Regulating the Off-Label Use of Artificial Intelligence and Machine Learning-Enabled Medical Devices

ABSTRACT

Through machine learning (ML) developments, medical devices are gaining more autonomous functions and taking on more central roles in medical care. Many scholars believe that artificial intelligence (AI) will revolutionize the healthcare industry, but the technology brings several concerns that implicate data privacy, patient security and safety, and professional responsibility. The Federal Drug Administration (FDA) acknowledged this fact, publishing proposed guidance in 2023 on artificial intelligence and machine learning (AI/ML) medical device approval that would tighten device regulation upfront and enhance supervision throughout the regulatory process. While some have addressed the premarket approval process or tort liability frameworks for artificial intelligence-enabled devices, this Note focuses on the regulatory concerns arising from off-label use of AI/ML-enabled medical devices. This Note agrees with FDA and other scholars that the current legal system does not support the proper use of AI/ML-enabled medical devices. To remedy that lack of systemic support, this Note considers which agencies, if any, have the proper regulatory authority to handle the matter and challenges the idea that nonbinding guidance is the proper regulatory vehicle for enforcement. Ultimately, this Note argues for a multilevel regulatory framework promulgated under the formal rulemaking process, state regulatory procedure, and private regulation.

TABLE OF CONTENTS

The traditional doctor's office may seem like the last place one would expect to see artificial intelligence (AI). Given the deeply personal, often vulnerable, nature of healthcare services, in conjunction with the extensive training required for healthcare professionals, a physician's role has traditionally been intrinsically human.[1] Despite the inherently human practice, however, healthcare providers increasingly rely on artificial intelligence in their practice; the use of AI in healthcare has "eclips[ed] the use of machine intelligence in other industries."[2] The AI industry within healthcare is only expected to grow.[3] Yet despite the many recognized benefits of the advancement

1. *See* Ilana Kowarski, *How to Become a Doctor: A Step-By Step Guide*, U.S. NEWS (Nov. 30, 2020), https://www.usnews.com/education/best-graduate-schools/top-medical-schools/articles/how-to-become-a-doctor-a-step-by-step-guide [https://perma.cc/F2YP-YWU4]; *see also* Sai Balasubramanian, *Can Doctors Truly Be Replaced by Technology?*, FORBES (Sept. 22, 2021, 5:33 PM), https://www.forbes.com/sites/saibala/2021/09/22/can-doctors-truly-be-replaced-by-technology/?sh=562bb8714a83 [https://perma.cc/6BRQ-E5P3] ("[N]o matter how advanced a robot becomes at surgery or how great an AI system is at predicting a diagnosis, there is a critical role that human physicians play and will continue to play for generations to come.").

2. Sharona Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L., & ETHICS 1, 4 (2020) (quoting Meryl Kornfield, *The Health 202: Artificial Intelligence Use Is Growing in the U.S. Health-Care System*, WASH. POST (Feb. 24, 2020, 7:41 AM), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/02/24/the-health-202-artificial-intelligence-use-is-growing-in-the-u-s-health-care-system/5e52f13188e0fa632ba81ec7/ [https://perma.cc/A7F3-MLH9]); *see* Sarah Kamensky, Note, *Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications*, 21 DEPAUL J. HEALTH CARE L. 1, 17 (2020) ("[A]pproximately 86% of health care providers utilize at least one form of artificial intelligence in their practices.").

3. GRAND VIEW RSCH., AI IN HEALTHCARE MARKET SIZE, SHARE & TRENDS ANALYSIS REPORT BY COMPONENT (SOFTWARE SOLUTIONS, HARDWARE, SERVICES), BY APPLICATION (VIRTUAL ASSISTANTS, CONNECTED MACHINES), BY REGION, AND SEGMENT FORECASTS, 2024–2030, https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-ai-healthcare-market [https://perma.cc/K2WA-7AFL] (last visited Feb. 25, 2024) ("The global AI in healthcare market size was estimated at USD 22.45 billion in 2023 and is expected to expand at a compound annual growth rate (CAGR) of 36.4% from 2024 to 2030.").

and use of AI in the healthcare sector,[4] patient safety implications cannot be overstated.[5] To balance these benefits and risks, regulatory oversight is critical to ensure both patient safety and data privacy.[6]

The US Food and Drug Administration (FDA), the governmental agency responsible for the regulation of medical devices,[7] has recognized these patient safety implications stemming from the growing use of AI in healthcare.[8] As early as 2019, the agency released a discussion paper proposing a regulatory framework for modifications to artificial intelligence and machine learning (AI/ML) software in medical devices.[9] As a response to stakeholder feedback on the 2019 discussion paper, it put out an action plan in 2021, noting its "longstanding commitment to support innovative work in the regulation of medical device software and other digital health technologies."[10] In 2023, the FDA called for comments on proposed guidance regarding predetermined change control plans for AI/ML-enabled medical devices.[11] Even more recently, the FDA's Center for Devices and

4. *See The Benefits of AI in Healthcare*, IBM (July 11, 2023), https://www.ibm.com/blog/the-benefits-of-ai-in-healthcare/ [https://perma.cc/3VXE-SS98] (noting that AI could improve administrative workflow, reduce dosage error, improve surgical outcomes, and serve in clerical or nursing roles).

5. *See, e.g.*, Sara Gerke, *Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 432, 436 (2021) ("Health AI also poses new legal challenges, including ensuring the products' safety and effectiveness . . . ."); W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 458 (2017).

6. *See, e.g.*, Gerke, *supra* note 5; Price, *supra* note 5, at 424.

7. *See* 21 U.S.C. § 371 (enabling the FDA to regulate medical devices under the Federal Food Drug and Cosmetic Act).

8. *See* Michele L. Buenafe, Jacob J. Harper & Andrew J. Gray IV, *AI in Medical Devices and Healthcare: Opportunities, Challenges, and What Lies Ahead*, MORGAN LEWIS (Mar. 8, 2023), https://www.morganlewis.com/pubs/2023/03/ai-in-medical-devices-and-healthcare-opportunities-challenges-and-what-lies-ahead [https://perma.cc/9AX3-NWFS].

9. FDA, PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD): DISCUSSION PAPER & REQUEST FOR FEEDBACK 2 (2019), https://www.fda.gov/media/122535/download?attachment [https://perma.cc/9DDR-NDTN] [hereinafter 2019 Discussion Paper]; *see Artificial Intelligence and Machine Learning in Software as a Medical Device*, FDA, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation [https://perma.cc/P956-PCBU] (last visited Feb. 27, 2024) [hereinafter *AI/ML in Software*].

10. FDA, ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN 1 (2021), https://www.fda.gov/media/145022/download [https://perma.cc/2QYU-7A9G] [hereinafter 2021 ACTION PLAN].

11. *See* FDA, MARKETING SUBMISSION RECOMMENDATIONS FOR A PREDETERMINED CHANGE CONTROL PLAN FOR ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-ENABLED DEVICE SOFTWARE FUNCTIONS 1–2 (2023), https://www.fda.gov/media/166704/download [https://perma.cc/L9E3-JDT6] [hereinafter 2023 PROPOSED GUIDANCE].

Radiological Health considered the need for transparency in AI/ML devices voiced by workshop participants.[12]

While the FDA has recognized the implications of machine learning (ML) functions in medical devices, it has passed very few regulations targeting these functions—the algorithms or software that a device may use.[13] Instead, most of the agency's regulatory action has taken the form of nonbinding guidance, none of which directly considers the approval process for AI/ML-enabled devices.[14] Importantly, after initial FDA approval, providers may use a medical device "off-label," which is in a manner "different than that approved by the FDA," and the FDA has failed to consider the implications of such off-label use in any capacity.[15] Though off-label use of pharmaceuticals is a common practice in the medical community, and is "frequently beneficial to patients," healthcare providers are not specialized in the implications of AI in off-label use.[16] As such, these medical professionals may not be able to make a fully informed decision regarding the use of an AI/ML-enabled medical device off-label.[17]

This Note explores the legal and safety implications of off-label use of AI/ML-enabled medical devices. In doing so, this Note proceeds by first explaining current medical device regulation and off-label use. From there, it critiques the FDA's current proposed guidance, highlighting its failure to address off-label use of AI/ML-enabled medical devices and the need to do so, and subsequently considers the regulatory authority of the FDA and the state medical boards to

12. Aubrey A. Shick, Christina M. Webber, Nooshin Kiarashi, Jessica P. Weinberg, Aneesh Deoras, Nicholas Petrick, Anindita Saha & Matthew C. Diamond, *Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices*, 7 NPJ DIGIT. MED. 1, 1 (2024).

13. Price, *supra* note 5, at 443 (citing Nathan Cortez, *Analog Agency in a Digital World*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 438, 445 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015)); *see* 2023 PROPOSED GUIDANCE, *supra* note 11, at 2 (encouraging submission of a PCCP with device application). *See generally* 21 C.F.R. §§ 800–1299 (2023) (medical devices and radiation emitting products).

14. Price, *supra* note 5, at 443. *See generally Guidances*, FDA, https://www.fda.gov/industry/fda-basics-industry/guidances [https://perma.cc/VKL6-SH73] (last visited Feb. 27, 2024).

15. Stephanie M. Greene, *After* Caronia*: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 647 (2014).

16. *Off-Label Use of Medical Products*, ECRI (June 8, 2015), https://www.ecri.org/components/HRC/Pages/LawReg17.aspx [https://perma.cc/6B4B-E9G3]. *See generally* N.Y. EDUC. LAW §§ 6520–29 (McKinney 2014); FLA. STAT. §§ 458.301–.351 (2023).

17. *See* Paul Greve, *Artificial Intelligence in Health Care: Risks and Benefits for Medical Professional Liability*, MARKEL (Sept. 20, 2023), https://www.markel.com/insights-and-resources/insights/artificial-intelligence-in-health-care-risks-and-benefits-for-medical-professional-liability [https://perma.cc/38J7-UCNJ].

regulate off-label use of AI/ML-enabled medical devices.[18] Finally, this Note questions whether guidance or rulemaking is the appropriate method of regulation and proposes a collaboration between the FDA and the Federal Trade Commission (FTC) to mitigate potential safety concerns—particularly those that come with off-label use of AI/ML-enabled medical devices.

I. BACKGROUND

AI/ML is already present in healthcare and its use is only expected to increase.[19] AI/ML is being used in a myriad of ways and, with industry investment into its continuous development, medical devices are becoming increasingly autonomous.[20] The increasing use of these technologies leaves implications of off-label use unaddressed and, as robots become more autonomous, exacerbates the dangers that improper off-label use presents. As a result, patient and data privacy protections are needed in the imminent future.[21] The current regulatory landscape, however, does not currently provide for these protections.

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18. *See* 2023 PROPOSED GUIDANCE, *supra* note 11.

19. *See Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, FDA (Oct. 19, 2023), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices [https://perma.cc/Y4JL-TDC4] ("Based on projected volume in 2023, the increase of AI/ML-enabled devices (compared to 2022) is expected to reach 30+%.").

20. *See, e.g.*, David Britton, Note, *Autonomous Surgery: The Law of Autonomous Surgical Robots*, 1 J.L. & TECH. TEX. 152, 157 (2016) ("[A]cademic researchers have worked on automating bone drilling for high-precision ear surgeries, the removal of dead scar tissue, suturing within a surgical site by a laparoscopic robot[,] . . . and needle navigation for lung biopsies.") (citations omitted); Conor Hale, *Siemens Healthineers' Corindus Surgical Robot Clears Brain Aneurysm Study*, FIERCE BIOTECH (Sept. 12, 2022, 12:14 PM), https://www.fiercebiotech.com/medtech/siemens-healthineers-corindus-surgical-robot-clears-brain-aneurysm-study [https://perma.cc/T5M7-KRFR]; *Projects*, CAL-MR, http://coecalmr.wpengine.com/projects/ [https://perma.cc/HUS5-A6DC] (last visited Feb. 26, 2024) ("We are developing algorithms and control methods to enable the automation of surgical subtasks . . . .").

21. Various agencies and the White House have emphasized this need. *See, e.g.*, Press Release, FTC, FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule (May 18, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-proposes-amendments-strengthen-modernize-health-breach-notification-rule?ref=ardentprivacy.ai [https://perma.cc/G5RC-BLAV] [hereinafter *FTC Proposes Amendments*]; Press Release, Joe Biden, Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (Oct. 30, 2023), https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/ [https://perma.cc/Z4A6-KE5J] [hereinafter Press Release, Joe Biden].

A. Artificial Intelligence in Medicine

Artificial intelligence is everywhere—from natural language searching on Google to the software on a phone or the smart lighting in a home.[22] Much of the current conversation on AI centers around machine learning, which is a subset of the broader category of AI in which a computer learns how to perform a task "without explicitly being programmed."[23] Although AI is often used as a blanket term, ML notably enhances the functions and capabilities of many devices by enabling systems to improve through experience and data, and medical devices are no exception.[24]

Working perfectly, these medical AI/ML-enabled devices can aid in the decision-making process for physicians and "secure better outcomes for patients."[25] Robotic software incorporating AI/ML may certainly have the capacity to be "the next generation of tools that can aid surgeon skills and improve surgical outcomes."[26] Yet preferred ML models with such capabilities also present at least two serious concerns that are likely to arise when not working perfectly.[27] First, the process of training ML algorithms implicates patient data privacy and potential

22. *See* Olaf Kopp, *How Google Uses NLP to Better Understand Search Queries, Content*, SEARCH ENGINE LAND (Aug. 23, 2022, 6:00 AM), https://searchengineland.com/how-google-uses-nlp-to-better-understand-search-queries-content-387340 [https://perma.cc/M6ZD-F9MP]; Andrew Williams, *What Does AI in a Phone Really Mean?*, TECHRADAR (Oct. 22, 2018), https://www.techradar.com/news/what-does-ai-in-a-phone-really-mean [https://perma.cc/74MM-AJZ7] (highlighting the various functions of a smartphone that use AI); Rebecca Haass, *AI—Putting the "Smart" in Smart Lighting Solutions*, IIOT WORLD (Apr. 15, 2019), https://iiot-world.com/smart-cities-buildings-infrastructure/smart-cities/ai-putting-the-smart-in-smart-lighting-solutions/ [https://perma.cc/22NX-3263] ("Not only can lights be programmed to turn on and off when there's movement or at certain times, but smart lights can actually use VLC to track people's movements and 'see' how many people are in a room at a given time.").

23. Sara Brown, *Machine Learning, Explained*, MIT SLOAN SCH. MGMT. (Apr. 21, 2021), https://mitsloan.mit.edu/ideas-made-to-matter/machine-learning-explained [https://perma.cc/EJ6U-4VK4].

24. *See id.*; Britton, *supra* note 20 and accompanying text; *see also* Ferdous Al-Faruque, *FDA Officials Say Different Communication Methods Needed to Ensure AI/ML Transparency*, REGUL. FOCUS (Feb. 2, 2024), https://www.raps.org/news-and-articles/news-articles/2024/2/fda-officials-say-different-communication-methods [https://perma.cc/6ZJ5-8RAP] ("[The] FDA has given marketing authorization to almost 700 AI/ML devices as of October 2023 . . . .").

25. Danny Maher, *Keeping Pace with Advancing Artificial Intelligence in Healthcare: A Call for Increased Regulation and Legislative Action to Avoid the Deflection of Liability*, 31 ANNALS HEALTH L. ADVANCE DIRECTIVE 165, 171 (2021).

26. *Id.* at 172.

27. *See Robots Are a Norm in Surgery. What Happens When AI Enters the OR?*, AMA (Aug. 16, 2023), https://www.ama-assn.org/delivering-care/ethics/robots-are-norm-surgery-what-happens-when-ai-enters-or [https://perma.cc/62RU-QGZT].

bias concerns in treatment.[28] Ideally, to account for a variety of biologies, the algorithms would initially be trained on massive amounts of sensitive, personal health data to obtain better outcomes in patient interactions.[29] These algorithms would then utilize that data to train themselves, as opposed to being programmed with specific rules.[30] Generally, however, the health data available to researchers in reality more closely resembles a homogenous population; medical science has yet to achieve equity in its data collection, leading to biased data sets and impacting the available data pool for people of color.[31] Programmers may tweak the algorithm, but in an ML model, the computer is the primary author of its algorithm—learning and improving based on the data it collects.[32] During the initial training process, inputting biased data can lead to biased results and a third party cannot discern why or how the algorithm produced these results.[33]

Second, in medical models, a "black box" problem tends to arise because a computer cannot explain its thinking.[34] In other words, outcomes are based on an opaque series of processes—computers lack the capacity to explain their decision-making processes and, beyond programmers, third parties lack access to or cannot understand those processes and their outcomes.[35] Consequently, black box algorithms make it difficult to discern the source of both outcome errors and successes.[36] This may not be an issue for simpler models, in which

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28. *See* Brown, *supra* note 23. *See generally* James Vincent, *The State of AI in 2019*, VERGE (Jan. 28, 2019, 7:00 AM), https://www.theverge.com/2019/1/28/18197520/ai-artificial-intelligence-machine-learning-computational-science [https://perma.cc/2G6M-B3CF] ("[B]ecause all the computer knows is the data you feed it, it might pick up a biased view of the world . . . .").

29. Google's search engine is a prime example of this. *See* Brown, *supra* note 23.

30. *Id. See generally* Vincent, *supra* note 28.

31. *See*, *e.g.*, Erin Garcia de Jesús, *How One Scientist Aims to Boost Black People's Representation in Genetic Datasets*, SCI. NEWS (Feb. 9, 2022, 7:00 AM), https://www.sciencenews.org/article/genetic-data-represent-black-people-tshaka-cunningham [https://perma.cc/9ZFM-5KFN] ("[O]ur understanding of [the human genome] has a dramatic and problematic bias: It's based primarily on white people."); Anne-Marie J. Audet, *To Advance Health Equity, We Must Bridge Gaps in Health Data and Measurement*, UNITED HOSP. FUND (Dec. 16, 2020), https://uhfnyc.org/publications/publication/advance-health-equity-we-must-bridge-gaps-health-data-and-measurement/ [https://perma.cc/U462-W9ST] (emphasizing that gaps in racial and ethnic data exists on both the population and individual levels).

32. *See* Brown, *supra* note 23 ("Machine learning takes the approach of letting computers learn to program themselves through experience."). The term "author" is used purely as a demonstrative, and not in a legal sense.

33. *See* Brown, *supra* note 23; Vincent, *supra* note 28.

34. *See* Price, *supra* note 5, at 430–31; Gerke *supra* note 5, at 440–41.

35. Price, *supra* note 5, at 430.

36. *See* Vincent, *supra* note 28 ("Machine learning systems can't explain their thinking, and that means your algorithm could be performing well for the wrong reasons.").

inputs and operations are visible to an interested party,[37] but a more complex model is often preferable to a simpler model because of its greater accuracy and capabilities.[38] While some industries have the freedom to choose not to share the details of how the algorithms works,[39] medical algorithms dealing with protected and private information necessitate that "developers *cannot* share the details of how the algorithm works in practice."[40]

Legal scholars on technology Roger Allan Ford and W. Nicholson Price II acutely summarize the issue, noting that "biological systems are so complex, and big-data techniques so opaque, that it can be difficult or impossible to know if an algorithmic conclusion is incomplete, inaccurate, or biased."[41] Thus, AI/ML-enabled medical devices, working perfectly, have the ability to advance the medical industry,[42] but such perfection is rarely achieved, implicating patient privacy concerns and signaling a legitimacy problem rooted in the inherent nature of the algorithm.[43]

B. Medical Device Regulation

The FDA regulates medical devices,[44] which are defined as any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other

37. *See* Daisy Tsang, *White Box vs. Black Box Algorithms in Machine Learning*, ACTIVESTATE (July 19, 2023), https://www.activestate.com/blog/white-box-vs-black-box-algorithms-in-machine-learning/ [https://perma.cc/YHE6-G534].

38. *See id.*

39. *See* Kinza Yasar & Ivy Wigmore, *Black Box AI*, TECHTARGET, https://www.techtarget.com/whatis/definition/black-box-AI [https://perma.cc/VP4Z-SJN8] (last visited Feb. 26, 2024).

40. *Id.*; Price, *supra* note 5, at 430; Roger Allan Ford & W. Nicholson Price II, *Privacy and Accountability in Black-Box Medicine*, 23 MICH. TELECOMMS. & TECH. L. REV. 1, 11 (2016). Relatedly, ML-based medical algorithms constantly develop based on new input data, complicating regulatory oversight. Maher, *supra* note 25, at 167.

41. Ford & Price, *supra* note 40, at 3.

42. *See, e.g.*, Gerke, *supra* note 5, at 435; Jessica Boubker, *When Medical Devices Have a Mind of Their Own: The Challenges of Regulating Artificial Intelligence*, 47 AM. J.L. & MED. 427, 427 (2021).

43. *See, e.g.*, Ali Aamir, Arham Iqbal, Fareeha Jawed, Faiza Ashfaque, Hafiza Hafsa, Zahra Anas, Malik Olatunde Oduoye, Abdul Basit, Shaheer Ahmed, Sameer Abdul Rauf, Mushkbar Khan & Tehreem Mansoor, *Exploring the Current and Prospective Role of Artificial Intelligence in Disease Diagnosis*, 86 ANNALS MED. & SURGERY 943, 945 (2024).

44. 21 U.S.C. § 371; *Is Your Product Regulated?*, FDA, https://www.fda.gov/medical-devices/overview-device-regulation/your-product-regulated [https://perma.cc/VV2Y-KJYG] (last visited Feb. 27, 2024).

animals."[45] To determine whether a product is a medical device, and thus subject to the FDA's regulatory authority, the FDA first considers the product's intended use when a manufacturer submits it to the FDA for approval.[46] While the manufacturer's knowledge of the device's use may be considered, the FDA looks to any relevant source of evidence in making its determination—including marketing materials, press releases, manufacturing claims, training documents, and consumer use of the product.[47] Once it is established that a product is indeed a medical device, the FDA regulates the product according to a device risk classification scheme.[48]

All medical devices regulated by the FDA are then subject to "registration, listing, and adverse-event-reporting requirements."[49] Depending on the classification, additional requirements may follow: low risk (Class I) devices do not have additional requirements,[50] but high risk devices (Class III) go through a premarket approval pathway (PMA), "which typically involves clinical trials and the presentation of extensive evidence of safety and efficacy to [the] FDA."[51] Moderate-risk devices (Class II), a class in which many medical devices fall, can be cleared through a PMA or by demonstrating that another similar device was already approved,[52] which is known as the 510(k) clearance process.[53]

Medical device manufacturers, who at the time of submission for FDA approval intend to change a device, may submit a supplemental application called a predetermined changed control plan (PCCP)

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45. 21 U.S.C. § 321(h)(1).

46. Price, *supra* note 5, at 437–38 (explaining that the FDA applies an objective intent standard).

47. 21 C.F.R. § 801.4 (2024); 21 C.F.R. § 201.128 (2024); Price, *supra* note 5, at 437–38; Jennifer L. Bragg, Maya P. Florence & William McConagha, *FDA's Final Rule on Intended Use: 'Getting Right Back to Where We Started From'*, SKADDEN (Aug. 18, 2021), https://www.skadden.com/insights/publications/2021/08/fdas-final-rule-on-intended-use [https://perma.cc/5CWH-BNGK] ("[F]DA may consider such knowledge—along with a host of other factors—as evidence of intended use.").

48. 21 C.F.R. § 860.1 (2024); *see* Sumatha Kondabolu, *The 3 FDA Medical Device Classes: Differences and Examples Explained*, QUALIO (Jan. 25, 2023), https://www.qualio.com/blog/fda-medical-device-classes-differences#differences [https://perma.cc/4LGJ-KK4F] (providing examples of devices in each of the three levels of classification).

49. Price, *supra* note 5, at 438.

50. *See* 21 C.F.R. § 860.3 (2024).

51. *See id.*; Price, *supra* note 5, at 438.

52. Through the 510(k) pathway, a medical device may be approved when it is "substantially equivalent" to a precedent device approved by the FDA. *See Premarket Notification 510(k)*, FDA (Oct. 3, 2022), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#se [https://perma.cc/R96B-YFFP]; 21 C.F.R. §§ 807.3, 860.3, 360e; Price, *supra* note 5, at 443.

53. *Premarket Notification 510(k)*, *supra* note 52.

describing the planned changes that may be made to the device.[54] Still, however, submissions under a PCCP require that the medical device remains safe and effective regardless of any change.[55] Thus, both the nature and the intended use of a particular device directly affect the level of FDA oversight.[56] Unequivocally, however, the FDA has emphasized its authority to regulate both software *in a medical device* and software *as a medical device*.[57] Yet certain medical devices with AI/ML functions have not been classified as such, leading to an increased risk of off-label misuse by physicians.[58] Consequently, the federal regulatory framework is insufficient to regulate AI/ML-enabled devices and this misuse.[59]

Even though it is within the FDA's purview to regulate medical devices, there are other sources of regulatory authority over the practice of medicine and medical patients as consumers.[60] Under the Tenth Amendment of the US Constitution, states have the power to regulate the practice of medicine and do so through statute.[61] Every state has some variation of a Medical Practice Act that governs the licensing and continuing medical education requirements of the medical profession to ensure proper physician practices.[62]

While the FDA is largely responsible for protecting patient health and safety, the Federal Trade Commission deals primarily with consumer protection, which can include data privacy concerns or

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54. 21 U.S.C. § 360e-4.

55. 21 U.S.C § 360e-4(a)(2), (b)(2).

56. *See* Price, *supra* note 5, at 437–38.

57. 2023 PROPOSED GUIDANCE, *supra* note 11, at 1 (emphasizing that machine learning software has become integral to many medical devices). *Id.* at 1 n.1 ("[The] FDA regulates software that meets the definition of a medical device . . . .").

58. *See* Phoebe Clark, Jayne Kim & Yindalon Aphinyanaphongs, *Marketing and US Food and Drug Administration Clearance of Artificial Intelligence and Machine Learning Enabled Software in and As Medical Devices,* JAMA NETWORK OPEN 1, 7 (2023); *see also* United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012) (discussing off-label promotion).

59. *See* 2021 ACTION PLAN, *supra* note 10, at 1.

60. *See* FED'N ST. MED. BDS., UNDERSTANDING MEDICAL REGULATION IN THE UNITED STATES, https://www.fsmb.org/siteassets/education/pdf/best-module-text-intro-to-medical-regulation.pdf [https://perma.cc/R74R-5GWD] (last visited Apr. 9, 2024); *FTC Proposes Amendments*, *supra* note 21.

61. U.S. CONST. amend X; *see, e.g.*, N.Y. EDUC. LAW § 6521 (McKinney 2014) (defining the practice of medicine as "diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity or physical condition"); FLA. STAT. § 458.305(3) (2023).

62. *See* FED'N ST. MED. BDS., *supra* note 60. *See, e.g.*, N.Y. EDUC. LAW § 6521; FLA. STAT. § 458.305(3). To achieve this goal, these statutes authorize the creation of a medical board that has the power to oversee the licensing and education requirements as well as to discipline those who violate the law and practice standards. *See* FED'N ST. MED. BDS., *supra* note 60.

protection against deceptive business practices.[63] The FTC has already acted on AI/ML concerns in the consumer space, investigating the risks associated with AI use and recommending transparency of algorithms.[64] Because the FTC largely covers consumer concerns, however, its enforcement in healthcare has primarily targeted health apps and devices that are not covered by federal privacy laws like the Health Insurance Portability and Accountability Act (HIPAA).[65]

C. Off-Label Use

The FDA's regulatory power extends to the approval of medical devices to reach the market for practitioners, but not to the manner in which physicians actually use those devices to practice medicine.[66] A provider may therefore choose to use a pharmaceutical, biologic, or medical device for some purpose other than that approved by the FDA,[67] a practice known as "off-label" use.[68] For example, the Stryker Wingspan Stent System is approved to "open narrowed arteries" of patients experiencing repeated strokes due to intracranial stenosis; use of the stent on patients that do not have this condition would be "off-label."[69] So long as the intent is the "practice of medicine" and there are

63. *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do [https://perma.cc/48N2-HS35] (last visited Feb. 27, 2024); *Protecting Consumer Privacy and Security*, FTC, https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security [https://perma.cc/PCF7-7X78] (last visited Feb 26, 2024).

64. Katyanna Quach, *FTC Interrupts Copyright Office Probe to Flip Out over Potential AI Fraud, Abuse*, REG. (Nov. 9, 2023), https://www.theregister.com/2023/11/09/ftc_ai_regulation/ [https://perma.cc/ZHD7-9JG9] ("The FTC has been exploring the risks associated with AI use . . . ."); Andrew Smith, *Using Artificial Intelligence and Algorithms*, FCC (Apr. 8, 2020), https://www.ftc.gov/business-guidance/blog/2020/04/using-artificial-intelligence-and-algorithms [https://perma.cc/Z9XF-XMRS]; Linda A. Malek & Blaze Waleski, *Significance of FTC Guidance on Artificial Intelligence in Health Care*, REUTERS (Nov. 24, 2021, 10:20 AM), https://www.reuters.com/legal/litigation/significance-ftc-guidance-artificial-intelligence-health-care-2021-11-24/ [https://perma.cc/5UB8-BZJZ].

65. *FTC Proposes Amendments*, *supra* note 21. It is possible that mobile medical apps could soon enough "practice medicine." *See* Drew Simshaw, Nicolas Terry, Kris Hauser & M.L. Cummings, *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH. 1, 17 (2016); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (1996), https://www.govinfo.gov/app/details/PLAW-104publ191 [https://perma.cc/F52F-X2QH] (last visited Apr. 9, 2024).

66. *See "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices*, FDA (May 6, 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices [https://perma.cc/GR5E-WE5F] [hereinafter *FDA Off-Label Use Information Sheet*].

67. *See id.*

68. *Off-Label Use of Medical Products*, *supra* note 16.

69. *See FDA in Brief: FDA Reminds Health Care Professionals About Risks of Wingspan Stent System After Study Shows Increased Risk of Stroke or Death When Used Outside of the FDA*

no changes to the device itself, the device does not have to go through the FDA approval process again.[70]

Off-label use of medical devices is not only common but even encouraged within the medical community.[71] Several professional medical associations overtly support the off-label use of medical devices when and where appropriate.[72] Due to the off-label nature of such use, however, providers must undertake additional risk management considerations: they have the duty to stay well-informed about the product and the risks and benefits of its use, and to base their decision to use it off-label on sound scientific rationale and evidence.[73] Thus, a physician's choice to use a device off-label could conceivably increase the risk of medical malpractice claims for negligence or lack of informed consent.[74]

The extent to which a device manufacturer may promote or advertise off-label use of medical devices is more restricted, as that falls directly within the FDA's regulatory authority under the Federal Food Drug & Cosmetic Act (FDC Act) to regulate medical devices.[75] While the FDC Act itself does not prohibit the promotion of off-label uses, the FDA

Approved Indications, FDA (Apr. 25, 2019), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-reminds-health-care-professionals-about-risks-wingspan-stent-system-after-study-shows [https://perma.cc/KA5L-QE25].

70. *FDA Off-Label Use Information Sheet*, *supra* note 66. Clinical trials are also not required but are strongly advised in order to comply with medical practice guidelines. *Id.*; *see Off-Label Use of Medical Products*, *supra* note 16.

71. *See Off-Label Use of Medical Products*, *supra* note 16.

72. *See generally* AM. ACAD. ORTHOPAEDIC SURGEONS, PHYSICIAN DIRECTED USE OF MEDICAL PRODUCTS (2016) https://www.aaos.org/contentassets/1cd7f41417ec4dd4b5c4c48532183b96/1177-physician-directed-use-of-medical-products.pdf [https://perma.cc/5WRL-A83K]; *Off-Label Use of Medical Products*, *supra* note 16; Kathy J. Jenkins, Robert H. Beekman, Michael G. Vitale & William L. Hennrikus, *Off-Label Use of Medical Devices in Children*, 139 PEDIATRICS 1, 2 (2017) (mentioning that off-label use is the "most common and appropriate practice in pediatrics"); *see also Off-Label Drug Use*, AM. CANCER SOC'Y (Mar. 17, 2015), https://www.cancer.org/cancer/managing-cancer/treatment-types/off-label-drug-use.html [https://perma.cc/JYH6-M6UM] (discussing off-label use of FDA-approved drugs).

73. *See Off-Label Use of Medical Products*, *supra* note 16 ("This is particularly so in the case of 'novel' or 'innovative' off-label uses, in which safety and efficacy have not been established to the extent associated with the FDA approval process.").

74. Patients may still bring medical malpractice claims. *See* Shariful A. Syed, Brigham A. Dixson, Eduardo Constantino & Judith Regan, *The Law and Practice of Off-Label Prescribing and Physician Promotion*, 49 J. AM. ACAD. PSYCHIATRY & L. 1, 5 (2021) ("To date, no appellate court has ruled that physicians must disclose off-label status as part of informed consent. [But as] a general rule, some physicians have suggested that providing patients with information about off-label use may afford greater protection from future liability suits.").

75. *See* Nancy Crotti, *Here's How FDA Officials Think You Can Legally Promote Off-Label Device, Drug Uses*, MED. DESIGN & OUTSOURCING (June 13, 2018), https://www.medicaldesignandoutsourcing.com/heres-how-to-legally-promote-off-label-device-drug-uses/ [https://perma.cc/PZV5-WVQU]; 21 U.S.C. § 371.

considers off-label promotion as evidence of "misbranding" under the Act.[76] In the past, companies have faced repercussions for promoting the off-label use of a medical device.[77] Yet in the interest of providing "truthful, non-misleading" information, the FDA published guidance documents clarifying that medical technology companies can explain to "payors and hospitals how their products can affect outcomes . . . beyond what the products' indication with the agency says."[78] The documents suggested that the approved use of a medical device would not guarantee its safe use in every application thereof, but emphasized transparency given the potential for a device's myriad of uses.[79] Although the FDA, as made clear by its guidance, allows clarifying explanations of off-label use, it does not endorse off-label use.[80] The court in *Taylor v. Intuitive Surgical Inc.* agreed.[81]

In *Taylor*, the Washington State Supreme Court imposed on a device manufacturer the duty to warn the hospital of potential safety concerns, including those that may arise from off-label use of the device.[82] *Taylor* dealt with a medical device, Intuitive's *da Vinci* surgical system, that was approved by the FDA for laparoscopic surgeries.[83] The user manual provided to physicians included a warning, in line with the FDA's safety and use requirements, that

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76. *See Labeling Requirements - Misbranding*, FDA, https://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding [https://perma.cc/KFC9-KZ9V] (last visited Feb. 27, 2024); *see also* United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012) ("While the [FDC] Act makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion. Rather, the [FDC Act] and [FDA] regulations reference 'promotion' only as evidence of a drug's intended use.").

77. *See* Nancy Crotti, *FDA to Clarify Role of Off-Label Uses in Medical Device Approvals*, MED. DESIGN & OUTSOURCING (Sept. 23, 2020), https://www.medicaldesignandoutsourcing.com/fda-to-clarify-role-of-off-label-uses-in-medical-device-approvals/ [https://perma.cc/GA7E-72JG].

78. *See* Crotti, *supra* note *75*; *Caronia*, 703 F.3d at 167. *See also* Maya Florence, Jennifer Bragg & William McConagha, *Recent Developments in the Government's Evolving Approach to Off-Label Promotion*, SKADDEN (Dec. 2023), https://www.skadden.com/-/media/files/publications/2023/12/recent_developments_in_the_governments_evolving_approach_to_off_label_promotion.pdf [https://perma.cc/5RED-Z3TG] (discussing draft guidance that would "expand[] the types of communications regarding unapproved uses" that a manufacturer may disseminate).

79. *See* Crotti, *supra* note 77.

80. *See id.*; Florence et al., *supra* note 78.

81. *See* 389 P.3d 517, 520 (Wash. 2017).

82. *See id.* at 530. Although the court did not label the surgeon's use as "off-label," it was just that. The surgeon in *Taylor* technically used the *da Vinci* for an approved procedure, but in a way that the manufacturer was aware could be dangerous for the patient. *See id.* at 521. Sections II and III of this Note consider whether this is better classified as an off-label use of a medical device.

83. *Id.* at 520. *See generally Intuitive da Vinci*, INTUITIVE, https://www.intuitive.com/en-us/products-and-services/da-vinci [https://perma.cc/NT68-EZKZ] (last visited Feb. 26, 2024).

prostatectomies should not be performed on obese patients or patients who had previously undergone lower abdominal surgeries.[84] Despite these warnings, a Washington physician performed a laparoscopic surgery on the plaintiff, who was an obese patient, that resulted in serious post-surgery complications.[85] The plaintiff passed away four years later as a result of the surgery's complications.[86] The court ruled that the manufacturer had a duty to warn both the hospital and the physicians, by way of user manual, of the potential risks of using the surgical system in a way that went against those warnings.[87]

III. ANALYSIS

The proper off-label use of AI/ML-enabled medical devices implicates multiple governmental entities.[88] Of course, the FDA has the most direct interest, as it has the power to regulate medical devices.[89] As regulators of the act of practicing medicine, however, states also have an interest in clarifying what constitutes the practice of medicine and ensuring that licensed professionals, as authorized by law, practice it properly.[90] Additionally, while the FTC does not directly regulate medical devices, it has its own interests in protecting patient-consumers' data and privacy against improper business practices.[91]

Each entity has a distinct set of regulatory tools at its disposal. As federal agencies, the FDA and the FTC have the power to promulgate binding rules that carry the force of law and the authority to preempt conflicting state approaches.[92] Despite state interest in professional responsibility and practice standards among physicians,[93] any patchwork response to this issue would dilute imperative foundations within the patient-physician experience and AI.

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84. *Taylor*, 389 P.3d at 520–21.

85. *Id.* at 521.

86. *Id.*

87. *Id.* at 530.

88. *See* Urs J. Muehlematter, Paola Daniore & Kerstin N. Vokinger, *Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis*, 3 LANCET DIGIT. HEALTH e195, e195 (2021), https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30292-2/fulltext [https://perma.cc/E9G4-LCKR].

89. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 1 n.1.

90. *See* Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, 7 ETHICS J. AM. MED. ASS'N 311, 312 (2005), https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04 [https://perma.cc/2LX7-VQ6K].

91. *See* 15 U.S.C. § 45.

92. 5 U.S.C. § 553.

93. *See* Carlson & Thompson, *supra* note 90.

A. Federal Regulators

1. The FDA: Actions Thus Far

The FDA has been granted regulatory authority under the FDC Act to regulate medical devices.[94] With the increasing sophistication of machine learning in the medical field, the FDA has recognized the need for regulatory intervention in AI/ML-enabled medical devices;[95] to inform such intervention, it has held several workshops and public meetings on AI/ML topics.[96] Based on its prior considerations of the issue, the FDA proposed nonbinding guidance for premarket submissions for AI/ML-enabled medical devices in 2023.[97] However, there is neither FDA regulation addressing the implications of AI/ML-enabled medical devices nor any broadly applicable guidance for the use of AI/ML-enabled medical devices by medical practitioners, which in turn, enhances the risk of misuse for these devices.[98]

2. The FDA's Proposed Guidance

In April 2023, the FDA posted draft guidance addressing the use of PCCPs in AI/ML-enabled medical devices and called for submission of comments in anticipation of devising a more official, and more

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94. *See* 21 U.S.C. § 371; 2023 PROPOSED GUIDANCE, *supra* note 11, at 2.

95. *See, e.g.*, FDA, TECHNICAL PERFORMANCE ASSESSMENT OF QUANTITATIVE IMAGING IN RADIOLOGICAL DEVICE PREMARKET SUBMISSIONS 5–6 (2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-quantitative-imaging-radiological-device-premarket-submissions [https://perma.cc/PBW3-XXXH]; FDA, CYBERSECURITY IN MEDICAL DEVICES: QUALITY SYSTEM CONSIDERATIONS AND CONTENT OF PREMARKET SUBMISSIONS 2 (2023), https://www.fda.gov/media/119933/download [https://perma.cc/PCT2-AZUH].

96. 2023 PROPOSED GUIDANCE, *supra* note 11, at 4; *FDA Workshop: "Evolving Role of Artificial Intelligence in Radiological Imaging,"* ACAD. FOR RADIOLOGY & BIOMEDICAL IMAGING RSCH., https://www.acadrad.org/wp-content/uploads/2020/03/fdaworkshop.pdf [https://perma.cc/9LYC-7CDH] (last visited Feb. 26, 2024). *See, e.g.*, *October 22, 2020: Patient Engagement Advisory Committee Meeting Announcement*, FDA, https://www.fda.gov/advisory-committees/advisory-committee-calendar/october-22-2020-patient-engagement-advisory-committee-meeting-announcement-10222020-10222020 [https://perma.cc/FF6M-KC5Q] (last visited Feb. 27, 2024); *Virtual Public Workshop—Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices*, FDA, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjY8cjk1MGEAxUO4ckDHZnLDsoQFnoECAoQAQ&url=https%3A%2F%2Fdownloads.regulations.gov%2FFDA-2019-N-1185-0138%2Fattachment_1.pdf&usg=AOvVaw2AmphDXTYeZtGvA6x2g6b1&opi=89978449 [https://perma.cc/6DN5-PDMB] (last visited Feb. 27, 2024).

97. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 3–4.

98. *See* Price, *supra* note 5, at 443 (citing Cortez, *supra* note 13). *See generally Guidances*, *supra* note 14.

responsive, approach to the use of AI/ML-enabled medical devices.[99] The draft guidance focused on AI/ML-enabled devices that a manufacturer intends to modify over time.[100] For these devices, the guidance recommends inclusion of a PCCP that identifies the "specific, planned" modifications the manufacturer intends to implement.[101] The PCCP would collect information in the marketing submission to the FDA from medical device manufacturers that is necessary for a user to understand safe and effective use.[102] While it is a step toward the regulation of AI/ML-enabled devices, the FDA should have considered off-label use to address the full scope of consequences presented by these devices.

The FDA will encourage the inclusion of a PCCP for manufacturers that intend to modify the device, as it allows the manufacturer to specify what those modifications might look like at the time of premarket submission, thereby reducing the likelihood that it would need to submit additional materials ahead of the modification.[103] According to the guidance, failure to include a PCCP may result in the manufacturer having to submit the AI/ML-enabled device for premarket review again if the modification significantly affects or could affect the safety or effectiveness of the device.[104] Yet manufacturers are neither required nor encouraged to consider safety implications of off-label use in the PCCP submission.[105] Medical device approvals are notoriously prolonged and can be quite costly to the manufacturer, so submission of a PCCP is beneficial to manufacturers that intend to make changes and already have those changed mapped out.[106]

Considering the current and growing prevalence of AI/ML-enabled medical devices, the FDA overly narrowed the scope of its proposed guidance, failing to consider two key issues that undermine

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99. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 6.

100. *Id.* at 5.

101. *Id.* at 3.

102. Gregory H. Levine & Lauren Sager, *Getting Smarter: FDA Publishes Draft Guidance on Predetermined Change Control Plans for Artificial Intelligence/Machine Learning (AI/ML) Devices*, ROPES & GRAY (May 2, 2023), https://ropesgray.com/en/insights/alerts/2023/05/getting-smarter-fda-publishes-draft-guidance-on-predetermined-change-control-plans-for-ai-ml-devices [https://perma.cc/PW8B-P9RS].

103. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 6.

104. *See id.*

105. *Id.* at 10–11.

106. *See* MedTech Leading Voice, *The FDA Draft Guidance on Predetermined Change Control Plans: What Does it All Mean?*, LINKEDIN (June 27, 2023), https://www.linkedin.com/pulse/fda-draft-guidance-predetermined-change-control/ [https://perma.cc/486G-3MBE] (summarizing an interview with Eric Henry, Senior Quality & Regulatory Compliance Advisory, FDA & Life Sciences Practice at King & Spalding).

patient safety.[107] First, it largely focused on the manufacturer's *initial* intentions,[108] neglecting autonomous algorithmic adaptations that change functions down the line.[109] Even more significantly, the FDA failed to discuss the increasingly consequential off-label use of these devices by medical professionals.[110]

Currently, medical device manufacturers are required to submit a new application for premarket review or another premarket notification if their device has a new intended use or when changes to the device could significantly affect its safety or effectiveness.[111] However, suppose—for practical reasons or otherwise—a manufacturer following the FDA's draft guidance did not plan for AI/ML modifications to a device and therefore did not submit a PCCP. The FDA's fully informed approval, therefore, could not be guaranteed without such a submission. The post-market risk demonstrates the severity of this issue: manufacturers, unclear as to what is or is not AI/ML, might not appropriately resubmit that device for premarket notification or review if it is later used inconsistently with the initial approved use.[112]

This holds true even if a manufacturer has not changed anything fundamental within the device.[113] If a manufacturer used a black box algorithm, the nature of the algorithm itself may unexpectedly change the intended use or make updates to the system that were not originally included or approved in the PCCP.[114] While a manufacturer could likely flag this update, it is unclear how long it would take to flag, whether harm would result, or if a manufacturer could "undo" the unplanned update to comply with the original FDA approval.[115]

The FDA has had several opportunities to resolve off-label use of AI/ML-enabled medical devices, but has not done so yet.[116] Neither the draft guidance nor the 2021 action plan and 2019 discussion paper

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107. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 5.

108. *See id.* at 5–6 (emphasis added).

109. *See id.*; Brown, *supra* note 23.

110. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 5–7.

111. 21 C.F.R. § 814.39(a)(1) (2024).

112. *See* Clark et al., *supra* note 58, at 5. Or perhaps a device that is not intended to have more advance AI/ML functions, such as a routine task robot, begins to take on more "ministerial" healthcare tasks. *See* Simshaw et al., *supra* note 65, at 16–18.

113. *See* Clark et al., *supra* note 58, at 2; Simshaw et al., *supra* note 65, at 16–18.

114. *See* Brown, *supra* note 23.

115. For discussion of the medical black box algorithm problem, *see supra* notes 34–43, 56 and accompanying text.

116. *See* 2019 Discussion Paper, *supra* note 9; 2021 ACTION PLAN, *supra* note 10; 2023 PROPOSED GUIDANCE, *supra* note 11, at 3.

discuss off-label use of such devices.[117] It is an error, albeit a remediable one, that the FDA has not considered the safety and privacy concerns arising from off-label use of AI/ML-enabled medical devices, given the customary usage of devices off-label "in the practice of medicine."[118]

Devices with AI/ML capabilities should be labeled as such by manufacturers, thus facilitating the FDA's proper assessment and monitoring of AI/ML concerns.[119] If the FDA or another regulatory body is unaware that the device has AI/ML functions, and the device makes it to market, both patients and providers may face serious, unintended consequences.[120] As it stands, it is not guaranteed that devices with AI/ML capabilities will be flagged as such by medical device manufacturers in their submissions for approval to the FDA, which allows manufacturers to circumvent safety procedures and increase the risk of harm to patients.[121] Moreover, a manufacturer who does not originally intend to make AI/ML changes to a device could be noncompliant and not be flagged as such on the FDA's website if that device later gains AI/ML capabilities.[122]

Insufficient warnings regarding the extent of AI/ML capabilities could exacerbate patients' safety problems, particularly when a doctor uses a device off-label.[123] As *Taylor* illustrates, manufacturers ought to provide such warnings to both hospitals and doctors.[124] Safety and effectiveness are, and will continue to be, critical considerations in the evaluation of medical devices.[125] With the inevitable rise of semi-

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117. *See* 2019 Discussion Paper, *supra* note 9; 2021 ACTION PLAN, *supra* note 10; 2023 PROPOSED GUIDANCE, *supra* note 11, at 3.

118. *See FDA Off-Label Use Information Sheet*, *supra* note 66.

119. *See generally* 21 U.S.C. § 372 ("The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees . . . .").

120. *See* OFF. SCI. & TECH. POL'Y, EXEC. OFF. PRESIDENT, BLUEPRINT FOR AN AI BILL OF RIGHTS: MAKING AUTOMATED SYSTEMS WORK FOR THE AMERICAN PEOPLE 15 (2022), https://www.whitehouse.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf [https://perma.cc/5SCJ-Q3XM] [hereinafter AI BILL OF RIGHTS].

121. *See* Clark et al., *supra* note 58, at 5. For example, a study that sampled 119 FDA-approved medical devices found eight to be contentious and fifteen to be discrepant. *Id.* Contentious devices were "not flagged by the FDA as AI or ML approved, nor did their 510(k) clearance summaries mention AI or ML." *Id.* at 4. Devices that were discrepant mentioned AI or ML capabilities on its website but there was no mention in FDA clearance, and it was "not listed in the FDA's public list of AI- or ML-enabled devices." *Id.*

122. *See id.* at 3–4.

123. *See* AI BILL OF RIGHTS, *supra* note 120.

124. *See* Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 520, 530 (Wash. 2017). Although it is a Washington state case and therefore not binding across the United States, some states have embraced its core doctrine. *See, e.g.*, *In re* 3M Combat Arms Earplug Prods. Liab. Litig., 545 F. Supp. 3d 1239, 1242 (N.D. Fla. 2021).

125. The FDA acknowledges and attempts to address this in its proposed guidance document. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 2; *see also* FDA, DECIDING WHEN TO

autonomous and autonomous medical devices in healthcare, the FDA must balance these safety implications with the benefits of the device.[126] AI/ML-enabled devices could arguably enhance the effectiveness of a device, leading to better patient outcomes in the aggregate.[127] But adding new AI/ML capabilities to a device, especially if it is a sophisticated algorithm, poses safety issues that require the FDA to consider—and if needed, reconsider—the off-label use of such devices.[128]

3. The Current Regulatory Response Is Not Adequate

The current regulatory response is not set up to "easily accommodate" AI/ML-enabled medical devices—and the FDA knows it.[129] One scholar notes that the "FDA faces unique challenges in developing a framework that sufficiently regulates these technologies, given how AI/ML-enabled devices change and adapt over time."[130] These challenges and their effects are especially concerning considering the widespread use of AI in healthcare; AI's processes and resulting outcomes remain opaque to lawmakers and other third parties.[131] The mere issuance of nonbinding federal regulatory guidance cannot adequately address the underlying issue, as such guidance is predicated on an extant approval framework that lacks the robustness necessary to manage the intricacies associated with medical devices powered by AI/ML.[132]

4. The FTC's Interest

The FTC, a federal regulatory agency that primarily addresses consumer concerns, has thus far targeted health apps and devices that are not covered by the Department of Health and Human Services and the patient privacy statute, HIPAA.[133] The evolving landscape of

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SUBMIT A 510(K) FOR A SOFTWARE CHANGE TO AN EXISTING DEVICE 14 (2017), https://www.fda.gov/media/99812/download#:~:text=Manufacturers%20are%20required%20to%20submit,effect%20could%20be%20positive%20or125 [https://perma.cc/BLF5-WSRK] [hereinafter 510(K) GUIDANCE].

126. *See* Gerke, *supra* note 5, at 442; Britton, *supra* note 20, at 162.

127. *See* Gerke, *supra* note 5, at 507.

128. For discussion of the medical black box algorithm problem, *see supra* notes 34–43, 56 and accompanying text.

129. Maher, *supra* note 25, at 167; *AI/ML in Software*, *supra* note 9 ("The FDA's traditional paradigm of medical device regulation was not designed for adaptive [AI/ML] technologies.").

130. Maher, *supra* note 25, at 167.

131. *See* Ford & Price, *supra* note 40, at 3; Kamensky, *supra* note 2, at 14–15.

132. *See* 5 U.S.C. § 553.

133. *FTC Proposes Amendments*, *supra* note 21. It is possible that mobile medical apps could soon enough "practice medicine." *See* Simshaw et al., *supra* note 65.

AI/ML-enabled medical devices within public markets, however, blurs the lines of its competing regulatory interests.[134]

As devices become more autonomous, it becomes less clear who is ultimately making the healthcare decision—the doctor or the device.[135] As a result, it becomes more difficult to discern to whom liability should be attributed and which regulatory authority appropriately governs. For example, it is possible that mobile medical apps could soon enough "practice medicine" without a license, thereby endangering the user as both a consumer and a patient.[136] The FTC's interest in consumer protection, therefore, is multidisciplinary, overlapping with both the practice of medicine and device or platform algorithms.[137]

Additionally, the FTC's and the FDA's interests in protecting data privacy in healthcare may also overlap as the line between patient and consumer becomes thinner.[138] A medical device with AI/ML capabilities collects vast amounts of personal health information to constantly learn and adapt, thereby increasing cybersecurity concerns for individuals in capacities as both patients and consumers.[139] Although the FTC does not typically regulate within the medical field, its role in healthcare AI/ML enforcement is expanding, as indicated by the White House and the FTC itself.[140] Despite the congressional delegation of authority to regulate the devices entering the medical sphere to the FDA, giving it a direct interest in the matter, the AI landscape is evolving and the nature of varying affected parties have

134. AI implicates several industries. *See Future of AI—6 Ways AI is Growing Rapidly*, KNOWTECHIE (Dec. 15, 2023), https://knowtechie.com/future-of-ai-6-ways-ai-is-growing-rapidly/ [https://perma.cc/CNL9-XAU5].

135. *See* Simshaw et al., *supra* note 65, at 17 ("[T]he likelihood that medical devices will become increasingly smarter until their diagnostic prowess begins to look suspiciously like the 'practice of medicine.'"). *See id.* at 18 (noting that medical devices' capabilities will be greater than mobile apps, leading to additional concerns). *See also* Letter from Cong. to Chiquita Brooks-LaSure, Adm'r, Ctrs. for Medicare & Medicaid Servs. (Nov. 3, 2023) (on file with author) (highlight that "problems posed by prior authorization have been exacerbated by [Medicare Advantage] plans' increasing use of AI or algorithmic software . . . .").

136. *See* Simshaw et al., *supra* note 65.

137. *See Protecting Consumer Privacy and Security*, *supra* note 63.

138. *See id.*; Anna Abram, Craig Bleifer, Nathan Brown, Marlee Gallant & Oluwaremilekun Mehner, *FDA Gets Digital, Agency Issues Digital Health Policies on PCCP, Cybersecurity and Drug Development*, JD SUPRA (Apr. 4, 2023), https://www.jdsupra.com/legalnews/fda-gets-digital-agency-issues-digital-3495967/ [https://perma.cc/P7WB-32FW].

139. *See* Simshaw et al., *supra* note 65, at 14.

140. *See supra* note 135 and accompanying text.

created a shared interest in more efficient and effective regulation between the two agencies.[141]

B. State Regulators

States are left as the regulators of the practice of medicine, which is defined as "diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity or physical condition."[142] As physicians supplement their practice with increasingly complex medical devices, there may be a point at which the decision-making process using AI/ML-enabled devices is so highly technical, demanding advanced knowledge of such devices, that the physician is no longer "practicing medicine" as contemplated by state regulation.[143] For example, operating on a patient is clearly practicing medicine, as is using a surgical system for an unapproved technique.[144] However, relinquishing professional discretion to an AI/ML-enabled surgical system for an unapproved surgery might stray from as the "practice of medicine."[145]

141. *See Protecting Consumer Privacy and Security*, *supra* note 63 (explaining the FTC's role in consumer privacy); 21 U.S.C. § 360n-2 ("ensuring cybersecurity of devices" through the FDC Act).

142. *See, e.g.*, N.Y. EDUC. LAW § 6521 (McKinney 2014); FLA. STAT. § 458.305(3) (2023); TENN. CODE ANN. § 63-6-204(a)(1) (2021).

143. Neither a technical background, such as computer science, nor comprehension of artificial intelligence technologies, is required for physician licensure. Though they vary somewhat state to state, the typical requirements for physician licensure include: (1) graduation from a medical school (M.D. or D.O. program), (2) passage of a licensure examination (e.g., USMLE, COMLEX, NBOME), (3) at least one year of postgraduate training in a residency program, and (4) a character and fitness examination. *See, e.g.*, *Examination Requirements: Physician Licensure*, TEX. MED. BD., https://www.tmb.state.tx.us/idl/84B15AC2-5428-389E-168A-034C319BA14C [https://perma.cc/Q48U-5UQB] (last visited Feb. 29, 2024); *License Requirements for Physicians*, N.Y. ST. EDUC. DEP'T, https://op.nysed.gov/professions/physicians/license-requirements [https://perma.cc/8KPP-SC5J] (last visited Feb. 26, 2024); *see* Price, *supra* note 5, at 423 ("[P]roviders must trust that algorithms are safe and effective to rely on them, but they lack the experience or knowledge to evaluate algorithms at the point of care, creating a need for systemic regulation.").

144. *See* N.Y. EDUC. LAW § 6521; FLA. STAT. § 458.305(3); *supra* Section I.C.

145. *See supra* note 135 and accompanying text; *e.g.*, N.Y. EDUC. LAW § 6521.

III. SOLUTION

A. FDA Regulation

1. A New FDA Framework

As demonstrated, the current regulatory framework, on both the federal and state levels, is not adequately equipped to manage AI/ML-enabled medical devices. Further, the FDA's current proposed guidance on PCCPs attempting to address the issue is too narrow;[146] not all manufacturers will initially intend to incorporate AI/ML functions within their devices and, under the current FDA approach, such a shortcoming presents fundamental issues.[147] While regulation for AI/ML-enabled medical devices is needed, applying regulations indiscriminately could hinder production of non-AI/ML-enabled devices.[148] Accordingly, this Note proposes a two-prong regulatory filtering process. Devices that are not intended to have AI/ML-enabled capabilities should go through the normal regulatory process.[149] However, a medical device manufacturer seeking approval for a product with AI/ML capabilities should go through an alternative approval process.

For AI/ML-enabled devices, the regulatory approval process conducted by the FDA should require manufacturers to consider the foreseeable off-label uses of the device and safety implications thereof.[150] Considerations may vary device to device, but standard inquiries would allow for the contemplation of foreseeable off-label uses and any pertinent safety implications. Considerations may also include the sophistication or autonomy of the device, any testing the device has undergone for off-label uses, and the ability for adulterated functions that differ from primary functions.[151]

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146. *See generally* 2023 PROPOSED GUIDANCE, *supra* note 11.

147. A breast implant, for example, is unlikely to at some point have AI/ML capabilities because it is made entirely of silicone and does not use software. *Breast Implants*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/treatments/21724-breast-implants [https://perma.cc/YZK9-BGLA] (last visited Feb. 26, 2024).

148. This is why this Note recommends a rule rather than guidance. *See* discussion *infra* Section III.A.2.

149. *See supra* Section I.B (explaining the current regulatory approval process).

150. *See* Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 530 (Wash. 2017); Press Release, Joe Biden, *supra* note 21 (directing "developers of the most powerful AI systems share their safety test results and other critical information with the U.S. government"); *Off-Label Use of Medical Products*, *supra* note 16.

151. *See, e.g.*, *FDA Off-Label Use Information Sheet*, *supra* note 66.

Requiring disclosure of a device manufacturer's off-label considerations during the FDA's device-approval process should also be included in the device's user manual as a means to encourage transparency of risk.[152] Along with the device, device manufacturers typically provide consumers with user manuals containing "various warnings related to the device."[153] For manufacturers that seek to minimize potential tort liability, this manual should also be provided to both hospitals and doctors, enabling courts to deal more effectively with issues of tort liability arising from off-label use.[154]

Although the FDA generally does not have authority over—and does not endorse—the practice of off-label use of medical devices, it does have authority over device safety.[155] Requiring publication of off-label implications, in a user manual, for example, would fall within the FDA's authority over the device approval process and advance its interest in patient safety.[156] Essentially, this filtering process adds a "step zero" to the current framework. Both types of devices would be classified according to their risk, but maintaining a separate approval process, in addition to clear definitions of AI/ML, would almost certainly lower the probability of the FDA approving devices with AI/ML capabilities without properly noting them as such by self-selecting for potential off-label uses.

Regardless of whether the FDA implements a new framework for approving AI/ML-enabled medical devices before they reach medical practitioners and patients, some form of regulation is needed. Although the FDA cannot directly oversee off-label use, it could certainly impose front-end regulations aimed at manufacturers.[157] Manufacturers have a duty to warn providers of dangers that arise from using the device,[158] and due to the ubiquitous nature of off-label use,[159] this naturally extends to foreseeable off-label uses.[160] Thus, the FDA should issue a regulation that requires manufacturers, during the premarket approval

152. *See Taylor*, 389 P.3d at 524.

153. *Id.* at 521.

154. *See id.* at 522.

155. *See, e.g.*, 21 U.S.C. § 360e(c)(1)(A) (requiring applicants to file a report "to show whether or not such device is safe and effective").

156. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 2; *Taylor*, 389 P.3d at 530.

157. *See* 21 C.F.R. § 820.1 (2024) (defining "manufacturer" under the FDC Act).

158. *See Taylor*, 389 P.3d at 530.

159. *See, e.g.*, AM. ACAD. ORTHOPAEDIC SURGEONS, *supra* note 72; Jenkins et al., *supra* note 72 ("[T]he off-label use of many devices has become the most common and appropriate practice in pediatrics . . . ."); *Off-Label Use of Medical Products*, *supra* note 16 ("['Off-label' use of medical products] is common.").

160. *See In re* 3M Combat Arms Earplug Prods. Liab. Litig., 545 F. Supp. 3d. 1239, 1242 (N.D. Fla. 2021).

process, to consider and clarify safety issues associated with off-label use. By informing providers of these potential risks, the manufacturers would fulfill their duties to patients and consumers and mitigate safety concerns of which providers might not otherwise have been aware.[161]

After approval, however, continued monitoring of the devices may be warranted given that AI/ML continues to adapt—both on its own and with manufacturer-planned updates.[162] While the FDA's proposed guidance addresses only planned updates, such an approach does not fully address the risks inherent to autonomous ML that exist outside of a manufacturer's scheduled updates.[163] Consequently, the FDA should propose a rule, rather than a guidance document, that sets the foundation for continuous monitoring to guarantee continued device safety. Agencies, including the FDA, use nonbinding guidance more frequently than the rulemaking process.[164] Due to the flexibility of the Notice and Comment Rulemaking process and the comparative ease of issuance, issuing such a rule would enable an effective response to emerging developments both now and as AI/ML continues to advance.[165] Given existing concerns with the overuse of guidance,[166] for important decisions such as AI/ML in healthcare devices, the rulemaking process may be preferable to yet another nonbinding and unresponsive guidance document.[167]

Although more restrictive than guidance, a rule is comparably easier to pass and overturn than a statute, and its force of law is necessary given the industry.[168] AI changes rapidly—regulations can therefore become outdated if not properly monitored.[169] In anticipation of such changes, the FDA would be well advised to add a sunset clause

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161. *See Taylor*, 389 P.3d at 530. *See generally* 2023 PROPOSED GUIDANCE, *supra* note 11.

162. *See supra* note 114 and accompanying text; Ford & Price, *supra* note 40, at 36–37.

163. *See* 2023 PROPOSED GUIDANCE, *supra* note 11, at 5.

164. *See* KATE R. BOWERS, CONG. RSCH. SERV., LSB10591, AGENCY USE OF GUIDANCE DOCUMENTS 2 (2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10591 [https://perma.cc/E3PU-M28H].

165. *See id.*

166. *See id.* at 3.

167. *See id.* at 2.

168. *See* Jon Sanders, *Crafting Laws vs. Making Rules*, LOCKE (Feb. 23, 2022), https://www.johnlocke.org/crafting-laws-vs-making-rules/ [https://perma.cc/YT4G-A2GM] (explaining that in North Carolina, it is easier to promulgate rules than to pass laws). *See generally* MAEVE P. CAREY, CONG. RSCH. SERV., IF1003, AN OVERVIEW OF FEDERAL REGULATIONS AND THE RULEMAKING PROCESS (2021), https://crsreports.congress.gov/product/pdf/IF/IF10003 [https://perma.cc/JZC2-FK6H].

169. *Future of AI–6 ways AI is growing rapidly*, *supra* note 134; *Embracing the Rapid Pace of AI*, MIT TECH. REV. (May 19, 2021), https://www.technologyreview.com/2021/05/19/1025016/embracing-the-rapid-pace-of-ai/ [https://perma.cc/ZLP7-PRZP].

to the rule that requires it to review the rule potentially every five years or "within a reasonable time frame."[170]

2. Call for Collaboration with the FTC

As AI/ML in a device becomes more sophisticated, the likelihood, and risk, that it could "practice medicine" increases.[171] Given this looming possibility, the FDA and FTC have increasingly overlapping interests in the cybersecurity of AI/ML-enabled medical devices for patients and the public health.[172] This Note thus recommends that the FDA and FTC work together to ensure the safety and cybersecurity of AI/ML-enabled medical devices. Although black box algorithms are preferred due to their predictive accuracy, research into the production of transparent and explainable healthcare algorithms is nonetheless necessary to mitigate potential safety concerns like off-label use.[173] Working together, the agencies could create a set of standards requiring the key aspects of algorithms to be made transparent, if and when that becomes feasible.[174] The FDA could review these standards during premarket review, while the FTC could enforce responsible data design ex post facto by developing consequences for manufacturers who may fail to update an algorithm they know is not "reasoning" properly.[175]

The FDA and FTC should also communicate with patients and consumers directly regarding AI/ML standards in medicine as these

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170. *See* 21 U.S.C. § 371(h) (guidance standards). Five is an arbitrary number. The point is that the FDA needs to review within a timeframe that is not at risk of the policies being too far advanced for the current policies. It does this with guidance, so it is reasonable to do so with a rule. *Id.*

171. *See* Simshaw et al., *supra* note 65, at 18–19.

172. *See Protecting Consumer Privacy and Security*, *supra* note 63 (explaining the FTC's role in consumer privacy); 21 U.S.C. § 360n-2 ("[e]nsuring cybersecurity of devices" through the FDC Act).

173. *See* Ameera Patel, *Why Lifting the Lid on Black Box AI Is Essential for Healthcare Adoption*, MED-TECH (July 24, 2023, 1:00 PM), https://www.med-technews.com/medtech-insights/ai-in-healthcare-insights/why-lifting-the-lid-on-black-box-ai-is-essential-for-healthc/ [https://perma.cc/FAS7-6SYM]; Yinglian Xie, *Does Your Machine-Learning Model Have to Be a Black Box to Work Well?*, FORBES (July 9, 2021, 8:50 AM), https://www.forbes.com/sites/forbestechcouncil/2021/07/09/does-your-machine-learning-model-have-to-be-a-black-box-to-work-well/?sh=13e1f0085f30 [https://perma.cc/D335-FBTD] (arguing that some aspects of complex machine learning models should be explainable).

174. There is some disagreement among scholars as to the efficacy of explainable AI. *Compare* Xie, *supra* note 173 (concluding that "for most applications, a degree of explainability is sufficient to meet legal and regulatory requirements"), *with* Price, *supra* note 5, at 429–30 (explaining that there are some situations in which algorithms are unavoidably opaque), *and* Gerke, *supra* note 5, at 490–91.

175. *See* Simshaw et al., *supra* note 65, at 30.

agencies serve the general population.[176] Although this Note recommends regulation from the FDA and some form of collaboration between the FDA and FTC, it does not do so at the expense of common understanding between the agencies and their constituents. Frequently updated lists of AI/ML-enabled devices and easy-to-navigate websites, for example, are two ways to facilitate clear communication between regulatory authority and the general public.

3. Addressing Potential Pushback

Medical device manufacturers will likely resist the proposed rule, primarily because the FDA has a reputation of taking a long time to approve medical devices.[177] Critics might argue that imposing more procedures for AI/ML-enabled medical devices will only extend the approval timeline and cause innovation in the medical field to lag more so than it already does.[178] But the FDA should not sacrifice patient safety in the interest of a speedy process. This argument is not a reason to refrain from regulation, but rather underscores the necessity of a new regulatory framework.[179] Even if prolonging the approval process, these regulations would help decrease medical device manufacturer tort liability should a physician use a device off-label and would thus ultimately be to the benefit of manufacturers.[180]

Another argument from medical device manufacturers may be that the FDA is inconsistent with standards and timeline in its review of "new" devices.[181] This Note's proposed solution addresses the main contributors to this inconsistency: the FDA's discretion through nonbinding guidance and overuse of the 510(k) proposal system.[182]

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176. FTC, P914502, MEMORANDUM OF UNDERSTANDING BETWEEN THE FEDERAL TRADE COMMISSION AND THE FOOD AND DRUG ADMINISTRATION (1971), https://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration [https://perma.cc/Z46P-STE8].

177. *See, e.g.*, Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 2*, 1 JACC BASIC TRANSLATIONAL SCI. 277, 277 (2016) ("[M]oving new medical devices from concept to market takes an average of 3 to 7 years . . . ."); Robert Fenton, *How Long Does the FDA Medical Device Approval Process Take? [Timeline]*, QUALIO (July 27, 2021), https://www.qualio.com/blog/fda-medical-device-approval-process [https://perma.cc/CAV5-KL96]; Elizabeth Cairns, *Device Approval Times Lengthen*, EVALUATE (Jan. 21, 2022), https://www.evaluate.com/vantage/articles/insights/other-data/device-approval-times-lengthen [https://perma.cc/N82P-32VF].

178. *See* Van Norman, *supra* note 177, at 280.

179. *See id.* at 286.

180. *See* Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 520, 530 (Wash. 2017).

181. *See generally* Gerke, *supra* note 5, at 475–77.

182. *See* BOWERS, *supra* note 164, at 1; Gerke, *supra* note 5, at 470–71; INST. MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 15–16 (2011) (citing concern over the 510(k) clearance process).

Using a rule, which is more consistent in its requirements, in this case would promote transparency and long-called-for consistency in the approval process, binding the agency's actions to the rule, unlike with nonbinding guidance.[183]

B. State Regulation to Fill the Gaps

Because state law regulates the practice of medicine, states can directly address off-label use and the practice of medicine in a way that federal agencies cannot.[184] Notably, states have the authority to amend the definition of the "practice of medicine" found within their Regulation of Medicine statute to clarify whether the practice of medicine includes—and if so, to what extent—AI/ML.[185] This is unlikely to happen since very few bills become law, but if such an amendment were to become state law, it might be too permanent of an action in the face of the rapidly changing AI/ML landscape.[186]

State medical boards, alternatively, could be the appropriate entity to act with a more responsive authority over the on-the-ground practice of medicine. Medical boards are tasked with serving "the public by protecting it from incompetent, unprofessional, and improperly trained physicians;"[187] a state's medical board has the oversight authority to promulgate a rule that clarifies the professional standards

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183. *See* 21 U.S.C. § 371(h); CAREY, *supra* note 168, at 1 (quoting Nat'l Latino Media Coal. v. FCC, 816 F.2d 785, 788 (D.C. Cir. 1987)); Shick et al., *supra* note 12, at 3 (explaining how the FDA currently promotes transparency and noting concerns with transparency as it relates to AI/ML devices); Dee Gill, *A Tool to Make FDA Drug Approval Practices Transparent*, UCLA ANDERSON REV. (Jan. 16, 2019), https://anderson-review.ucla.edu/fda-flexibility/ [https://perma.cc/PW5H-99LP] ("The FDA often *makes exceptions to its own approval guidelines*, sometimes deeply frustrating patients and drug sponsors that do not understand why one drug passed while another failed.") (emphasis added); *FDA in Brief: FDA Announces Draft Guidances to Help Increase Transparency, Assist Reporting and Timely Completion for Certain Medical Device Studies After FDA Approval or Clearance*, FDA (May 26, 2021), https://www.fda.gov/news-events/press-announcements/fda-brief-fda-announces-draft-guidances-help-increase-transparency-assist-reporting-and-timely [https://perma.cc/J7EF-J2P5].

184. *See* UNDERSTANDING MEDICAL REGULATION IN THE UNITED STATES, *supra* note 60.

185. *See* U.S. CONST. amend. X; N.Y. EDUC. LAW § 6521 (McKinney 2014); FLA. STAT. § 458.305(3) (2023).

186. *See* Sanders, *supra* note 168 (noting that 80 percent of proposed bills in North Carolina fail to become law); *The Main Purpose of State Legislatures: A Comprehensive Guide*, GOOD PARTY (July 6, 2023), https://goodparty.org/blog/article/the-main-purpose-of-state-legislatures [https://perma.cc/DS84-T9QW].

187. Carlson & Thompson, *supra* note 90, at 311; *see About Physician Discipline*, FED'N ST. MED. BDS., https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-discipline/ [https://perma.cc/VS8N-SCWC] (last visited Feb. 26, 2024) (outlining the role of Medical Boards in regulating the practice of medicine and in physician discipline).

for the "practice of medicine."[188] Furthermore, as a more flexible process than amending state law, this form of practitioner oversight would be a more efficient option in light of the evolution of AI/ML in medicine.[189] Where the FDA and FTC primarily protect patient-consumers through regulation of devices or other device business practices, state medical boards regulate the medical professionals whose practice directly affects those patient-consumers.[190] The ability of the state medical boards to directly regulate medical practice, and therefore off-label use, could serve to fill the gap in which the FDA and FTC may only regulate indirectly.[191]

As AI becomes commonplace in every discipline, collaboration between professionals to better educate current and future doctors on the risks of off-label use of AI/ML-enabled medical devices could additionally mediate some safety and privacy concerns. Like lawyers, doctors in most states must satisfy continuing medical education (CME) requirements to maintain board certification.[192] State medical boards have the authority to require doctors to complete CME courses that cover AI/ML to maintain their licensure or encourage such lessons in medical school educational curricula.[193] As this issue implicates law, healthcare, and computer science, ideally the CME would be the product of an interdisciplinary effort of lawyers, physicians, and AI/ML computer scientists—with room for input from both FDA and FTC

188. *See* Carlson & Thompson, *supra* note 90, at 311. *See, e.g.*, N.Y. EDUC. LAW § 6521; FLA. STAT. § 458.305(3); TENN. CODE ANN. § 63-6-101 (2021) (conferring administrative powers to the board of medical examiners); DIV. ADMIN. RULES, N.Y. DEP'T ST., WHAT IS RULE MAKING IN NEW YORK? (2022), https://dos.ny.gov/system/files/documents/2022/02/whatisrulemaking_flyer_0_0.pdf [https://perma.cc/4P3A-5KJ7] (describing a rulemaking process similar to the federal level).

189. *See* Sanders, *supra* note 168.

190. *See About Physician Discipline*, *supra* note 187; *Protecting Consumer Privacy and Security*, *supra* note 63; 21 C.F.R. § 1.76 (2024).

191. *See FDA Off-Label Use Information Sheet*, *supra* note 66.

192. *See CME Guide: Continuing Medical Education Requirements by State*, CMELIST (Apr. 16, 2018), https://www.cmelist.com/state-cme-requirements/ [https://perma.cc/XDF5-H3SP]. All but five states—Colorado, Indiana, Montana, New York, and South Dakota—require some sort of continuing medical education for doctors to maintain their licenses. *Id.*

193. *See CME State Requirements*, AM. COLL. SURGEONS, https://www.facs.org/for-medical-professionals/education/tools-and-platforms/mycme/cme-state-requirements/ [https://perma.cc/3B54-KK2E] (last visited Feb. 26, 2024). For example, Texas requires twenty-four CME hours every two years. *Continuing Medical Education for MDs/DOs*, TEX. MED. BD., https://www.tmb.state.tx.us/page/resources-cme-for-md-dos [https://perma.cc/N2XW-R3UD] (last visited Feb. 26, 2024). Of these twenty-four hours, two must be in medical ethics and two in pain management and the prescription of opioids. *See id.* Physicians must also complete a course in human trafficking prevention to renew their license. *See id.*

experts that may provide another shield if faced with liability for such use.[194]

A blanket CME requirement from states may not completely resolve the issue, as some doctors are less likely to interact with the technology to the extent that this Note suggests,[195] but medical specialty boards could nonetheless require additional CME of those physicians that work directly or especially with AI/ML-enabled medical devices.[196] CME requirements established by a state do not discriminate according to practice specialty, but it is within the power of a medical specialty board to determine its own preferred practices and would be in its interest to encourage full competency and reduce patient safety concerns.[197] Doctors are not presently required to learn about AI/ML, and therefore it is not reasonably within the scope of the "practice of medicine."[198] That being so, implementing the CME described above could bring AI/ML use within the purview of medical

194. *See Why Accredited CME Matters*, ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., https://www.accme.org/why-accredited-CME-matters [https://perma.cc/24TJ-4PPT] (last visited Feb. 26, 2024) (explaining the benefits of accredited CME for physicians and participant programs); *Standards for Integrity and Independence in Accredited Continuing Education*, ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC. (Dec. 2022), https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce [https://perma.cc/JWX8-2V8E] ("Standard 1: Ensure content is valid.").

195. A pediatrician, for example, is less likely to use complex AI/ML-enabled medical devices than a radiologist. *See Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, *supra* note 19 (listing 122 AI/ML-enabled device approvals in Radiology but none in Pediatrics).

196. *See What Is ABMS Board Certification?*, AM. BD. MED. SPECIALTIES, https://www.abms.org/board-certification/ [https://perma.cc/6XNU-9RZ2] (last visited Feb. 26, 2024).

197. *See About Accreditation*, ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., https://www.accme.org/about-accreditation [https://perma.cc/LE6B-KALZ] (last visited Feb. 26, 2024) (listing several benefits of CME including "[enhancement of the clinician's] knowledge, skills, and ability to deliver safe, compassionate, and effective care for [their] patients" and the ability for education providers to "make a meaningful difference in the lives of patients and their communities"). *See, e.g.*, *Continuing Medical Education for MDs/Dos*, *supra* note 193 (explaining Texas CME requirements for MDs/Dos); *Medical Doctor – Unrestricted*, FLA. BD. MED., https://flboardofmedicine.gov/renewals/medical-doctor-unrestricted/#tab-cme [https://perma.cc/2368-CSXT] (last visited Feb. 26, 2024) (describing Florida's CME requirements for MDs); *State Regulation of Physicians*, USLEGAL, https://physicians.uslegal.com/state-regulation-of-physicians/ [https://perma.cc/2X75-5H79] (last visited Feb. 26, 2024) (detailing the powers of state medical boards). *Cf.* TENN. CODE ANN. § 63-1-402(c) (2021) (requiring all licensed physicians who prescribe controlled substances to complete two of their forty hours of CME courses on the federal drug enforcement administration's guidance for prescribing such medications).

198. *See Examination Requirements: Physician Licensure*, *supra* note 143 and accompanying text; *License Requirements for Physicians*, *supra* note 143 and accompanying text. *See, e.g.*, N.Y. EDUC. LAW § 6521 (McKinney 2014); FLA. STAT. § 458.305(3) (2023).

practice, allowing physicians to sufficiently manage the potential risks associated with off-label use of AI/ML-enabled medical devices.[199]

Despite the potential for fostering a well-informed medical profession, not every state requires continuing medical education.[200] Thus, while an accredited CME requirement may be preferable to both medical board regulation and to state law amendments in terms of ease of access and adaptation with the AI landscape, states without CME requirements will have to look first to a medical board's regulation.[201] Additionally, while it may be easier to implement CME requirements than to amend state law, practical application may be hampered for medical boards that lack accessibility to adequate resources.[202] Insufficient resources to review granular requirements for re-licensure makes it unlikely that a medical board would implement the CME requirement proposed above, but if proposed in the name of patient safety, the FDA may have some role in facilitating such procedures.[203] The likelihood of doctors becoming sufficiently sophisticated in AI/ML such that they can flawlessly use every AI/ML-enabled device off-label is unlikely,[204] but with adequate CME training, a physician may, at the very least, safely use AI-enabled devices.[205]

IV. CONCLUSION

With the increasing sophistication of AI/ML and its rapidly growing integration in the healthcare industry, definitive regulation is

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199. The Accreditation Council for Continuing Medical Education has demonstrated interest in AI education. *See ACCME Newsletter: Learn More About Learn to Thrive PLUS; Participate in the Learn to Thrive 2024 Call for Proposals; Check Out the 2024–25 Annual Accreditation Fees*, ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC. (Sept. 28, 2023), https://accme.org/september-23-newsletter [https://perma.cc/T42W-JQBG] (promoting a session topic on the use of AI in medicine).

200. *See CME Guide: Continuing Medical Education Requirements by State*, *supra* note 192.

201. *See id.*

202. *See* Sanders, *supra* note 168; *see, e.g.*, *Board of Medical Examiners*, TENN. DEP'T HEALTH, https://www.tn.gov/health/health-program-areas/health-professional-boards/me-board/me-board/statutes-and-rules.html [https://perma.cc/2BJE-8ABV] (last visited Feb. 26, 2024).

203. *See* Jaqueline Landess, *State Medical Boards, Licensure, and Discipline in the United States*, 17 FOCUS: J. LIFELONG LEARNING PSYCHIATRY 337, 340 (2019) ("[O]ften SMB funding and resources are scarce . . . ."). Disciplinary enforcement of the CME by the medical board would suffer for the same reason. *See id.*; *Georgia Composite Medical Board – Physician Oversight*, GA. DEP'T AUDITS & ACCTS. (Nov. 24, 2020), https://www.audits.ga.gov/PAO/19-14_GCMB.html [https://perma.cc/25QB-RX9X] (reporting that only 2% of cases resulted in formal discipline).

204. *See* Price, *supra* note 5, at 423. *See generally* Brown, *supra* note 23.

205. *See About Accreditation*, *supra* note 197 and accompanying text; *see, e.g.*, N.Y. EDUC. LAW § 6521 (McKinney 2014); FLA. STAT. § 458.305(3) (2023) (defining "practice of medicine").

crucial to ensure patient safety. The FDA, with its authority over medical device approval, has indicated interest in regulation through topic-adjacent guidance documents, conferences, and a proposed guidance document on PCCPs.[206] However, it has overlooked potential off-label use of these devices.[207] Physicians are typically able to use medical devices off-label in the "practice of medicine," but the statutory definition makes no mention of AI/ML, and they are not trained in the area.[208] Using these devices off-label, without adequate training, could lead to significant patient harm and relying on a patchwork of state approaches leaves patient protections inconsistent and location-dependent.[209]

The FDA should attempt to remedy the potential harms of off-label use of AI/ML-enabled devices by promulgating a rule that requires medical device manufacturers to consider the foreseeable risks associated with using the device off-label. It should work with the FTC to ensure patient-consumer safety and cybersecurity on this issue and enhance communication with the general population. Additionally, medical boards can directly oversee physician practices by mandating CME on AI/ML-enabled medical devices as a prerequisite for license renewal. The more complex and less transparent the algorithm or device, the greater the challenge for physicians to employ it responsibly, particularly for off-label purposes. Therefore, a dual strategy of mandating manufacturer transparency as guided by the FDA, in tandem with medical board enforcement of regulations and CME prerequisites, could substantially support physicians in their use of AI/ML medical devices. This approach would better safeguard patient welfare and ensure efficacious treatment.

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206. *See* 2019 Discussion Paper, *supra* note 9, at 3; 2021 ACTION PLAN, *supra* note 10, at 2; 2023 PROPOSED GUIDANCE, *supra* note 11, at 2. *See, e.g.*, *Patient Engagement Advisory Announcement*, *supra* note 96.

207. *See generally* Clark et al., *supra* note 58.

208. *See Off-Label Use of Medical Products*, *supra* note 16; *see, e.g.*, N.Y. EDUC. LAW § 6521; FLA. STAT. § 458.305(3).

209. *See Off-Label Use of Medical Products*, *supra* note 16; *CME Guide: Continuing Medical Education Requirements by State*, *supra* note 192.

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