially outpace human brain function. AI development in the area of "predictive analytics" (also known as "Black-Box Medicine")[1] has become one of the most compelling and important abilities of AI.[2] This technology is an analytic process which utilizes compiled data from across information systems to make predictions about unknown future events or activities that provide guidance for human decision-making.[3]

Predictive analytics is a powerful tool that has been applied to commercial industries across various disciplines including health care.[4] For use in health care, "[a]lgorithms in precision medicine guide care by predicting patient risks, making accurate diagnoses, selecting drugs, and even prioritizing patients to preserve or assign limited health resources."[5] However, with such a powerful tool, equally dangerous risks are present. As predictive technology develops, there is an important and necessary role for lawmakers to play in regulating the implementation of predictive analytic technology across various fields and disciplines. Currently, AI is increasingly being used across various industries, but there is limited guidance and regulation on AI liability and the use of this specific technology by federal authorities."[6] The Trump administration implemented initiatives to promote the growth of AI development to keep pace with other nations such as China and Japan. President Trump made his intentions clear in promoting AI technology, stating, "[c]ontinued American leadership in Artificial Intelligence is of paramount importance in maintaining the economic and national security of the United States."[7]

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[1] W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L.REV. 421, 423 (2017).

[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] KYLIE WATSON, DELOITTE INSIGHTS, PREDICTIVE ANALYTICS IN HEALTH CARE 2 (2019).

[4] *Id*.

[5] Sullivan & Schweikart, *supra* note 2, at 160.

[6] Ruben Amarasingham, Rachel E. Patzer, Marco Huesch, Nam Q. Nguyen & Bin Xie, *Implementing Electronic Health Care Predictive Analytics: Considerations and* Challenges, 33 HEALTH AFFS. 1148, 1149 (2014).

[7] Dep't of Energy*, White House Fact Sheet: President Donald J. Trump Is Accelerating America's Leadership in Artificial Intelligence*, ENERGY.GOV (Feb. 11, 2019),

Contrastingly, the Biden administration has remained silent as to its direction on AI development, but early agency nominees and selections give hope in maintaining the Trump Administration's progress. According to MIT Technology Review, "Biden elevated the director of the Office of Science and Technology Policy (OSTP) to a cabinet-level position, and appointed top geneticist Eric Lander, the founding director of the MIT-Harvard Broad Institute, to the role."[8] This selection is important in that the OSTP advises the president on science and technology issues and guides science and technology policy. Technology pundit Karen Hao suggests "while Trump mainly viewed AI as an important geopolitical tool—investing in its development for military purposes and to compete against China—Biden will also view it as one for scientific progress."[9] Moreover, prior to being sworn in, President-elect Biden's team outlined a $300-billion commitment to research and development, with an allocation of some of the funding to development of AI.[10]

In an effort to outline the potential liability risks of AI in healthcare, this note proposes an amendment to the current framework of federal regulations governing medical devices in healthcare. The recommendation guides how the FDA and Congress could regulate predictive analytic technology in the field of healthcare, basing such regulation upon various theories of tort liability, ethics, and existing law. Regulation is necessary, particularly because it is forecasted that there will be explosive growth in the AI health market, increasing more than "10-fold between 2014 and 2021."[11] However, such a proposal must consider the importance of promoting growth, development, and expansion of AI technology.

https://www.energy.gov/articles/white-house-fact-sheet-president-donald-j-trump-accelerating-america-s-leadership.

[8] Karen Hao, *The Biden Administration's AI Plans: What We Might Expect,* MIT TECHNOLOGY REVIEW (Jan. 22, 2021), https://www.technologyreview.com/2021/01/22/1016652/biden-administration-ai-plans-what-to-expect/ (last visited March 22, 2021).

[9] *Id.*

[10] *Biden, AI and Innovation: How the New Administration Will Guide Advancing Technologies*, THE UNIVERSITY OF CALIFORNIA INSTITUTE FOR PREDICTION TECHNOLOGY, https://predictiontechnology.ucla.edu/biden-ai-and-innovation-how-the-new-administration-will-guide-advancing-technologies/ (last visited March 22, 2021).

[11] SARA GERKE, TIMO MINSSEN & GLENN COHEN, ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295 (Adam Bohr & Kaveh Memarzadeh eds., 2020).

## II. The Broad Scope of Predictive Analytics

As a concept, predictive analytics refers to a process by which computer algorithms statistically analyze data, utilizing such analysis to predict future outcomes.[12] In an increasingly data-driven world, predictive analytics has the potential to be implemented in various far-reaching trades, industries, and personal uses.[13] An example of the broad applicability of predictive analytics is a baseball team implementing predictive analytics to analyze past data and player performances in order to recruit professional baseball players based on *anticipated* performance derived from the analytics.[14]

Predictive analytics has the potential to benefit consumers, businesses, and entities as well through both its ability to locate overlooked or otherwise invisible data and its ability to maximize desired outcomes based on that information.[15] Within the last decade, the United States government has begun to implement predictive analytics to defend against fraud and abuse of its various government programs.[16] To provide an example, the Small Business Jobs Act of 2010 provided funds for the Centers for Medicare and Medicaid Services (CMS) to develop a predictive analytic system for its Medicare and Medicaid programs.[17] In 2012, the CMS developed this system of predictive analytics to implement AI technology that uses various automated systems and processes to identify particular types of behavior, including fraud, before transactions are completed.[18]

Recently, there is an increasing acceptance and promotion of AI technology and its broad applicability in enhancing American life. Under the Obama administration, the United States government emphasized AI technology regulation with a focus on "fairness, safety,

[12] Jessica M. Eaglin, *Predictive Analytics' Punishment Mismatch*, 14 I/S: J. L. & POL'Y 87, 87 (2017).

[13] *Id.* at 87-88 ("Beyond sports, predictive analytics informs decisions about employment, advertising, healthcare and more.").

[14] *Id.*

[15] *Id.* at 88.

[16] U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-104, MEDICARE FRAUD PREVENTION: CMS HAS IMPLEMENTED PREDICTIVE ANALYTICS SYSTEM, BUT NEEDS TO DEFINE MEASURES TO DETERMINE ITS EFFECTIVENESS 2 (2012).

[17] Small Business Jobs Act of 2010, Pub. L. No. 111-240, § 4241, 124 Stat. 2504, 2599 (codified as amended at 42 U.S.C.§ 1320a-7m).

[18] MEDICARE FRAUD PREVENTION, *supra* note 13, at 2.

and governance."[19] However, there was a shift in the Trump administration's approach, emphasizing a free-market development of AI.[20] In 2019, President Trump signed the "Executive Order on Maintaining American Leadership in Artificial Intelligence" aimed at "(1) investing in AI [research and development], (2) unleashing AI resources, (3) setting AI governance standards, (4) building the AI workforce, and (5) international engagement and protecting the advantage of the US in AI."[21]

Consequently, predictive analytics has immensely developed in the private sector. For example, in the field of e-commerce merchants have begun using predictive analytics to identify consumers who share a common interest, factor, or some other pattern that leads them to the products or services sold by the merchant.[22] Once the factor is identified the merchant then develops a well-tested and well-refined model to use in practice, maximizing the number of page-views and purchases.[23] For better or worse, depending on perspective, the process has the effect of increasing profits for the merchant while limiting consumer knowledge of the business's solicitation .

This effect has caught the attention of many industries that want to maximize factors including profit, safety, speed, or, in the context of baseball, "wins." Accordingly, predictive analytics has developed in sensitive fields that create risk and, thus, a cause for concern. In healthcare, predictive algorithm-based "personalized medicine" aims to remedy the problem of improper diagnosis and treatment by demonstrating scientific links between biological patient characteristics, diagnoses, and treatment options.[24] Thus, healthcare has the potential to maximize results in treatment at a quicker and more successful rate than ever thought possible. However, those with the desire to implement personalized medicine in healthcare need to ensure both safety and ethicality if it is to be employed in such a sensitive field. This should be done through proper regulation and accountability.

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[19] GERKE, *supra* note 8 at 296.

[20] *Id*. at 297.

[21] *Id.*

[22] Shaun B. Spencer, *Privacy and Predictive Analytics in E-Commerce*, 49 NEW ENG. L. REV. 629, 631 (2015).

[23] *Id.* at 632-33.

[24] Jerry I-H Hsiao, *Patent Eligibility of Predictive Algorithm in Second Generation Personalized Medicine*, 22 SMU SCI. & TECH. L. REV. 23, 25 (2019).

## III. The Rise of Predictive Analytics in Health Care

The development of "black box" predictive medicine in healthcare is the product of decades of development in automated learning and methodical algorithm technology.[25] To put the growth of such technology in perspective, in the year 2015more than $2.4 billion in venture capital was invested into the development of AI-based technologies.[26] Moreover, "vast, real time data sets, such as those collected by electronic health record (EHR) systems" have led to the development of what is now known as "big data."[27] The immense scope and practicality of "big data" and electronic health records (EHRs) are exemplified by their adoption and implementation by more than eighty-seven percent of hospitals in the United States as of 2014.[28]

### A. Benefits of Predictive Analytics in Healthcare

One reason for such a high rate of implementation is predictive analytics' broad ability to treat complex diseases. For example, predictive analytics has been implemented into practice in the diagnosis, prevention, and treatment of cancer.[29] Predictive algorithms can identify high-risk cancer patients with a high chance of readmission after surgery or chemotherapy. Such data will then recommend crucial preventive care, reducing costs and strain on patients.[30]

Patient experience will also improve through the implementation of Black Box Medicine. Not only can predictive analytics help guide a course of treatment for complex diseases such as cancer, but the AI can

[25] W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine* 1-15 (Mich. Law Sch. Pub. Law & Legal Theory Working Paper Grp., Paper No. 536, 2017), https://ssrn.com/abstract=2910417.

[26] *Artificial Intelligence Litigation: Can the Law Keep Pace with The Rise of the Machines?*, QUINN, EMANUEL, URQUHART & SULLIVAN, LLP, https://www.quinnemanuel.com/the-firm/publications/article-december-2016-artificial-intelligence-litigation-can-the-law-keep-pace-with-the-rise-of-the-machines/ (last visited Jan. 18, 2021).

[27] I. Glenn Cohen, Ruben Amarasingham, Anand Shah, Bin Xie & Bernard Lo, *The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care,* 33 HEALTH AFFS. 1139, 1139 (2014).

[28] *Id.* at 1140.

[29] Hsiao, *supra* note 22, at 29.

[30] Kevin Joy, *How Are Predictive Analytics Applications Changing Oncology?*, HEALTHTECH MAG. (Aug. 29, 2019), https://healthtechmagazine.net/article/2019/08/how-are-predictive-analytics-applications-changing-oncology-perfcon.

also streamline workflows to boost staff efficiency in the medical center, thus improving the patient experience.[31]

Black-box technologies have additionally allowed clinicians and health care facilities to "determine an individual's real-time risk of a clinical event" in order to "predict risk and personalize care to substantially improve value."[32] Increasing healthcare costs drive the need for a process that avoids preventable treatment and hospital visits. Therefore, another prevailing use for predictive analytics is its ability to limit post-discharge care. Hospital readmissions account for more than $41 billion annually of hospital costs, and predictive analytics offers an economically efficient way to determine the probability of clinical readmission.[33] With such information, hospitals are developing early "evidence-based" intervention methods that lessen the number of necessary readmissions for high-risk patients.[34]

Another benefit for healthcare industries is a more accurate rate of diagnoses, inherently resulting in the more effective treatment of patients' illnesses.[35] This is achieved through the black-box's successes in "utilising historical data, overflow data from nearby facilities, population data, demographic data, reportable diseases, and seasonal sickness patterns."[36] Increased diagnostic accuracy allows the involved parties to uncover new or unknown correlations, insights into illness or treatment, and hidden patterns through examining the large datasets and forming predictions based on them.[37] The benefits of predictive analytics are so robust that widespread implementation is inevitable.

In practice, IBM's "Watson" is utilized to display the powerful capabilities of predictive analytics.[38] The AI program utilizes predictive analytics to explore and understand the entire body of medical knowledge alongside the personal records of a patient, in order to develop a diagnosis or treatment plan in less than three seconds.[39] Notably, the program saved a sixty-year-old woman in Japan by

[31] *Id.*

[32] Ravi B. Parik, Meetali Kakad & David W. Bates, *Integrating Predictive Analytics Into High-Value Care the Dawn of Precision Delivery*, 315 AM. MED. ASS'N 651, 651 (2016).

[33] *Id.*

[34] *Id.* at 652.

[35] WATSON, *supra* note 3, at 6.

[36] *Id.* at 5.

[37] *Id.* at 6.

[38] Hsiao, *supra* note 22, at 29.

[39] *Id.*

identifying her rare form of leukemia.[40] Even more astonishing, Watson took "just about" ten minutes to compare the patient's genetic changes with a database of twenty million cancer research papers to identify the rare disease.[41]

Despite these widespread benefits, transforming the healthcare industry into a system reliant upon unsupervised learning algorithms – used to expose patterns and structure in data and cluster them into groups – has far-reaching legal and ethical implications.[42] Regarding Watson, "recent studies show [the program] making wrong and unsafe treatment recommendations in some cases."[43] Risks such as improper diagnosis or incorrect treatment suggestion raise serious concerns about the software's safety. It has been stated with grim warning that "models are our tools and not our masters,"[44] and thus there exists the need for an established regulatory system to combat such risks.

## B. Risks Associated with Predictive Analytics

The need for a regulatory standard is consequential of the inherent risks associated with the implementation of AI in healthcare. It is nearly impossible to analyze and understand the *basis* for which the system provides a diagnosis of a patient's illness or treatment.[45] The processes underlying the autonomous conclusions offered by predictive analytic software are complex, and treating patients without understanding such processes threatens the occurrence of a malfunction, misreading, or "imperfect implementation."[46] An imperfect initial implementation of predictive analytics across the nation runs the increased risk of imperfect diagnosis and treatment, particularly for disadvantaged communities with lesser-equipped healthcare professionals.[47]

Moreover, there are dangerous risks in the collection, application, and utilization of patient data that guides black box medicine's predictions. Collected data contains inherent biases, resulting

[40] *Id*.
[41] *Id.*
[42] WATSON, *supra* note 3, at 2, 8.
[43] Hsiao, *supra* note 22, at 29-30.
[44] WATSON, *supra* note 3, at 11.
[45] *Id.* at 6.
[46] Cohen, *supra* note 25, at 1146.
[47] *Id.* at 1140.

from skewed "big data" that was collected from those building and programming the technology. This "big data" reflects the implicit values of the people coding and training the systems.[48] Therefore, unless very clear risk controls and assurance processes are actively engaged and addressed during coding, these biases result in heightened risk for incorrect diagnosis and treatment recommendation.[49] This risk is present because most of the algorithms driving predictive analytics are developed by "fallible human beings who all hold prejudices and biases—whether conscious or unconscious."[50]

To combat potential biases, providers implementing the AI must ensure potential skews in the data are acknowledged and remedied.[51] A continuous updating of systems and altering of algorithms is necessary to ensure the elimination of biases and serious statistical errors likely to occur with the technology's initial use.[52] Regulatory procedures and liability standards must be imposed on those attempting to financially benefit from the implementation of predictive analytics. Providers must necessarily address the potential causes of injury that could result from this software before injury is realized. Nonetheless, having a system of redress and compensation for injury once it occurs is equally vital.

President Trump and his administration attempted to address such concerns, providing guidance on the implementation of AI. In January 2020, President Trump issued a guidance document outlining 10 principles that must be considered in AI application: "(1) public trust in AI, (2) public participation, (3) scientific integrity and information quality, (4) risk assessment and management, (5) benefits and costs, (6) flexibility, (7) fairness and nondiscrimination, (8) disclosure and transparency, (9) safety and security, and (10) interagency coordination."[53]

## IV. Liability on Healthcare Providers

Placing accountability on parties potentially responsible for injury via the use of predictive analytics is both a complex and crucial

[48] WATSON, *supra* note 3, at 8.
[49] *Id.* at 12.
[50] *Id.*
[51] *Id*. at 8.
[52] *Id*. at 12.
[53] GERKE, MINSSEN & COHEN, *supra* note 8, at 297.

aspect of such a fast-growing, dangerous field of technology. "As the AI system becomes more autonomous, fewer parties (i.e., clinicians, health care organizations, and AI designers) actually have control over it . . . ."[54] The difficulty in imposing liability is due to the complexity and variation in how the numerous legal doctrines would treat different situations. The ability for a plaintiff to recover damages for personal injury resulting from a physician's use of predictive analytics is likely grounded in common law negligence doctrines. On one hand, theories of medical malpractice, vicarious liability, and agency law place responsibility on providers, while on the other hand, doctrines such as products liability and common enterprise theories place responsibility upon manufacturers and developers of the technology.[55]

## A. Medical Malpractice and Vicarious Liability

It is well-established law that liability for physical harm is dependent upon an act, or an omission to act when there is a duty to do so.[56] The healthcare industry is not immune to tort liability, and thus the standards of negligence are imposed up liable parties in the form of medical malpractice. "[T]he essential elements of medical malpractice are (1) a deviation or departure from accepted medical practice, and (2) evidence that such departure was a proximate cause of injury."[57]

The doctrine of medical malpractice is one that lawmakers may use to regulate black-box predictive analytics. This is done through the imposition of tort-based medical malpractice standards of care on the healthcare providers utilizing the technology. There are, however, numerous shortcomings that make this standard difficult to apply to AI predictive analytics. First, the autonomous nature of AI predictive analytics makes it difficult to impose liability on any one party for using

[54] Sullivan & Schweikart, *supra* note 2, at 163.

[55] *See generally id*. (discussing a liability regime similar to that discussed in relation to autonomous vehicles, where malpractice, products liability, and vicarious liability would combine to address legal challenges "while encouraging professionals to purchase and use [AI] systems."); *see also Artificial Intelligence Litigation*, *supra* note 24 (discussing the need for creative concepts to address issues of causation and liability related to AI technology).

[56] *See* RESTATEMENT (SECOND) OF TORTS § 282 (AM. L. INST. 1965).

[57] Ongley v. St. Lukes Roosevelt Hosp. Ctr., 725 F. App'x 44, 46 (2d Cir. 2018) (citing DiMitri v. Monsouri, 754 N.Y.S.2d 674, 675 (N.Y. App. Div. 2003).

such technology.[58] When a medical malpractice standard is employed "a physician's usage of nearly any new medical technology runs the risk of failing to comport with custom."[59] Because all new and unfamiliar technology such as predictive analytics would constitute a deviation from custom, liability would fall on those who use it.[60]

Custom and duty of care are factors in negligence theory that underlie the basis for medical malpractice law. Evidence of compliance with or departure from custom is admissible to prove negligence.[61] This reflects the notion that recurring patterns of conduct have a bearing on what constitutes reasonable care.[62] Thus, in medical malpractice, evidence of compliance with *non-customary* practices are insufficient to coincide with custom, unless the defendant proves the practice to be a "reasonable alternative."[63]

Implementation of predictive analytics would therefore not yet be included in customary practice. However, even if a majority is believed not to use the technology, testimony is still commonly admitted to show that an increasing number of physicians – a "respectable minority" – follow the new practice that the defendant followed. This, if accepted by the court, creates another school of thought sufficient for meeting "custom,"[64] thus providing a would-be defendant with a defense against the medical malpractice theory of negligence.

Custom may become an inapplicable standard because the standard governing the use of AI will change as such technology develops and becomes more widespread. One group of scholars succinctly noted, "As medical AI improves, however, its use might itself become customary or even necessary, especially if the algorithm has a sufficiently long track record of outperforming human physicians in diagnosing a disease."[65]

[58] Sullivan, *supra* note 2, at 163.

[59] Zach Harned, Matthew P. Lungren & Pranav Rajpurkar, Comment, *Machine Vision, Medical AI, and Malpractice*, HARV. J.L. & TECH. DIG. 1, 6 (2019).

[60] *Id*.

[61] Kenneth S. Abraham, *Custom, Noncustomary Practice, and Negligence*. 109 COLUM. L. REV., 1784, 1784 (Nov. 2009).

[62] *Id*.

[63] *Id*. at 1812.

[64] *Id*.

[65] Harned, Lungren & Rajpurkar, *supra* note 57, at 7.

Differently, some scholars have proposed analogizing AI in the healthcare industry to a medical student-in-training.[66] This method would have the dual purpose of giving a particular personhood to the technology, as well as enabling the law to treat the physician as principle and impose a theory of vicarious liability. "Vicarious liability applies when 'one individual can be held legally responsible for the acts of another.'"[67] This offers an avenue for overcoming some of the aforementioned difficulties in applying medical malpractice standards to artificial intelligence.

Imposing liability on the provider for the errors of a machine has its own legal issues. Treating the AI technology that offered the diagnosis and treatment recommendations as a medical student would enable plaintiffs to sue *providers* without facing the defense that the predictive analytics were acting autonomously and without the control of the provider.[68] However, there is an obvious intermediary event that occurs between a machine's proposal of treatment and the injury to the patient.

To overcome this issue of the intermediary event, vicarious liability could center on the *decision-making event* that occurs between the machine's proposing of treatment and the physician's administering of that treatment. Doctors and caregivers should thus record data from the AI and discuss the diagnosis and treatment pathways in detail with patients. "[A]s part of this treatment process they clearly track the decision-making point between the human and the machine."[69] Centering the liability theory upon the moment a provider makes the decision to follow the advice of the machine incentivizes against over-reliance and ensures providers do not rely solely on the algorithms utilized by the machine but instead continue to apply a human mental process to diagnoses.[70]

[66] Jason Chung & Amanda Zink, *Hey Watson – Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine*, 11 ASIA PACIFIC J. HEALTH L. & ETHICS 51, 53 (2018).

[67] *Id*. at 67.

[68] *See id*. at 69 ("Watson and medical students share another key similarity: they perform complex work as part of the direct patient care team but do not have the autonomy and decision-making authority of attending physicians or even residents.").

[69] WATSON, *supra* note 3, at 10.

[70] *Id*.

## B. Agency Theory

Vicarious liability may be imposed on the provider or facility employing the functions of AI technology through an imposition of "agency" theory. Under this doctrine, "[a]n employer is subject to vicarious liability for a tort committed by its employee acting within the scope of [his or her employment.]"[71] The Restatement (Third) of Agency makes clear that:

> An employee acts within the scope of employment when performing work assigned by the employer or engaging in a course of conduct subject to the employer's control. An employee's act is not within the scope of employment when it occurs within an independent course of conduct not intended by the employee to serve any purpose of the employer.[72]

Thus, if lawmakers interpret the functions of predictive analytic technology as acting as an "employee," under the directive of the "employer," a theory of agency could apply.

Similar to the issue that arose with malpractice negligence and vicarious liability, issues arise again when one considers the autonomous nature of the AI. This is a compelling counterargument to the use of agency theory because "once an autonomous machine decides for itself what course of action it should take, the agency relationship becomes frayed or breaks altogether."[73] There is precedent, however, of courts applying agency theory to the use of medical devices in the analogous instances of automated surgical robots and cancer treatment devices.[74] Thus, the legal analogy to conferring personhood upon the AI itself, as described above, may offer the best solution in overcoming the issue of autonomy.[75] Conferring personhood upon the AI would allow the plaintiff to bring suit upon the AI, by way of the employer acting as

[71] RESTATEMENT (THIRD) OF AGENCY § 7.07(1) (AM. L. INST. 2006).

[72] RESTATEMENT (THIRD) OF AGENCY § 7.07(2) (AM. L. INST. 2006).

[73] *Artificial Intelligence Litigation*, *supra* note 24.

[74] *Id*. *See generally* Payas v. Adventist Health System/Sunbelt, Inc., 238 So.3d 887 (2018) (holding that surgical staff utilizing surgical robots were liable under the agency theory of liability).

[75] David C. Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence,* 89 WASH. L. REV. 117, 150 (2014).

principle, in an effort to overcome the above issues inherent in the agency theory of liability.

There are clear difficulties that are implicit in the above negligence doctrines. Noteworthy and intriguing is the possibility courts and legislatures could seek to impose more rigorous standards such as a theory of *res ipsa loquitur* on healthcare providers. This would serve as both a strict standard of care to compensate for injuries and a deterrent for potential tortfeasors.

### C. Res Ipsa Loquitur

In the past, courts have applied the theory of *res ipsa loquitur* on behalf of individuals harmed as a result of automated technologies.[76] The theory of negligence rests upon a situation where the fact and nature of the injury itself affords proof of negligence, so as to relieve the plaintiff of the initial obligation to show negligence, or rather, to discharge that obligation on his or her part.[77] Courts have applied *res ipsa loquitor* in instances where devices have likely caused injury to a plaintiff, holding that the burden be shifted to the defendants on the theory that the "device" was under the exclusive control of the defendants, and the injury was one which in the natural course of events would not have occurred had the defendants used due care.[78]

This standard of *res ipsa loquitor* is quite harsh in its application to predictive analytics, particularly in light of the ever-developing nature of the technology. This is the unlikeliest of the aforementioned standards in that the imposition of this liability standard would probably deter the use of such a beneficial technology altogether.

Moreover, the incidents governed by this doctrine are easily defended on the grounds that "the doctrine should not apply when it is unreasonable to infer that the accident was caused by a design or manufacturing defect, or when the accident in question is not one ordinarily seen with design defects."[79] The difficult nature in proving

[76] *See generally Nelson v. American Airlines, Inc.,* 263 Cal. App. 2d 742 (1968) (applying the doctrine of *res ipsa loquitur* in finding an inference of negligence by American Airlines relating to injuries suffered while one of its planes was on autopilot).

[77] Fred E. Heckel & Fowler V. Harper, *Effect of the Doctrine of Res Ipsa Loquitur*, 22 ILL. L. REV. 724, 724 (1928).

[78] *See generally* Chauvin v. Krupin, 4 Cal. App. 2d 322 (1935) (holding defendant liable via res ipsa loquitor for the burn injuries of a defendant resulting from the use of a curling iron).

[79] *Artificial Intelligence Litigation*, *supra* note 24.

proximate cause of injuries resulting from predictive analytics makes this defense applicable.

If none of the aforementioned proposed liability standards on providers apply, imposition upon AI *manufacturers*, rather than providers, is a logical next inquiry.

## V. Liability on AI Developers

As stated above, a second party with which lawmakers should be equally concerned is the manufacturer or developer of the AI predictive analytic systems. One way to impose liability on developers and manufacturers is through a theory of products liability, where a manufacturer can be found liable for its product causing harm to a subsequent user.[80] Specifically, manufacturers can be liable for injuries caused by *medical* devices deemed to be "defective" under the law.[81] An analysis of how the FDA treats "medical devices" is found later in this article. Alternatively, "common enterprise theory," or the spreading of liability across multiple parties, may also be a logical remedy for injured parties to consider.

### A. Products Liability and the Learned Intermediate Doctrine

Injuries resulting from a medical device deemed "defective" or "inherently dangerous" would fall under the products liability theory because "medical products have *inherent and unavoidable risks*."[82] Therefore, the use of a medical device operating with inherent risks, some of which were described earlier in this note, allows the courts to hold manufacturers strictly liable under a theory of products liability when the device is defective or inherently dangerous.[83]

The legal issue with applying a products liability standard is that the plaintiff needs to overcome the "learned intermediary defense."[84]

[80] Harned, Lungren & Rajpurkar, *supra* note 57, at 8.

[81] RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §6(A) (AM. L. INST. 1998) (A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription).

[82] Sullivan & Schweikart, *supra* note 2, at 162.

[83] Chung & Zink, *supra* note 65, at 68.

[84] Sullivan & Schweikart, *supra* note 2, at 162.

This is a manufacturer's defense to a claim of products liability on the grounds that the manufacturer owed no duty to the injured patient, and that the physician is the end-consumer of the product.[85] As an end-consumer, the liability to prevent injury to the plaintiff falls upon the medical provider and not the manufacturer. An applicable exception to this rule is "if the physician is *not* playing an active role with regard to the product and patient."[86] In such a case, the manufacturer cannot make use of the learned intermediary defense.

Imposing products liability upon manufacturers faces difficulty in the courts, as the technology itself is so complex and liability for resulting injury may fall on any number of the aforementioned parties, including the patient, physician, or medical provider. Scholars note that "it would be up to the courts to expand the products liability doctrine to include pure software and hold such manufacturers responsible."[87] The argument in favor of imposing products liability on manufactures rests on the basic premise that the more accurate and interpretable these AI devices become, the more they behave like physicians. Thus, it is more likely that using such technology could be seen as necessary to comport with typical medical practice, thereby minimizing physician liability for its use and increasing developer liability for its improper construction.[88]

## B. Common Enterprise Theory

It is clear from the various legal theories proposed that the legislature has a difficult task in crafting law that will properly provide redress for injuries resulting from the implementation of predictive analytics. Therefore, an interesting option is to construe the law to impose a theory of Common Enterprise: a standard that will apportion responsibility among the different the parties that participated in building, maintaining and implementing the predictive analytics.[89]

Imposing a theory of common enterprise would enable the injured party to recover, without the difficult task of determining who is

[85] *Id*.

[86] Harned, Lungren & Rajpurkar, *supra* note 57, at 9 (emphasis added). *See generally* MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69 (Mass. 1985) (holding the relatively passive role the physician plays in prescribing oral contraceptives to young women as one of the reasons the learned intermediary doctrine did not apply).

[87] Harned, Lungren & Rajpurkar , *supra* note 57, at 8.

[88] *Id*.

[89] *Artificial Intelligence Litigation*, *supra* note 24.

responsible. A common enterprise theory might allow the law to impose joint liability, without having to assign every aspect of wrongdoing to one party or another.[90] Scholars have considered this standard in the analogous field of autonomous self-driving vehicles. However, scholars argue that substantial change to the doctrine would need to happen in order for it to apply to AI technology in healthcare.[91] Under a theory of common enterprise, liability is applied to all participating wrongdoers acting jointly. Applied to AI technology in healthcare, however, there would be no wrongdoers. Instead, there would be "an inference of liability drawn by operation of law to protect a *blameless* party (the person who sustained [injuries]) . . . ."[92] This would be done by making others, whether legally responsible or not, bear the cost.[93]

Despite the ethical obstacle of imposing liability on a potentially blameless party, the doctrine offers the beneficial prospect of permitting the law "to impose joint liability without having to lay bare and grapple with the details of assigning every aspect of wrongdoing to one party or another."[94] Courts would thus infer the liability on the fact the separate parties were in pursuit of a common goal, and consequently engaged in an act resulting in harm.[95] Crafting the law in this manner allows the doctrine to reach any party with an interest in the performance of the AI device and financial gain thereof. This allows the injured plaintiff to recover from all *potentially* responsible parties and overcome the technical limitations normally applied in negligence suits.

## VI. Current Federal Regulation and Preventative Measures

It is necessary for lawmakers and courts to address compensation for injured parties. But preventative regulations are equally crucial, if not more so, because they address the potential harms before they happen. Before proposing any measures on the use of predictive analytics, we must determine who has authority to do so, and how those measures should be imposed.

[90] *Id*.
[91] *See* Vladeck, *supra* note 74, at 149.
[92] *Id*. (emphasis added).
[93] *Id*.
[94] *Id*.
[95] *Id*.

The primary regulatory agency of "medical devices" is the US Food and Drug Administration (FDA), authorized under 21 U.S.C. ch. 9, also known as the Food, Drug and Cosmetic Act (FDCA).[96] The FDCA defines a "medical device" as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" which is "*intended for use in the diagnosis of disease* or other conditions, or in the *cure, mitigation, treatment, or prevention of disease*."[97] Thus, if predictive analytic technology is understood as one of the listed "devices" intended for diagnosing and treating medical conditions, black-box AI would fall under this provision and be subjected to regulation under that law.

The most appropriate classification of AI predictive analytic software, used for the purposes of medical treatment, is the category of "medical devices." Under its already-granted authority, the FDA may impose and enforce certain regulatory provisions on the manufacturers of certain medical devices, ensuring their safety and effectiveness.[98] Examples of such safety provisions already in place include

[96] Price, *supra* note 1, at 437.

[97] 21 U.S.C. § 321(h)(2) (2016) (emphasis added). The full statutory definition of a medical device under this provision is:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or
> any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals,
> and which does not achieve its primary intended purposes through chemical action
> within or on the body of man or other animals and which is not dependent upon being
> metabolized for the achievement of its primary intended purposes.

[98] 21 U.S.C. § 360j(f)(1)(A) (2021). The full statutory authority provides that:

> the Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

manufacturing practice requirements such as premarket clearance and premarket approval processes.[99] If predictive analytics fall under the proper definitions governed in the cited provision, manufacturers will be subject to these above-stated requirements.

The complexity in classifying the software and algorithms controlling predictive analytics as a "medical device" under the proper FDCA section makes carrying out the enactment of such a provision difficult on manufacturers. On December 13, 2016, Congress attempted to clarify the growing ambiguities by enacting the 21st Century Cures Act (Cures Act).[100]

Under the applicable provision of the Cures Act, §3060(a) "Clarifying Medical Software Regulation," Congress amended the FDCA to include §520(o), which outlines software functions that are *excluded* from the definition of "medical device" already defined in § 201(h) of the FDCA.[101] Under the exclusions, the definition of "medical devices" does *not* include software functions that perform various administrative roles. Also, the statute may exclude software that is "clinical decision support software" (CDS), performing data analysis for the purpose of "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition."[102]

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[99] *See Artificial Intelligence and Machine Learning in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (last updated Jan. 12, 2021) ("Traditionally, the FDA reviews medical devices through an appropriate premarket pathway, such as premarket clearance (510(k)), De Novo classification, or premarket approval.").

[100] *See* U.S. FOOD & DRUG ADMIN., CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21ST CENTURY CURES ACT: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 1-2 (2017) [hereinafter MEDICAL SOFTWARE POLICY CHANGES].

[101] H.R. Res. 34, 114th Cong. §3060 (2016) (enacted) (amending 21 U.S.C. § 360j (2012)). *See also id*. § 3060(d). The definition of "medical device" under §201(h) of the FDCA is codified at 21 U.S.C. § 321(h).

[102] 21 U.S.C. §360j(o)(1)(E). The full provision excludes software:

> unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—
>
> (i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
>
> (ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

The technology and software that the FDA deems "clinical decision support software" is likely inclusive of the AI black-box predictive analytics, which *exclude* such technology from the definition of "medical device." As a result, manufacturers are excluded from the aforementioned clearance requirements and thus need additional regulation. This is only true if AI also meets the remaining criteria of the statute.

The FDA examines the nature of clinical decision support software in its September 27th, 2019, "guidance document," a series of draft guidance language aimed at expressing the agency's thinking and interpretations regarding a topic or statute.[103] The FDA distinguishes between device and non-device clinical decision software, stating in pertinent part that software is *not a device* when intended for the purpose of enabling a health care provider to "*independently* review the basis for such recommendations that such software presents so that it is not the intent that such health care professionals rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."[104] It follows that a non-device CDS will not be governed under the medical device regulations of the FDCA. Moreover, the FDA clarifies that the above-stated exclusion on software functions providing recommendations on treatment and prevention of diseases does not encompass such software that is designed for use by *patients or caregivers*, which the FDA intends to continue governing under the statutory definition of "medical device."[105] Predictive analytics are thus not covered under this interpretation because they are not intended for personal use.

As stated, a non-device CDS that is exempt from FDA regulation encompasses a software that, among other factors, is (1) intended for purposes of displaying and analyzing medical information; (2) intended for purposes of providing recommendations, based on such analysis of

> (iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

[103] *See* U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 1, 5 (2019) [hereinafter CLINICAL DECISION SUPPORT SOFTWARE].

[104] *Id*. at 8 (emphasis added).

[105] *Id*. at 23.

patient-specific data; (3) is intended to support or provide recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition; and most importantly (4) is intended to enable the providers to *independently review the basis* for such recommendations so that they do not rely upon them in clinical decisions.[106]

Predictive analytics, as applied in healthcare, runs the risk of failing the fourth criterion of enabling providers to independently review the basis for the system's recommendations. The FDA interprets independent review as the ability to "describe the underlying data used to develop the algorithm and should include plain language descriptions of the logic or rationale used by an algorithm to render a recommendation."[107] However, considering the complexity of predictive analytic responses, the provider undoubtedly remains incapable of understanding the underlying basis for the recommendations of predictive analytics software.[108] Consequently, if the basis is not understandable, AI predictive analytics does not enable providers to "independently review the basis"[109] for the presentations of information and thus are classified as a device-clinical decision support software included under §520(o)(1)(E).[110] It follows that predictive analytic software is a device-CDS, subject to current FDCA regulation of medical devices. As a result of failing the exclusion requirements, predictive analytics are likely subject to the FDA regulations on device-CDS technology.

Pertinent to the issue at hand the FDA has addressed the future of FDA regulation on device-CDS software.[111] The FDA has said it plans to focus oversight on higher-risk software functions, including those used in serious or critical situations, as well as machine learning-based algorithms, "where the program's logic and inputs may not be fully explained to the user."[112] Such machine-learning algorithm technology, lacking the ability to explain the basis and logic for its recommendations,

[106] *See id*. at 10-12.
[107] *Id*. at 12.
[108] *See* WATSON, *supra* note 3, at 6.
[109] See 21 U.S.C. §360j(o)(1)(E)(ii) for further discussion of this term.
[110] *See generally* 21 U.S.C. § 360j (codifying §520 of the FDCA).
[111] *See* CLINICAL DECISION SUPPORT SOFTWARE, *supra* note 102, at 23.
[112] Conor Hale, *FDA Delivers Regulatory Guidance on AI Software and Clinical Decision-Making Aids*, FIERCE BIOTECH (Sep. 26 2019, 1:01 PM), https://www.fiercebiotech.com/medtech/fda-delivers-regulatory-guidance-ai-software-and-clinical-decisionmaking-aids.

is representative of the AI predictive analytics being developed and implemented today.

Under future regulation, the FDA intends to impose regulatory oversight in an effort to "inform clinical management" of such technology implemented for treatment of serious or critical situations or conditions.[113] The FDA is not presently concerned with the implementation of software intended to inform critical management of non-serious situations or conditions, but the following proposal would cover both serious and non-serious conditions.[114]

It is clear that a new regulatory framework is needed to govern the implementation of predictive analytics, as the software is not yet governed under FDA law. Because the AI technology likely falls under FDCA governance, not excluded under 520(o)(1)(E)(iii) of the Act, current laws need to adapt to the ever-changing functions of predictive analytics in healthcare.[115] The following sections will outline what should currently apply to predictive algorithm-driven AI under the law. Also outlined is a legislative proposal on how Congress and the FDA should amend the FDCA to regulate and impose liability on developers of new and recently developed predictive analytics software intended for use in healthcare.

## VII. Federal Regulation of Medical Devices

There are various regulations currently in place that may govern the implementation of black-box AI. These are basic regulations that US-based manufacturers and distributors must understand and comply with. Minor regulations such as establishment registration, premarket notification and premarket approval all apply to predictive analytic technology.[116]

[113] CLINICAL DECISION SUPPORT SOFTWARE, *supra* note 102, at 23.

[114] See *id*. at 21. Examples of such non-serious uses include: software intended "to alert HCPs to potential triggers that may be indicative of cholesterol management issues," software intended for providers "where the basis for the recommendation is not disclosed to the user to analyze patient information to determine which over-the-counter (OTC) allergy drug class is likely to be most effective in alleviating the patient's seasonal allergies," and "software that provides recommendations of potential allergens and common cold symptoms based on location-specific electronic health records, environmental conditions, and patient-reported outcomes."

[115] *See generally* 21 U.S.C. § 360j(o)(1)(E).

[116] *See* Anand Borad, *An Overview of FDA Regulations for Medical Devices,* EINFOCHIPS (Feb. 22, 2018), https://www.einfochips.com/blog/an-overview-of-fda-regulations-for-medical-

More important is the provision for clinical studies, titled the "Investigational Device Exemption" (IDE) and governed under 21 C.F.R. Part 812.[117] This provision "allows manufacturers to collect device-specific safety and effectiveness data for the proposed device before commercialization, which can be used to support premarket approval application or in some cases for premarket notification submission."[118] Due to the complex process that underlies the functions of predictive analytics and the important need for safety, this law should govern the software. Under the current law, manufacturers are required to: (1) undergo a clinical study plan approved by an institutional review board (where the study involves a "significant risk device," the FDA must also approve the IDE); (2) obtain the informed consent of all patients; (3) label the device with a statement that"the device is for investigational use only"; (4) allow monitoring of the study and; (5) produce all the records and reports.[119] After satisfying all the above requirements, the predictive analytics would be ready for widespread implementation.

In cases of serious injury or death resulting from the *use* of a medical device, 21 C.F.R. Part 803 governs Medical Device Reporting. This mandates the reporting to the FDA of all medical devices that cause death, serious injury, or certain device malfunctions.[120] "The goal of this regulation is to timely detect and correct problems by identifying and monitoring significant negative effects of a particular medical device."[121] The shortcoming of this law provision is that, despite mandatory reporting of injury, [122] it provides little redress for those suffering. The law merely addresses the reporting of injuries to keep a record of potentially dangerous devices on the market. This note proposes an amendment that will craft an avenue for the law to govern liability and liable parties following the filing of an 803 Report.

As stated, there are shortcomings to the current regulatory regime, particularly any provisions explicitly governing penalties,

devices/; *see also* 21 C.F.R. pt. 807; 21 C.F.R. pt. 807 subdiv. E; 21 C.F.R. pt. 814 (applicable provisions).

[117] *See generally* 21 C.F.R pt. 812.

[118] Borad, *supra* note 115; *see also* 21 C.F.R. pt. 812.

[119] Borad, *supra* note 115.

[120] 21 C.F.R. pt. 803.

[121] Borad, *supra* note 115.

[122] *See id*. (discussing mandatory reporting when a manufacturer has identified that a device caused death or serious injury).

consequences, and deterrents for improper use. There is also a lack of clarity in what technologies are covered under numerous provisions of various statutes. Therefore, because predictive analytics falls under the current law as device-clinical decision support software (CDS), and thus is governed under current framework of the FDCA, a proper amendment to this body of law is necessary to address the growing use of predictive analytics specifically, ensuring clear and effective governance.

## VIII. Proposed Amendment to the FDCA

To follow is a framework proposed as an amendment to the current legislative rules governing devices and software that utilize predictive algorithm technology specifically implemented in healthcare. The proposed amendment of the FDCA will be divided into three parts. The first section is titled "covered devices," explicitly stating which predictive analytic and applicable various technologies fall under the proposed legislation. The covered software will include provisions for devices used for both critical and non-serious-intended uses. The covered software will be based on the guidance from the FDCA Guidance Documents dated September 27, 2019, and December 8, 2017.[123]

The second section of the amendment will impose preemptive regulations on all covered predictive analytics in the healthcare industry. This section is designed to address safety concerns and impose measures to prevent injury while maximizing AI capabilities. Finally, the third section of the proposed amendment will outline the procedures necessary for claimants to follow, subsequent to injury or death resulting from the use of predictive analytics. This section will also include remedies for injuries or death related to the use of the covered technologies.

### A. Part 1: Covered Devices

Covered software under the new amendment to the FDCA will coincide with the relevant statutory language in 21 U.S.C. Section

[123] *See generally* CLINICAL DECISION SUPPORT SOFTWARE, *supra* note 102, at 1; *see also* MEDICAL SOFTWARE POLICY CHANGES, *supra* note 99, at 1.

360j(o)(1)(E).[124] However, this proposal is separate and distinct. This amendment states that the provisions of this law cover both lower and higher-risk software functions, including those used in serious or critical situations. Moreover, all machine learning-based algorithms, where the program's logic and inputs may not be fully explained to the user, are covered under this new amendment to the FDCA.[125] All unsupervised machine-learning algorithms, used in exposing patterns and structure in data to deduce both diagnosis and proper treatment for serious and non-serious conditions, fall under these provisions.

All Device-CDS implemented by healthcare providers with the intention of being used by these providers exclusively, and whose functions do not provide the opportunity for independent basis review, will also fall under this amendment.[126] Finally, devices classified as Device-CDS intended for *patient use*, and intended to inform clinical management of non-serious situations or conditions do not fall under this proposed amended provision.[127] The exclusion of patient-used software such as smartphone apps or online medical forums is intended to create a law that focuses on preventing and compensating patient injuries caused by those who owe a duty of care.

### B. Part 2: Preemptive Regulation

The proposed amendment to the FDCA is to be comprised of both preemptive and remedial provisions. First, any medical provider or manufacturer intending to implement a covered device or software under Part 1 of this amendment will be subject to the immediate premarket approval and clearance processes already utilized in other areas of the law.[128] The standard for such an approval process will coincide with 21 U.S.C. Section 360e which states, in pertinent part, "the Secretary shall by administrative order . . . require that such device have an approval under this section of an application for premarket approval."[129] The premarket approval for the covered devices under Part 1 will mirror, in relevant part, the premarket approval process under Section 360e. The

[124] *See* CLINICAL DECISION SUPPORT SOFTWARE, *supra* note 102 at 12; *see also* 21 U.S.C. § 360j(o)(1)(E).
[125] *See* CLINICAL DECISION SUPPORT SOFTWARE, *supra* note 102 at 23.
[126] *See id*. at 12.
[127] *See id.* at 23.
[128] *See* 21 U.S.C §360e(b)(1).
[129] *Id*.

provision will mandate an application for the manufacturing and sale of above-covered software, including:

> (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;
> (D) a report showing the device meets a standard of reasonable assurance of safety and effectiveness;
> (E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;
> (F) specimens of the labeling proposed to be used for such device.[130]

The proposed premarket approval process for manufacturers is consistent with the most stringent levels of device marketing applications required by the FDA. This is intended to ensure the proper precautions are taken before the covered device hits the market.

This premarket approval application also promotes proper development at the early stages of implementation. The requirements outlined above are a proper way to discourage the inherent and implicit biases reflected in the programming of many predictive algorithms

[130] *Cf.* 21 U.S.C §360e(c)(1)(A)-(F). Note that the author's provision mirrors §360e, with the exception of part (D).

today.[131] However, regulation of predictive technology must go beyond the premarketing stages, and the legislature must ensure continued oversight of the technology once approved by the FDA.

The second provision of this section will consist of regulatory oversight on the instruction and education of predictive analytics technology and its processes during implementation in the facility. Regulatory oversight allows for the information obtained from any clinical and/or non-clinical testing, such as clinical trials or product performance testing, to be taken into account during the premarket review process and FDA's benefit-risk determination..[132] The proposed regulatory oversight includes continuing to inform physicians of options for treating, diagnosing, preventing, or mitigating a disease or condition. Also, regulatory oversight will provide clinical information by aggregating relevant information such as disease, condition, drugs, medical devices, and population.[133] Regulatory oversight will aid in the collection of relevant clinical and non-clinical information used in extensive risk assessment. If the predictive analytic technology is regularly determined to pose little hazardous risk to patients, its continued use will be permitted.

Additionally, coinciding with current legislation, all Part 1 covered devices and software will be subject to a "clinical study plan" approved by an institutional review board (which also must first be approved by the FDA, separately). The plan will require informed consent from all patients; labeling stating that the device is for investigational use only; monitoring of the study; and all the records and reports.[134] These pre- and post- market clinical studies will determine the safety and effectiveness of the device, assisting regulators in making judgments about the intervention of the new device, resting on the strength of the evidence arising from the data collected in the study. Clinical study plans will aim to: determine safety for human use and efficacy of the device; eliminate systematic biases and increase the statistical power of the device; and lastly, obtain last-minute information about the risks, benefits, and optimal use of an intervention. The findings

[131] *See* WATSON, *supra* note 3, at 12.

[132] FOOD AND DRUG ADMINISTRATION, FDA-2011-D-0577, FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVAL AND DE NOVO CLASSIFICATIONS (2019).

[133] Id. at 8.

[134] Borad, *supra* note 115; *see also* 21 C.F.R. pt. 812.

will subsequently be used to assess the long-term effects of treatment, and to reveal rare but serious side effects.[135]

The preemptive procedures outlined are to be established and followed for all Part 1 covered devices and software. These procedural guidelines should be in place as preemptive and preventative measures to limit the number of improper diagnoses and treatments. The final section of this proposed amendment will cover procedure for injuries resulting from the use of covered devices. It will also outline proper redress for injuries that resulted from the use of predictive analytics.

### C. Remedial Opportunities for Victims

Following an instance in which a patient is injured or killed as a result of false diagnosis or improper treatment, the amended statute will require immediate mandated reporting. The aptly named "Predictive Analytic Mandated Reporting Provision" will mirror the requirements of 21 C.F.R. Part 803.1. The provision requires all manufacturers and providers to report to the FDA all instances in which covered predictive analytic technology causes a death or a serious injury through misdiagnosis, improper treatment, or device malfunction.[136] The specific language of this provision will read:

> If you are a device user facility, you must report *deaths and serious injuries* that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report *deaths and serious injuries* that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files.[137]

[135] The clinical study plan follows recommendations and reasoning from guidance published by the National Academy of Sciences. *See generally* INST. OF MED. (US) COMM. ON STRATEGIES FOR SMALL-NUMBER-PARTICIPANT CLINICAL RSCH. TRIALS, SMALL CLINICAL TRIALS: ISSUES AND CHALLENGES - DESIGN OF SMALL CLINICAL TRIALS (2001) (ebook).

[136] *Cf.* 21 C.F.R pt. 803.1.

[137] *Id.* (emphasis added).

The report must be filed within an immediate time frame, specifically within a period of five business days.[138] The report must be filed with sufficient detail to enable the FDA to determine whether the specific predictive analytic system poses a broader risk to the public and whether further intervention is needed regarding that device.

Death or serious injury will be defined as an injury or illness that is:

> (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.[139]

This definition does not prevent claimants from filing suit under the statute for less serious injuries. It merely outlines when physicians and manufacturers are required to *report* serious injury or death to the FDA. Following the death or serious injury resulting from the use of a covered device or software, the amendment will also provide an avenue for victim compensation. The statute will state that any victim who qualifies as suffering serious injury or death under the above mandatory reporting provision will be entitled to recovery under a standard of common enterprise liability. Suing under the common enterprise standard would entitle a qualified party to apportion the liability among all of the parties that participated in building, maintaining and implementing the predictive analytics.[140] It is the claimant's burden to prove all elements of proximate cause and damages.

The provision will provide a legally protected opportunity for injured parties to recover, without meeting the burden of proving a specific party was at fault.[141] This protection will not be in place to deter the use of predictive analytics. Instead, the law will infer liability solely

[138] *Cf.* 21 C.F.R. pt. 803.3(h) (also operating with a five-day report).

[139] *Cf.* 21 C.F.R. 803.3(w)(1)-(3).

[140] For further explanation of standard of common enterprise liability, see *Artificial Intelligence Litigation*, *supra* note 24.

[141] *See id*.

to protect a blameless, injured party by making others, whether proximately responsible or not, bear the cost.[142]

The significance of this final provision is that it statutorily guarantees an avenue for parties to receive compensation for their injuries resulting from the misuse of predictive analytics. Moreover, the liability standard would have the effect of incentivizing potentially liable parties to follow the guidelines of the proposed statute. More importantly, because of the joint liability, potential tortfeasors could be held jointly liable in an action as part of a group with a common interest in using predictive analytics.".[143] Therefore, parties will be less inclined to avoid the software's use altogether as the liability and compensation will be split amongst multiple parties rather than one potentially blameful provider or manufacturer.[144]

## IX. Concluding Considerations

The aforementioned statutory proposition is offered as a guideline to regulate the evolving field of AI in healthcare. It is inevitable that this technology will become commonplace in various industries, including healthcare, because of its potential to benefit human productivity. However, as suggested, healthcare places AI technology in a unique position because of the relationship between patient and physician.[145]

The considerations implemented into this statutory proposition, most important of which include patient consent and regulatory oversight, are necessary to maximize the algorithm's success while simultaneously maximizing patient safety and awareness of how their injuries are being treated. It is inevitable that the FDA will implement some level of regulation on programs utilizing predictive algorithms, as they have begun discussions in the latest Guidance Documents issued on the subject.

It is crucial, however, that despite the risks associated with AI's use in healthcare, the FDA and the Biden administration do not stifle the development and implementation of these products, as it is clear the

[142] Vladeck, *supra* note 74, at 149.
[143] *See Artificial Intelligence Litigation*, *supra* note 24.
[144] *See id*.
[145] *See* Amarasingham, *supra* note 6 at 1151.

potential of AI goes beyond any human capacity.[146] Instead, a framework of promotion, funding and safety regulation will combine to utilize AI to take America into the next generation of healthcare.

[146] *See* WATSON, *supra* note 3, at 2.