The Analysis of Relevant Social Groups Dynamics:
Influences on the Development of AI/ML based Medical Device Regulations

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

Last year, the U.S. Food and Drugs Administration (FDA) authorized 171 additional artificial intelligence (AI) and machine learning (ML)-based medical devices, which is 33% more than in 2022 (FDA, 2023). The increase in AI/ML-enabled devices has steadily increased since 2019, with more than 14% year-over-year increase (FDA, 2023). The application of AI and ML algorithms in healthcare has the potential to improve patient care by deriving significant insights from the enormous amount of data generated during everyday practices. For instance, AI/ML-based medical devices have been used in clinical settings to enhance treatment outcomes and reduce mortality significantly (Muehlematter et al., 2021). Several other studies have also suggested improving diagnostic accuracy and treatment effectiveness (Tang, 2019).

However, appropriate regulations for AI/ML-based medical devices are necessary because these technologies also present various risks. Developing accurate and effective AI/ML-based medical devices is still challenging due to the quantity and quality of datasets (Liu et al., 2022). Beyond the technical challenges, there are safety concerns as AI/ML tasks change frequently along the device's continuous learning from new datasets and are introduced to new errors or biased data (Muehlematter et al., 2021). Thus, constant checkups are needed to ensure the safety and effectiveness of these advanced technologies.

Traditionally, the FDA reviewed and authorized AI/ML-based medical devices through an appropriate premarket pathway, such as 510(k) clearance, De Novo classification, or premarket approval. When the manufacturer makes software changes in a medical device, the FDA will review the modification via 510(k) clearance (FDA, 2019). By demonstrating that the modified medical device is substantially equivalent to the approved devices, the FDA would

approve the use of the device due to low risk or evaluated risks. If the updated AI/ML-based medical device is not substantially equivalent to the legally marketed devices, the FDA evaluates the risks based on scientific evidence through the De Novo request and premarket approval pathway and determines the use of the medical device in the clinical setting. Under the traditional regulatory framework, the FDA ensured the safety and effectiveness of these devices with a risk-based approach.

However, as continuous learning AI/ML updates its performance over a much shorter period, the traditional regulations cannot check over the risks of software modifications at the speed of change. Adaptive AI/ML-based medical devices can learn and optimize real-time performance to continuously improve patient healthcare (FDA, 2019). Following the traditional regulatory framework, the manufacturer must submit a premarket application when a change occurs. Keeping up with real-time adaptation is impossible under traditional regulations, resulting in significant risks of using continuous learning AI/ML-based medical devices in the clinical setting. Therefore, a new regulatory approach is necessary to ensure the safety and effectiveness of these advanced medical devices.

After recognizing the limitations of static regulatory frameworks in ensuring the safety and effectiveness of the continuous learning AI/ML algorithms, the FDA took a proactive step and proposed a more dynamic regulatory framework in 2019. This new approach aims to accommodate the real-time learning and optimization capabilities of AI/ML algorithms while maintaining standards for the safety and effectiveness of these devices. The FDA strived to balance innovation in AI/ML-based medical devices and safety by actively modifying regulations.

The FDA's regulatory process for AI/ML-based medical devices is not a solitary endeavor. It actively seeks and values the input of stakeholders in developing new regulatory paradigms. With the proposal of the new regulatory framework, the FDA requested public feedback on modifications (FDA, 2019). As of March 19, 2024, 135 comments from diverse perspectives, including IT companies, biotech companies, healthcare professionals, and general consumers, were submitted on the FDA docket (FDA, 2019). This collaborative approach ensures that a wide range of information is provided about the FDA's actions, expertise, and perspectives. After receiving feedback, the FDA published the "Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan" to describe the FDA's potential action as a response to feedback from the public (FDA, 2021).

My STS research presents novel findings on the effect of social factors on the development of new regulations for AI/ML-based medical devices. I focus on the contributions of various stakeholder groups organized around their shared understanding of these technologies. Through a comprehensive literature review, my STS project explores the advancement of AI/ML technologies in healthcare, delineating their advantages and challenges. In the literature review, I critically assess the traditional AI/ML-based medical device regulations, underscoring areas where modifications are necessary to address emerging complexities. My research investigates how and why these diverse viewpoints have shaped proposed regulatory modifications by utilizing primary sources from the FDA, tech companies, healthcare professionals, and general consumers. I also analyze their involvement in regulatory modification by examining the FDA's publications and comparing its traditional and proposed AI/ML-based medical device policies. The findings reveal the intricate interplay between the new AI/ML-based medical device regulations and each stakeholder's perspective, underscoring the importance of social group

opinions in influencing the selection of concerns regarding AI/ML-based medical technologies and the formulation of potential regulatory solutions.

Literature Reviews

As technology continues to advance every aspect of healthcare, the application of AI, specifically the subset of AI known as ML, in the healthcare field has grown rapidly. Continual learning is one of the fundamental concepts of ML, which enables models to learn and evolve based on new input data while retaining their previously acquired knowledge (Habehh & Gohel, 2021). As such, these algorithms have become increasingly relevant in medical imaging for purposes such as computational segmentation, classification, or detection of anatomical structures and anomalies for diagnosis, prediction, or prognosis (Perkonigg et al., 2021). Some studies found that AI/ML algorithms can diagnose more accurately than human experts, making them a potential tool for using imaging data for diagnosis and supporting treatment decisions (Liu et al., 2022; Perkonigg et al., 2021). With these advantages, there continues to be potential for widescale application of AI/ML technologies in healthcare.

Nevertheless, the clinical application of AI/ML models faces several challenges. One significant issue is catastrophic forgetting. The purpose of continually learning AI/ML algorithms is to improve the performance of the software by creating new and critical insights from the vast amount of real-time generated data. However, AI/ML models may forget previous knowledge quickly and significantly during new learning. Such phenomena cause decreased performance and eventually harm the users. Despite numerous research to overcome the challenge of catastrophic forgetting, it is still visible when continual learning requires performing multiple tasks (Ramasesh et al., 2021). Therefore, constant performance checkups are crucial for

ensuring the safety and effectiveness of AI/ML-based technologies. In addition, data availability and quality are also limiting factors (Liu et al., 2022). Adaptive AI/ML algorithms pose inaccurate outcomes by training on new data subject to errors or bias (Vokinger et al., 2021). For instance, an algorithm that used health costs as a proxy for health needs falsely predicted that black patients were healthier than white patients, even though both groups were equally sick (Obermeyer et al., 2019). Such bias can be introduced across various stages, including when AI/ML-based medical devices are used in the clinical setting. Furthermore, privacy concerns arise when using AI/ML technologies (The Lancet Public Health, 2019). Due to the confidentiality of health data, collecting and sharing massive amounts of health data to train the model can raise privacy concerns. Although the Health Insurance Portability and Accountability Act (HIPAA) 1996 ensures patient privacy and data confidentiality, data breaches and cyber-attacks can easily invade privacy rights. In order to use these technologies in the clinical setting, all the discussed concerns should be addressed beforehand.

Appropriate regulations could address these concerns, but some studies have found that the traditional FDA regulatory framework is insufficient to evaluate the safety and effectiveness of AI/ML-based medical devices. Of 64 approved AI/ML-based medical devices and algorithms, 85.9% were cleared with a 510(k) clearance (Benjamens et al., 2020). Notably, the 510(k) clearance does not require scientific and regulatory processes to determine their safety and effectiveness but focuses on demonstrating similarity to previously authorized devices (Benjamens et al., 2020). Also, many 510(k) cleared devices received approval through equivalence determinations that go back several decades before the widespread use of AI/ML technologies in the medical field (Lee et al., 2023). These findings indicate that current

regulatory approaches must address AI/ML-based medical device concerns, highlighting the need for new regulatory frameworks.

Researchers conducted many studies to evaluate the benefits and challenges of AI/ML-based medical devices and the limitations of the current FDA regulations for these devices. However, more research is needed to analyze the recently proposed FDA regulatory framework. Like how regulations can either encourage or hinder technological advancements, the current regulations only allow for locked algorithms with limited capabilities, and as a result, the use of adaptive AI/ML-based medical devices is restricted in healthcare systems (Abràmoff et al., 2018; Lee & Lee, 2020). Regulation changes impact design, specifications, and technology features tremendously. Therefore, the intended purposes of new regulations must be studied.

In my research, I will use the Social Construction of Society (SCOT) framework to evaluate the new FDA approach to regulate AI/ML-based medical devices. According to SCOT, technological artifacts result from different groups coming to a common understanding of what problems must be addressed and what solutions can be used to solve them (Pinch & Bijker, 1984). These different groups, or relevant social groups, have a shared perspective on technology and can be anything from tech companies, regulatory agencies, or general consumers (Pinch & Bijker, 1984). By identifying these relevant social groups and their perspectives on the technology, we can better understand which groups' needs and desires are considered in the regulation modifications and the intentions behind these changes. Ultimately, the SCOT framework allows for understanding the dynamics between relevant social groups in developing the regulatory framework for shaping AI/ML-based technology in the medical field.

Methods

I conducted two policy analyses to find changes in the regulations. First, I compared the proposed FDA regulations from 2019 to the traditional FDA regulatory framework to analyze the initial regulation modifications. The first comparison revealed the significant concerns the FDA aimed to address and the most efficient ways to solve them. In the second policy analysis, I investigated changes in the proposal after receiving public feedback by comparing the 2019 FDA proposal to FDA publications of new regulation plans and guidelines from 2021 to 2024. From the following analysis, I observed the power dynamics among relevant social groups in selecting concerns to address by new regulations.

Furthermore, I collected primary resources such as FDA reports on AI/ML-based medical devices and comments by representatives of relevant social groups from the 2019 governmental docket (FDA-2019-N-1185), called "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)—Discussion Paper and Request for Feedback." I analyzed the FDA's publications, discussing a new regulatory framework for AI/ML-based medical devices to determine further the FDA's stance on these technologies and the reason for modifying the regulations. Based on what the AI/ML-based medical device meant, I categorized the comments on the public docket into four other relevant social groups: technology companies, academia, healthcare professionals, and individual consumers. Then, I randomly selected five submissions from each category for discourse analysis to identify their perspective on AI/ML-based medical devices. The findings from the analysis were connected to the results of the second policy analysis to evaluate further how and why the relevant social groups contribute to developing new regulations.

Analysis

The FDA's decision to modify its regulations to allow adaptive AI/ML applications in the medical field was motivated by the positive perspectives from many relevant social groups. According to the FDA's discussion paper proposing a regulatory framework for modifying AI/ML-based software as a Medical Device (SaMD), the FDA highly valued SaMD's capabilities to learn from the vast amount of real-world data and improve performance (FDA, 2019, p.1). The FDA also stated that AI/ML applications can lead to earlier disease detection, more accurate diagnosis, identification of new observations or patterns on human physiology, and development of personalized diagnostics and therapeutics (FDA, 2019, p.1). Most tech companies and academia have also supported using AI/ML medical devices in the clinical setting. For example, endorsements from organizations like Intel and the Duke Margolis Center for Health Policy highlighted the positive impacts that AI/ML can bring to healthcare, including improvement in care quality and delivery (Duke-Margolis, 2019; Intel, 2019). Moreover, the FDA, Duke Margolis Center, and Intel approved the regulation modifications to allow adaptive AI/ML technology use in the clinical setting with their positive views on the innovation (Duke-Margolis, 2019; FDA, 2019, p.1; Intel, 2019). Thus, the collective positive meanings of the technology from regulatory agencies, tech companies, and academics led to harnessing the full potential of adaptive AI/ML technologies in healthcare.

These positive meanings of AI/ML-based medical devices stemmed from desires to accelerate innovations and improve medical care. The FDA's commitments to employing innovative regulatory approaches for medical devices and multiple tech companies' emphasis on being frontiers of innovations reflected their investment in innovations (Evidation, 2019; FDA,

2019; Intel, 2019). Both groups also expressed their hopes of improving medical practices with innovation. For instance, the FDA stated, "Our vision is that with appropriately tailored regulatory oversight, AI/ML-based SaMD will deliver safe and effective software functionality that improves the quality of care that patients receive." (FDA, 2019, p.1). Based on this statement, the FDA aimed to modify regulations to improve healthcare using AI/ML-based medical devices. The relevant social groups' desires to advance technologies and improve healthcare led to fostering a positive view of AI/ML-based medical devices among these social groups, leading to the development of new regulations for these innovative technologies.

The positive perspectives on AI/ML-based medical devices are also formulated from profit motives. By articulating their dedication to AI and ML development and accentuating the benefits of their technologies, they encouraged their products to make changes in healthcare. For instance, Intel, Microsoft, and Evidation emphasized their work in developing AI and ML to accelerate the discovery of health problems and treatment progression (Evidation, 2019; Intel, 2019; Microsoft, 2019). The tech companies' motives to accelerate innovation and make clinical improvements intertwined with business success resulted in the positive perception of AI/ML-based medical devices.

However, concerns regarding environmental sensitivity also prompted significant changes in the regulatory framework for AI/ML-based medical devices. Environmental sensitivity refers to the variability in performance based on local conditions, such as differences in patient populations. Even if the performance of AI/ML algorithms is initially validated through testing, there is recognition that ongoing evaluation in real-world clinical settings is essential due to potential changes in performance influenced by local conditions. The reluctance

of some healthcare professionals to embrace continual learning of AI/ML applications in healthcare highlighted the importance of rigorous evaluation in the field (Bayliss, 2019; Torous, 2019). Regulatory agencies and academia have also echoed this concern. Awareness of environmental sensitivity led to discussions about implementing a predetermined change control plan to manage device modifications and monitor real-world performance (FDA, 2019, p. 2-4). This plan allowed for mitigating environmental sensitivity problems by establishing the region of potential changes and how the algorithm will learn. Although there are no finalized regulations on monitoring the actual performance of these devices, the FDA stated that they will further develop the predetermined change control plan based on the strong community interest in it (FDA, 2021, p. 4).

Concerns regarding algorithm bias due to inappropriate training and validating data are another negative societal perspective that has been given considerable attention. Bias in the AI/ML system are closely related to data used for training and validation. The FDA noted that healthcare system biases could be introduced into the algorithms (FDA, 2019, p. 9-11). Likewise, tech companies and academia emphasized the danger of using the low quality and small quantity of datasets to train and validate AI/ML-based medical devices. For example, Intel stated the potentially detrimental effects of training AI/ML models on specific populations without considering broader demographics (Intel, 2019). In response to these concerns, the FDA integrated numerous good data management practices into its proposed regulations, known as Good Machine Learning Practices (GMLP) (FDA, 2021, p. 5). As part of its strategy, the FDA planned collaboration with AI/ML-focused organizations supporting research endeavors to refine GMLP standards (FDA, 2021, p. 5). With these practices, the FDA will ultimately achieve

fairness and reliability in AI/ML-based medical devices and advance patient safety in healthcare systems.

Unlike how hopes of improving diagnosis and treatment fostered positive views, desires to ensure safety raised negative views on AI/ML-based medical devices. Regulatory agencies, healthcare professionals, and academia are worried that using AI/ML in specific environments or training with insufficient or biased datasets can lead to marginalized performance on specific populations and harm unrepresented patients (FDA, 2019; Intel, 2019; Torous, 2019). Dr. John Torous highlighted the connection between the desire to ensure clinical safety and concerns about environmental sensitivity (Torous, 2019). He warned that the lack of specific criteria in the current draft leaves much room for patient harm (Torous, 2019). One academic submitter commented, "The FDA should also consider drafting a guidance document on assessing and testing for biases. I believe this is vital to ensuring the SaMD released with ML and AI components are safe and effective for diagnostics and decision support systems." (Doucette, 2019). Referring to this feedback, ensuring safety is a reason for considering the problems of training the model with lower quality and quantity datasets.

Tech companies identified cybersecurity attacks as a significant problem that needs to be evaluated under FDA regulations. Intel, Leica Biosystems Imaging Inc., and Microsoft called attention to the susceptibility of AI/ML systems to adversarial attacks, which can lead to unauthorized and potentially malicious updates to device algorithms (Biosystems Imaging Inc., 2019; Intel, 2019; Leica, 2019). Companies also recommended implementing access control protocols for devices using established security practices such as physical key access, software encryption key exchange, and checksum signature validation of software (Intel, 2019, p. 6).

Interestingly, after receiving feedback from these tech companies, the FDA expressed its security concerns and added regulations to address cybersecurity attacks in its 2021 regulation plan. For example, the FDA stated in the 2021 plan that they committed to improving security by expanding efforts within the Good Machine Learning Practice (GMLP) framework and collaborating with the Agency's Medical Device Cybersecurity Program (p. 4). This proactive approach demonstrates how feedback from a relevant social group can influence critical issues' identification, prioritization, and resolution.

Due to safeguarding technical integrity, tech companies have identified cybersecurity as a significant problem that should be evaluated under FDA regulations. Unlike other relevant social groups, tech companies are often responsible for technical aspects of AI/ML-based medical devices, such as algorithm architecture, model training, and performance validation. If these devices are hacked, their technical aspects could be negatively affected. Intel has supported this by stating, "Device security and access control procedures should also be included as part of the TPLC approach to reduce the risk of unauthorized (potentially malicious) updates being made to the algorithm." (p. 6). Therefore, it is reasonable for tech companies to want to prevent cybersecurity threats through FDA regulations.

By not prioritizing the resolution of privacy concerns through regulations, the relevant social groups influence the development of regulations for AI/ML-based medical devices. One of the general consumers responded that ensuring patient privacy through potential multiple iterations and updates of AI/ML technologies is also the manufacturer's responsibility (Goldstein, 2019). A few healthcare professionals and tech companies explicitly raised concerns about protecting privacy and obtaining consent in their feedback (Evidation, 2019; Northwell

Health, 2019). Despite the awareness of privacy issues, these concerns were not addressed in the FDA's proposed AI/ML-based medical device regulations nor its action plan. Some may claim that the relevant social groups do not shape the regulation revision based on this incident. However, employing the SCOT framework can explain that the relevant social groups still influence the regulations even though no modified regulations address privacy. One of the significant aspects of SCOT is that the relevant social groups reach closure by deciding what problems to prioritize and solutions to address these selected problems (Pinch & Bijker, 1984). Although Evidation expressed privacy concerns, they only mentioned this in one sentence in the twelve feedback pages, while three pages were about ensuring high-quality and quantity data. Northwell Health also raised a question regarding protecting privacy and obtaining consent only once as an example of their concerns about data selection and management for training. By prioritizing other concerns and not adding regulations to address privacy issues, relevant social groups still impact the construction of FDA regulations.

Conclusion

With the great benefits and challenges that AI/ML-based medical devices can bring, the social groups formed based on their understanding of the devices changed the regulatory framework for these technologies. I discovered four primary methods that relevant social groups influenced the modifications in regulations for AI/ML-based medical devices. First was the common positive perspective of the AI/ML applications in healthcare, motivated revision of regulations to orient to the adaptive AI/ML-medical devices. All relevant social groups acknowledged the potential of AI/ML, especially continual learning AI/ML, in transforming patient care and driving changes in the FDA's regulations. Opposite to the first trend, the

regulations were changed to address the concerns of the multiple relevant social groups. The third pattern was one social group's understanding of the technology impacting the construction of the regulatory framework. Finally, relevant social groups influenced the regulatory framework modifications by selecting other concerns instead of privacy problems to address by regulations. In these four ways, relevant social groups came to common ground to shape AI/ML-based medical devices.

Moreover, the relevant social groups intentionally selected these problems of AI/ML-based medical devices and regulatory solutions. Desires for innovations and medical care improvement led the regulatory agencies, tech companies, healthcare professionals, and academia to view AI/ML-based medical devices as having great potential to advance innovations and improve the accuracy of diagnosis and the effectiveness of treatments. Tech companies also hope to expand their business by supporting the modification of regulatory frameworks to allow the clinical use of their adaptive AI/ML technologies. Many stakeholders also selected the concern of environmental sensitivity and dangers of insufficient or biased datasets to ensure safety as significant problems to address. As a result, the regulations changed to address these problems.

The findings from this research provide an overview of how and why social factors affect regulations through the lens of SCOT theory. Nonetheless, this research has its limitations. The primary resources that are collected to analyze the perspectives of each group on AI/ML-based medical devices are responses to the FDA's request for feedback on their discussion paper, "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for

Feedback" (FDA, 2019). Some of these comments are responses to the FDA's questions, leading to potential interviewer bias. Additionally, Future research could mitigate these limitations by employing more diverse data sources, using multiple methods for data collection and analysis, and ensuring rigorous validation of subject categorization.

Overall, this research reiterates the importance of considering social factors when developing and implementing AI/ML-based medical device regulations. By comprehending the perspectives and concerns of relevant social groups, policymakers and regulatory agencies can establish more robust and responsive frameworks that promote innovation while ensuring patient safety and well-being.

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