Emerging AI Technology Meets Medical Device Policy

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Introduction

The GAO-24-106122 report (*Report to Congressional Requesters*, *GAO-24-106122*, 2024) by the United States Government Accountability Office or GAO was published on January 25, 2024. It was a collaborative effort by several federal agencies to consider the regulatory opportunities and challenges posed by emerging technologies. In this paper, the focus will be on the findings and response to GAO-24-106122 for the use of Artificial Intelligence or AI as related specifically to medical devices which are under the authority of the Food and Drug Administration or FDA.

Per *(Federal Regulation: Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination*, 2024*)*, the GAO report indicates that the FDA's scorecard was less than desirable given the agency had not yet presented any well documented information to Congress on the use of AI in medical devices. This was a concern since Congress would likely move ahead without any specific direction on necessary legislative changes which could translate into "missed opportunities to fully realize the public health benefits of this technology."

For context, in December of 2022 legislation was passed by the U.S. Congress (*Public Law 117–328 117th Congress*, 2022) to address emerging cybersecurity concerns. This was an update to the Federal Drug and Cosmetic Act that included a new section that laid out specific requirements for medical device manufacturers. Prior to this, the FDA had already circulated a draft Cybersecurity Guidance and subsequent to the legislation from Congress finalized the Cybersecurity Guidance in September of 2023 (*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (2023, September).

Given this background, it appears the FDA may be behind the curve with respect to guidance on AI use in medical devices. As stated in *(Federal Regulation: Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination*, 2024) the purpose of the GAO investigation was to examine:

(1) challenges and opportunities that government agencies report facing in regulating emerging technologies

(2) government agency collaboration and cooperation activities

(3) lessons that government agencies can learn from other governments' experiences

FDA Analysis and Discussion

The GAO report *(Federal Regulation: Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination*, 2024*)* recommended the following action for the FDA: "The Commissioner of FDA should identify and document the specific changes to its statutory authorities that would enable FDA to take the actions it determines best to oversee AI/ML-enabled medical devices, and then communicate these potential legislative changes to Congress."

Figure 1: (Gerald Rigdon Production)

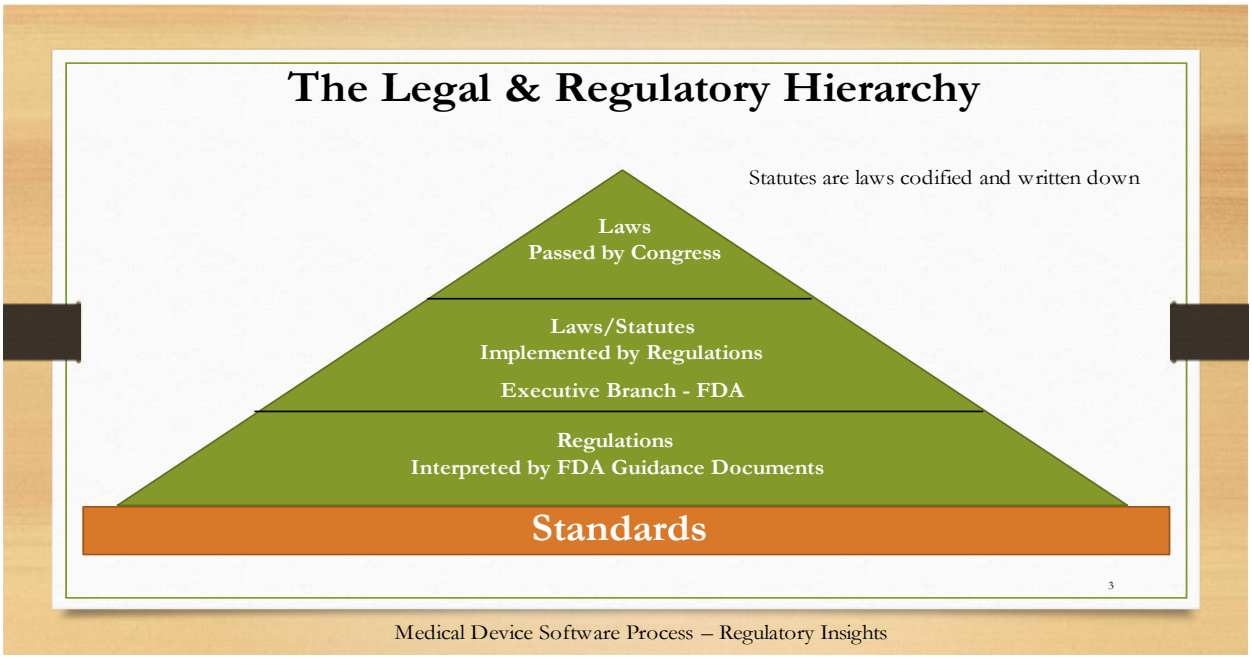

Figure 1 depicts the Legal and Regulatory Hierarchy which is important considering that the FDA is an arm of the Executive Branch of government and has no authority to create laws. Instead, laws are passed by Congress and then implemented in the form of regulations known as the Code of Federal Regulations. Finally, the regulations are interpreted by the FDA in the form of guidance documents and typically state what is found in the most recent Cybersecurity Guidance (*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, 2023): "In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations…" This is pertinent given the GAO report recommended actively seeking input from the FDA that would be used to create binding law. However, in doing so, the GAO report did acknowledge the downsides of regulating too quickly which could impede progress and so focused on 5 U.S.C. Section 553 which describes formal and informal rule making, the latter being the recommended process to be followed at present.

In defense, it should be noted that the FDA has not been completely silent on this topic. Per (*Good Machine Learning Practice for Medical Device Development: Guiding Principles*, 2021) the FDA in cooperation with Health Canada and the U.K.'s Medicines and Healthcare Products Regulatory Agency identified ten guiding principles for machine learning. More recently, in October of 2023 they released a memo citing 171 AI/ML enabled devices that were added to their existing list of such devices (*Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices*, 2023). In this release they stated: "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."

Policy Recommendations for AI in Medical Devices

Using the recent 2022 cybersecurity legislation as a model, the most straightforward and reasonable approach would be another amendment to the Federal Drug and Cosmetic Act, similar to cybersecurity Section 524B (*Public Law 117–328 117th Congress*, 2022), but specific to AI. For example, the definition language could be something like:

An AI device is any device with software that implements algorithms based on processes or techniques related to:

1. *Machine Learning*
2. *Deep Learning*
3. *Natural Language Processing*
4. *Robotics*
5. *Expert Systems*
6. *Fuzzy Logic*

Moreover, an AI device includes but is not limited to:

a. *Software validated, installed, or authorized by the sponsor as a device or in a device*
b. *Contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats or make decisions derived from learning models that could impact patient safety*

Additionally, the other cybersecurity requirements from 524B seem applicable to AI such as requiring a plan to monitor and address post-market activity, designing and developing procedures for AI development while making updates available, providing a Software Bill of Materials disclosing all AI software components including open-source, and finally demonstrating AI powered devices and related systems are both reasonably safe and secure.

Then, following suit, one could foresee an FDA AI Guidance Document that is structurally similar to the Cybersecurity Guidance (*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, 2023), and that promotes the use of an AI framework. For example, the Secure Product Development Framework or SPDF

could have a counterpart in a new guidance document such as an Artificial Intelligence Product Development Framework or AIPDF.

Conclusion

Since the Medical Device Amendments were added to the Federal Drug and Cosmetic Act in 1976, the FDA has been charged with the oversight of an industry with substantial and ever-emerging technological change over the past forty-eight years. Medical devices have evolved from mechanical devices to sophisticated electro-mechanical products that are operated by complex software. With the advent of connected medical devices in recent years, the FDA has had to face a new world where devices are now subject to cybersecurity breaches. And now on the heels of a recent response to cybersecurity in the form of FDA guidance, the agency is now faced with the even more expansive frontier of Artificial Intelligence. Given the recent GAO report reviewed in the paper, it remains to be seen how the FDA will respond to this latest emerging technology. There is no doubt that AI will challenge the FDA's balancing act of protecting public health without impeding innovation in ways that are not easily anticipated. As both citizens and patients in the health-care system, we should remain engaged and add our voices to the creation of democratic policy-making as the opportunities allow. Hopefully, the brief analysis and policy recommendations in this paper help further the conversation to that end.

References

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