AN ARTIFICIALLY INTELLIGENT APPROACH TO MEDICAL DEVICE MONITORING

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ABSTRACT

The integration of artificial intelligence (AI) in medical devices, particularly the subset of AI technologies known as machine learning, has sparked a new era of precision and efficiency in healthcare. AI/ML-enabled medical devices are proving to be invaluable as they have already improved patient diagnosis, treatment, and disease prediction. As machine learning continues to be adopted in medical devices, the U.S. Food and Drug Administration (FDA) continues to receive more marketing submissions and pre-submissions for AI/ML-enabled medical devices, a trend that is expected to increase over time. While the FDA has made significant progress in proposing regulatory frameworks that will implement the use of AI/ML-enabled medical devices, it has not considered whether these devices should be monitored based on the level of risk they pose. Therefore, this Comment aims to advance conversations that will promote the safe use of machine learning in healthcare and argues that the FDA should adopt a risk-based approach to the monitoring of AI/ML-enabled medical devices. Adopting such an approach is warranted for several reasons and will provide significant benefits to manufacturers, patients, and the FDA. By tailoring monitoring requirements to device risk levels, the FDA can strike a balance between ensuring patient safety and fostering efficiency in the rapidly evolving field of machine learning in healthcare.

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TABLE OF CONTENTS

INTRODUCTION

Central to the prevention, diagnosis, and treatment of illnesses and diseases, medical devices play a critical role in patient healthcare. Traditionally, a medical device's performance was predictable, limited to providing expected results within a fixed scope of possibilities. Common examples of such devices include thermometers, blood pressure monitors, and X-ray machines. However, with the emergence of artificial intelligence (AI), particularly machine learning, medical devices can now learn from data and achieve unexpected results, effectively transcending the capabilities of traditional medical devices. Today, medical devices that utilize machine learning are increasingly being used in the healthcare industry to improve patient care, increase operational efficiency, and contribute towards the development of medical solutions.[1] Remarkably, these devices have demonstrated performances on par with healthcare practitioners in task-specific applications.[2]

Given that the healthcare industry accounts for 11% of the global GDP, entrepreneurs are striving to integrate machine learning into medical tools to achieve unprecedented efficiency for healthcare stakeholders. Consequently, the U.S. Food and Drug Administration (FDA) has experienced a notable increase in marketing submissions and pre-submissions for AI/ML-enabled medical devices over the past decade, a trend that is expected to continue.[3] Companies developing such devices have successfully infiltrated medical specialties such as radiology, cardiology, orthopedics, anesthesiology, and pathology.[4] According to the latest data, as of October 19, 2023, the FDA has authorized 694 AI/ML-enabled medical devices, highlighting the significant presence of these devices in the market.[5]

While the benefits of integrating AI/ML-enabled medical devices into patient care are undeniable, these devices pose novel regulatory challenges, as their market performance may differ from their initial pre-market testing due to their ability to learn and adapt over time.[6] This unpredictability in market

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[1] *See* ARTIFICIAL INTELLIGENCE IN HEALTHCARE 51–52 (Adam Bohr & Kaveh Memarzadeh eds., 2020).

[2] *See* Anders Lenskjold et al., *Should Artificial Intelligence Have Lower Acceptable Error Rates Than Humans?*, BJR OPEN, 1–2 (Apr. 13, 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10301708/.

[3] *See* FDA, *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices* (Oct. 19, 2023), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices ("Over the past decade, the FDA has reviewed and authorized a growing number of devices (marketed via 510(k) clearance, granted De Novo request, or premarket approval) with AI/ML across many different fields of medicine—and expects this trend to continue.").

[4] *See id.*

[5] *See id.*

[6] *See* FDA, PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) 3 ("To date, FDA has cleared or approved several AI/ML-based SaMD. Typically, these have only included algorithms that are 'locked' prior to marketing, where algorithm changes likely require

performance presents risks that make the safe and effective implementation and regulation of these devices a present concern and necessity. Since 2019, the FDA has responded to advances in AI/ML-enabled medical devices by proposing regulations and seeking industry feedback on their current plans.[7] One such proposal suggests the continuous monitoring of these devices to evaluate their real-world performance.[8] However, this approach is impractical for several reasons, including its myopic nature, burden on stakeholders, increased healthcare costs, and inefficiencies in resource allocation for both manufactures and the FDA.

While the FDA has made significant progress in proposing regulatory frameworks to govern the usage of AI/ML-enabled medical devices, it has not considered whether these devices should be monitored based on the level of risk they pose. This Comment advocates for the FDA to adopt a risk-based approach to the real-time monitoring of AI/ML-enabled medical devices, enabling manufacturers to prioritize the monitoring of high-risk devices. Such an approach would provide numerous benefits for patients, manufacturers, and the FDA, including the efficient allocation of resources, increased safety, and the encouragement of innovation.

Part I provides an overview of the development of AI in medical devices and introduces key definitions. Part II examines the FDA's proposed regulatory framework and emphasizes its shortcomings. Part III outlines the reasons for adopting risk-based monitoring for AI/ML-enabled medical devices. Part IV outlines the advantages of adopting such an approach. Lastly, part V suggests specific regulatory amendments to facilitate the efficient monitoring of these devices.

I. THE RISE OF AI IN MEDICAL DEVICES

A. ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING

AI is a broad field of computer science that focuses on building smart machines capable of performing tasks that typically require human intelligence.[9]

FDA premarket review for changes beyond the original market authorization. However, not all AI/ML-based SaMD are locked; some algorithms can adapt over time.").

[7] *See* FDA, *Artificial Intelligence and Machine Learning in Software as a Medical Device* (Sep. 22, 2021), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device ("The Action Plan is a direct response to stakeholder feedback to the April 2019 discussion paper, 'Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device' and outlines five actions the FDA intends to take.").

[8] *See* FDA, *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* 1, 6 (2021), https://www.fda.gov/media/145022/download ("As part of this Action Plan, the Agency will support the piloting of real-world performance monitoring by working with stakeholders on a voluntary basis.").

[9] *See* Iqbal H. Sarker, *AI-Based Modeling: Techniques, Applications and Research Issues Towards Automation, Intelligent and Smart Systems*, SN COMPUT. SCI. (Feb. 10, 2022),

These tasks include functions such as perception, reasoning, learning, planning, and prediction.[10] Consequently, AI encompasses many fields of study including machine learning, natural language processing, and search algorithms.[11] Accordingly, there is not a single widely accepted definition for AI used by all.[12] However, the FDA defines AI as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.[13] Despite the lack of a universally accepted definition, AI is generally used to refer to the simulation of human intelligence by a system or a machine.[14] Much like humans, AI finds application in various sectors and impacts industries such as banking, finance, logistics, marketing, coaching services, customer relationship management, and, as emphasized in this Comment, healthcare.[15]

Similarly, machine learning serves as an umbrella term encompassing a wide array of algorithms capable of intelligent predictions based on a given dataset.[16] This predictive capability, akin to learning, distinguishes machine

https://doi.org/10.1007/s42979-022-01043-x ("Artificial intelligence (AI) is a broad field of computer science concerned with building smart machines capable of performing tasks that typically require human intelligence.").

[10] *See* Yongjun Xu et al., *Artificial Intelligence: A Powerful Paradigm for Scientific Research*, THE INNOVATION (Oct. 28, 2021), https://doi.org/10.1016/j.xinn.2021.100179 ("The goal of AI is to develop a machine that can think like humans and mimic human behaviors, including perceiving, reasoning, learning, planning, predicting, and so on.").

[11] *See id.* ("Numerous scientists are focusing on the field of AI, and this makes the research in the field of AI rich and diverse. AI research fields include search algorithms, knowledge graphs, natural languages processing, expert systems, evolution algorithms, machine learning (ML), deep learning (DL), and so on.").

[12] *See* Michael Cheng-Tek Tai, *The Impact of Artificial Intelligence on Human Society and Bioethics*, TZU CHI MED. J. (Aug. 14, 2020), https://journals.lww.com/tcmj/fulltext/2020/32040/the_impact_of_artificial_intelligence_on_human.5.aspx ("Artificial intelligence (AI) has many different definitions.").

[13] *See* Artificial Intelligence Medical Devices (AIMD) Working Group, *Machine Learning-Enabled Medical Devices: Key Terms and Definitions*, INT'L MED. DEVICE REGULS. F. 1, 4 (May 6, 2022), https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20AIMD%20WG%20Final%20Document%20N67.pdf ("Artificial Intelligence (AI) is a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions.").

[14] *See* Xu et al., *supra* note 10 ("AI refers to the simulation of human intelligence by a system or a machine.").

[15] *See* Donghau Chen et al., *The Impact of Artificial Intelligence on Firm Performance: An Application of the Resource-Based View to e-Commerce Firms*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Apr. 7, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9022026/ ("A broad study of the impact of AI and its capability on business performance appears. The existing literature dedicated to the study of the impact of AI on industries, such as banking and finance, manufacturing, automated retailing, logistics, marketing, coaching services, and customer relationship management, among other areas.").

[16] *See* James A. Nichols et al., *Machine learning: applications of artificial intelligence to imaging and diagnosis*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Sep. 4, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6381354/ ("Machine learning (ML) is an umbrella term that refers to a broad range of algorithms that perform intelligent predictions based on a data set.").

learning technology and makes it unique. The FDA defines machine learning as a subset of AI that allows machine learning models to be developed by machine learning training algorithms through analysis of data, without being explicitly programmed.[17] One of the most notable demonstrations of machine learning capabilities is Google's AlphaGo Zero.[18] After only three days of reinforcement learning and forty days of self-learning, AlphaGo Zero was considered the best Go player of all time.[19] Naturally, this impressive achievement sparks contemplation on the substantial role machine learning may potentially serve in the healthcare industry.[20]

In healthcare, machine learning has been applied to aid in the early detection and diagnosis of diseases, the creation of personalized diagnostics and therapeutics, and the development of supportive functions aimed at enhancing the utilization of devices.[21] It has also been applied in clinical medicine to aid in segmentation of radiological images and classification of images in diagnostic categories.[22] This diverse utilization highlights the ability of machine learning to be effectively used in various settings. However, machine learning's ability to efficiently analyze medical images makes it particularly well-suited for the field of radiology, where vast electronic databases containing standardized

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[17] *See* Artificial Intelligence Medical Devices (AIMD) Working Group, *supra* note 13, at 7 ("The subset of AI known as Machine Learning (ML) allows ML models to be developed by ML training algorithms through analysis of data, without models being explicitly programmed.").

[18] *See* Nichols et al., *supra* note 17.

[19] *See id.*

> Google's AlphaGo Zero is an advanced example of unsupervised learning, where adversarial neural network models competed to learn winning moves in the game of Go. After only [three] days of reinforcement learning, AlphaGo Zero surpassed the level of the first supervised learning model from 2016, AlphaGo Lee; and after [forty] days of self-learning, it became the best Go player of all time, man or machine, and all with no human intervention.

Id.

[20] *See* Christof Kock, *How the Computer Beat the Go Master*, SCI. AM. (Mar. 19, 2016), https://www.scientificamerican.com/article/how-the-computer-beat-the-go-master/

> With its breadth of 250 possible moves each turn (go is played on a [nineteen] by [nineteen] board compared to the much smaller eight by eight chess field) and a typical game depth of 150 moves, there are about 250, or [ten] possible moves. This is a number beyond imagination and renders any thought of exhaustively evaluating all possible moves utterly and completely unrealistic.

Id.

[21] *See* U.S. Food and Drug Administration, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions* (Apr. 3, 2023), https://www.fda.gov/media/166704/download ("Examples of ML applications in [thirty-one] medicine include earlier disease detection and diagnosis, development of personalized [thirty-two] diagnostics and therapeutics, and development of assistive functions to improve the use of [thirty-three] devices with the goal of improving user and patient experience.").

[22] *See* Nichols et al., *supra* note 16 ("The applications of machine learning to clinical medicine align strongly with computer vision tasks of detection, segmentation and classification; for example, the detection of the presence or absence of metastases on histological sections, segmentation of radiological images into known anatomical correlates and the classification of images into certain diagnostic categories.").

images with labeled diagnoses already exist.[23] However, the application of machine learning in medicine is not without its caveats. The effectiveness of an algorithm's output is dependent on the data quality, which could potentially lead to erroneous conclusions if the training set is not properly analyzed.[24]

Ultimately, AI and machine learning based technologies have the ability to transform the healthcare industry by gathering new insights from the vast amount of data obtained daily during the delivery of healthcare.[25]

B. CONVENTIONAL MEDICAL DEVICES

Since the passage of the Medical Device Amendments Act in 1976, the FDA has assumed authority over a wide range of medical devices, placing them into various categories, including physical medicine devices, radiology devices, cardiovascular devices, dental devices, and more.[26] Over the years, numerous essential medical devices have come under the purview of the FDA, including crutches, mechanical wheelchairs, stationary X-ray systems, and magnetic resonance devices.[27] Despite their significant roles in modern healthcare, these devices have inherent limitations. Primarily, their functionality is dependent on human operation and interpretation, which limits their efficiencies to that of their users. Additionally, the absence of machine learning technology precludes them from continuously improving their performance in real-time without assistance.

C. AI/ML-ENABLED MEDICAL DEVICES

Today, devices that utilize AI or machine learning technologies are commonly known as AI/ML-enabled medical devices.[28] These devices have the ability to transform the healthcare industry by extracting new insights from the vast amount of data obtained daily during the delivery of healthcare.[29] One of

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[23] *See id.* ("A field highly suited to classification applications of machine learning algorithms is that of radiology where large electronic databases of standardized images with labelled diagnoses already exist, and computer-aided diagnosis (CAD) is a rapidly emerging field.").

[24] *See id.*

> ML applications in medicine are not without pitfalls. Cabitza et al. argue that skill reduction in medical practitioners is a distinct possibility. The quality of the output of an algorithm is also largely determined by the quality of the data, which can result in erroneous conclusions if the training set is not correctly vetted.

Id.

[25] *See* FDA, *supra* note 6 ("Artificial intelligence (AI)-and machine learning (ML)-based technologies have the potential to transform healthcare by deriving new and important insights from the vast amount of data generated during the delivery of healthcare every day.").

[26] *See generally* 21 C.F.R. §§ 814–92 (2023).

[27] *See generally* 21 C.F.R. §§ 890–92 (2023).

[28] *See* FDA, *supra* note 3 ("The FDA is providing this list and insights of AI/ML-enabled medical devices marketed in the United States as a resource to the public about these devices and the FDA's work in this area.").

[29] *See* FDA, *supra* note 6 ("Artificial intelligence (AI)-and machine learning (ML)-based technologies have the potential to transform healthcare by deriving new and important insights from the vast amount of data generated during the delivery of healthcare every day.").

their greatest benefits is their ability to learn from real-world use and experience, resulting in improved performance over time.[30] Notable applications for these devices include the early detection of diseases, more accurate diagnosis, identification of new observations or patterns in human physiology, and the advancement of personalized diagnostics and therapeutics.[31] Remarkably, they have even demonstrated performance comparable to healthcare practitioners in certain applications.[32]

As of October 19, 2023, data reveals that the FDA has authorized 694 AI/ML-enabled medical devices, emphasizing the significant presence of these devices in the market.[33] These devices are used across various medical specialties, including radiology, screening, psychiatry, primary care, disease diagnosis, and telemedicine.[34] Of these, most fall within the medical specialties of radiology and cardiology, with 533 devices pertaining to radiology, and seventy devices pertaining to cardiology.[35] However, the prevalence of these devices today was not as significant in the past as they are now. Notably, most of the recent advances have been within radiology due to the large datasets available of radiological imaging acquired by clinicians.[36]

D. NOVEL ISSUE RAISED BY AI/ML-ENABLED MEDICAL DEVICES

The uniqueness of AI/ML-enabled medical devices stems from their integration of software that utilizes machine learning.[37] Accordingly, these devices are capable of improving their output performance through iterative

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[30] *See id.* ("One of the greatest benefits of AI/ML in software resides in its ability to learn from real-world use and experience, and its capability to improve its performance.").

[31] *See id.*, at 2 ("Example high-value applications include earlier disease detection, more accurate diagnosis, identification of new observations or patterns on human physiology, and development of personalized diagnostics and therapeutics.").

[32] *See* Lenskjold et al., *supra* note 2 ("Previous studies have found a 3–6% human error rate on general radiographic examinations and a 10–14% on knee osteoarthritis binary scoring compared to experts in a controlled research environment. The same AI algorithm that failed in our implementation had a 13% error rate in an external validation.").

[33] *See* FDA., *supra* note 3 (listing the authorized medical devices in the October 19, 2023 update).

[34] *See generally id*. (listing a large variety of medical specialties in the various AI/ML-enabled devices are used).

[35] *See generally id.* (listing most AI/ML-enabled devices as pertaining to radiology and cardiology).

[36] *See* Ahmed Hosny et al., *Artificial Intelligence in Radiology*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6268174/ (last visited Mar. 18, 2024) ("As imaging data are collected during routine clinical practice, large data sets are—in principle—readily available, thus offering an incredibly rich resource for scientific and medical discovery. Radiographic images, coupled with data on clinical outcomes, have led to the emergence and rapid expansion of radiomics as a field of medical research.").

[37] *See* FDA, *supra* note 3.

> As technology continues to advance every aspect of health care, software incorporating artificial intelligence (AI), and specifically the subset of AI known as machine learning (ML), has become an important part of an increasing number of medical devices. One of the greatest potential benefits of AI/ML resides in its ability to create new and important insights from the vast amount of data generated during the delivery of health care every day.

Id.

modifications by learning from real-world data as it is gathered.[38] This results in medical devices that continuously refine themselves over time, much like medical professionals honing their work performance with experience. However, conventional medical devices had predictable outputs based on particular inputs, and the FDA's traditional regulatory paradigm for medical devices was not tailored for adaptive artificial intelligence and machine learning technologies.[39] Thus, overseeing AI/ML-enabled medical devices presents new challenges for the FDA. As such, the FDA is currently proposing regulations designed to implement machine learning technologies, capitalizing on their advantages while ensuring patient safety and device effectiveness.[40]

II. FDA'S PROPOSED REGULATIONS

The FDA, an agency of the Department of Health and Human Services, is entrusted with regulating the production, sale, and distribution of food, drugs, medical devices, and cosmetics under the 1938 Federal Food, Drug, and Cosmetic Act (FDCA).[41] With the mission to safeguard public health, the FDA ensures the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.[42] The FDA also has a longstanding dedication to devising and implementing innovative strategies for overseeing medical device software and other digital health technologies to ensure their safety and effectiveness.[43] Since 2019, the FDA has actively sought industry guidance to regulate AI/ML-enabled medical devices, aiming for their safe and effective integration into the medical field.[44] Despite significant progress, the current proposed FDA regulations could be further improved, particularly in terms of considering risk-based monitoring for these devices.

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[38] *See id.* ("One of the greatest potential benefits of ML resides in the ability to improve ML model performance through iterative modifications, including by learning from real-world data.").

[39] *See* FDA, *supra* note 7 ("The FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies.").

[40] *See* FDA, *supra* note 6.

[41] *See* U.S. Food and Drug Administration, *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do ("FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.").

[42] *See id.* ("The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.").

[43] *See* FDA, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions* (Apr. 2023) ("FDA [has a] longstanding commitment to develop and apply innovative approaches to the regulation of medical device software and other digital health technologies to ensure their safety and effectiveness.").

[44] *See* FDA, *supra* note 7.

A. FDA INITIATIVES FOR REGULATING AI/ML-ENABLES MEDICAL DEVICES

On April 2, 2019, the FDA initiated its response to advances of AI in healthcare with the release of a discussion paper, "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device (SaMD)."[45] This marked the beginning of the FDA's efforts to regulate AI/ML-enabled medical devices and gather stakeholder feedback. The 2019 discussion paper outlines the basis for a potential strategy to premarket review for machine learning driven software modifications.[46] Notably, the FDA evidenced its plan to require real-world performance monitoring for AI/ML-enabled medical devices.[47]

This intent for real-world performance monitoring was reiterated in its January 12, 2021, action plan "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan."[48] It outlines the FDA's approach to regulating AI/ML-enabled medical devices in a holistic, collaborative, and multidisciplinary manner.[49] Ultimately, the action plan details five intended actions by the FDA, two of which are of particular relevance. First, it intends to update the proposed regulatory framework for these devices by issuing a draft guidance on a predetermined change control plan.[50] Second, it will advance real-world pilots to clarify what a real-world evidence generation program could look like for AI/ML-based medical devices.[51]

Most recently, on March 3, 2023, the FDA published a draft guidance titled "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions" proposing the establishment of a predetermined change control plan that would permit postmarket modifications based on real-time learning while upholding the software's safety and effectiveness.[52] It is intended to foster a forward-thinking strategy for the advancement of devices

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[45] *See* FDA, *supra* note 6.

[46] *See id.*

> To address the critical question of when a continuously learning AI/ML SaMD may require a premarket submission for an algorithm change, we were prompted to reimagine an approach to premarket review for AI/ML-driven software modifications. Such an approach would need to maintain reasonable assurance of safety and effectiveness of AI/ML-based SaMD, while allowing the software to continue to learn and evolve over time to improve patient care.

Id.

[47] *See id.* ("To fully adopt a TPLC approach in the regulation of AI/ML-based SaMD, manufacturers can work to assure the safety and effectiveness of their software products by implementing appropriate mechanisms that support transparency and real-world performance monitoring.").

[48] *See* FDA, *supra* note 8.

[49] *See id.*

[50] *See id.*

[51] *See id.* ("Advance real-world performance pilots in coordination with stakeholders and other FDA programs, to provide additional clarity on what a real-world evidence generation program could look like for AI/ML-based SaMD.").

[52] *See* FDA, *supra* note 41.

using machine learning models trained by machine learning algorithms.[53] The predetermined change control plan will enable the FDA to embrace the iterative improvement capabilities machine learning based software as a medical device, while ensuring patient safety.[54] The predetermined change control plan was proposed as a "least burdensome approach to support iterative improvement" of machine learning-enabled device software functions "while continuing to provide a reasonable assurance of device safety and effectiveness."[55]

B. REAL-WORLD PERFORMANCE MONITORING

As the presence of AI continues to grow in the healthcare industry, it only makes sense that the FDA begins to implement measures to manage these systems and safeguard against any malfunctions. Accordingly, the FDA's inclination towards implementing monitoring for AI/ML-enabled medical devices to evaluate their real-world performance seems well-founded. Monitoring, in this context, refers to software or hardware that operates simultaneously with a component and monitors, records, analyzes, or verifies its activity.[56] This process emphasizes the interpretation of the collected metrics related to the observed object.[57] Typically, monitoring involves the following steps: (1) identification of abnormal values, (2) determination of potential causes, and (3) consideration of appropriate corrective actions.[58] The primarily goal of monitoring is to detect quality issues and propose effective counter-measures.[59] In the context of AI, monitoring involves the continuous observation and analysis of AI applications to ensure the optimal performance and resource efficiency of these applications.[60] This involves the ongoing tracking of various metrics, including model performance, resource consumption, and cost tracking.[61] By continuously tracking various metrics, monitoring teams can ensure the smooth operation of AI applications and promptly address issues that arise.[62]

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[53] *See id.* ("This draft guidance is intended to provide a forward-thinking approach to promote the development of safe and effective medical devices that use ML models trained by ML algorithms.").
[54] *See id.*
[55] *See id.* ("This draft guidance proposes a least burdensome approach to support iterative improvement through modifications to an ML-DSF while continuing to provide a reasonable assurance of device safety and effectiveness.").
[56] *See* Tim Schroder, *Monitoring machine learning models: a categorization of challenges and methods*, SCI. DIRECT (Aug. 2, 2022), https://www.sciencedirect.com/science/article/pii/S2666764922000303 ("A monitor refers to software or hardware that operates simultaneously with a component and monitors, records, analyzes, or verifies its activity.").
[57] *See id.*
[58] *See id.*
[59] *See id.*
[60] *See* Marie Fayard, *What Is AI Monitoring and Why Is It Important*, CORALOGIX (Aug. 16, 2023), https://coralogix.com/blog/ai-monitoring/.
[61] *See id.*
[62] *See id.*

Nevertheless, despite the benefits offered by monitoring AI/ML-enabled medical devices, it also presents certain challenges.[63] Primarily, effectively monitoring AI requires a carefully considered plan that accounts for the specific metrics, inherent characteristics of devices, and complexity of the external environment.[64] Merely subjecting each AI-enabled device to the same monitoring standards is inadequate as it fails to consider the unique characteristics and external environments presented by each device.[65] Consequently, manufacturers of AI/ML-enabled medical devices will soon encounter new challenges when introducing these devices to the market as they must ensure that each device is appropriately accounted for with a unique monitoring plan. By developing a regulatory framework which accounts for the unique characteristics and external environments of these devices, the FDA will assist manufacturers in successfully monitoring these devices.

C. CHALLENGES WITH MONITORING EACH AI/ML-ENABLED MEDICAL DEVICE

Throughout these developments, the FDA has maintained its commitment to continuously monitor each AI/ML-enabled medical device to evaluate its real-world performance. While AI monitoring represents a positive initiative to safeguard the public health, this monitoring strategy is hindered by its myopic nature, burden on stakeholders, increased healthcare costs, and inefficiencies in resource allocation for both manufactures and the FDA. Requiring manufacturers to monitor each of the potentially thousands of FDA-cleared AI/ML-enabled medical devices will prove burdensome and expensive, while the FDA's oversight of real-world performance for these devices could be equally demanding. This would likely result in increased healthcare costs for patients, as they may be responsible for reimbursing manufacturers for the expenses related to AI monitoring. Moreover, such an approach would lead to inefficient resource allocation, as manufacturers would need to employ personnel to oversee low-risk devices, and the FDA would be tasked with monitoring these devices as well.

An alternative approach, more practical for stakeholders, would involve adopting a risk-based approach to the monitoring requirement for AI/ML-enabled medical devices. Such an approach should not be misconstrued as advocating for reduced monitoring by manufacturers, but rather to call for more targeted oversight to address factors that are most likely to have adverse effects on patient outcomes in high-risk scenarios.

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[63] *See* Zhibin Zhao et al., *Challenges and Opportunities of AI-Enabled Monitoring, Diagnosis & Prognosis: A Review*, CHINESE J. OF MECH. ENG'G (CJME) (June 9, 2021), https://cjme.springeropen.com/articles/10.1186/s10033-021-00570-7#Sec2.
[64] *See id.*
[65] *See id.*

III. REASONS FOR ADOPTING RISK-BASED MONITORING

Several reasons justify the FDA's adoption of a risk-based monitoring approach for AI/ML-enabled medical devices. First, a uniform approach to monitoring these devices is impractical due to the diverse risk levels associated with their intended application in the medical field, as it would not differentiate between non-serious and critical situations or conditions. Second, certain AI/ML-enabled medical devices perform tasks with low error rates similar to those of healthcare practitioners, rendering continuous monitoring of these devices unnecessary.[66] Lastly, the FDA already tailors its regulations based on device risk levels, emphasizing the need to adopt a similar risk-based approach for monitoring AI/ML-enabled medical devices.[67]

A. AI/ML-ENABLED MEDICAL DEVICES PRESENT DIVERSE RISK LEVELS

Although the 694 FDA cleared AI/ML-enabled medical devices offer significant advantages, they are not without their risks.[68] This is consistent with the understanding that all legally-marketed medical devices offer benefits but also entail inherent risks.[69] However, AI/ML-enabled medical devices also present varying levels of risk based on their intended application.[70] For instance, machine learning is commonly incorporated into software as a medical device (SaMD).[71] SaMD refers to software intended for one or more medical purposes that perform these purposes without being part of a hardware medical device.[72] SaMD itself may be used for various purposes, including treating or diagnosing, driving clinical management, or informing clinical management.[73] SaMD is also used in various healthcare situations or conditions, including critical situations or conditions, serious situations or conditions, or non-serious situations or conditions.[74]

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[66] *See* Lenskjold et al., *supra* note 2.
[67] *See* 21 U.S.C. § 360c(a)(1) (2023).
[68] *See* FDA, *Cybersecurity*, https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity (last visited Mar. 19, 2024) ("All legally-marketed medical devices have benefits and risks.").
[69] *See id.*
[70] *See* FDA, *supra* note 3.
[71] *See* FDA, *supra* note 7.
[72] *See* IMDRF, *Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations*, INT'L MED. DEVICE REGUL. F. (Sep. 18, 2014), https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf ("SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.").
[73] *See id.*
[74] *See id.*

A critical situation or condition, in which accurate or timely diagnosis or treatment is vital to avoid death, long-term disability, or other serious deterioration of health of a patient, may involve a type of disease or condition that is life-threatening, requires major therapeutic interventions, or is time critical due to the progression of a disease.[75] A serious situation or condition, where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions or timely interventions are important to mitigate long-term irreversible consequences, may involve a type of disease or condition that is moderate in progression, does not require major therapeutic interventions, or intervention is not normally expected to be time critical in order to avoid death.[76] A non-serious situation or condition, in which an accurate diagnosis or treatment is important but not critical for interventions to mitigate long-term irreversible consequences, may involve a type of disease or condition that is slow with predictable progression of disease state, may not be curable but can be managed effectively, or requires only minor therapeutic interventions.[77]

Given the variance in risk levels associated with the application of machine learning in SaMD, it becomes apparent that a uniform monitoring approach for AI/ML-enabled medical devices is impractical, and regulatory oversight should understandably differ between critical and non-serious situations or conditions. Adopting a risk-based monitoring approach would effectively manage this diversity in risk by prioritizing the oversight of devices in critical situations or conditions.

B. MONITORING CERTAIN AI/ML-ENABLED MEDICAL DEVICES IS UNNECESSARY

Another reason for adopting a risk-based monitoring approach stems from it being unnecessary to monitor certain AI/ML-enabled medical devices. Particularly, studies have shown that some of these devices are already capable of performing diagnostic tasks with error rates on par or better than those of healthcare professionals, rendering their monitoring unnecessary, as similar error rates by humans do not warrant additional oversight.[78] In a recent study conducted by an AI research group at the Department of Radiology at Bispebjerg-Frederiksberg University Hospital, in Copenhagen, Denmark, the goal was to determine an acceptable error rate for a low-risk AI diagnostic algorithm compared to radiologists when diagnosing patients with knee osteoarthritis.[79] The study revealed that humans are willing to accept significantly lower error rates for AI (6.8 %) compared to humans (11.3 %).[80] However, it

[75] *See id.*
[76] *See id.*
[77] *See id.*
[78] *See* Lenskjold et al, *supra* note 2.
[79] *See id.*
[80] *See id.*

also demonstrated that the AI diagnostic algorithm performed just as well as human practitioners, exhibiting an error rate of 13%—while humans exhibited an error rate ranging from 10% to 14%.[81] Consequently, this study highlights the ability of some AI/ML-enabled medical devices to perform diagnostic tasks at a level comparable with healthcare practitioners, emphasizing the need to reevaluate the necessity of monitoring in certain cases. There are also other AI algorithms performing better than humans in various tasks, including analyzing medical images and correlating symptoms from electronic medical records.[82]

However, the FDA's Action Plan suggests to uniformly monitor these devices.[83] This fails to consider that practitioners, performing similar diagnostic tasks with comparable error rates, are only subject to peer review.[84] Peer review is a "continuous, systematic, and critical reflection and evaluation of physician performance using structured procedures."[85] While intended to mitigate and prevent errors, peer review has its limitations.[86] Due to its time and resource intensity, members of a peer review may choose to conduct the process only in significant cases.[87] Furthermore, radiologists' commitment to continuous peer review is limited due to increased workload, a shortage of radiologists, and reluctance to strain relationships with colleagues by providing negative feedback, which hinder their relationships.[88] Accordingly, peer review falls short of continuous AI monitoring as it does not involve oversight of each diagnosis made by a radiologist.[89] Therefore, additional oversight, in the form of continuous AI monitoring, is unnecessary for certain AI/ML-enabled medical devices in healthcare applications where similar requirements for healthcare practitioners are not mandated. For these reasons, certain AI/ML-enabled medical devices should be exempt from the continuous monitoring requirement.

C. FDA ALREADY VARIES REGULATIONS BASED ON MEDICAL DEVICE RISK LEVEL

Implementing a risk-based approach would also be in accordance with the FDA's current approach to regulating all medical devices: hold the riskier devices to a higher standard.[90] The FDA already regulates medical devices

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[81] *See id.*
[82] *See* ARTIFICIAL INTELLIGENCE IN HEALTHCARE, *supra* note 1 ("There is already a large amount of evidence that AI algorithms are performing on par or better than humans in various tasks, for instance, in analyzing medical images or correlating symptoms and biomarkers from electronic medical records (EMRs) with the characterization and prognosis of the disease.").
[83] *See* FDA, *supra* note 8, at 1.
[84] *See* Rathachai Kaewlai & Hani Abujudeh, *Peer Review in Clinical Radiology Practice*, AM. J. OF ROENTGENOLOGY (Nov. 23, 2012), https://www.ajronline.org/doi/full/10.2214/AJR.11.8143.
[85] *Id.*
[86] *See id.*
[87] *See id.*
[88] *See id.*
[89] *See id.*
[90] *See* FDA, *Overview of Device Regulation*, https://www.fda.gov/medical-devices/device-advice-

according to their respective risk-level due to the Medical Device Amendments of 1976 to the FDCA which established three regulatory classes for medical devices.[91] Pursuant to those amendments, each medical device is classified into one of the three classes to determine the level of controls necessary to assure the device's safety and effectiveness.[92] As a device's class increases, so do the regulatory controls.[93]

The classes are either Class I, Class II, or Class III, depending on the devices' intended use, indications for use, and risk level.[94] Class I comprises devices with the lowest risk and Class III comprises devices with the highest risk.[95] Class I devices are "not intended for use in supporting or sustaining life or of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury."[96] These devices are subject to General Controls, which represent the baseline requirements of the FDCA that apply to all medical devices, irrespective of their classification.[97] Class II devices are devices for which "general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device."[98] Therefore, these devices are subject to special controls to provide a reasonable assurance of safety.[99] Class III devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.[100] These devices are subject to premarket approval, in which the applicant must submit an application and demonstrate that it contains sufficient scientific evidence to confirm that the device is safe and effective for its intended uses.[101]

Accordingly, these various standards for medical devices based on their intended use or inherent risk demonstrates how the FDA already uniquely regulates each medical device, emphasizing the need to adopt a similar approach for monitoring each AI/ML-enabled medical device. However, despite the various applications and inherent risks posed by AI/ML-enabled medical devices, the FDA insists on mandating uniform real-time monitoring.[102] This begs the question: why not implement distinct monitoring requirements for AI/ML-enabled

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comprehensive-regulatory-assistance/overview-device-regulation (last visited Mar. 19, 2024).

[91] *See* FDA, *A History of Medical Device Regulation & Oversight in the United States*, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last visited Mar. 19, 2024).

[92] *See* 21 U.S.C. § 360c(a)(1) (2024).

[93] *See id.*

[94] *See id.*

[95] *See id.*

[96] § 360c(a)(1)(A).

[97] *See id.*

[98] § 360c(a)(1)(B).

[99] *See id.*

[100] § 360c(a)(1)(C).

[101] *See* FDA, *Premarket Approval (PMA)*, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma (last visited Mar. 19, 2024).

[102] *See generally* FDA, *supra* note 8, at 6.

medical devices contingent on their intended use or risk levels? Such an approach aligns with the principle that devices posing higher risks should be subjected to stricter scrutiny, while lower-risk devices require less oversight. Therefore, the monitoring regulations for these devices should also reflect these differences.

IV. BENEFITS OF ADOPTING RISK-BASED MONITORING

Adopting a risk-based approach to monitoring AI/ML-enabled medical devices will improve the FDA's currently proposed regulations because it will prove advantageous for manufacturers, patients, and the FDA.

A. ADVANTAGEOUS FOR MANUFACTURERS

Manufacturers of AI/ML-enabled medical devices are poised to derive substantial benefits from the implementation of a risk-based approach to monitoring by the FDA, given their current responsibility for monitoring each device.[103] This transition promises manufacturers various benefits, including a diminished regulatory burden, more efficient allocation of resources, and the potential for heightened business recognition. The reduction in regulatory burden is rooted in the prevalent classification of FDA-cleared AI/ML-enabled devices as Class II, which are anticipated to be subject to monitoring.[104] However, as discussed earlier, certain devices with low error rates, comparable to those of healthcare practitioners, may warrant exemption from monitoring. It is also crucial to note that the FDA's proposed action plan does not distinguish among AI/ML-enabled medical devices, potentially holding manufacturers responsible for also monitoring Class I AI/ML-enabled medical devices.[105] By adopting a risk-based approach, manufacturers would be allowed to focus their efforts on fewer devices, particularly Class III devices and Class II devices. This immediate reduction in the number of devices to be monitored holds the potential to relieve manufacturers of unnecessary burdens.

Manufacturers would also benefit from more efficient resource allocation. By focusing on fewer devices to ensure the accuracy of the high-risk ones, they could avoid expenses associated with monitoring unnecessary Class I or potentially exempt Class II devices. These expenses may include employing company personnel to monitor devices, software development, maintenance and support, and data storage and processing. Alternatively, the resources allocated for monitoring unnecessary devices could be redirected toward critical areas such as research and development. This may not only improve the quality of

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[103] *See* FDA *supra* note 8, at 1 ("In this approach, FDA expressed an expectation for transparency and real-world performance monitoring by manufacturers that could enable FDA and manufacturers to evaluate and monitor a software product from its premarket development through postmarket performance.").
[104] *See* FDA, *supra* note 3.
[105] *See* FDA, *supra* note 8, at 6.

current medical products but also position manufacturers for growth in the rapidly involving market for AI/ML-enabled medical devices. By focusing on monitoring the high-risk devices, manufacturers may also avoid expenses associated with product liability claims from products that malfunction in the market.

Finally, manufacturers may stand to gain increased business visibility when their medical products perform better in the market. This advantage may be achieved by monitoring the AI/ML-enabled medical devices that are more likely to have errors, consequently minimizing their errors rates and increasing consumer trust in the brand. This enhanced trust has the potential to increase sales, providing manufacturers with additional resources to direct towards research and development. As a result, this continuous cycle can lead to an overall improvement in the quality and performance of their products.

B. ADVANTAGEOUS FOR PATIENTS

Patients also stand to gain from the implementation of a risk-based approach to monitoring by the FDA for two main reasons. Firstly, safety is likely to increase through heightened surveillance of high-risk devices because they present the most danger if they malfunction. Accordingly, an increase in the surveillance of these devices would mitigate their potential dangers and consequently lower their error rates. Moreover, patients will realize financial benefits by avoiding the monitoring costs associated with low-risk devices, as manufacturers might not pass on these expenses. The healthcare sector is already grappling with escalating costs attributed to the integration of new technologies.[106] Imposing monitoring costs on patients for unnecessary AI/ML-enabled medical devices would only exemplify this trend. Therefore, the implementation of risk-based monitoring not only contributes to enhanced patient safety but also alleviates the financial burden on patients by sparing them from incurring avoidable expenses.

C. ADVANTAGEOUS FOR THE FDA

Finally, the FDA will also benefit from implementing a risk-based approach to AI monitoring, considering that it is the entity responsible for ensuring compliance with the monitoring requirements. This entails ensuring the real-world performance of each AI/ML-enabled medical device is being continuously evaluated, including the vast majority that are not Class III high-risk.[107] As mentioned earlier, this in inefficient since it is unnecessary to monitor certain AI/ML-enabled medical devices. Accordingly, a risk-based monitoring

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[106] *See* C. Lee Ventola, *Challenges in Evaluating and Standardizing Medical Devices in Health Care Facilities*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. 11 (June 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683611/ ("Economic losses discourage the use of new technologies and lessen the incentive for manufacturers to innovate.").

[107] *See* FDA, *supra* note 3, at 1.

approach would reduce the burden of the FDA's policing efforts to the far few devices. Furthermore, looking ahead, the FDA's regulatory burden is poised to escalate as the amount of cleared AI/ML-enabled medical devices continues to grow annually.[108] Similar to manufacturers, shifting away from the universal monitoring requirements of the FDA's Action Plan would enable the FDA to allocate its resources more efficiently by avoiding expenses associated with monitoring unnecessary Class I or potentially exempt Class II devices.

V. PROPOSED REGULATORY REVISIONS

In this section, I propose specific amendments to the FDA's proposed regulatory framework to facilitate the efficient monitoring of AI/ML-enabled medical devices.

A. REQUIRE MONITORING FOR CLASS III AI/ML-ENABLED MEDICAL DEVICES

Class III medical devices that utilize machine learning should be subject to monitoring because they are inherently dangerous since they "usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury."[109] Class III devices include breast implants, pacemakers, prosthetics, and ventilators.[110] Accordingly, it is foreseeable that a malfunction by one of these devices may significantly harm a patient. Therefore, Class III AI/ML-enabled medical devices should be subject to monitoring to ensure patient safety.

B. REQUIRE MONITORING FOR CERTAIN CLASS II AI/ML-ENABLED MEDICAL DEVICES

As mentioned earlier, monitoring should be required for certain Class II medical devices that utilize machine learning because they are devices for which "general controls . . . are insufficient to provide reasonable assurance of the safety and effectiveness of the device," but which may perform tasks with error rates on par or better than healthcare practitioners.[111] Class II devices include catheters, blood pressure monitors, and diagnostic tools.[112] Accordingly, it is foreseeable that a malfunction by one of these devices may result in a patient suffering harm, but it has also been demonstrated that some of these devices perform as well as practitioners.[113] Therefore, if these devices utilize machine learning, then their monitoring requirements should be determined on a case-

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[108] *See id.*
[109] 21 U.S.C. § 360c(a)(1)(C) (2024).
[110] *See* Sumatha Kondabolu, *3 FDA medical device classes: differences and examples explained*, QUALIO (Jan. 25, 2023), https://www.qualio.com/blog/fda-medical-device-classes-differences.
[111] *See* § 360c(a)(1)(B).
[112] *See* Kondabolu, *supra* note 108.
[113] *See* Lenskjold et al., *supra* note 2.

by-case basis by considering the devices' risk-level and intended use. If a Class II AI/ML-enabled medical device performs a particular task with an error rate that is equal to or better than the acceptable error rate for a healthcare practitioner performing the same task, then such device should not be subject to monitoring. In essence, certain Class II AI/ML-enabled medical devices should be subject to monitoring, while others should be exempt.

C. DO NOT REQUIRE MONITORING FOR CLASS I AI/ML-ENABLED MEDICAL DEVICES

Class I medical devices that utilize machine learning should not be subject to monitoring because they are not intended "for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and do "not present a potential unreasonable risk of illness or injury."[114] Class I devices include bandages, oxygen masks, hospital beds, non-electric wheel chairs, and electric toothbrushes.[115] Accordingly, it is foreseeable that a malfunction by one of these devices would not likely significantly harm a patient. Therefore, Class I AI/ML-enabled medical devices should be exempt from mandatory monitoring to facilitate the efficient monitoring of AI/ML-enabled medical devices.

CONCLUSION

The integration of AI/ML-enabled medical devices is significantly transforming the healthcare industry, introducing a new era of precision and efficiency in healthcare.[116] These devices are proving to be invaluable as they have already improved patient diagnosis, treatment, and disease prediction.[117] As machine learning continues to be adopted in medical devices, the FDA continues to receive more marketing submissions and pre-submissions for AI/ML-enabled medical devices, a trend that is expected to increase over time.[118] While the FDA has made significant progress in proposing regulatory frameworks that will implement the use of these devices, it has not considered whether they should be monitored based on the level of risk they pose.[119] Adopting such an approach is warranted for several reasons and has the potential to provide significant benefits to manufacturers, patients, and the FDA, including reduced regulatory burdens, enhanced patient safety, and efficient resource allocation for both manufacturers and the FDA. By tailoring monitoring requirements to device risk levels, the FDA can strike a balance between ensuring patient safety

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[114] § 360c(a)(1)(A).
[115] *See* Kondabolu, *supra* note 108.
[116] *See* ARTIFICIAL INTELLIGENCE IN HEALTHCARE, *supra* note 1, at 26.
[117] *See id.*
[118] *See* FDA, *supra* note 3.
[119] *See* FDA, *supra* note 8, at 1.

and fostering efficiency in the rapidly evolving field of machine learning in healthcare. Particularly, the FDA should consider amending its proposed regulatory framework by mandating monitoring for Class III AI/ML-enabled medical devices, instituting monitoring requirements for select Class II AI/ML-enabled medical devices, and exempting Class I AI/ML-enabled medical devices from mandatory monitoring. These amendments would represent a significant step toward the efficient monitoring of these devices.