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Medical Device Artificial Intelligence: The New Tort Frontier

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The Machine is much, but it is not everything.[1]

– E. M. Forster

The medical device industry and new technology start-ups have dramatically increased investment in artificial intelligence (AI) applications, including diagnostic tools and AI-enabled devices. These technologies have been positioned to reduce climbing health costs while simultaneously improving health outcomes. Technologies like AI-enabled surgical robots, AI-enabled insulin pumps, and cancer detection applications hold tremendous promise, yet without appropriate oversight, they will likely pose major safety issues. While preventative safety measures may reduce risk to patients using these technologies, effective regulatory-tort regimes also permit recovery when preventative solutions are insufficient.

The Food and Drug Administration (FDA), the administrative agency responsible for overseeing the safety and efficacy of medical devices, has not effectively addressed AI system safety issues for its clearance processes. If the FDA cannot reasonably reduce the risk of injury for AI-enabled medical devices, injured patients should be able to rely on ex post recovery options, as in products liability cases. However, the Medical Device Amendments Act (MDA) of 1976 introduced an express

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1. E.M. FORSTER, THE MACHINE STOPS 2 (1909), https://www.ele.uri.edu/faculty/vetter/Other-stuff/The-Machine-Stops.pdf.

preemption clause that the U.S. Supreme Court has interpreted to nearly foreclose liability claims, based almost completely on the comprehensiveness of FDA clearance review processes. At its inception, MDA preemption aimed to balance consumer interests in safe medical devices with efficient, consistent regulation to promote innovation and reduce costs.

Although preemption remains an important mechanism for balancing injury risks with device availability, the introduction of AI software dramatically changes the risk profile for medical devices. Due to the inherent opacity and changeability of AI algorithms powering AI machines, it is nearly impossible to predict all potential safety hazards a faulty AI system might pose to patients. This Article identifies key preemption issues for AI machines as they affect ex ante and ex post regulatory-tort allocation, including actual FDA review for parallel claims, bifurcation of software and device reviews, and dynamics of the technology itself that may enable plaintiffs to avoid preemption. This Author then recommends an alternative conception of the regulatory-tort allocation for AI machines that will create a more comprehensive and complementary safety and compensatory model.

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INTRODUCTION

In December 2018, Corindus Vascular Robotics made an important announcement: the creation of a telerobotic surgical

system.[2] The CorPath surgical robot had conducted its first "in-human" non-surgical health intervention for percutaneous coronary intervention (PCI).[3] PCI, or coronary angioplasty, involves inserting a catheter into a patient's coronary arteries and placing a stent to promote blood flow.[4] The medical procedure is fairly routine, but CorPath's solution is not: the surgical robot is controlled remotely by a physician in a different geographic location, aided by artificial intelligence (AI) technology.[5] While CorPath has the potential to transform healthcare, especially for patients in developing countries and rural locations, it also has the potential to cause serious injuries.

The AI healthcare industry is quickly developing as medical device manufacturers take advantage of rapid advancements in AI technologies, including machine learning, neural networking, and deep learning. And the investment marketplace has taken note. *Forbes Insights* has labeled AI and healthcare a "giant opportunity,"[6] with a Compound Annual Growth Rate (CAGR) of 28% accelerating over the next five years, and 49% of that growth in North America.[7] Medical device companies are considered a relatively sound investment, with margins consistently between 20–30%.[8] With a backdrop of nearly 10% of venture capital in AI

2. *Corindus' Technology Successfully Used in World's First-in-Human Telerobotic Coronary Intervention*, BUSINESSWIRE (Dec. 6, 2018, 6:45 AM), https://www.businesswire.com/news/home/20181206005067/en/Corindus%E2%80%99-Technology-Successfully-Used-in-World%E2%80%99s-First-in-Human-Telerobotic-Coronary-Intervention.

3. *Id.*

4. *Percutaneous Coronary Intervention (PCI or Angioplasty with Stent)*, HEART & STROKE FOUND. OF CAN., https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention (last visited Mar. 7, 2021).

5. *See Corindus' Technology Successfully Used in World's First-in-Human Telerobotic Coronary Intervention*, *supra* note 2; Press Release, Corindus Vascular Robotics, Corindus Receives FDA Clearance for First Automated Robotic Movement in technIQ™ Series for CorPath GRX Platform (Mar. 5, 2018), https://www.corindus.com/news-events/press-releases/corindus-receives-fda-clearance-for-first-automated-robotic-movement-in-techniq-series-for-corpath-grx-platform.

6. *AI and Healthcare: A Giant Opportunity*, FORBES INSIGHTS (Feb. 11, 2019), https://www.forbes.com/sites/insights-intelai/2019/02/11/ai-and-healthcare-a-giant-opportunity/.

7. *Global Artificial Intelligence (AI) Market in Healthcare Sector 2019–2023*, BUSINESSWIRE (Aug. 23, 2019, 12:52 AM), https://www.businesswire.com/news/home/20190822005747/en/Global-Artificial-Intelligence-AI-Market-Healthcare-Sector.

8. MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 208 (2017), http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf.

technology development, it is no wonder that healthcare would see a share of that investment, approximated to grow to $6.6 billion annually by 2021.[9]

Accompanying this investment opportunity is its share of concerns. Pending lawsuits related to the Tesla self-driving car have raised the profile of design flaws in AI, revealing the potential for AI to cause catastrophic injury in any number of sectors.[10] The inherent "black-box" nature of AI algorithms, coupled with their potential to self-learn, or what I will call dynamic inscrutability, complicates the ability of both manufacturers and regulators to actually understand whether these algorithms are safe and effective.[11] Healthcare is not immune from these issues, and the FDA has not done much to assuage attendant concerns.[12]

The FDA, an agency that regulates nearly $2.4 trillion worth of consumer goods, has regulated food, drugs, cosmetics, and medical devices since 1938,[13] with a more extensive role in medical device oversight since 1976. As of 2019, the U.S. medical device market has grown to $156 billion in medical devices,[14] roughly 4–6% of total U.S. spending on healthcare.[15] According to Medicare spending reports in 2014, hospitals spent $14 billion on implantable medical devices for Medicare patients.[16] Based on cost alone, the medical device industry, and its potential impact on patients, is incredibly significant.

As part of the 1976 Medical Devices Amendments Act (MDA), which established a model for medical device oversight, Congress included an express preemption provision barring civil liability

9. *See AI and Healthcare: A Giant Opportunity*, *supra* note 6; Jeb Su, *Venture Capital Funding for Artificial Intelligence Startups Hit Record High in 2018*, FORBES (Feb. 12, 2019, 2:58 PM), https://www.forbes.com/sites/jeanbaptiste/2019/02/12/venture-capital-funding-for-artificial-intelligence-startups-hit-record-high-in-2018/.

10. Lance Eliot, *Tesla Crash Lawsuit Nails the Achilles Heel of Driverless Cars*, FORBES (May 5, 2019, 11:37 AM), https://www.forbes.com/sites/lanceeliot/2019/05/05/tesla-crash-lawsuit-nails-the-achilles-heel-of-driverless-cars/.

11. W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419 (2015) (introducing the concept of black-box medicine).

12. *See infra* Parts II and III and accompanying notes.

13. 21 U.S.C. §§ 301–399a.

14. *U.S. Medical Device Market Reaches $156 Billion Mark*, CISION PR NEWSWIRE (Mar. 4, 2019, 8:45 AM), https://www.prnewswire.com/news-releases/us-medical-device-market-reaches-156-billion-mark-300805696.html.

15. *See* MEDPAC, *supra* note 8, at 209.

16. *Id.* at 208.

actions where injuries resulted from failure to meet requirements "different from" or "in addition to" federal requirements.[17] At the time, it was expected that the FDA could completely regulate the medical device industry, a task that is increasingly more difficult with a substantial variety of devices on the market, in larger numbers, and with a wide range of potential threats and attendant risks.[18]

This preemption language was reinforced in the *Medtronic, Inc. v. Lohr* (1996)[19] and *Riegel v. Medtronic, Inc.* (2008)[20] cases, where the Supreme Court held that MDA expressly preempted both explicit state statutory requirements and common law tort actions that are different from or add to federal requirements. The net effect, combined with an implied conflict preemption case, *Buckman Co. v. Plaintiffs' Legal Committee* (2001),[21] is that medical device injuries, at least those caused by devices that have undergone extensive FDA review, are nearly non-recoverable except in very limited circumstances.[22] Specifically, tort actions may only be brought when non-compliance with a federal requirement is demonstrated in pleadings: a so-called "parallel claim."[23]

The combined challenges of a new technology environment that could pose catastrophic injury to the public, a lack of extensive FDA expertise and oversight, and a heavy preemption framework raise major concerns for the future of patient safety and injury compensation for AI machines. The future of technology innovation depends heavily on confidence in the safety system. Without an effective regulatory-tort allocation model, manufacturers may not create life-saving devices due to upfront regulatory compliance expense, and without regulatory oversight, patients and physicians may forego cutting-edge solutions due to safety concerns.

17. 21 U.S.C. §§ 360c–360n.

18. *See* MEDPAC, *supra* note 8, at 212 (citing JAMES C. ROBINSON, PURCHASING MEDICAL INNOVATION (2015)).

19. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

20. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

21. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001).

22. *See infra* Part II and accompanying notes.

23. *See infra* text accompanying note 128 (describing the parallel claim exception for preemption).

This Article responds to calls for examination of the tort system with respect to software technologies using AI as a recent example of a longstanding challenge: addressing the viability of tort recovery for medical devices within the narrow margin left by the *Lohr*, *Riegel*, and *Buckman* cases (the "preemption trilogy").[24] An effective regulatory-tort allocation model, involving reinforcing preventative and responsive legal modes, will collectively promote innovation and reinforce consumer confidence by effectively bootstrapping safety measures and providing injury compensation. An effective model should permit patients who will not benefit from regulatory activity and otherwise may be left without compensation for their injuries to successfully plead a case that survives summary judgment, with the reasonable goal for parties to engage in discovery related to actual device design failures.[25] Although resolving the question of tort viability after preemption is a valuable effort, this Author will not do so here.

Part I introduces the basics of AI software, specifically the opaque and inscrutable "black-box" nature of AI algorithms, paired with the dynamic and adaptive capacity of AI to self-learn.[26] AI software is fundamentally different from historically regulated medical devices, and these differences may inform where opportunities are available for tort recovery within MDA preemption doctrine. Part II recounts the current and insufficient state of FDA regulation, including the structure and requirements that form the premarket approval (PMA) process, the most restrictive and comprehensive of FDA reviews and the principal motivator for express preemption doctrine. I then discuss the inherent regulatory limitations of FDA processes for preventing AI medical device injuries, including structural limitations and design insufficiencies. Part III discusses the nature of the regulatory-tort bargain, specifically risk allocation, as the motivating factor for

24. *See* W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 429–30 (2017).

25. I will note that this Article does not examine potential tort liability related to labeling. Rather, it addresses concerns related to design-based injuries, largely because failure to warn and other labeling claims have shown likely to be dismissed by circuit courts. *See, e.g.*, *infra* note 128.

26. *See generally* FRANK PASQUALE, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION (2015) (introducing the concept of algorithms as a black box and describing the range of uses in everyday life for algorithms in decision-making).

preemption and identifies how tort recovery is central to this risk allocation for emerging technologies like AI. Part IV applies these arguments against the existing FDA processes to propose a three-party inquiry, involving structural, design, and technology considerations that courts can use to effectively analyze preemption claims.[27]

I. AI TECHNOLOGY AND THE FDA

Although the term "artificial intelligence" calls to mind popular science fiction, such as the advanced AI system from *2001: A Space Odyssey*, Hal, or the humanoid replicants in *Blade Runner*, current AI algorithms function more like human-designed algorithms combined with the ability to change and adapt themselves based on changing data inputs and feedback loops.[28] The most common AI model used today is an algorithm or system of algorithms based on data supplied, or machine learning.[29] Machine learning is an application of AI where a computer program, the machine-learning utility or software, evaluates a large volume of data to identify relationships between data elements, creating a machine-generated algorithm informed by the data.[30] Because the data collected will

27. Please note: this Article is designed to expand thinking on new technology, especially software-based technologies reviewed by the FDA with respect to torts. AI offers a useful example for illustrating one technology that the FDA has not yet adequately regulated, as well as the likelihood of potential downstream injuries.

28. 2001: A SPACE ODYSSEY (Metro-Goldwyn-Mayer 1968); BLADE RUNNER (Warner Bros. 1982); Mindy Weisberger, *Why You Shouldn't Expect to See "Blade Runner" Replicants Anytime Soon*, LIVE SCI. (Oct. 17, 2017), https://www.livescience.com/60703-no-blade-runner-replicants-yet.html; Bobby Azarian, *The Myth of Sentient Machines*, PSYCH. TODAY (June 1, 2016), https://www.psychologytoday.com/us/blog/mind-in-the-machine/201606/the-myth-sentient-machines. Although Elon Musk and the late Stephen Hawking have warned of AI's dangers in sentience, it seems unlikely that machines able to make decisions on more than one topic, "artificial general intelligence," could be years or decades in the future. Still, these machines may not operate with human-like intelligence. Anthony Cuthbertson, *Elon Musk and Stephen Hawking Warn of Artificial Intelligence Arms Race*, NEWSWEEK (Jan. 31, 2017, 8:09 AM), https://www.newsweek.com/ai-asilomar-principles-artificial-intelligence-elon-musk-550525; *How Far Away Are We Really from Artificial Intelligence?*, TECHNATIVE (Apr. 21, 2017), https://www.technative.io/how-far-away-are-we-really-from-artificial-intelligence/.

29. Bernard Marr, *What Is the Difference Between Artificial Intelligence and Machine Learning?*, FORBES (Dec. 6, 2016, 2:24 AM), https://www.forbes.com/sites/bernardmarr/2016/12/06/what-is-the-difference-between-artificial-intelligence-and-machine-learning/.

30. Libby Kinsey, *A Machine Learning Primer*, MEDIUM (Apr. 14, 2016), https://medium.com/@libbykinsey/a-machine-learning-primer-6d7b5a96a3b0.

likely change, this machine-generated algorithm updates automatically as new data collected through use alter these relationships, presumably making the algorithm more effective over time.

One example of an AI-enabled medical device is the QuantX platform.[31] QuantX reviews breast cancer images using an increasing collection of data related to these images to recommend when breast cancer seems likely, according to imaging scans.[32] QuantX requires radiologists to validate diagnoses, prompting a lower potential risk to patients and correspondingly less comprehensive Food and Drug Administration review,[33] but it is not hard to imagine systems in the future that either automate analysis or provide these diagnoses to medical practitioners who do not have an oncology specialization.[34]

When an AI utility, or software program, leverages computing power to evaluate relationships between data elements in a big data repository, the AI software may identify previously unconsidered or novel relationships, which create a complex, system-generated algorithm.[35] The QuantX system, for example, is likely trained on images with positive breast cancer diagnoses and images with negative breast cancer diagnoses. As more accurate diagnoses and images are fed into the system, the AI algorithm should become more accurate through self-learning.[36] These images may include hundreds or thousands of unique data points related to the images, captured with a variety of machines and machine operators, across

31. QUANTITATIVE INSIGHTS, *Efficiently Incorporating AI into the Clinical Workflow* (2019), https://www.qlarityimaging.com/next-gen-integration.

32. *Id.*

33. *Id.*

34. It should be noted that QuantX has been designated as Class II, a lower-risk classification, likely because of the radiologist's involvement in diagnosis. Berkman Sahiner, Aria Pezeshk & Nicholas Petrick, *An Update on FDA Perspectives for Machine Learning in Medical Image Interpretation*, SIIM (2018), https://cdn.ymaws.com/siim.org/resource/resmgr/mimi18/presentations/18cmimi-sahiner.pdf.

35. *See* INFO. COMM'R'S OFF., BIG DATA, ARTIFICIAL INTELLIGENCE, MACHINE LEARNING AND DATA PROTECTION 7 (2017), https://ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf.

36. Alejandro Rodríguez-Ruiz, Elizabeth Krupinski, Jan-Jurre Mordang, Kathy Schilling, Sylvia H. Heywang-Köbrunner, Ioannis Sechopoulos & Ritse M. Mann, *Detection of Breast Cancer with Mammography: Effect of an Artificial Intelligence Support System*, 290 RADIOLOGY 1, 6 (2018).

a wide population of human beings with variable physiological characteristics.[37]

To be reasonably accurate, algorithms must accommodate human variations as well as different radiological imaging practices. The result is a highly complex algorithm or algorithms, which must adapt and change to integrate new data as it is supplied.[38] This continuous updating, or tuning, may be labeled *dynamic* for our purposes, as the QuantX algorithm in operation when it was first released has learned, through new data, to create the algorithm used today. Humans, however, are not usually involved in this change: AI learns independently of its creator.

A. Artificial Intelligence Systems Create Dynamically Inscrutable Algorithms

Machine learning may be implemented as supervised or unsupervised learning systems. In supervised learning systems, data scientists are involved in labeling and otherwise restricting the function of the machine learning utility.[39] In unsupervised learning systems, unlike supervised learning systems, data scientists do not restrict utility function to a specific model, and the machine learning utility can leverage any data available to it.[40]

When a machine learning utility has fewer constraints, it creates algorithms that may be highly complex and partially or completely inscrutable to data scientists—an inherent opacity.[41] The net effect of unsupervised learning systems, which are frequently used in AI-enabled medical devices like QuantX, is that creators can no longer understand their creations as the algorithms themselves become

37. *Id.* at 2. Although this example involves over 100 images, many imaging solutions include thousands of images. *See, e.g.*, Wenya Linda Bi, Ahmed Hosny, Matthew B. Schabath, Maryellen L. Giger, Nicolai J. Birkbak, Alireza Mehrtash, Tavis Allison, Omar Arnaout, Christopher Abbosh, Ian F. Dunn, Raymond H. Mak, Rulla M. Tamimi, Clare M. Tempany, Charles Swanton, Udo Hoffmann, Lawrence H. Schwartz, Robert J. Gillies, Raymond Y. Huang & Hugo J.W.L. Aerts, *Artificial Intelligence in Cancer Imaging: Clinical Challenges and Applications*, 69 CA: CANCER J. FOR CLINICIANS 127, 133 tbl.1 (2019) (listing the number of images associated with specific cancer applications).

38. Tom Grigg, *Algorithmic Complexity [101]*, MEDIUM (Nov. 15, 2018), https://towardsdatascience.com/algorithmic-complexity-101-28b567cc335b.

39. *See* INFO. COMM'R'S OFF., *supra* note 35, at 7.

40. *Id.* at 8.

41. Inscrutability, or opacity, results from complex interrelated rules as well as some of the techniques employed when designing the algorithm. These algorithms are distinguished from strategic opacity, as in trade secrecy. Price, *supra* note 24, at 430.

complex and unreadable.[42] When creators can no longer understand how their creations work, and those creations have materially changed, new risks to patient safety arise, often after FDA approval.[43]

Algorithmic complexity may result not only from the vast multitude of relationships between data elements but also from the relevant weightings of the elements, or the number of "neurons" in the case of a more advanced AI neural network.[44] Neural networks are more advanced AI systems than their machine learning relatives. Neurons, or nodes, in a network make calculations based on their relationship to other neurons, often within several layers of intelligence. Because deep learning involves more complex neural networks with several layers, some of which may be hidden, it can identify more complex relationships between data in the layers.[45]

Medical researchers are increasingly using neural networks to solve more complex imaging problems.[46] One example, led by Massachusetts General, required the use of 50,000 MRI brain scans just to train a single neural network, which has resulted in better,

42. Jenna Burrell, *How the Machine "Thinks": Understanding Opacity in Machine Learning Algorithms*, 3 BIG DATA & SOC'Y 1, 4 (2016).

43. FDA regulatory processes involve both pre- and postmarket activities. Where a premarket activity, such as the PMA process, might not catch a potential issue until the algorithm has learned on real-world data, postmarket activity should be able to detect and respond to these issues. Often the FDA requires any number of actions after manufacturer notification, such as deploying a fix, stopping additional sales, or recalling devices. *See* U.S. FOOD & DRUG ADMIN., *Postmarket Information – Device Surveillance and Reporting Processes* (Sept. 27, 2018), https://www.fda.gov/medical-devices/human-factors-and-medical-devices/postmarket-information-device-surveillance-and-reporting-processes.
Unfortunately, if functionality is inscrutable due to inherent technical complexity, even data scientists may not be able to determine whether an issue will arise and how to minimize harm to patients. *See* Burrell, *supra* note 42, at 5.

44. Neurons are specific functioning units of a neural network, a more advanced version of an AI utility. *See* Mingzhe Chen, Ursula Challita, Walid Saad, Changchuan Yin & Mérouane Debbah, *Artificial Neural Networks-Based Machine Learning for Wireless Networks: A Tutorial*, 21 IEEE COMMC'NS SURVS. TUTORIALS 3039, 3058 (2019); Brian K. Lee, Justin Lessler & Elizabeth A. Stuart, *Improving Propensity Score Weighting Using Machine Learning*, 29 STAT. MED. 337 (2010).

45. *See* Fei Jiang, Yong Jiang, Hui Zhiuh, Yi Dong, Hao Li, Sufeng Ma, Yilong Wang, Qiang Dong, Haipeng Shen & Yongjun Wang, *Artificial Intelligence in Healthcare: Past, Present and Future*, 2 STROKE & VASCULAR NEUROLOGY 230, 237 (2017).

46. Jeff Lagasse, *FDA Approves First AI Tool for Detecting Retinopathy, NIH Shows Machine Learning Success in Imaging*, HEALTHCARE FIN. (Apr. 12, 2018), https://www.healthcarefinancenews.com/news/fda-approves-first-ai-tool-detecting-retinopathy-nih-shows-machine-learning-success-imaging.

faster, and more accurate imaging processes.[47] Neural networks and deep learning networks exhibit an even higher level of complexity due to weighting for data sets within a number of layers.[48] Systems with a greater number of layers generally produce more accurate decisions and more complex algorithms.

B. Infrastructure Complexity Increases Overall Artificial Intelligence Complexity

Algorithmic complexity not only results from ephemeral data element relationships and weightings, but it also results from the complexity of the code and machine communication itself. As suggested by Alan Turing, computers require a more efficient mechanism for communication in high-powered systems via high-level coding languages.[49] The development of complex computer codes from the 1960s through the 1980s enabled these operations, continuing to increase efficiency in recent years.[50] Modern machine learning utilities often leverage Python, C++, R, JavaScript, and Julia coding languages.[51] Machines must also communicate with other machines, specifically when an AI system directs an additional medical device or computer system to function in some way, an artificially intelligent machine (AI machine).[52]

Machine to machine communication, or M2M, adds further complexity to inherent coding and algorithmic complexity.[53] Because human languages are highly inefficient for computers using higher order mathematics, M2M languages enable computers

47. *Id.*

48. *See* Burrell, *supra* note 42, at 5.

49. *See* Stephen Muggleton, *Alan Turing and the Development of Artificial Intelligence*, 27 AI COMMC'NS 3, 4 (2014).

50. *Id.*

51. Nick Heath, *GitHub: The Top 10 Programming Languages for Machine Learning*, TECHREPUBLIC (Jan. 25, 2019), https://www.techrepublic.com/article/github-the-top-10-programming-languages-for-machine-learning/.

52. The Author adopts this name to distinguish between AI standalone system and physical devices directed remotely by AI, which may or may not include the robotics field. For purposes of this Article, AI machine means an AI-enabled medical device inclusive of diagnostic applications and connected physical devices with AI capabilities. It should be noted that historically AI has been analyzed principally as "robotics," although "AI machine" as it is used in this Article is inclusive of robotics applications, such as surgical robots.

53. John Breeden II, *What Is M2M, and Why Is It the Future of Code?*, GCN (Mar. 22, 2013), https://gcn.com/articles/2013/03/22/m2m-future-of-code.aspx.

to communicate more efficiently using a shorthand computer-readable language, especially for devices connected to one-another.[54] When algorithms prompt activity within a computer system or to standalone devices, such as Internet of Things (IoT) devices or robotics, M2M is used to deliver the message over wireless or cellular-enabled networks.[55] This technology makes it feasible to communicate between a central system housing AI-generated algorithms and receiving devices that are distributed remotely.[56] Further, interconnected devices running on the same network may communicate with each other, such as an insulin pump sharing information with a pacemaker.[57] *Figure 1* illustrates this infrastructure.

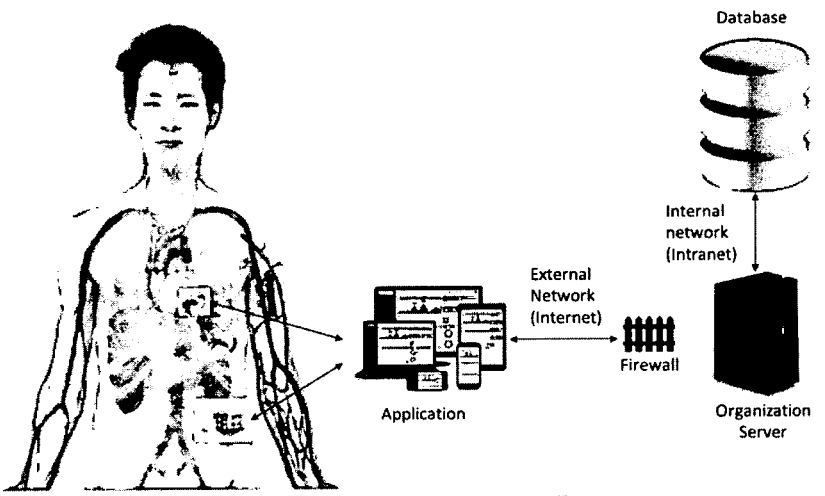

FIGURE 1: AI MEDICAL DEVICE INFRASTRUCTURE

54. Jen Clark, *What is M2M Technology*, IBM BLOG (Oct. 20, 2016), https://www.ibm.com/blogs/internet-of-things/what-is-m2m-technology/.

55. Andrew Parker, *Intelligent Connectivity: The Fusion of 5G, AI and IoT*, GSMA (Sept. 7, 2018), https://www.gsma.com/iot/news/intelligent-connectivity-5g-ai-iot/; Chen et al., *supra* note 44.

56. *See* Chen et al., *supra* note 44 at 3043.

57. PLASMATIC TECHS., *Smart Home Interoperability: The Key Hurdles*, IOT FOR ALL (Mar. 1, 2019), https://www.iotforall.com/smart-home-interoperability-key-hurdles/.

C. Artificial Intelligence Is Created by Humans and Compromised by Humans

Although AI is designed to be inherently self-learning, distinctly human choices in their design dramatically affect performance.[58] Designing an AI system is no trivial task, filled with choices that can increase or decrease safety.[59] Data scientists not only must make choices in designing the AI software but must also develop methods for the software to identify changes or receive feedback to "tune" the system. Facially, therefore, it is impossible to determine which algorithms are high quality or safe.[60] Without effective feedback loops, the software cannot become more effective or be safe for new patient populations.

Relevant choices for machine learning applications include code selection, database structure, training data sets, rule design, machine learning training, and ongoing system updates.[61] Technology that integrates AI into its functionality requires design, testing, and user feedback—more comprehensively and continuously than existing FDA technology submitted for review.[62] Further, AI machines may be exposed to cybersecurity risks at a greater frequency: the dynamic inscrutability of AI systems makes them even more vulnerable to cyberattacks because unauthorized changes to the underlying data sets or the algorithm may not be noticeable until after injuries occur.[63]

58. *See* Chen et al., *supra* note 44, at 3049.

59. Richard Harris, *How Can We Be Sure Artificial Intelligence Is Safe for Medical Use?*, NPR (Apr. 14, 2019, 8:03 AM), https://www.npr.org/sections/health-shots/2019/04/14/711775543/how-can-we-be-sure-artificial-intelligence-is-safe-for-medical-use; *Why AI Safety?*, MACH. INTEL. RSCH. INST., https://intelligence.org/why-ai-safety/ (last visited Feb. 16, 2021).

60. *See* Price, *supra* note 24, at 433.

61. Martin Zinkevich, Rules of Machine Learning: Best Practices for ML Engineering, Invited Talk at Reliable Mach. Learning in the Wild (Dec. 2016), http://martin.zinkevich.org/rules_of_ml/rules_of_ml.pdf.

62. Jiang et al., *supra* note 45, at 241 (2017); Andrew Tutt, *An FDA for Algorithms*, 69 ADMIN. L. REV. 83, 104 (2017) (describing the lack of standards setting bodies for identifying appropriate testing thresholds).

63. Meg King & Jacob Rosen, *The Real Challenges of Artificial Intelligence: Automating Cyber Attacks*, WILSON CTR.: CTRL FORWARD (Nov. 28, 2018), https://www.wilsoncenter.org/blog-post/the-real-challenges-artificial-intelligence-automating-cyber-attacks; *see, e.g.*, Cade Metz & Craig S. Smith, *Warnings of a Dark Side to A.I. in Health Care*, N.Y. TIMES (Mar. 21, 2019), https://www.nytimes.com/2019/03/21/science/health-medicine-artificial-

When AI utilities run on geographically dispersed, or remote, systems, additional selections must be made, including the communication languages and models for transmitting data and direction to devices and transmitting data from devices to the AI software to create a complete ecosystem.[64] Further, additional choices must be made for receiving devices, such as how much data devices will retain in their local cache, whether limited decisions can be made locally and without connectivity to the primary AI software, and which data produced by the device should be transmitted back to central AI systems.[65] In robotics, systems must effectively, safely, and reliably operate any number of kinetic activities as a robot moves, performs tasks, or interacts with human beings using a variety of sensors and actuators.[66]

Each of these choices can enhance or reduce effectiveness, safety, and reliability. The volume and quality of data collected and used for an AI system can dramatically affect the system's function for specific communities and populations.[67] Without sufficient data volume or representation from different communities, data may produce discriminatory or ineffective results. For example, the algorithm may have learned from data not representative of a specific patient sub-group or economic background, suggesting a diagnosis inaccurate for a specific group.[68] Training data, on which

intelligence.html (describing the prevalence of adversarial attacks); *see also* Charlotte A. Tschider, *Enhancing Cybersecurity for the Digital Health Marketplace*, 26 ANNALS HEALTH L. 1 (2017) (describing limitations in the FDA's review of potential cybersecurity risks).

64. Charlotte A. Tschider, *Regulating Cybersecurity and Artificial Intelligence*, 5 SAVANNAH L. REV. 177, 179–85 (2018) (describing the IoT architecture, including big data solutions, remote connectivity, and remote AI utility use); *see also* Chen et al., *supra* note 44.

65. Gretchen Hoffman, *Being Smart about Product Design with IoT and AI*, ALTITUDEINC.COM, https://www.altitudeinc.com/being-smart-about-product-design-with-iot-and-ai/ (last visited Apr. 15, 2019).

66. *See* Chen et al., *supra* note 44, at 3049.

67. Bernard Marr, *Why AI Would Be Nothing Without Big Data*, FORBES (Jun. 9, 2017, 12:29 AM), https://www.forbes.com/sites/bernardmarr/2017/06/09/why-ai-would-be-nothing-without-big-data/; Joshua New, *AI Needs Better Data, Not Just More Data*, CTR. FOR DATA INNOVATION (Mar. 20, 2019), https://www.datainnovation.org/2019/03/ai-needs-better-data-not-just-more-data/.

68. W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 65, 91–94 (2019). Professor Nicholson Price describes AI algorithmic training in high-resource contexts, such as university medical centers, and describes the challenge of applying these algorithms to environments with lower comparative resources and differing patient populations, which could result in less accurate algorithmic decision-making. *Id.* However,

algorithms are developed, may codify discrimination present in the data supplied to the system.[69] It may also discriminate by proxy, even when data do not directly identify groups likely to endure discrimination.[70]

Poorly designed AI software may also be vulnerable to security compromise, leading to safety issues.[71] Because data from any number of sources drive algorithmic function, if data are modified in an unauthorized manner, the algorithm itself can function incorrectly, giving instructions causing downstream system or device malfunction.[72] For example, a brain stimulation device's software could be remotely updated or given automated direction by an AI algorithm. If the data are changed in an unauthorized manner, AI software instructions could increase the electrical stimulus beyond its typical thresholds, causing brain damage. Similarly, during an availability attack, when data used to direct system functions are made unavailable, the system dependent on AI might not work, for example in the middle of a surgery assisted or completed using surgical robotics.

In AI diagnostic applications, such as QuantX, the potential for cyber-kinetic attacks or poor AI design causing direct physical

other structural limitations not mentioned in Professor Price's article could also apply to a provider's choice to use such an algorithm. For example, the status of algorithmic use as a standard of care for purposes of insurance and avoiding malpractice might reinforce use of inaccurate algorithmic decision-making if the algorithm is endorsed due to its use in a higher-context environment.

69. Paul Teich, *Artificial Intelligence Can Reinforce Bias, Cloud Giants Announce Tools for AI Fairness*, FORBES (Sept. 24, 2018, 6:00 AM), https://www.forbes.com/sites/paulteich/2018/09/24/artificial-intelligence-can-reinforce-bias-cloud-giants-announce-tools-for-ai-fairness/.

70. Charlotte A. Tschider, *Regulating the Internet of Things: Discrimination, Privacy, and Cybersecurity in the Artificial Intelligence Age*, 96 DENVER U.L. REV. 87, 98–100 (2018); *see generally* Daniel Schwarcz & Anya Prince, *Proxy Discrimination in the Age of Artificial Intelligence and Big Data*, 105 IOWA L. REV. 1257 (2020) (describing the likelihood of discrimination when big data and highly powerful AI systems can result in discriminatory application of decisions to protected groups).

71. *See generally* Tschider, *supra* note 64 (raising issues related to security under FDA reviews, including lack of specific rules, the superimposition of past models including panel reviews, the modulation of device classification through separate component review, and failure to review from the position of actual risk with distributed technology architectures). Cybersecurity is an essential aspect of good AI, in that poor cybersecurity will likely compromise the data feeding algorithms and their subsequent recommendations.

72. *See* Tschider, *supra* note 70, at 118–20.

injury may be less likely.[73] However, a physician with limited cancer knowledge relying on the tool itself may still make an inaccurate diagnosis and pursue medical interventions, such as radiation or chemotherapy, that could harm an otherwise healthy patient.[74] For AI directing machine activity, such as automated surgery or AI-enabled updates to implanted or affixed medical devices, physical harms are more likely. The impact of any issues, including unintentional AI issues, could mean catastrophic injuries for patients.[75]

Consider, for example, a connected insulin pump like the DreaMed Diabetes' Advisor Pro.[76] Advisor Pro, like many AI solutions, uses cloud technology, a distributed technology system that connects over the open internet,[77] making it potentially susceptible to cyber-kinetic attacks as well as AI design safety issues. Insulin pumps like the Advisor Pro deliver insulin direct to the body via a user interface the patient controls, and the interface also provides recommendations for insulin delivery to the physician.[78] If the system tells a patient that the patient's blood sugar is high, it is unlikely that a patient will question whether the reading is accurate.[79] Although the FDA seems to view the patient

73. Tutt describes simple mistakes, such as bugs or typos that could result in, for example, discriminatory effect. *See* Tutt, *supra* note 62, at 106.

74. *See* Jasmine Just, *Overdiagnosis: When Finding Cancer Can Do More Harm than Good*, CANCER RSCH. UK (Mar. 6, 2018), https://scienceblog.cancerresearchuk.org/2018/03/06/overdiagnosis-when-finding-cancer-can-do-more-harm-than-good/ (describing the role of cancer screening and subsequent treatment for benign cancers as impacting human health); *Screening: How Overdiagnosis and Other Harms Can Undermine the Benefits*, HEALTHNEWSREVIEW.ORG, https://www.healthnewsreview.org/screening-how-overdiagnosis-and-other-harms-can-undermine-the-benefits/ (last visited Feb. 5, 2021).

75. Olaf J. Groth, Mark J. Nitzberg & Stuart J. Russell, Opinion, *AI Algorithms Need FDA-Style Drug Trials*, WIRED (Aug. 15, 2019, 9:00 AM), https://www.wired.com/story/ai-algorithms-need-drug-trials/.

76. Amanda Pedersen, *How AI Is Personalizing Insulin Therapy for Diabetes Patients*, MED. DEVICE + DIAGNOSTIC INDUS. (June 18, 2018), https://www.mddionline.com/how-ai-personalizing-insulin-therapy-diabetes-patients.

77. *Advisor Pro*, DREAMED, https://dreamed-diabetes.com/advisor/ (last visited May 1, 2021).

78. *Id.*

79. The FDA has illustrated this view of "human as quality control" via its AI diagnostic software approvals. If a physician is providing a diagnosis based on AI, rather than automating the diagnosis, usually this software will receive a lower classification. However, even professionals may fall victim to automation bias or trained incapacity. Trained incapacity results from the regression of humans when they have a tool or

as quality control, equipped to spot machine failures, automation bias and trained incapacity are far more likely to promote a false sense of security.[80]

Diabetes, like cancer, is a key area of focus for much of medical device development; the possibility of a bionic pancreas, for example, could dramatically change how diabetes patients live. In 2018, Beta Bionics received an Investigational Device Exception (IDE), which is required to clinically test a device on humans, for its iLet Bionic Pancreas System, an artificial pancreas powered by AI and designed for children and adults living with Type-1 diabetes.[81] Of course, a bionic pancreas by design would function with little engagement from the patient at all,[82] potentially introducing additional safety hazards.

D. Artificial Intelligence Systems Cannot Be Made Safe by Process-Based Solutions

Although the FDA has expressed an interest in AI-enabled medical devices, including diagnostic systems and implanted or affixed devices, the FDA has not effectively developed any specific plan or direction for regulating them.[83] It has similarly failed to

alternative knowledge that permits them to gain greater efficiency or shift human attention. *See generally* Erin Wais, *Trained Incapacity: Thorstein Veblen and Kenneth Burke*, 2 J. KENNETH BURKE SOC'Y (2005) (quoting THORSTEIN VEBLEN, THE INSTINCT OF WORKMANSHIP AND THE STATE OF THE INDUSTRIAL ARTS (1914)), https://www.kbjournal.org/wais.

80. Automation bias usually results from reliance on technology, where an individual takes less personal responsibility due to their trust and dependence on something other than their own judgment. Additionally, over time individuals begin to rely more heavily on computers to perform tasks they previously performed. These two conditions simultaneously create a situation ripe for injuries to occur. Human interfaces and judgment do not cure safety issues presented by AI machines. *See* Cosima Gretton, *The Dangers of AI in Health Care: Risk Homeostasis and Automation Bias*, MEDIUM (June 24, 2017), https://towardsdatascience.com/the-dangers-of-ai-in-health-care-risk-homeostasis-and-automation-bias-148477a9080f.

81. Omar Ford, *Combining AI and CGM to Make a Bionic Pancreas*, MED. DEVICE + DIAGNOSTIC INDUS. (May 22, 2018), https://www.mddionline.com/combining-ai-and-cgm-make-bionic-pancreas; *Beta Bionics Receives IDE Approval From the FDA to Begin a Home-Use Clinical Trial Testing the a New Bionic Pancreas System*, DRUG DEV. & DELIVERY, https://drug-dev.com/beta-bionics-receives-ide-approval-from-the-fda-to-begin-a-home-use-clinical-trial-testing-the-a-new-bionic-pancreas-system/.

82. Press Release, Am. Diabetes Assoc., The iLet Bionic Pancreas Increased Time in Range for Adults with Type 1 Diabetes (June 8, 2019), https://www.diabetes.org/newsroom/press-releases/2019/the-ilet-bionic-pancreas.

83. *See* Jiang et al., *supra* note 45, at 241.

implement specific rules or best practices related to medical device cybersecurity. The most concrete of its recent contributions for manufacturers was in the form of an AI discussion paper describing AI system design and the agency's new Digital Health Software Precertification (Pre-Cert) Program, a pilot program for medical devices that use AI software.[84]

While technical best practices may exist, AI software is typically fit for specific uses and designed to be contextually applied, which can make recipe-like legal requirements destined to fail.[85] Engineers and data scientists design AI software to fulfill specific goals or tasks of a relevant adjacent system with any number of rules, and infrastructure design depends on the purpose and use of the system.[86] For example, AI software that supports medical diagnosis will be designed differently, both in system and in process, than AI software for self-driving cars, which have very different tasks to perform.[87] Even when AI infrastructure is used for a variety of different AI implementations, the software itself will be context-specific to its implementation.

84. U.S. FOOD & DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) 4 (2019), https://www.fda.gov/media/122535/download. It should be noted that both of these contributions advance a "hands-off" approach to FDA device clearance, rather than increased requirements the FDA will review as part of a more comprehensive premarket approval (PMA) process.

85. Training data and system design must be tailored to specific goals or outcomes. Without specific goals or outcomes designed in a system, AI systems cannot train or continue to improve when performing tasks or rendering specific decisions.

86. B.J. Copeland, *Artificial Intelligence*, ENCYC. BRITANNICA (Aug. 11, 2020), https://www.britannica.com/technology/artificial-intelligence.

87. *See* Daniel Faggella, *Machine Learning for Medical Diagnostics – 4 Current Applications*, EMERJ A.I. RSCH. (Mar. 14, 2020), https://emerj.com/ai-sector-overviews/machine-learning-medical-diagnostics-4-current-applications/; Alex Davies, *The WIRED Guide to Self-Driving Cars*, WIRED (Dec. 13, 2018, 6:00 AM), https://www.wired.com/story/guide-self-driving-cars/; Tonya Riley, *Get Ready, This Year Your Next Job Interview May Be with an A.I. Robot*, CNBC (Mar. 13, 2018, 10:28 AM), https://www.cnbc.com/2018/03/13/ai-job-recruiting-tools-offered-by-hirevue-mya-other-start-ups.html. AI utilities are designed specifically to fulfill or maximize certain codified goals. For example, medical diagnostics might be designed to identify breast cancer from mammogram images, while a self-driving car might be designed to identify and follow traffic signals, and an AI employment application might be designed to detect false narratives or measure reliability. *See generally* Jim Guszcza, *Smarter Together: Why Artificial Intelligence Needs Human-Centered Design*, DELOITTE REV., January 2018, at 36, https://www2.deloitte.com/content/dam/insights/us/collections/issue-22/DI_Deloitte-Review-22.pdf.

The FDA appears to have rejected this concept, focusing on process-based solutions rather than individual review. The AI discussion paper created by the FDA, which was first published for feedback in April 2019, describes best practices for machine-learning enabled diagnostic systems, more specifically for image-based systems.[88] The discussion paper envisions a pre-certification process, consistent with the FDA's pre-certification software process launched in January 2019, by which organizations might implement a Total Product Life Cycle regulatory approach (TPLC) to AI-ML-based software as a medical device.[89] In it, the FDA proposes a similar type of approach to its existing model for quality process facility inspection, where the Federal Trade Commission (FTC) visits and inspects facilities planned for manufacturing a specific device.[90]

The TPLC maps well onto the facility inspection portion of existing FDA approval, which includes both a review of the design of the device itself (including associated clinical trial results and proposed labeling) and a review of the facility and quality system processes for producing it.[91] Although the TPLC should improve the overall safety profile for some AI software, the process will not effectively support a detailed, use-specific device design review.[92]

88. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84, at 3–4.

89. *Id.* at 3. The Total Product Life Cycle Regulatory approach is a model wherein organizations implement process-based solutions, such as testing procedures, requirements development, and AI modeling. *Id.* at 4. In this approach, administrative agencies like the FDA can regulate the *organization*'s practices rather than specific products. *Id.*

90. The facility inspection process, conducted by a third party or the FDA, assesses the quality system implemented in the manufacturing facility for higher risk medical devices and reviews proposed compliance with appropriate requirements from a manufacturing perspective. *See* U.S. FOOD & DRUG ADMIN., GUIDE TO INSPECTIONS OF QUALITY SYSTEMS (1999), https://www.fda.gov/files/Guide-to-Inspections-of-Quality-Systems.pdf; U.S. FOOD & DRUG ADMIN., ACCREDITED PERSONS INSPECTION PROGRAM (2018), https://www.fda.gov/medical-devices/third-party-inspection-devices/accredited-persons-inspection-program. These programs adhere to Good Manufacturing Practices (GMP), general established practices that are reviewed in addition to specific quality process requirements for the device being manufactured.

91. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84, at 8–9. The TPLC even uses a surrogate for GMP, Good Machine Learning Practices (GMLP), to echo the standardization of GMP. *Id.* at 9. It should be noted, however, that even GMP require special adaptation to the device being manufactured in a traditional facility. This makes intuitive sense: a pacemaker might require different processes for quality enforcement of specific leads used to stimulate the heart than the port for an insulin pump.

92. *Id.* at 8–9.

A singular model for premarket review cannot provide direction for other medical devices or even for different types of diagnostic systems, simply because the methods used to create safe and reliable diagnostic imaging systems would not necessarily be effective for other systems.[93] In short, process-based models are part of, rather than a comprehensive solution for, effective FDA review. For example, diagnostic software for colon cancer using medical chart data might be designed differently than diagnostic software using mammogram images for breast cancer.[94] Depending on the target population and relative frequency of a disease's occurrence or variability, the system might also be designed differently to ensure a high level of reliability.[95] Although the TPLC might be tremendously useful as a starting point for machine learning diagnostic software, the variables selected by data scientists in creating any AI system, as well as the system's interface and direction of physical devices, are highly specific to the device and population at hand. This inherent "fit-for-purpose," or customized nature of software design, especially for AI, does not lend itself well to a broad, manufacturer-level certification process as the primary model for safety and efficacy.

93. *See* Copeland, *supra* note 86; Charles Aunger, *Should the FDA Regulate AI?*, FORBES (Aug. 14, 2019, 9:45 AM), https://www.forbes.com/sites/forbestechcouncil/2019/08/14/should-the-fda-regulate-al/.

94. Different AI techniques can provide different results with the same goals and application, let alone different goals. *See* Guy Nir, Davood Karimi, S. Larry Goldenberg, Ladan Fazli, Brian F. Skinnider, Peyman Tavassoli, Dmitry Turbin, Carlos F. Villamil, Gang Wang, Darby J.S. Thompson, Peter C. Black & Septimiu E. Salcudean, *Comparison of Artificial Intelligence Techniques to Evaluate Performance of a Classifier for Automatic Grading of Prostate Cancer from Digitized Histopathologic Images*, 2 JAMA NETWORK OPEN 2–4 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2727273. In Nir et al.'s comparative analysis, prostate cancer benefitted from certain patient CV models and multi-expert data rather than histopathologic images (a digitized camera image from a microscope of cancer cells). *Id.* at 8.

95. W. Nicholson Price's arguments related to high-context and low-context environments is particularly salient here, as systems are not easily transferrable from one population to another. *See* Price, *supra* note 68. This is precisely why the FDA requires specific labeling that adheres to the test populations from clinical trials in traditional medical device approvals, and while it permits off-label use, off-label use cannot be promoted by medical device manufacturers, and physicians are not protected from medical malpractice related to off-label use, unless off-label use reflects the standard of care. *See* Christopher M. Wittich, Christopher M. Burkle & William L. Lanier, *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 986–87 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/pdf/main.pdf.

Although industry best practices might inform system design, they also cannot completely prevent algorithmic discrimination, privacy, or safety issues specific to the AI software's implementation, as designed. AI algorithms might integrate certain principles, but they necessarily must be designed, tested, and continuously monitored for their specific purposes and codified goals. Algorithmic outputs are typically personalized with respect to the user and change dynamically, unless it is "locked," or rendered non-learning, at the time of FDA submission, which dramatically reduces its potential efficacy.[96]

The customized aspect of AI combined with its dynamic inscrutability for unlocked algorithms poses unique challenges for effective preventative oversight,[97] as what is a perfectly reasonable design for one AI software application may not appropriately acknowledge issues for another.[98] With AI, potential risks can only be anticipated to a limited extent because the algorithm making the decisions is a completely different algorithm in clinical trials than when used post-trial.[99] The world is a clinical trial for health AI, full

96. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84, at 3 n.7; Jiang et al., *supra* note 45, at 241. The most effective algorithms require updated data be supplied so that the algorithm is able to learn from a greater variety of data inputs. *Id.* This renders algorithms static versus dynamic.

97. Aunger, *supra* note 93.

98. For example, many training data sets might contain information that is more or less useful for specific uses and may result in less useful functionality. *See* Drew Roselli, Jeanna Matthews & Nisha Talagala, *Managing Bias in AI*, COMPANION PROC. 2019 WORLD WIDE WEB CONF., May 2019, at 539, https://people.clarkson.edu/~jmatthew/publications/ManagingBiasInAI_CAMERAREADY.pdf.

99. The FDA has focused on developing an acceptable framework for adapting clinical trials for AI machines, including two formal guidance documents. U.S. FOOD & DRUG ADMIN., ADAPTIVE DESIGNS FOR MEDICAL DEVICE CLINICAL STUDIES (2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/adaptive-designs-medical-device-clinical-studies; U.S. FOOD & DRUG ADMIN., USE OF REAL-WORLD EVIDENCE TO SUPPORT REGULATORY DECISION-MAKING FOR MEDICAL DEVICES (2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices; U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE DEVELOPMENT TOOLS (MDDT) (2021), https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt. These, respectively, permit broader indications for use based on accumulated information after the trial phases are over to bolster clinical trial data and the ability to alter the clinical trial to some extent based on pre-planned and expected deviations. These guidance documents do signal that the FDA understands, at least facially, the development of AI technologies. However, they do not address design-specific issues.

of unanticipated issues unlikely to arise in a limited clinical-trial scheme and difficult to anticipate at the time of FDA submission.[100]

Countless human decisions result in automated decision-making via AI algorithms, including those powering low-risk and high-risk applications, from diagnostic software to surgical robotics. The depth of human ingenuity paired with machine computer power and longitudinal extensibility will revolutionize life as we know it. While the risks are high, the incentives and potential outcomes are similarly high. The most crucial step is finding the appropriate balance for incentivizing development while reducing potential issues. Where preventative regulation is undesirable or unlikely to provide safe and effective medical devices, the tort system may provide a complementary opportunity to reinforce safety while providing injury compensation.

II. MEDICAL DEVICE REGULATION AND TORT PREEMPTION

The medical device preemption trilogy of *Medtronic, Inc. v. Lohr* (1996), *Buckman Co. v. Plaintiffs' Legal Committee* (2001), and *Riegel v. Medtronic, Inc.* (2008) dramatically reduced the probability of plaintiffs successfully recovering in tort for injuries caused by medical device use.[101] In total, the preemption trilogy has nearly foreclosed any opportunity for patient recovery when medical devices have undergone a complete FDA review, with only a narrow opportunity to successfully bring a tort claim that survives summary judgment.[102]

100. The model of "the world as a clinical trial" is a common model for medical products that would prove too expensive to fully test in a clinical trial environment, such as vaccines. *See* Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 453 (2010). The FDA has also embarked on useful efforts to better gather and use data for purposes of improving device functionality. One example of this effort is the NEST platform, which "generate[s] evidence across the total product lifecycle of medical devices." U.S. FOOD & DRUG ADMIN., NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY (NEST) (2019), https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest. These types of platforms will be indispensable for AI machines.

101. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); Riegel v. Medtronic, Inc., 552 U.S. 312 (2007).

102. The Author focuses on the potential for a plaintiff to bring a tort action that survives preemption. However, this Article does not address a variety of other medical device tort complexities, such as heightened pleadings standards combined with the inability to produce highly specific claims due to confidentiality commitments between the Food and Drug Administration and manufacturers.

A. The Medical Devices Amendments Act of 1976 and Subsequent Preemption Cases Have Nearly Foreclosed Tort Recovery

In response to widespread and well-publicized pharmaceutical and medical device injuries, John F. Kennedy championed passage of two amendments that would focus on more comprehensive regulation of pharmaceuticals and medical devices—the Drug Amendments of 1962 and a medical device-focused amendment.[103] However, the thalidomide disaster, where a pharmaceutical used for morning sickness resulted in serious birth defects for more than 10,000 children, prompted Congress to prioritize passing the Drug Amendments of 1962.[104]

In 1976, Congress finally passed the Medical Device Amendments (MDA) against a backdrop of catastrophic Dalkon Shield injuries, where an intrauterine device used by 2.2 million women caused pelvic infection, infertility, and death.[105] At the time, although Congress was aiming to provide greater protection for medical device consumers,[106] Congress could not have anticipated the potential challenges of regulating the diverse and fast-growing medical device industry.[107]

The MDA established a PMA process for medical devices,[108] a substantial process involving a "multivolume application."[109] As part of this act, Congress statutorily integrated a risk management model into its ambits, based on a classification system of Class I,

103. INST. OF MED., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: BALANCING PATIENT SAFETY AND INNOVATION 4 (Theresa Wizemann ed., 2010), https://www.nap.edu/read/12960/chapter/1#ii.

104. *Id.*; *Thalidomide*, SCI. MUSEUM (Dec. 11, 2019), http://broughttolife.sciencemuseum.org.uk/broughttolife/themes/controversies/thalidomide.

105. *See Riegel*, 552 U.S. at 336 (Ginsburg, J., dissenting); CDC, *Elevated Risk of Pelvic Inflammatory Disease Among Women Using the Dalkon Shield*, MORBIDITY & MORTALITY WKLY. REP. (May 06, 1983), https://www.cdc.gov/mmwr/preview/mmwrhtml/00000072.htm.

106. *Riegel*, 552 U.S. at 337 (Ginsburg, J., dissenting). Because the MDA did not, on its own, provide a compensatory remedy, it is hard to believe that the MDA was intended to preempt state torts quickly following a high-profile tragedy. *Id.*

107. Jeffrey K. Shapiro, *The Medical Device Amendments of 1976: The Statute that Went Awry*, FDA L. BLOG (June 3, 2013), http://www.fdalawblog.net/2013/06/the-medical-device-amendments-of-1976-the-statute-that-went-awry/; *see* MEDPAC, *supra* note 8, at 219.

108. Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. § 360c).

109. *See Riegel*, 522 U.S. at 317–18.

Class II, and Class III (from lowest to highest risk).[110] Additionally, Congress charged the FDA to determine the safety and efficacy of a device "weighing any probable benefit to health . . . against any probable risk of injury or illness from . . . use."[111] This combined approach illustrated that medical device safety and efficacy review should take into account both potential risk to individuals using such devices and (1) actual device users, (2) recommended or suggested labeling, (3) cost and benefit analysis, and (4) device reliability.[112]

The preemption provision that accompanied the tiering system made sense from the perspective of a fully regulating central agency, if Congress believed that the FDA would have the appropriate resources to fully regulate safety and efficacy for the medical device sector. They could not have anticipated that the U.S. medical device sector would grow to become one of the biggest industries in healthcare, with 7,000 medical device companies accounting for some $136 billion in annual sales as of 2015, or 45% of the global medical device market.[113]

In addition to establishing the classification system and the PMA and abbreviated 510(k) processes for medical device clearance, Congress also included a limited preemption clause in the MDA.[114] Under the MDA preemption clause, plaintiffs may not recover for injuries resulting from a "requirement . . . which is different from, or in addition to, any requirement applicable under [the MDA], and . . . which relates to the safety or effectiveness of the device."[115]

This preemption clause seemed, at its passage, to embrace the role of the FDA as primary regulator for the medical device

110. *Id.*; U.S. FOOD & DRUG ADMIN., DEVICE CLASSIFICATION PANELS (2018), https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels. Practically speaking, classifications are proposed by the applicant for a particular medical device based on definitions for specific families of devices in the Code of Federal Regulations (CFR) and predicate devices previously approved. Each classification integrates general controls further illustrated in the CFR for all devices, with special controls offered for Class II and Class III devices, respectively.

111. Medical Device Amendments § 513(a)(2)(C).

112. *Id.*; 21 C.F.R. § 860.7 (2020).

113. Sarah Collins, *A Must-Read Overview of the Medical Device Industry*, MKT. REALIST (Nov. 19, 2015, 4:40 PM), https://marketrealist.com/2015/11/must-read-overview-medical-device-industry/.

114. *See* text accompanying notes 108–109.

115. 21 U.S.C. § 360k(a).

industry by barring state laws that establish different or additional state requirements beyond federal requirements.[116] The operative function of this preemption clause, then, was to dismiss patient claims, usually as a negligence or negligence per se tort, claiming injury related to non-compliance with state law.[117] However, at the time of passage, Congress could not have anticipated how preemption law under the MDA would develop.

Medtronic, Inc. v. Lohr (1996) was the first case to fully address preemption related to FDA regulation of medical devices. In *Lohr*, the Supreme Court established an initial skeleton of how the MDA preempted state tort actions.[118] First, the Court established that preemption would only apply where the FDA had completed a detailed review a given device, specifically through the PMA process generally used for new Class III devices.[119] Practically speaking, this meant that plaintiffs seeking recovery for device injuries reviewed in abbreviated processes could survive express preemption by the MDA.[120] Abbreviated processes include the 510(k) process for substantially equivalent (SE) devices, other abbreviated reviews, and lower-risk classification reviews (Class II and Class I, which include the 510(k) process and exempted status, respectively).[121] This interpretation of the MDA reinforced the balance between investment in comprehensive ex ante regulatory approval and recovery for less comprehensive premarket processes.

Riegel v. Medtronic, Inc. (2008) expanded PMA-informed preemption to additional tort actions. Until *Riegel*, courts typically found tort recovery preempted where a statute established additional or different requirements from FDA requirements

116. Much has been written on the meaning of preemption within the MDA, both for explicit and implied preemption. This Article does not attempt to reopen this discussion specifically, but rather to work within established case law to explain how AI might present specific challenges related to the Court's interpretation of the MDA preemption language.

117. State laws consist of statutory obligations specifically codified and common law-established duties.

118. Medtronic, Inc. v. Lohr, 518 U.S. 470, 492 (1996).

119. *Id.* at 494.

120. *Id.*

121. *Id.*; *see* 21 C.F.R. § 807.92(a)(3) (2020); Suzanne Hodsden, *FDA Releases List of Class I Medical Devices Exempt from 510(k) Notifications*, MED DEVICE ONLINE (Apr. 17, 2017), https://www.meddeviceonline.com/doc/fda-releases-list-of-class-i-medical-devices-exempt-from-k-notifications-0001.

promulgated as part of the Code of Federal Regulations (CFR). In *Riegel*, the Court expanded preemption application from positive state law to include common law tort actions.[122] The cumulative effect of this interpretation is that where the FDA has established overt requirements and reviewed compliance with these requirements via the PMA process, all tort actions are preempted except where the tort action parallels the FDA requirement, insofar that they are not different or additional requirements.[123]

Riegel established that most common law claims stemming from PMA-reviewed medical devices could not survive preemption. First, the PMA approval process had to have established requirements of "safety and effectiveness" under the MDA because the FDA cannot approve devices that do not meet reasonable safety and effectiveness standards.[124] Second, because common law tort actions in part determine "reasonable" duties with respect to products, a jury could establish additional or different requirements than the FDA has established.[125] However, common law claims that parallel federal requirements could survive preemption because they are not different or additional requirements: they are the same requirements.[126] Parallel claims, or claims for recovery premised on violation of federal requirements, *may* survive preemption under both *Lohr* and *Riegel*.[127]

Parallel claims may still be preempted under an implied preemption model.[128] Under implied preemption, preemption may still apply even when language does not specifically determine preemption, such as when such an activity does not occupy a "field which the states have traditionally occupied."[129] In *Buckman Co. v. Plaintiffs' Legal Committee* (2001), the Court found implied

122. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008).

123. In this way, *Lohr* introduced the possibility of parallel claims and *Riegel* subsequently established recovery in these circumstances.

124. Jarret Sena, *The Contours of the Parallel Claim Exception: The Supreme Court's Opportunity to Define the Ill-Defined*, 42 FORDHAM URB. L.J. 291, 304 (2014).

125. *Id.*

126. *Id.*

127. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 494–95 (1996); *Riegel*, 552 U.S. at 330.

128. Parallel claims may or may not be supported for recovery. *Lohr* and *Riegel* likely created space for such a claim, but claims related to failure to warn or labeling may not succeed under implied preemption. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017).

129. Sena, *supra* note 124, at 306 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

preemption when a consultant for Buckman may have misrepresented information to the FDA amounting to fraud.[130] The Court reasoned that the burden on manufacturers of exposure to potential liability would become a disincentive for greater competition and "delay the prescription of beneficial off-label uses."[131] *Lohr*, *Riegel*, and *Buckman* collectively recognize an express and implied preemption for devices approved via the PMA process, with a narrow exception for parallel claims to federal requirements.[132]

If only such federal requirements were sufficiently clear and specific. As a threshold issue, it is unclear what is considered a "genuinely equivalent" claim to a federal requirement.[133] Moreover, it is unknown what even constitutes a "requirement." The MDA references the requirement as "any requirement applicable under [the MDA] to the device" or "which relates to the safety or effectiveness of the device or to any other matter included in requirement applicable to the device under th[e] Act."[134] Where there is not "sufficient information to establish a performance standard . . . to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities . . . to develop or obtain such information."[135]

If medical device preemption were not already imprecise, a recent circuit court decision has complicated it further, specifically for component devices subject to modulated review.[136] In *Shuker v.*

130. The Court held that activities like preventing fraud were principally within the responsibilities of the FDA, rather than traditional state responsibilities. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001).

131. Sena, *supra* note 124, at 307.

132. *See id.* at 323–24 (examining Riley v. Cordis Corp., 625 F. Supp. 2d 769 (D. Minn. 2009)). Preemption follows from a two-step framework: (1) the government has established requirements for the specific device at issue, and (2) whether the claims are based on requirements different from or in addition to these federal requirements. *See* Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 771 (3d Cir. 2018).

133. Sena, *supra* note 124, at 308–11 (quoting McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005)). The Seventh Circuit has held that genuine equivalence applies to the medical device context. *Id.* at 310.

134. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

135. *Id.* It should be noted that this section directly follows the section on classification, which means that this interpretation of performance standards applies regardless of classification.

136. At the time of writing, only the Third Circuit had considered this question, but the expected reliance of device companies on third parties creating software, including AI, could result in substantially more component-based preemption inquiries.

Smith & Nephew, PLC (2018), the Third Circuit examined whether components that were reviewed as separate classifications but integrated into one device would survive preemption, which requires courts to apply the "presumption against the pre-emption [sic] of state police power regulations."[137] In *Shuker*, a component was approved for a specific hip resurfacing system via the PMA process set out in 510(k), but the plaintiff's doctor used the component off-label for a total hip replacement.[138] The plaintiff argued that claims related to the PMA component should not be preempted because of the device's component status within a 510(k)-reviewed system. However, according to the Third Circuit, the use of the PMA component for off-label use essentially divorced the component from the system, as the FDA identifies each component as a separate device.[139]

Next, the Third Circuit applied the two-step test and found that *Riegel* did not sufficiently explain how to examine mixed-class components within a device.[140] Under an argument of PMA adherence, wherein any component of a 510(k)-approved device inherits PMA status, the court ultimately held that each component, including the component of the device that caused Mr. Shuker's injury, was subject to PMA approval.[141] Ultimately, claims related to the PMA-reviewed component were preempted.[142] Although district courts have not completely deviated from the Third Circuit's analysis,[143] the potential for "preemption by adherence," regardless of actual FDA review, is very troubling when considering the potential for AI injuries. For example, courts have yet to decide whether claims involving a PMA-approved system

137. *Shuker*, 885 F.3d at 770–71 (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 518 (1992)).

138. *Id.* at 769.

139. *Id.* at 772–73.

140. *Id.* at 774.

141. *Id.* at 773–74.

142. *Id.* at 775.

143. *See, e.g.*, LaFountain v. Smith & Nephew, Inc., No. 14cv1598 (WWE), 2016 WL 3919796 (D. Conn. July 18, 2016). In *LaFountain*, multiple components of a hip replacement system caused injury, and although some components were PMA-approved, the overall system alleged to have injured LaFountain was not PMA-approved. The claims were alleged to parallel federal requirements. In this case, the District of Connecticut court looked, as the Third Circuit did, to the classification of the system, though the District also made explicit the relationship between what caused the injury (e.g., the system, rather than a specific component) to make this determination.

with a 510(k) component are preempted. If the component is responsible for injury, such as a defective AI software component, but the system nevertheless was approved under a PMA, it is unclear whether the component would inherit PMA status and tort claims would be preempted or whether the component could be analyzed independently.

AI software will likely be one component of physical medical devices, potentially medical devices that are implanted or otherwise could cause injury to the human body. However, the AI software may be reviewed and approved as a separate component from the physical medical device, and in some cases the AI may be created by a third party, not a device manufacturer.[144] While the PMA process has, in most cases, almost fully preempted potential recovery from PMA-cleared devices, the PMA process may extend to injuries caused by components that nevertheless were not subject to PMA review.

Except for cases involving injuries related to separately classified component devices, *Lohr*, *Buckman*, and *Riegel* have collectively established the following precedent for a tort claim to survive summary judgment when a PMA or similarly stringent FDA review process is used[145]:

> 1. Does the tort claimant aim to recover on the basis of different or additional state requirements (including general tort duties determined by a jury) beyond federal or FDA requirements?
>
> 2. For claims that allege a state-law requirement parallel to an FDA-established requirement, is the requirement sufficiently specific?
>
> 3. Is the state-law requirement mandatory or compulsory in nature?

144. In the Author's recent work with start-up medical device manufacturers, these organizations have shared that they frequently use third-party AI software. Although not dispositive, the practice is not rare.

145. It should be noted that these cases do firmly establish that when a non-comprehensive review process is used, such as the 510(k) process, tort actions may go forward. *Buckman* was determined via implied preemption analysis but nevertheless demonstrates the Court's willingness to expand preemption beyond its express bounds. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001).

> 4. If a state-law claim is mandatory, sufficiently specific, and parallel to federal requirement, is it still within the traditional boundaries of what a state should regulate?

The cumulative effect of these cases is to almost completely preempt tort actions when the FDA has used a PMA or similarly stringent approval process for medical device clearance. Of course, this preemption model will likely prevent recovery for AI-enabled medical devices that are cleared through PMA or similarly stringent approval processes, regardless of whether the FDA has in fact reviewed the AI system running the medical device.

B. The Comprehensive Premarket Approval Process and Requirements Are Not Designed for AI Devices

The FDA has used a variety of resources to provide direction to manufacturers offering medical devices for sale in the United States.[146] Organizations are traditionally responsible for proposing a specific classification for a new device.[147] Organizations proposing Class III devices (and other devices that cannot demonstrate Class I- or Class II-appropriate classification) must not only successfully receive approval via the PMA process, but manufacturing facilities must also meet quality management standards.[148] Manufacturers planning for the PMA process must also meet pre-clinical trial requirements, including device design, bench testing, and animal testing prior to a clinical trial.[149]

Clinical trial requirements for an IDE,[150] the first step for PMA approval, usually includes, *inter alia,* a two-trial approach to

146. It should be noted that the definition of "medical device" is quite broad, including potentially any health device, although the FDA may use its discretionary authority to not review some medical devices, such as Class I health apps and other software. *See* U.S. FOOD & DRUG ADMIN., HOW TO DETERMINE IF YOUR PRODUCT IS A MEDICAL DEVICE (Dec. 16, 2019), https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device.

147. *See* 21 C.F.R. § 860 (2020).

148. *See* 21 C.F.R. §§ 808, 812, 820 (2020). Manufacturing facilities must meet Current Good Manufacturing Processes (CGMP) through an effective quality control system. It should be noted that these inspections do not include virtual or technical infrastructure reviews, wherein code might be reviewed; instead, CGMPs usually include sanitary and repeatable quality facility operation checks.

149. Owen Faris, *Clinical Trials for Medical Devices: FDA and the IDE Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/87603/download (last visited Mar. 5, 2021).

150. *See* 21 C.F.R. § 812 (2019).

determine feasibility followed by a clinical trial testing safety and efficacy, or a pivotal study, for a patient population.[151] Within the PMA process, organizations must submit evidence of safety and efficacy via scientific evidence, including a well-controlled clinical investigation consisting of one or more trials, that includes a clear statement of study objectives, a method for subject selection, methods explanation, and articulation and comparison of results using reliable statistical methods.[152]

The PMA application, which includes both clinical results and labeling details, is reviewed by panels of FDA-employed experts, who are assembled within a panel designation as part of the Medical Devices Advisory Committee, which has eighteen panels.[153] These panels typically include experts in the principal device's primary scientific field; for example, the Circulatory Systems Devices Panel consists of four cardiologists and one expert in regulatory affairs.[154]

Classification typically flows from predicate devices within a panel's statutory classification scheme. For example, portions of a pacemaker will likely be classified under the Circulatory Systems Devices Panel, with a similar classification to previously approved devices.[155] A pacemaker programmer, a hand-held device that non-invasively makes software changes to an implanted pacemaker within a short physical distance from the pacemaker, will typically be classified as a Class III medical device and required to meet PMA requirements.[156] Each device type typically must follow requirements communicated in the CFR and specific requirements the FDA analyst and panel identifies in reviewing the PMA file. The challenge, of course, is that a panel of radiologists may not be experts in AI

151. *See* Faris, *supra* note 149.

152. U.S. FOOD & DRUG ADMIN., PMA CLINICAL STUDIES (May 22, 2020), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-clinical-studies.

153. *See* U.S. FOOD & DRUG ADMIN., *supra* note 110; U.S. FOOD & DRUG ADMIN., MEDICAL DEVICES ADVISORY COMMITTEE (2019) [hereinafter FDA, MED. DEVICES ADVISORY COMM.], https://www.fda.gov/advisory-committees/medical-devices/medical-devices-advisory-committee.

154. *Roster of the Circulatory System Devices Panel*, U.S. FOOD & DRUG ADMIN. (2019), https://www.fda.gov/advisory-committees/circulatory-system-devices-panel/roster-circulatory-system-devices-panel.

155. 21 C.F.R. § 870 (2020).

156. 21 C.F.R. § 870.3700 (2020).

software or even general software design, and requirements in the CFR usually are not specific enough to guarantee software quality.[157]

However, classification and associated review can be modulated, whereby certain portions of a device, such as the software running a device, can be reviewed using different classification standards that require less restrictive attendant controls.[158] For example, a physical pacemaker that is "new" for purposes of review would likely be a Class III device requiring the PMA process. However, if classified as separate modules, the software running on the pacemaker would likely be a Class II device not requiring the PMA process.[159] When software is integral to a medical device's operation yet is reviewed in an isolated manner, modulation in the review process likely prevents a holistic safety review and preempts a comprehensive risk analysis.[160]

If the FDA was implementing a regulatory model that anticipated patient risks associated with software and its interaction with physical devices, such as AI-enabled device systems, a modulated approach might not fully anticipate potential risks. For example, an AI-enabled surgical robot might cause a patient injury, not just because of the robot itself, but because of the AI instructing the robot's surgical moves. In this case, AI software might have been reviewed in the 510(k) truncated process, while the surgical robot and its basic local software was reviewed via the PMA process. Therefore, the AI software may have received a less stringent FDA review. However, because the robot received a PMA review, and the AI software is part of the broader robotics system,

157. *See infra* Section II.C and accompanying notes.

158. Although Class II and Class III devices would both require special controls, a PMA process review, through the FDA's inquiry, would likely be more restrictive than the 510(k) process in that the FDA and associated expert panels might ask questions to better understand how manufactures have met special controls in this precise case.

159. Different component classifications could increase risks to patients when lower classification components are implemented into a higher classification system. *See* Bill Siwicki, *Next-Gen Medical Devices: Security, AI, Rethinking Design for Patient Experience*, HEALTHCARE IT NEWS (June 19, 2018), https://www.healthcareitnews.com/news/next-gen-medical-devices-security-ai-rethinking-design-patient-experience (describing the potential for AI-driven device failure and the need for holistic device review). Logically, if a Class II component inherits the preemptive power of the primary Class I device, injuries are both (1) not prevented through comprehensive review and (2) preempted from tort recovery.

160. *Id.*

the entire system may be viewed from the preemption perspective as having received a PMA review.[161]

Moreover, the PMA process is not, however, intended to be the end of the process, at least for devices that are modified after PMA clearance. A PMA supplement or PMA amendment must be created when the device subject to the PMA process has significantly changed from the material submitted in the PMA submission. The PMA amendment is used when a change is needed for a submitted, but not yet approved, PMA file.[162] The PMA supplement is used when the device has significantly changed or the change affects the safety and efficacy of the device.[163] Under some circumstances, manufacturers may be required to resubmit a PMA rather than as supplement, such as when changes to the device might raise different types of safety or effectiveness questions or where there are no accepted test methods for evaluating these new questions.[164]

The PMA process is somewhat comprehensive for what it regulates, yet there are serious gaps, especially for AI-enabled medical devices. These systems have the potential to create safety hazards for patients but likely leave patients without any opportunity for recovery in tort. Medical devices under PMA review are often reviewed by experts, but not necessarily experts in AI or software development; components of a medical device, which are nevertheless incorporated into the final product, may not receive a Class III classification or PMA review although they may introduce new safety hazards.[165] AI-enabled devices will usually function differently than at their approval. But as a foundational question, it is unclear which FDA instructions actually constitute a "requirement" for purposes of the PMA process. The lack of clear

161. *Id.*

162. 21 C.F.R. § 814.37 (2020).

163. U.S. FOOD & DRUG ADMIN., PMA SUPPLEMENTS AND AMENDMENTS (2019), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-supplements-and-amendments. These supplements may be specific to another indication for use, for significant change to performance, changes in components or materials, changes in design, or changes in labeling, amongst others. Some supplements are "real time," or supplements for minor changes. From a practical perspective, dynamically inscrutable AI software will not likely be a good candidate for this kind of administrative process because it is constantly evolving. Manufacturers would likely need to continuously fill out paperwork to stay current, leading to administrative nightmares.

164. *Id.*

165. *See infra* Section III.B and accompanying notes.

requirements and a reliance on non-binding "guidelines" or "guidance" may create substantial downstream issues for tort recovery.

C. The MDA Preemption Term "Requirement" Is Imprecise

Organizations must use FDA documents to guide the development of products that will meet panel expectations, such as requirements, regulations, and guidelines, or guidance.[166] However, the term "requirement" is not as clear as might be expected on its face. The FDA describes "regulatory requirements" as including establishment registration, where manufacturing facilities must be registered, medical device listing, premarket notification or PMA processes, the IDE process for clinical trials, quality system regulations, labeling requirements, and ongoing issue reporting.[167]

Within the CFR sections specific to FDA processes, the term "requirements" is used typically in relation to specific information provided as part of the PMA process, such as details to be included in clinical trial results, although some specific regulatory requirements have been promulgated via the CFR.[168] For example, coronary vascular physiologic simulation (CVPS) software visually simulates blood flow using data extracted from an coronary imaging device.[169] The results of such simulation software might inform whether a patient requires medical treatment, such as surgery or medication, to treat a coronary blood-flow issue that increases a patient's risk of a heart attack or stroke. This type of software requires, according to the CFR, "verification and validation based on comprehensive hazard analysis," which includes "any proprietary algorithm(s) used to model the vascular

166. U.S. FOOD & DRUG ADMIN., PMA REVIEW PROCESS (2019), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-review-process.

167. U.S. FOOD & DRUG ADMIN., OVERVIEW OF DEVICE REGULATION (2018), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation; 21 C.F.R §§ 801, 803, 807, 812, 814, 820 (2020).

168. *See, e.g.*, 21 C.F.R. § 814.82 (2020). The term "requirements" is used throughout the CFR in a variety of different contexts. Additional, device-specific regulatory requirements are codified in 21 C.F.R. §§ 800–1299 for medical devices.

169. 21 C.F.R. § 870.1415 (2020).

anatomy."[170] The same provision of the CFR also requires "adequate consideration of privacy and security issues in [software's] system design."[171]

It is clear from the CFR "requirements," the closest approximation of which are special controls, that manufacturers have discretion in how risks related to algorithm reliability and other data integrity issues might be mitigated. In this example, a manufacturer may rely on published yet nonbinding FDA guidance to interpret how to meet CFR special controls, or they may not. As guidance documents are non-binding, it is unclear whether such documents could form the basis for a "requirement" under the MDA even if they are integrated into PMA review by the FDA analyst or panel.

D. Guidance Enhances Regulatory Requirement Breadth and Depth but Does Not Address AI Concerns

Although regulatory requirements provide some direction in terms of system design for a software product like CVPS software, additional guidance is provided via other FDA documents.[172] It is unclear whether and to what extent guidance documents are used in the PMA approval process as binding requirements.[173] The FDA, for its part, has contextualized guidance as "not creat[ing] or confer[ring] rights for or on any person . . .[,] not operat[ing] to bind FDA or the public," and offering the possibility for alternative means to meet the underlying regulatory requirement.[174]

However, it is generally accepted that guidance operates, at least for PMA reviews, as a pseudo-requirement. Specifically, FDA

170. *Id.* The CFR continues, "Data must be provided within the clinical validation study or using equivalent datasets demonstrating the consistency of the output that is representative of the range of data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment." *Id.*

171. *Id.*

172. Although guidance documents are not legally binding, they often elucidate more specificity for a regulatory requirement. For example, "adequate security and privacy" might be appropriately implemented using premarket security guidance and used as the basis for meeting this regulatory requirement in the PMA process.

173. 21 C.F.R. § 870.1415.

174. U.S. FOOD & DRUG ADMIN., GUIDANCE DOCUMENTS (MEDICAL DEVICES AND RADIATION-EMITTING PRODUCTS) (2021), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.

personnel, for example the analyst assigned to the file, usually evaluate compliance with a special control, such as "[a]dequate consideration of privacy and security issues" through the lens of guidance documents.[175] In this way, guidance seems to operate, at least for some types of reviews, as a rebuttable presumption: so long as organizations demonstrably meet the guidance, they also demonstrate compliance with associated special controls. If the organization does not meet the guidance, they must provide documentation to demonstrate that they still comply with the special control. To what degree FDA personnel or panel members actually provide expert direction in this review process is unknown, though facially it seems unlikely that personnel and panel members are equipped to review software design and anticipate real patient risks for new software technology like AI from a position of deep expertise.

For software-enabled medical devices, guidance documents consist of software-specific documents and cybersecurity documents, with the potential for future artificial intelligence documents, amongst many planned software and cybersecurity-related documents.[176] Despite the plethora of different software

175. *See* 21 C.F.R. § 870.1415(b)(1)(B)(ii).

176. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84; U.S. FOOD & DRUG ADMIN., POSTMARKET MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES (2016) [hereinafter FDA, POSTMARKET], https://www.fda.gov/media/95862/download; U.S. FOOD & DRUG ADMIN., SOFTWARE AS A MEDICAL DEVICE (SAMD): CLINICAL EVALUATION (2017), [hereinafter FDA, SAMD] https://www.fda.gov/media/100714/download; U.S. FOOD & DRUG ADMIN., CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES (2018) [hereinafter FDA, PREMARKET], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices. AI has not received the direct attention of software and cybersecurity, although the recent whitepaper is illustrating an interest in the subject. Additional interest has revived for software validation, prompting a 2019 goal for new final guidance on *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* and *Clinical and Patient Decision Support Software*. *See* U.S. FOOD & DRUG ADMIN., CDRH FISCAL YEAR 2019 PROPOSED GUIDANCE DEVELOPMENT AND RETROSPECTIVE REVIEW (2018), https://www.fda.gov/news-events/fda-voices/cdrh-fy-2019-proposed-guidance-development-and-retrospective-review. Planned draft guidance includes *Computer Systems Assurance for Manufacturing, Operations, and Quality System Software; Content of Premarket Submissions for Cybersecurity of Medical Devices of Moderate and Major Level of Concern;* and *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Id.*

guidance documents, software bugs and security vulnerabilities continue to plague medical devices.[177]

The FDA has not developed many guidance documents related to AI or algorithms specifically, though it has developed general guidance for software.[178] It is unknown, however, to what degree guidance actually informs specific PMA decisions, and the extent of software or similar review, when panel members may be experts in the physical device, but not the software or other computerized technology that run it.[179] Of course, modulated reviews may not provide any direct PMA review for portions of a full device, although the device, as operating, may pose patient risks.

Given these challenges in control review, personnel and panel expertise, and modulated reviews, it is no surprise that the FDA has taken a predominantly responsive rather than proactive approach for new technologies, first relying on postmarket guidance rather than PMA review.[180] When this approach has become more proactive, it often is managed separately, in a non-PMA-integrative manner.[181]

177. *See* Jay G. Ronquillo & Diana M. Zuckerman, *Software-Related Recalls of Health Information Technology and Other Medical Devices: Implications for FDA Regulation of Digital Health*, 95 MILBANK Q. 535 (2017). The existence of a continuing issue in software-related recalls demonstrates the imprecise nature of upfront review and approval, even through a rigorous PMA process.

178. *See* Price, *supra* note 24, at 443; *see, e.g.*, U.S. FOOD & DRUG ADMIN., OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES (1999), https://www.fda.gov/media/71794/download; U.S. FOOD & DRUG ADMIN., GENERAL PRINCIPLES OF SOFTWARE VALIDATION (2002), https://www.fda.gov/media/73141/download; FDA, SAMD, *supra* note 176; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MEDICAL DEVICES (2005), https://www.fda.gov/media/73065/download.

179. *See* FDA, MED. DEVICES ADVISORY COMM., *supra* note 153; U.S. FOOD & DRUG ADMIN., *supra* note 154.

180. *See, e.g.*, FDA, PREMARKET, *supra* note 176; FDA, POSTMARKET, *supra* note 176. The FDA issued postmarket guidance prior to drafting premarket requirements. There is reason to believe that the FDA is following as similar path with AI machines to promote innovation via responsive rather than preventative measures. *See* Bibb Allen, *The Role of the FDA in Ensuring the Safety and Efficacy of Artificial Intelligence Software and Devices*, 16 J. AM. COLL. RADIOLOGY 208 (2018). Despite the value of postmarket surveillance, it cannot solve AI safety issues on its own. *See* Price, *supra* note 24, at 462–64 (describing the value of postmarket surveillance activities both for continuous improvement and to support the inherent dynamism of changing, self-learning AI technologies). Nicholson Price cautions against relying on postmarket surveillance as a silver bullet for safety concerns. *Id.*

181. SUZANNE MURRIN, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., FDA SHOULD FURTHER INTEGRATE ITS REVIEW OF CYBERSECURITY INTO THE PREMARKET REVIEW

This responsive, rather than proactive, approach has raised some concerns. For example, the Office of Inspector General (OIG) has urged the FDA to integrate cybersecurity risk reviews into the premarket review process for medical devices.[182] The OIG has identified the need for "Refuse-to-Accept" checklists, the FDA's Smart template, and a dedicated cybersecurity review section, none of which the FDA has previously implemented.[183] AI software, although making news headlines for years, has not been examined other than development of a single discussion paper in 2019.[184]

Collectively, this seems to suggest that although the FDA is aware of new technology risks, the review process is not currently designed to identify and prevent cyber-kinetic safety hazards and poorly designed AI software.[185] And, in a preemption world, injured patients are unlikely to recover despite an insufficient or non-existent review. When the MDA was passed in 1976, the regulatory structure, including preemption language, was designed to rely on deep expertise from the FDA. Today, even the comprehensive and rigorous PMA process does not effectively anticipate AI machine issues, including components and device review modulation or the integration of AI software into analog medical devices. Based on its current structure and processes, it is unknown whether the FDA will direct its resources to comprehensively regulate AI software and whether patients be left with no remedy for their injuries.

PROCESS FOR MEDICAL DEVICES (2018), https://oig.hhs.gov/oei/reports/oei-09-16-00220.pdf.

182. *See generally id.*

183. *Id.* at 12. Pre- and postmarket guidance began in 2014 for cybersecurity risks, and although FDA personnel usually requested cybersecurity documentation for medical devices, the FDA "almost always cleared or approved the cybersecurity aspect of networked medical devices." *Id.* at 11. Although cybersecurity risks are not necessarily the same as artificial intelligence risks, they illustrate a useful model of what can be improved with new technology risks.

184. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84.

185. For example, a cyber attacker that alters an AI utility that provides direction to a connected pacemaker may cause physical heart damage via digital means. Poor AI design could, as the algorithm changes, create many of the same physical safety issues when the algorithm drives physical function of an associated device.

III. THE REGULATORY-TORT RISK CALCULUS

Effective product safety regimes, including medical device products, balance both regulatory systems and tort recovery as part of a complementary model. In determining this balance, it is crucial to examine circumstances from the perspective of the administrative agency's ability to regulate and associated costs, the consumer's ability to avoid injury, and the inherent nature of the technology itself, which could promote latent issues due to its changeability or opacity. An appropriate regulatory-tort allocation likely includes elements of both to promote information dispersion for safety purposes and promote compensation for injured parties.

A. Risk Management Legal Systems Allocate Risks Between Regulatory Activity and the Tort System as Complementary, Rather than Competing, Solutions

Consumer protection has historically included ex ante and ex post solutions as part of a holistic legal framework. Ex ante legal solutions usually take the form of regulation and administrative clearance and approvals, preventative measures intended to reduce consumer injury. For example, manufacturers of general use products have a duty to warn consumers of any reasonably likely injury and communicate appropriate instructions for product use.

FDA-reviewed products have, for some time, illustrated a kind of gold standard for preemption. The FDA is one of the best-funded agencies in the United States combined with both a congressionally defined obligation to ensure the safety and effectiveness of medical products. The FDA, for its part, has changed its position regarding preemption from case to case.[186] Under certain administrations, funding for the FDA and executive orders have influenced the FDA's priorities and degree of review.[187] Dynamic shifts in

186. *Compare* Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners, Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (No. 95-754), 1996 WL 118035, at *13 (stating the FDA's view that state tort claims generally *are not preempted*), *with* Brief for the United States as Amicus Curiae Supporting Respondent, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (No. 06-179), 2007 WL 3231418, at *20 (stating the FDA's view that state tort claims *are preempted* insofar as they assert that a device in its FDA-approved form is not safe or effective for use as directed in the FDA-approved labeling).

187. INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 207 (2011), https://www.nap.edu/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance.

regulatory direction demonstrate the limits of regulatory solutions to enhance consumer confidence and ensure consumer safety.

Selecting federal agency regulation and preemption as the preferred solution for regulating health and safety requires a belief in the "rationality of the regulatory agency's agenda and the agency's assessment and allocation of risks."[188] The challenge, of course, is that agencies are often at the direction of the executive branch and subject to executive orders, creating a variable regulatory model, and their ability to prioritize activities is based on the availability of funding approved by Congress and the current state of the marketplace.[189] Agency behavior, therefore, is not static.

Legal scholars and economists have debated the merits of regulatory and tort approaches to regulating behavior. For example, economists have often argued that agencies provide better oversight than courts due to "specialized knowledge," especially around technical subject matter.[190] Specialized knowledge is implemented via cost-benefit analysis, which presumably includes risk assessment of a specific scenario or system-level assessment, wherein some scenarios receive more attention than others. It is system-level assessment that created the class structure for the FDA and a specialized knowledge expectation that likely motivated express preemption language under the MDA.[191] Also, this expectation of specialized knowledge likely influenced the Court's recognition of implied preemption in *Buckman.*

Catherine Struve has addressed the FDA regulatory-tort allocation question, noting that relying too heavily on preemption

188. *Id.* at 153.

189. Richard Epstein has argued that preemption of tort claims will not necessarily hamper information sharing or prevent risk information from being available. *See generally* Catherine M. Sharkey, *Field Preemption: Opening the "Gates of Escape" from Tort Law*, J. LEGAL STUD. (forthcoming 20XX), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3159537. Epstein seems to suggest that individuals, with appropriate information, can self-select from a variety of options available to them. *See id.* (manuscript at 5-6). Unfortunately, most medical devices have few competing options. Further, the dynamic inscrutability of key aspects of AI machines makes explainability and "information" difficult if not impossible to produce for purposes of making an informed decision.

190. Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 138, 139 (1995) (citing Susan Rose-Ackerman, *Tort Law in the Regulatory State*, *in* Tort Law and the Public Interest (Peter Schuck ed., 1991)).

191. *See* 21 U.S.C. § 360k(a); Sena, *supra* note 124.

rejects the value of tort for complementing safety goals, and it simultaneously denies patients compensation.[192] Justice Stevens, writing for the majority in *Lohr*, seemed to echo this concept, reasoning that a damages remedy in state court does not amount to a different or additional requirement for purposes of preemption.[193] After *Riegel*, however, Catherine Sharkey has questioned whether the Court's view has rejected the concept of tort as a complementary compensatory model in favor of a competitive view of state and federal law.[194]

Further, tort systems signal opportunities for greater regulation and oversight. Although regulatory agencies may carry the long-term burden of regulation to prevent known injuries, the tort system offers an opportunity to understand new injuries from causes yet to be understood, often while drawing upon historical principles.[195] In many cases, the tort system and regulatory agencies may perform a reinforcing function for each other.[196] The question, however, is one of balance: how might a regulatory-tort system allocate risk appropriately for given scenarios?

Due to resource constraints and device variability, the FDA cannot comprehensively regulate an industry, and the tort system may uncover important safety hazards that escape review.[197] The FDA has implemented a model that includes both preventative activities as clearance, continuing organizational monitoring obligations, and responsive actions in the case of safety or efficacy problems, such as recalls, replacements, and updates. However,

192. Catherine T. Struve, *The FDA and the Tort System: Postmarking Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 591 (2005). For allocation systems without strong preemption, the tort system is seen as complementary to agencies for creating safety standards or signaling proposed changes.

193. Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

194. Catherine M. Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims (Part II)*, 102 NW. U. L. REV. COLLOQUY 415, 417 (2008). Typically Congress creates a complementary model by including not only an express preemption clause but also a savings clause that preserves common law liability. *Id.* at 416. The Court in *Wyeth v. Levine*, 555 U.S. 555, 578 (2009), though examining preemption related to the drug rather than device industry, has echoed the value of complementary models. *See* Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 932, 933 n.18 (noting tort remedies "'reinforce[] a norm of attentiveness to safety' and 'serve[] as a counterweight to regulatory capture.'") (citation omitted).

195. Lyndon, *supra* note 190, at 169.

196. *Id.*

197. *See id.* at 141.

when the administration desires to stimulate innovation, the FDA often reduces its preventative oversight activities, relying more heavily on manufacturers, hospitals, and device users to report issues.[198]

The ex post tort system, then, provides additional controls to regulatory requirements a given organization must follow.[199] Amongst a substantial history of scholars focusing on FDA preemption, Struve proposes alternative options to a traditional tort system wherein the FDA might be part of technical review in federal court or the court might adjudicate safety reviews referred to an FDA panel.[200] These proposals identify some value in the tort system, whether the system focuses on tort law's signaling function regarding safety or considers compensation of the injured party who might otherwise be left without remedy.

Although courts are often criticized for a lack of expertise in technical subject matters, adjudication does have its benefits. For one, courts have access to any number of experts and documents, which can explore a specific technology in depth.[201] Second, courts have the benefit of the adversarial system, wherein additional information can be explored or exposed by the plaintiff and defendant as part of the legal process. Finally, the court operates in a social context, applying social principles to resolve conflicts rather than specifically operating according to an established agenda.[202]

Sometimes, even the regulatory system cannot perform its role as keeper of specialized knowledge. In Struve's example, as in many other proposals for preemption prior to *Lohr*, the FDA is positioned as an information broker and risk manager. For traditional and well-known technologies, it is less likely for common issues to be missed; for new technologies, the FDA may be required to invest much more time and effort to understand the risk profile affecting device safety and efficacy. For these new

198. Susan Kelly, *FDA Details Ramp-Up of Postmarket Device Oversight*, MEDTECH DIVE, (Nov. 21, 2018), https://www.medtechdive.com/news/fda-details-ramp-up-of-postmarket-device-oversight/542787/.

199. *Id.*

200. Struve, *supra* note 192, at 592, 591 n.14.

201. Lyndon, *supra* note 190, at 157. Certainly, the FDA has an information-generating function and has the ability to collect a great deal of data. The challenge, however, is that the FDA's information-generating function is limited by resource constraints, specifically funding and qualified personnel.

202. *Id.* at 163.

technologies, agencies typically rely on known technologies to assess risk, which may not be accurate.[203] In short, the more cutting edge the device, the more time the FDA will expend. And the time spent reviewing these devices will be based on available information from the manufacturer.

However, based on the FDA's reluctance to regulate AI as part of traditional device review and its lack of informative reference documents, the FDA is not an expert agency for AI.[204] It can also be argued that although the FDA has created a number of software-related documentation, it is ineffective in its review of software-related risks.[205] When an agency like the FDA does not completely review a technology or component of a technology, it is unclear whether the FDA has engaged in a system-level cost-benefit calculation meriting complete preemption, or whether the FDA has only conducted risk analysis with respect to the aspects it has actually reviewed.[206] For example, if the FDA is conducting a PMA review for the bionic pancreas and fails to effectively prevent AI-related injuries, it is unknown whether the FDA has opted not to review AI based on system-level risk, has not reviewed the AI component because the component introduces comparatively less risk than other technical aspects of the pancreas, or simply has not reviewed the AI component because it lacks the expertise.

203. *Id.* at 154.

204. In fact, the agency best positioned to regulate AI technologies or promote standardization is the National Institute for Standards and Technology (NIST), which is not explicitly integrated into the medical device review process and does not currently perform any regulatory approval role. *See* 15 U.S.C. § 271.

205. *See supra* text accompanying note 177. I should mention that for some types of technologies, for example software and AI software, it is tremendously difficult, if not impossible, to identify potential issues at the time of PMA submission based on partial software functionality, especially software that may require updates or self-update after the time of approval.

206. In system-level cost-benefit analysis, AI may not present enough risk to be reviewed at all, but other high-risk aspects of the medical device might be fully reviewed. For example, an artificial pancreas that relies on AI may be reviewed as an implantable device under a PMA, while the AI infrastructure only qualifies as a Class II device requiring a 510(k). Differing technology system components reviewed separately demonstrate that the FDA is not taking a holistic risk approach. When AI systems are part of the system but are modulated, their impact on the full medical device system is not analyzed. Decisions are often made under conditions of uncertainty, and both regulation and responsive legal process provide additional information through ex ante and ex post processes. Lyndon, *supra* note 190, at 143.

Innovative technologies like AI are challenging to regulate because they are not often created by sophisticated medical device manufacturers. More frequently, innovative technologies are produced by third parties, including start-ups, that have a niche knowledge base and little capital, for purposes of selling the technology or the company to larger manufacturers.[207] Practically speaking, this means that start-ups most frequently will spend their capital on development and proofs of concept, rather than compliance measures.[208] The goal is to create something that works, rather than to expend capital on proving safety for a large population.

By the time the FDA reviews these devices, the FDA may not have the expertise or time to complete a thorough review, and the acquiring manufacturer may not have the requisite knowledge or expertise to anticipate potential safety issues without prompting by an expert regulator. The issue, then, is one of knowledge dispersion.[209] And agencies like the FDA do not have a monopoly on knowledge about innovation.[210] Most specialized knowledge resides in the developers and experts themselves, especially for innovative technologies.[211]

B. The Tort System Provides a Mechanism for Information Dispersion and Plaintiff Compensation

The tort system, by design, functions to verify appropriate duties and measure whether a defendant has met its duty with respect to a plaintiff(s). Most frequently, and especially after *Lohr*, plaintiffs bring common law negligence tort lawsuits for products causing injury. Common law negligence actions require four elements: (1) the manufacturer has a duty, established as a common-law "reasonable" duty; (2) the manufacturer breaches that duty; (3) the breach of duty is the proximate cause of the

207. *See* MEDPAC, *supra* note 8, at 210.

208. *See id.*

209. Lyndon, *supra* note 190, at 149–51.

210. *Id.* at 157.

211. *Id.* at 157–58.

plaintiff's injury; and (4) the plaintiff has a compensable injury meeting Article III standing requirements.[212]

The calculus for these systems considers the burden on organizations to meet upfront requirements, the burden of individual consumers to protect their own interests (*caveat emptor*), and potential impacts when consumers may recover in tort or other litigation. These systems consider a number of factors with respect to offering consumer products for sale: (1) the expense associated with implementing quality control or other upfront processes (preventative expense), (2) the cost of funding government oversight for these processes and overall ability of a government agency to effectively oversee these processes (regulator efficiency), (3) the ability of a consumer to select products with appropriate safety knowledge (consumer self-protection), (4) the potential for consumer injury (injury risk), (5) the market-chilling potential of large lawsuits to slow innovation (innovation interest), and (6) the direct costs of large class actions impacting business performance and subsequent investment (market interest).[213] These factors are highly dependent on the industry and sub-groups within an industry, and the distribution of burdens between business, government agencies, and consumers depends on the industry, history of abuse or injury, and political leanings of federal and state legislators.

Preemption language that limits state powers is a key hallmark of ex ante regulation when a federal regulator is positioned to

212. It should be noted that some commentators on AI have suggested a strict liability approach to AI regulation. *See generally* Ryan Abbott, *The Reasonable Computer: Disrupting the Paradigm of Tort Liability*, 86 GEO. WASH. L. REV. 1 (2018) (proposing that where AI is safer than a reasonable person, strict liability should be replaced by a negligence standard); Andrew D. Selbst, *Negligence and AI's Human Users*, 100 B.U. L. REV. 1315, 1331–33 (2020) (describing the lack of foreseeability for AI injuries needed for traditional concepts of strict liability). As Rebecca Crootof notes, in products liability cases, strict liability is typically reserved for manufacturing defects, rather than labeling or design decisions causing injury. *See* Rebecca Crootof, *An Internet of Torts: Expanding Civil Liability Standards to Address Corporate Remote Interference*, 69 DUKE L.J. 583 (2019).

213. Cost discussions for high-risk devices usually are motivated via a law and economics approach to the regulatory-tort allocation, and typically a law and economics approach will reinforce preemption where an administrative agency, like the FDA, carries specific expertise and the risk-benefit calculus swings towards safety rather than availability. *See, e.g.*, Keith N. Hylton, *An Economic Perspective on Preemption*, 53 B.C. L. REV. 203, 207 (2012) (describing the calculus for products liability lawsuits, wherein regulatory compliance solutions present a net benefit "only if the social benefit from reducing risk exceeds the loss in utility").

effectively promote social utility due to their relative expertise. Preemption is an extension of the Supremacy Clause wherein federal law, by statutory language, meaning, or intent, ensures state laws do not apply under certain circumstances. Preemption is either direct, or explicit, in nature when Congress specifically includes preemption language, or it is implied when a federal court determines that Congress intended for preemption to apply either because the federal and state laws are in conflict (conflict preemption) or when the agency is intended to completely occupy a specific field (field preemption).[214] The effect of both express and implied preemption, as applied by the courts, is that state law claims cannot be effectively brought, and usually preempted claims are dismissed before summary judgment.

Although preemption may appear to be limiting to plaintiffs (and it is), the expected allocation usually involves greater focus on ex ante obligations, as would be the case with FDA requirements in Food, Drug, and Cosmetics Act (FDCA), the MDA, and associated CFR special controls. When organizations are required to invest in preventative consumer or population safety, federal legislators have embraced preemption to ensure organizations are not paying twice: both for preventative measures and potentially in tort. Preemption has often been used as a model for establishing both baseline and maximum obligations for a given organization, an important tool to improve outcomes for consumers, such as medical device patients, while increasing the consistency of global organizational behavior. Preemption is not always a negative, unless the agency providing direction cannot reasonably prevent consumer injury.

C. The FDA's Risk Calculus for AI Software-Enabled Machines Does Not Effectively Prevent Patient Injury

Following *Lohr* and *Riegel*, the Court has been clear about where tort recovery is possible: when medical devices have not undergone

214. While express preemption is specifically included by Congress in a given law, implied preemption is most typically constructed as field preemption, or where Congress has positioned an agency primarily responsible for a specific area of commerce or activity and when such an agency has specialized knowledge or when the state has engaged in activities typically reserved for a federal agency (as in *Buckman*). Sena, *supra* note 124, at 350 (resolving that express preemption and implied preemption in *Buckman* would result in little remaining for tort recovery).

a PMA process and, if they have been approved via PMA, when claims are drawn specifically to FDA requirements, or parallel claims.[215] Several scholars have criticized this line of reasoning, arguing that Congress' intent with the MDA was not to establish a near-bar on tort recovery both at statute and within the common law.[216] Further, after *Buckman*, it appears that other claims, such as failure to warn or labeling claims, may still be barred on the basis of implied preemption if the court can find that the type of claim is not something the state would have typically regulated, or "state-law claims that seek to privately enforce duties owed to the FDA."[217] Commentators have surmised that recovery for injuries caused by PMA-cleared medical device use is nearly foreclosed due to the exceptionally "narrow gap" occupied by the parallel claim exception to preemption.[218]

The risk allocation presented at the system level may not seem problematic. Devices undergoing more truncated review, such as Class II medical devices and Class III medical devices that are deemed substantially equivalent to a predicate device, will undergo the abbreviated 510(k) process, and tort actions will not be preempted. Claims resulting from Class I medical device injuries, devices subject to general controls and usually not reviewed by the FDA at all, will also not be preempted. This means that claims for injuries resulting from 95% of devices marketed for sale will not be preempted.[219]

However, when patients are injured by the highest-risk devices, which may use AI, their claims will most likely be preempted because presumably the FDA has comprehensively reviewed device design and attendant risks. This model may work effectively to minimize injury when the FDA is able to effectively review and

215. *See supra* text accompanying note 122–123.

216. I do not seek to retread this discussion but rather to introduce new challenges within the existing framework, which may frustrate the delicate tradeoffs established through the MDA and court decisions.

217. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017) (describing the holding of *Buckman*).

218. *In re* Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

219. Michael Drues, *Are You Sure You Know the Best Regulatory Pathway for Your New Medical Device?* MED DEVICE ONLINE (Mar. 18, 2015), https://www.meddeviceonline.com/doc/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device-0001.

prevent large-scale risks of a certain type, but it will likely leave patients using AI-enabled devices who have suffered injury uncompensated.

The risk calculus adopted through Congress' preemption language and the Court's implied preemption analysis demonstrates a view of the FDA that is largely inaccurate with respect to AI machines. The FDA, at this time and likely in the future, is ill-prepared to effectively provide the specialized knowledge that will inform effective ex ante regulation contemplated by the MDA. It is crucial to reiterate that, based on the specificity of special controls, the lack of detailed guidance, and the existence of a singular discussion paper on AI, the FDA is clearly not positioned to guide manufacturers to produce safe AI machines. Further, the structure of the review process, including the expertise of FDA analysts and panel members, limits the potential for holistic device reviews that effectively anticipate potential patient risks.

These realities, however, do not alone permit tort actions to move forward. In the preemption trilogy, the Court has not yet identified a lack of expertise on specific subject matter or modulated review as justification for avoiding preemption. The injuries in these cases have, from the Court's perspective, been contemplated by Congress as a natural result of the FDA's cost-benefit analyses, regardless of whether those analyses were conducted from a position of actual expertise or not.

IV. SOLVING THE ARTIFICIALLY INTELLIGENT MEDICAL DEVICE PREEMPTION PROBLEM

Although scholars, including this Author, have consistently urged better and more comprehensive and effective regulatory activity for AI, the FDA has not responded with useful solutions. AI technologies, due to their dynamic inscrutability, inherently are a poor fit for a regulatory clearance model largely dependent on point-in-time information disclosure that reasonably reflects how a device will operate after clinical trials. However, much of what the FDA does is effective for purposes of minimizing broad-scale injuries, especially for technologies where the FDA and its panel members have developed considerable expertise.

In the current regulatory environment, tort actions may be desirable both as an opportunity to indirectly affect safety decisions

and to afford plaintiffs compensation. If the FDA is not effectively regulating software, especially AI, for safety and efficacy, as is their Congressional mandate, surely any conception of an effective risk-benefit allocation, especially one turning on regulator expertise, will leave plaintiffs without remedy for their injuries. And although it seems unlikely for most tort claims to withstand summary judgment, for AI machines, opportunities may not be completely foreclosed. Plaintiffs harmed by AI machines may successfully avoid preemption with arguments related to structure, regulation, or technology.

A. FDA Improvement Proposals Cannot Fully Manage AI Safety Risks

Scholars have argued for a number of improvements in the clearance process, and this Author does not aim to retread these valuable efforts here. In particular, scholars have argued for a more effective and complete review process, including specific governance by a separate regulatory agency for algorithms,[220] the movement of more explicit requirements and guidance to special controls,[221] a system-based regulatory model including producers and users to improve quality,[222] disclosure of details around AI design to other parties in the health system and ongoing review,[223] the competition of private entities with the opportunity for consumer selection,[224] and the opportunity for certification by experts.[225]

220. *See* Tutt, *supra* note 62, at 107 (proposing a classification and standardization approach for algorithms to be reviewed according to their complexity). Following Ford and Price, Tutt also sees value in third-party organization certification or some public disclosure for purposes of inspection. *Id.* at 110; *see also* Roger Allan Ford & W. Nicholson Price II, *Privacy and Accountability in Black-Box Medicine*, 23 MICH. TELECOMM. & TECH. L. REV. 1 (2016).

221. *See* Tschider, *supra* note 64, at 209 (proposing collaborative efforts to develop documents with NIST).

222. *See* Price, *supra* note 24, at 467–70 (highlighting the role of providers, hospital systems, and insurers in enhancing algorithmic quality and use).

223. *Id.* Price proposes that other players in the systems, in addition to the FDA, monitor ongoing algorithmic performance to prevent safety issues. This proposal offers a unique addition to upfront and ongoing regulation where a collaborative systems approach might improve overall safety. This Author proposes that perhaps another portion of this collaborative effort involves the courts, as needed, to address compensatory concerns.

224. Richard Williams, Robert Graboyes & Adam Thierer, *US Medical Devices: Choices and Consequences*, MERCATUS CTR. AT GEO. MASON U. (Oct. 2015), https://www.mercatus.org/system/files/Williams-Medical-Devices.pdf.

225. Ford & Price, *supra* note 220, at 19.

In its present state, and likely due to the FDA's lack of resources to build out a complete program for AI software-enabled devices, external certification appears to be the most likely of ex ante solutions that could protect patients to a greater extent. Scholars at the Mercatus Center of George Mason University have advocated for competing certification entities that can directly communicate to consumers through labeling and branding solutions, consumers who presumably will be able to better select "safe" devices.[226] In a more practical solution, especially for AI-enabled devices, Roger Allen Ford and Nicholson Price have, in relation to medical AI, argued for expert certification wherein trade secrets present in AI algorithms or processes will be preserved, though the algorithms themselves may be verified by third-party experts.[227]

Unsurprisingly, and in an effort to control costs and promote innovation, the FDA has also been interested in self-regulation models to address these issues.[228] These models include a policy for self-regulated "low-risk" wellness devices, where the FDA takes a hands-off approach to regulation,[229] and the Pre-Cert for digital health software, where organizations pre-certify, as described in the TPRC discussion paper, as well.[230] The proposed software to be regulated under Pre-Cert has a quantum of quality issues, hardly the medical devices requiring less FDA involvement.[231] Further, the Trump Administration's direction towards truncated and expedited reviews as an opportunity for innovation opened additional approval doors in addition to the traditional PMA and

226. *See* Williams et al., *supra* note 224.

227. This proposal offers much for upfront regulatory approaches where the FDA cannot provide the appropriate expertise for algorithmic validation and does solve the AI expertise issue with respect to the algorithm itself. It does not, holistically, involve a complete device system analysis, which might reveal new or different risks to patients.

228. *See, e.g.*, Medical Device De Novo Classification Process, 83 Fed. Reg. 63127 (proposed Dec. 7, 2018) (proposing an alternative pathway truncated pathway to the PMA for new devices that are not substantially equivalent under a 510(k) process); U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH SOFTWARE PRECERTIFICATION (PRE-CERT) PROGRAM (2020) [hereinafter FDA, PRE-CERT], https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program (offering an alternative pathway for digital health software wherein the organization rather than the device is certified to maintain certain standards, speeding release of software on an ongoing basis).

229. U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW-RISK DEVICES (2016), https://www.fda.gov/media/90652/download.

230. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84; FDA, PRE-CERT, *supra* note 228.

231. *See* Price, *supra* note 24, at 455–57 (examining Nathan Cortez's work on mHealth apps and offering examples of health software device failure).

510(k) reviews. However, if the FDA cannot advance patient safety with full PMA reviews for certain types of technology risks, it is unlikely that the FDA will advance patient safety for truncated reviews. Essentially, third-party reviews will enhance upfront processes and are an excellent supporting process for FDA clearance. However, for adaptive software, such as AI, many issues simply cannot be anticipated at the time of clearance.

As medical devices increasingly become AI-enabled, the FDA appears to be even less, rather than more, involved in preventing safety hazards. In part due to expertise issues, approaches like a pre-certification process put more onus on organizations to internally adhere to certified processes, similar to Quality Management System processes in manufacturing facilities. However, software design, especially AI system design, is not manufacturing.

While manufacturing relies on repeatability to a specific standard deviation, software design, especially AI engineering, is "fit for purpose" and personalized. A given organization, even with good processes and responsible developers and data scientists, could produce good or bad AI, because one AI utility could work well for one type of device or population and poorly for another.[232] AI is designed to fulfill specific goals for a specific device and the people who use it. Nicholson Price has examined the impact of low- and high-context environments, or environments with a low or high degrees of specialization and resources, respectively, as one factor in how effective AI might be.[233] It has also been noted that AI that are not tuned to serve certain communities may end up producing discriminatory (and in health, unsafe or less effective), results.[234] If the same algorithm can be more or less effective under specific circumstances or with specific populations, it is unreasonable to believe that AI safety could be managed through manufacturer pre-certification processes.

The FDA has moved away from both preventative solutions to increasingly truncated and self-managed solutions. And if these processes are dovetailed or serve as surrogates for the PMA

232. Third-party software usage in this context presents significantly more risk for this reason.

233. *See* Price, *supra* note 68.

234. Charlotte A. Tschider, *The Consent Myth: Improving Choice for Patients of the Future*, 96 WASH. U. L. REV. 1505 (2019).

process, manufacturers will enjoy an almost comprehensive defense for any claims brought against these devices while simultaneously benefitting from a less stringent FDA review and associated investment. The net effect, then, is that manufacturers benefit twice, while consumers, often patients with serious health conditions, lose. It cannot be ignored that tort preemption of AI machines under these circumstances could result in injury, including death, of human beings without any opportunity for compensation.

B. Tort Solutions May Promote Information Sharing and Compensate Victims for Largely Unknown Technologies[235]

In situations where technology is largely unknown and substantial risks still exist after ex ante regulatory solution, the law has turned to torts as an effective ex post opportunity for injury compensation. For this reason, when innovative technology offers substantial public benefit but agencies lack the ability to comprehensively regulate either due to expertise or inherent technology dynamics, courts should find opportunities to avoid preemption and appropriately compensate victims when injuries result.[236]

1. Preventative expense

When examining potential factors that inform how courts may consider the role of preemption within the regulatory-tort framework, AI software-enabled medical devices demonstrate a need for both ex ante and ex post solutions. From the perspective of preventative expense, implementing a comprehensive and

235. It is completely unknown and truly anyone's guess what the potential cost of lawsuits in the AI device space might be, but the cost of device lawsuits is well-known and very high. This Author makes the contention, however, that the other factors related to tort recovery might outweigh potential costs if this is the only factor cutting towards regulatory primacy.

236. This result is consistent with regulatory trade-offs as well as FDA communication on the topic. The FDA is seeking to promote innovation and reduce time to market for purposes of improving human life. *See* Scott Gottlieb, *FDA's Comprehensive Effort to Advance New Innovations: Initiatives to Modernize for Innovation*, U.S. FOOD & DRUG ADMIN. (Aug. 29, 2018), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fdas-comprehensive-effort-advance-new-innovations-initiatives-modernize-innovation. When the regulatory process is truncated or efficacy is reduced, it makes sense that the court system will take the slack if injuries result.

preventative regulatory quality control for software likely will not, if completely reliant on regulatory review, make sense for most AI-enabled medical devices. Although the FDA has an opportunity to improve upfront regulatory processes by improving requirements, bolstering review panels and analyst expertise, and setting standards for AI creation, and, potentially, by independent third-party review, there are certain realities about AI that are not cured by these types of processes. For example, unlocked AI is dynamic.[237] This dynamism means that any point in time, review, especially before it has been used by a large population, cannot accurately predict what potential safety hazards might be, at least those originating from the algorithm.

Further, the inscrutability aspect of more advanced AI complicates ongoing and preventative monitoring, or even postmarket surveillance, a crucial part of the FDA regulatory structure that enables the FDA to take action, such as recalling devices to prevent further injury.[238] In terms of regulatory efficiency, heavy upfront clearance processes and postmarket surveillance processes will likely reduce, but not reasonably prevent, downstream patient injuries, as in a typical medical device environment manufacturers are disincentivized to timely communicate safety information.[239] Practically speaking, the FDA will likely incur a substantial burden if it is completely responsible for reviewing all algorithms, even if these algorithms are not completely inscrutable.[240]

237. *See* Statement from FDA Commissioner Scott Gottlieb, M.D. on Steps Toward a New, Tailored Review Framework for Artificial Intelligence-Based Medical Devices, U.S. FOOD & DRUG ADMIN. (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-steps-toward-new-tailored-review-framework-artificial; Grigg, *supra* note 38.

238. All devices that undergo a 510(k) or PMA process must engage in postmarket monitoring activities. U.S. FOOD & DRUG ADMIN., POSTMARKET REQUIREMENTS (DEVICES) (2018), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices; *see* Struve, *supra* note 192, at 599–601 (describing the importance of postmarketing surveillance for latent issues).

239. *See* Struve, *supra* note 192, at 601–02. Certainly, postmarket studies, a good option to ensure some degree of safety for self-learning AI machines, could be made public, as Efthimios Parasidis has recommended. *See* Parasidis, *supra* note 194, at 935.

240. Allen, *supra* note 180. Even if the FDA has the resources to review algorithms, this presupposes that such algorithms are both able to be meaningfully reviewed and are locked rather than dynamic.

2. Regulator efficiency

Next, although the FDA receives considerable government funding, the current structure for FDA review cannot, as it stands, appropriately anticipate AI issues in an efficient manner. At its core, FDA review is incompatible with the realities of AI because it is a linear process, designed for product development lifecycles. Although FDA review's effectiveness as a risk prioritization mechanism can be debated, and injuries, some catastrophic, still occur, it is indisputably true that the MDA's general structure has dramatically reduced the potential for widespread patient injury. For sophisticated medical device manufacturers, quality control manufacturing procedures, and upfront design review processes with experts in the field have improved patient confidence and ultimately created a marketplace for these devices, spurring economic growth.[241]

Medical devices reviewed by the FDA under a PMA are, by definition, new and innovative technologies demanding expert knowledge, and the FDA does not, and may not desire to have, comprehensive expertise.[242] The use of AI not only in diagnostic software but also integrated into functioning medical device software amplifies this knowledge demand because the rate of technological change for AI software is so incredibly high. Even AI experts cannot keep up with the variety of models and methods created for AI, and the cost of complete FDA regulation meriting broad preemption will likely lead to inefficiencies of cost and availability delays inconsistent with innovation goals.

241. In part, this may be explained not only by regulatory action, but also by standards-bearing organizations that collectively develop baseline standards, such as the International Organization for Standards or the American National Standards Institute. *See* Paul H. Rubin, *Markets, Tort Law, and Regulation to Achieve Safety*, 31 CATO J. 217, 222 (2011).

242. It should be noted that even if the FDA took a comprehensive stance on AI, the reality is that the FDA cannot anticipate every safety issue, and the technology itself would frustrate this model to some degree. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 337–38 (2008) (Ginsburg, J., dissenting) (quoting the former chief counsel of the FDA: "Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection . . . .").

3. Consumer self-protection

From the perspective of consumer self-protection, labeling will not be able to effectively advise physicians or patients of the risks. If the FDA and AI experts cannot fully appreciate the extent of potential risks, how will manufacturers knowledgeably communicate risks to physicians and patients? FDA labeling requirements not only identify approved uses ("on-label" uses) but also provide specific warnings to prescribing physicians and, in some cases, directly to patients. If FDA experts cannot anticipate or understand potential cyber-kinetic risks or the potential for AI design flaws due to the algorithm's dynamic inscrutability, it is unlikely these risks could be effectively communicated on a label in a curative manner. It is unlikely that physicians, trained in a specific field of medicine, would understand risks posed to their patients by an algorithm.

Labeling also provides information to physicians and patients, who rely on labels and associated marketing materials to compare products. Although superficially AI technologies might appear to pose the same challenges as device software, the ephemeral nature of dynamically inscrutable AI makes labeling tasks nearly impossible, dramatically reducing the ability of physicians to advise patients of potential risks to make an informed decision. The foundational problem for relying on patients and even physicians to select safe products relates to information asymmetries both in the PMA process and in practical expertise.[243]

Unlike general use consumer products, usually patients are dependent on physicians' expertise to recommend the appropriate device and advise of potential risks. This relationship is so well developed that courts apply a doctrine that prevents patients from successfully bringing injury claims related to information in labeling or warning, the learned intermediary doctrine. The learned intermediary doctrine, recognized in a majority of states, prevents patients from bringing these actions precisely because a physician is responsible for explaining any risk to the patient and the patient is not the audience for such warnings and labels.[244]

243. *See* Rubin, *supra* note 241.

244. *See, e.g.*, Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (1966) (establishing the term "learned intermediary"). The rationale for this doctrine usually involves the following:

The physician likely has limited knowledge with respect to the technology as well, especially for latent design defects that may not appear obvious on the surface. For example, a physician who is trained in remote surgery using CorPath may advise a patient of the potential risks, but these risks will likely be related to the surgery itself, rather than CorPath's AI design and potential risks related to the AI software itself. If CorPath includes a third party's design for the AI software, the manufacturer may not have fully vetted or disclosed these details to the FDA.[245] In other circumstances, the FDA may have confidential information from the manufacturer or third party from the PMA process, but those details included in the PMA may not be available to physicians or consumers. Regardless of whether the FDA, manufacturer, or third party have the most information, physicians and patients are comparatively in a less beneficial position to appropriately avoid potential risks.[246] The presence of AI amplifies the level of information asymmetry under these circumstances due to the algorithm's dynamic inscrutability.

4. Injury risk

The aforementioned factors might have less bearing if AI software posed little risk to patients. Unfortunately, AI software and its infrastructure dramatically increase potential injury risks to patients because medical device risk models have not taken into account the risk of automation bias in human-interfaced AI

(1) the physician is in a superior position to give a warning and can provide an independent medical decision, (2) manufacturers lack effective means to communicate with the patient, and (3) imposing a duty to warn upon the manufacturer would interfere with the physician-patient relationship. *See* Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763–64 (Ky. 2004).

245. This notion is exemplified by what Paul Rubin calls a "Type 1 error," or when overregulation results when individuals are injured but an agency has been positioned as primary regulator in a field. In this error, the injury prompts heavier regulation based on the expectation that the agency can or does have complete information to prevent injury. *See* Rubin, *supra* note 241, at 227.

246. One lens for evaluating information asymmetries involves the economic implications of competition between products. When information is available, consumers in general might be better able to consider alternative options and perform their own cost-benefit analyses. However, FDA-regulated markets are not competitive in the traditional sense either, because usually few options are available for a given drug or device due to the cost of entry in the market and the role of patent for establishing limited monopoly, amongst others. *See* Stephen R. Munzer, *Risk and Reward in Stem Cell Products: A New Model for Stem Cell Product Liability*, 18 B.U. J. SCI. & TECH. L. 102, 125–26 (2012).

machines.[247] Medical devices no longer pose risk solely due to their inherent physical characteristics or installed in-device software. AI infrastructure demands tremendous computing power through distributed architectures, such as the cloud, internet connectivity, and large and changing data sets. Dynamic inscrutability not only is a moving target for purposes of understanding the technology's current risk profile, but the inscrutable nature of the algorithm prevents even its creator from understanding the AI's decision. Increasingly more often, AI technologies do not rely on humans to validate a recommendation and take action; the most cutting-edge technologies, such as advanced surgical robotics, will make any number of decisions for the user. While these technologies will likely save lives, they may also introduce different, and sometimes more serious, risks to patients.

C. The Existing FDA Review Structure Offers Opportunities for Avoiding Preemption

When the FDA cannot effectively regulate a specific technology, an opportunity exists for torts to complement the regulatory structure and provide compensation to injured parties. In all inquiries, courts would need to accept a micro, rather than macro, view of risk-benefit decisions. This means that courts would need to examine each case as a specific risk-based inquiry by the FDA. Practically speaking, courts could not "write off" a lack of review or insufficient review as part of a systematic risk calculus for the medical device industry as a whole. This model works well for AI software-enabled medical devices, but the three-part inquiry described in the remainder of this section could also reinforce FDA regulatory efficacy for other technology innovations while simultaneously providing some compensation for parties injured in the name of innovation.

There is plenty of reason to believe that Congress intended for plaintiffs to have some right of recovery, the least of which because they did not explicitly bar any recovery. As Justice Ginsburg noted in her *Riegel* dissent:

> Congress' inclusion of a preemption clause in the MDA was not motivated by concern that similar state tort actions could be

247. *See* Gretton, *supra* note 80.

> mounted regarding medical devices. Rather, Congress included § 360k(a) and (b) to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level.[248]

Without more specific MDA preemption language, it would be "difficult to believe that Congress would, without comment, remove all means of judicial recourse."[249] Although the FDA has been positioned as a central regulator under the MDA and the agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use,"[250] it does not necessarily follow that recovery is all but foreclosed. The *Buckman* decision, however, has opened up the potential for the Court to find implied preemption under certain circumstances, which could become a slippery slope effectively amounting to field preemption.[251] It is centrally important for AI software that at least some opportunity to recover is permitted in circumstances where the FDA has not developed the appropriate expertise, when truncated processes are used, or, due to the technology itself, when the FDA cannot effectively and comprehensively regulate.

Although the preemption trilogy may not leave much room for avoiding preemption, the existing FDA review structure, regulatory design, and the degree of similarity or difference from the submitted technology may offer some opportunity for success in surviving summary judgment.[252] A three-part inquiry for claims,

248. Riegel v. Medtronic, Inc., 552 U.S. 312, 340–41 (2007) (Ginsburg, J., dissenting).

249. *Id.* at 337 (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984)).

250. *Id.* at 318 (majority opinion) (alteration in original) (quoting 21 U.S.C. § 360c(a)(2)(C)).

251. Although the Court recognized implied preemption under a conflict preemption analysis, it is possible to envision an argument for field preemption, due to the comprehensive nature of FDA reviews. Drug cases offer a more likely candidate for field preemption, due to the non-existence of express preemption language for drugs while the MDA does contain such language. *See* Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54, 55 (2008). Nevertheless, without due care by the courts, scope creep regarding conflict preemption could practically result in field preemption, even under the MDA.

252. This section does not attempt to fully describe how a prima facie case could be successfully argued or how, for example, expertise should be solicited or judgments fulfilled. Rather, this section has one aim: to demonstrate how a plaintiff injured by an AI machine might successfully avoid preemption under the MDA. Indeed, this section follows the

focused on *Lohr*'s recognition of a parallel claim preemption exception, would likely offer a more complete review than indiscriminately applied preemption, and dismissal *ab initio*, would provide.[253]

1. Structural inquiry

The structure of FDA reviews could offer an opportunity for courts to resolve tort actions in favor of surviving summary judgment. First, the principle thrust of *Lohr* was to distinguish between resource-intensive reviews where the FDA had fully reviewed a particular medical device in a PMA process and more passive reviews, like the 510(k) process. The introduction of new, abbreviated reviews could increase the speed to device access. For example, the FDA's De Novo review takes devices that would normally go through a full PMA process and instead permits a truncated review more similar to the 510(k) process for devices that, in the manufacturer's view, do not present substantial risk.[254] The software self-certification process and discussion paper prescribe a system-level or manufacturer review process, rather than a design-focused process, for AI diagnostic software.[255] In these cases, courts should continue to uphold *Lohr*'s outcome: that anything short of a full review should be preempted. Without a more severe approach to restricting preemption, it is possible that some slippage could occur, resulting in preemption of truncated review processes.

relatively clear direction from *Lohr* in its presumption that parallel claims are not completely foreclosed under implied preemption, both based on the Court's reasoning and on the practical realities of the FDA's actual documentation related to AI and its broad regulatory scope. *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996).

253. This is no trivial task. Courts are split on the question of parallel claims, despite recognition in *Lohr* and *Riegel*. The Fifth and Seventh Circuits, for example, have demonstrated a more liberal view of parallel claims, whereas the Eighth Circuit has held that such claims are expressly preempted if the plaintiff cannot definitely demonstrate a federal claim specifically referring to the device. *See* Elliot Sheppard Tarloff, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196, 1207–14 (2011). In Tarloff's view, for both doctrinal and public policy reasons, courts should adopt a more flexible definition of requirements. *Id.* at 1219. From a regulatory-tort allocation perspective, parallel claims support a compensatory model of consumer protection and complement the FDA's regulatory function. *Id.* at 1219–26.

254. U.S. FOOD & DRUG ADMIN., EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) (2019), https://www.fda.gov/medical-devices/premarket-submissions/evaluation-automatic-class-iii-designation-de-novo (showing the De Novo review process).

255. *See* U.S. FOOD & DRUG ADMIN., *supra* note 84.

In a similar vein, the *Shuker* decision has marked another opportunity for courts to consider the impact of preemption slippage for component parts.[256] In *Shuker*, the Third Circuit, in acknowledging that the part of a device that caused injury was independently reviewed via the PMA process, also noted that for entire device systems, components are usually listed within the PMA process for review.[257] Although this was not the case in question, it raises important issues of the role components play within systems that have been reviewed by the FDA.[258]

Because AI will likely be considered a module of larger systems, the risk of slippage for these systems is quite high. It is not hard to imagine that a defendant medical device manufacturer might assert preemption for AI injuries if an entire AI machine has been reviewed under a PMA, even if the AI infrastructure, as a component part, received a 510(k). For injuries implicating specific components, courts could instead examine whether the component itself was reviewed via a separate PMA process and, if not, whether the manufacturer can demonstrate a comprehensive review of the component as part of the system that received premarket approval. Although this approach might require a manufacturer to reveal confidential information from the FDA approval process to determine the degree of component re-review under the PMA, it might be reasonable to expect such a showing to preempt tort claims under these circumstances.[259]

For example, if the bionic pancreas's AI software malfunctions and causes injury, the court would first look to determine whether a full PMA had been conducted on the bionic pancreas as a system. After that had been verified, the court would next determine whether the AI software component that caused injury was

256. *See* Shuker v. Smith & Nephew, 885 F.3d 760 (2017).

257. *Id.* at 766.

258. Although for purposes of this Article, the Author focuses on PMA-approved processes that may include 510(k) approved components, which is most likely for AI systems, certainly the reverse arrangement might also complicate medical device tort litigation.

259. This approach might also reasonably balance stricter pleadings standards advanced by *Ashcroft v. Iqbal*, which likely has made bringing products liability suits for medical device injuries much more difficult given the confidentiality of the FDA-manufacturer process. Ashcroft v. Iqbal, 556 U.S. 662 (2009). If plaintiffs must meet heightened pleadings standards, manufacturers may need to demonstrate more to escape liability.

reviewed as part of the bionic pancreas system PMA, whether the AI software was reviewed in a separate device PMA, or whether the AI software was classified separately and was not independently reviewed as part of the bionic pancreas system PMA. If one of the first two conditions is met, the court could verify that the structural inquiry was satisfied. If the third circumstance applies and the software component is alleged to have caused the injury, tort claims would not be preempted.

2. Design inquiry

Both *Lohr* and *Riegel* hinged on preemption language in the MDA preempting state laws with "different or additional requirements." In both cases, the Court focused on the process of the PMA versus the 510(k) as providing sufficient requirements for purposes of preemption. However, the Court did not go into great detail, in either case, of what could qualify as requirements, nor did it examine the veracity of such requirement review by the FDA. Construing requirements in a more inclusive definition and requiring demonstration of actual review might tighten a fairly loose preemption standard via the parallel claims exception.[260]

As an initial matter, both *Lohr* and *Riegel* left open the possibility of recovery under parallel claims despite Justice Scalia's skepticism regarding a jury's ability to determine an appropriate cost-benefit model in *Riegel*'s comparatively more preemption-friendly majority opinion.[261] Parallel claims, established under *Lohr*, permit plaintiffs to avoid MDA preemption by demonstrating that their injury resulted from non-compliance with a federal requirement. For purposes of plaintiff recovery, especially for technologies that are not yet comprehensively regulated under traditional CFR requirements due to a lack of expertise, the definition of "requirement" should be construed broadly.

It is well known that often the FDA considers not only special controls but also guidance as it reviews the PMA file. If a plaintiff

260. This model is consistent with Catherine Sharkey's agency reference model, wherein details of the FDA's views would be useful in determining the compatibility of these views with state law tort claims and would necessarily include some deference to the FDA's position on certain matters. *See* Sharkey, *supra* note 194, at 418. Although Sharkey directs this conversation at the largely unaddressed area of implied preemption, the concept can easily be integrated into express preemption analysis.

261. *See* Sharkey, *supra* note 194, at 417–18 (quoting Justice Scalia's majority opinion).

can demonstrate that the manufacturer did not adhere to guidance, and the FDA has developed guidance on AI and software topics, it may be possible for a plaintiff to recover.[262] Courts could also look to broad language in the special controls, such as the example given earlier in this Article, "adequate consideration of privacy and security issues in the system design," to permit further inquiry beyond a motion to dismiss and summary judgment.[263] This inquiry might enable a plaintiff to determine, in discovery, whether a manufacturer did or did not adequately consider such issues in its design of an AI-enabled medical device. Where language is broadly written, the FDA and other experts could explain what compliance with that language would entail. This model cabins potential conversations by restricting them within the *Lohr* parallel claims exception, while maintaining the exception's breadth to maximize fact-specific inquiry and relying on institutional statutory interpretation.

A parallel claim inquiry could be further reinforced by permitting a fact-specific inquiry, based on FDA documentation, into whether a specific requirement has been reviewed. In most preemption cases, the successful approval of a medical device via the PMA process does not go much further to demonstrate preemption. However, if the court views its role in tort as ensuring appropriate safety for patients, it could engage in a more fact-specific inquiry to determine whether the FDA factually reviewed a design requirement that ultimately led to patient injury. For example, evidence of a review could include specific sheets requiring disclosure of information related to the requirement (e.g., a "checklist"), versions of PMA documentation illustrating changes to a specific design element, or copies of FDA correspondence on the topic. Although this would likely demand resources from the FDA and the manufacturer to demonstrate the FDA's actual review, this model could be used to better probe the validity of the

262. Guidance is often positioned as the FDA's most current views on a topic and is tied to special controls. Although not legally binding, it could be used as an interpretive tool for understanding often broadly written special controls and industry reasonableness in implementing such controls.

263. *See supra* notes 169–171 and accompanying text.

parallel claim argument.[264] In this model, manufacturers and the FDA could not make an argument of confidentiality while simultaneously arguing for preemptive effect.

Functionally, the court would conduct a secondary analysis from the perspective of validating the parallel claims in requirement and actual review only if the first inquiry, the structural inquiry, supports preemption. The court would first look to the existence of some requirement, construed in favor of the plaintiff, to support the claim. The court's direction, then, would construe a common law negligence action as a type of negligence per se claim, wherein the basis for duty and breach is established through a type of institutional comity.[265]

For example, if a plaintiff alleges negligence due to a bionic pancreas's malfunction or poor design, the court would look to special controls and guidance to determine whether these documents apply to the AI used in the bionic pancreas. If such documents, broadly construed, exist, the court would then conduct a fact-specific inquiry into whether the FDA reviewed the device's design with respect to these requirements. If the FDA sufficiently reviewed the design for specific safety considerations, courts could uphold preemption. If the FDA did not sufficiently review these requirements, the court could deny any preemption defense, which would balance regulatory and compensatory interests in the parallel claims context.[266] Although this may not be a perfect solution for plaintiffs, it rewards good regulatory behavior and promotes effective investment in upfront processes.

264. A parallel claims model could actually cut both ways: if the FDA did review a given requirement, the plaintiffs would be preempted in their claims. If the FDA did not review a given requirement, the plaintiffs would still need to prove the remainder of their prima facie case to recover.

265. Mark A. Geistfeld, *Tort Law in the Age of Statutes*, 99 IOWA L. REV. 957, 965 (2014). The benefit to deferring to standing regulatory standards, at least from a parallel claims perspective, is that the torts system, then, can be reinforcing rather than competitive with regimes that have an institutional advantage. *Id.* at 967. It might also draw additional attention to the insufficiency of existing standards, prompting the FDA to take action.

266. The goal in an effective compensatory model is not necessarily to always provide compensation but to ensure appropriate cost-benefit analyses have been conducted and that safety measures have been considered.

3. Technology inquiry

The AI technology itself may also provide an opportunity for plaintiffs to successfully survive preemption. In the third prong of inquiry, courts should evaluate whether the technology that allegedly caused the injury has changed materially from the technology reviewed in the PMA, and whether the manufacturer timely submitted a required PMA supplement. For AI, this analysis would likely involve reviewing the type of AI used when the plaintiff sustained an injury. Ultimately, not all AI is alike: some AI software may be designed using test data and refined in clinical trials, only to be launched in that form for the medical device. These locked forms of AI software are, by definition, static rather than dynamic. If the FDA has actually reviewed these devices in a full PMA process and requirements have been applied to the AI, these devices likely pose less risk for patients.

However, if software or other technologies are designed to be dynamic on an ongoing basis, as is common in unsupervised machine learning AI and most neural networks, the court could presume that the technology is different from its approved form. Then, the court could shift the burden to the manufacturer to demonstrate that the device is not different from its approved form. If the manufacturer successfully demonstrates a lack of material change, the manufacturer would survive the proposed prong three inquiry. If the manufacturer does not, plaintiffs will survive preemption and will be permitted to bring claims, assuming such claims meet pleading requirements.

The question of material change has a crucially important impact for FDA medical device preemption. If the medical device or device component has changed so substantially that it could be a newly functioning device yet is similar to its predecessors, it would be treated as a substantially equivalent (SE) device for purposes of initial FDA review. Under an SE review, the FDA would likely require a limited 510(k) submission, which, according to *Lohr*, would not preempt later tort recovery. While in practice, a manufacturer could submit a PMA supplement to amend the initial PMA report, courts could create a legal fiction of 510(k) status. If a 510(k) status exists, plaintiff claims are not preempted. There is some technical justification and background that could support this kind of legal fiction. First, manufacturers are starting to release AI machines that are next generation versions of analog and non-AI-

enabled medical devices, outfitted with new AI infrastructure.[267] In many cases, these may be submitted as 510(k) submissions because the manufacturer has argued for substantial equivalence to a predicate device. This fiction could inform court behavior when the physical device has not been altered but the AI has effectively changed device functionality.

Alternatively, if the medical device changed materially, the manufacturer would have needed to submit a PMA supplement, which would have been reviewed by the FDA. If the manufacturer did not submit such a supplement, the FDA would not have reviewed the device at issue, referring this third prong back to the second prong of inquiry, where likely the FDA would not have actually reviewed the design against the requirement.

Both of these approaches address an important issue noted in Justice Ginsburg's dissent in *Riegel*, that "[t]he Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval."[268] Although not specifically contemplating AI dynamism, latent defects and fast-track technology innovation certainly would trigger this important question.[269]

D. The Viability of Tort Actions Requires Further Inquiry

By focusing on the challenging space of preemption for innovative technologies, this Article has not addressed the potential viability of tort actions, such as products liability actions, specifically for AI software. Although scholars are beginning to examine the challenges and potential solutions for successfully arguing these cases, the area of AI software torts should receive additional attention. Initial areas of inquiry could include the relative responsibility of manufacturers for their AI software when

267. *See* Allen, *supra* note 180.

268. Riegel v. Medtronic, Inc., 552 U.S. 312, 333 n.1 (2007) (Ginsburg, J., dissenting).

269. Catherine Sharkey has also identified this issue with respect to pharmaceutical labeling defects, where the label is nonetheless incorrect after a latent design issue comes to light. *See* Catherine M. Sharkey, *Drug Advertising Claims: Preemption's New Frontier*, 41 LOY. L.A. L. REV. 1625, 1646 (2008). The question of labeling versus design defects for purposes of preemption is an important distinction given how the courts have responded to labeling issues for products (more likely to preempt) than for design defects, assuming such defects can be sufficiently narrowly tailored to a federal requirement.

the algorithm itself is inscrutable, contributory negligence in the form of patient-operated AI-enabled medical devices, or the challenges in discovery due to algorithmic complexity, inscrutability, or trade secrecy. Importantly, the inscrutability of medical device AI causes specific problems for successfully demonstrating proximate cause.

CONCLUSION

AI and other innovative technologies like it inherently complicate regulatory-tort allocation: manufacturers are not required to demonstrate that AI-enabled medical devices will adequately prevent consumer injury in the clearance process, yet it is likely that consumers will also not be able to recover for their injuries in tort, either. The equation, therefore, is not remotely what Congress aimed for in the MDA's passage. The FDA's reluctance and lack of expertise in this area, as well as software's inherent qualities, such as its dynamic inscrutability and reliance on distributed systems, makes a comprehensive and effective ex ante solution nearly impossible for innovative, adaptive technologies.

The tort system is an integral part of both effective safety regimes and consumer injury compensation. An effective regulatory-tort system for new technology, including AI-enabled medical devices, balances interests of manufacturers and consumers through effective regulation and opportunities for recovery when regulatory solutions fail. Courts can champion new technology development by permitting legitimate parallel claims in the AI-enabled medical device context, which may change medicine for the better, all while reinforcing consumer confidence.