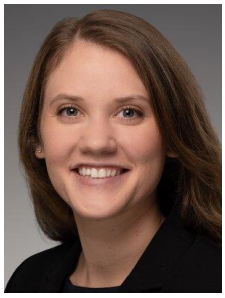
Comparing US And EU Approaches To Health AI Regulation

By **Victoria Larson and Julia Cotney** (August 11, 2023)



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ChatGPT's rise to fame in November 2022 has pushed artificial intelligence to the forefront of everyone's mind. As one of the first projects to grant the public such large access to this innovative technology, there is now a race to include generative AI capabilities in many organizations across all sectors.

However, with popularity comes scrutiny. The Federal Trade Commission is investigating whether the chatbot's platform violates consumer protection laws, and there have been several class actions regarding the use of private information. While scrutiny of this fast-evolving technology is imperative, AI has been positively used in many sectors for years.

In the medical device space, AI technologies expand beyond chatbots and include several types of technology such as natural language processing, machine learning, deep learning and more. These technologies have been used for years to advance medical treatments.

The U.S. Food and Drug Administration approved its first AI- and machine learning-enabled medical device in 1995 and approvals for such devices have increased rapidly over the last five years. For example, AI and machine learning has been used to analyze CT scans, monitor electrocardiograms, enhance health monitoring devices like glucose monitors and assist surgeons through medical robotic devices.

For the U.S. health care sector to continue to benefit from this innovative technology, legislation and guidance will need to not only keep up with the fast-paced technology of AI itself but also be aligned with the competing regulations and acts in other countries.

This article briefly summarizes the U.S. and EU approach to AI and machine learning in medical devices, and identifies areas that health care providers and health technology developers should be aware of.

U.S. Approach to AI and Machine Learning in Medical Devices

In the U.S., the FDA regulates the sale of medical devices, including those using AI. Most medical devices that receive FDA approval fall into three classes — Class I, II and III.

Class I contains low-to-moderate-risk devices, such as handheld surgical instruments, which require general controls.

Class II contains devices with moderate risk, such as CT scanners, which require special controls.

Class III contains high-risk devices, such as pacemakers, which require premarket approval.

A device's classification dictates which regulations a device will need to comply with, and

which review processes a device will participate in.

Class I devices are typically exempt from review if they are deemed low-risk or are like existing devices, though FDA quality control standards must still be followed.

Class II devices can be submitted for a Section 501(k) review, which examines if the new device is equivalent to an existing device.

For Class III — and sometimes Class II — a device must undergo clinical trials to ensure the efficacy and safety of the device, before submitting a premarket approval application.

Though these regulations have been effective over the years, they do not account for adaptive software, such as AI and machine learning technologies. Under current regulations, any software modifications require additional review by the FDA.

Part of the beauty of AI and machine learning is that it is constantly learning and evolving, but with beauty comes pain. The constant evolution makes it extremely difficult for device manufacturers to maintain their devices' approval.

The FDA envisions that in the not-so-distant future, devices using AI and machine learning technologies will require a premarket review containing a redetermined change control plan that specifies the anticipated modifications and the methodology that will be used to implement the changes, ensuring that changes made are not a risk to patients.

This process would allow oversight from the FDA to monitor software products and assure patient safety while also allowing machine learning and modifications without the burdensome modification approval process each time the software adapts.

In March, building on its 2019 discussion paper and its action plan for medical devices that use AI and machine learning software, the FDA laid out its updated plan for approving AI and machine learning for use in the health care and health technology spaces.

A key focus of the plan is to ensure that software is safe and effective for patients, while allowing the software to be modified and improved as it learns.

The guidance outlines recommendations that could be used in a predetermined change control plan that would be included in a submission for machine learning software, such as: planned modifications, methodology to implement and validate the modifications as well as an assessment of the impact of the modifications.

This guidance would allow AI and machine learning devices to learn and rapidly adapt, without requiring reapproval. Additionally, this guidance would not only apply to AI- and machine learning-enabled devices, but also to devices that use AI and machine learning as part of their hardware.

As the FDA continues to seek comments and develop guidance, health care providers and health technology companies should be aware of other developments in the AI space.

Laws and regulations are still pending, but in July, leading AI companies provided voluntary commitments that ensure future AI developments are safe, secure and trustworthy.

The commitments include:

- "Internal and external security testing of AI systems before release;"

- "Sharing information across the industry and with governments and academics on managing AI risks;"

- "Investing in cybersecurity and insider threat safeguards to protect proprietary and unreleased model weights;"

- "Facilitating third-party discovery and reporting of vulnerabilities in AI systems;"

- "Developing robust technical mechanisms to ensure that users know when content is AI generated;"

- "Publicly reporting AI systems' capabilities, limitations and areas of appropriate and inappropriate use;" and

- "Prioritizing research on societal risk that AI systems pose such as harmful bias and protecting privacy."

The White House expects that other companies will follow these commitments.

Although the commitments were voluntary and there is no clear path to enforcement, health care organizations and AI developers should keep the seven commitments in mind, particularly as they relate to transparency, privacy and the risk of harmful bias. These commitments will likely be used as a foundation for future legislation and be incorporated into future agency guidance.

EU Approach to AI and Machine Learning in Medical Devices

The EU, on the other hand, regulates medical devices with integrated software such as AI or machine learning under the European Union Medical Devices Regulation. The MDR utilizes a risk-based system to classify devices based on their intended purpose and inherent risk.

Class I includes low-risk devices, Class IIa and IIb include medium-risk devices, and Class III includes all high-risk devices.

Software or algorithms that include AI and machine learning are typically regarded as Class IIa. To enter the market, manufacturers can either seek approval of the device on its own

or as a component of another medical device.

Releasing the software as a component is a less rigorous option as it relies on the conformity assessment of the parent device. But like the U.S. regulatory framework, the EU regulatory framework will need to adapt to account for AI and machine learning technologies that learn rather than remain static.

As in the U.S., developers should continue to monitor the AI regulatory landscape as a whole, not just the laws and regulations specific to medical devices. Since April 2021, the EU has made strides toward passing the first regulatory framework, the Artificial Intelligence Act, to address and govern the use of AI within the EU.

The proposed legislation's main goal is to ensure that the use and development of AI is done responsibly and ethically. The act classifies AI systems as limited, high and unacceptable risk. Limited-risk AI systems are systems that pose a lower risk to the users and public and meet a transparency requirement. For example, transparency requires that when a user speaks to a chatbot, the chatbot prompts the user that he or she is speaking to a machine.

High-risk AI systems are those that might negatively affect the safety and rights of citizens and include health care systems and medical devices.

Unacceptable risk AI systems are systems that are considered too risky and harmful to be used at all. Examples of unacceptable risk are social scoring systems and systems that use facial recognition.

For companies and researchers developing high-risk AI systems, products will need to complete a conformity assessment before use, which includes evaluating the safety, performance and compliance with ethical standards and guidelines.

The act also emphasizes the importance of unbiased and quality data for training the AI systems, especially in health care, to avoid bias and discrimination. The AI systems are required to have oversight by humans to mitigate potential risks and will need to be transparent on their decisions so that health care professionals and patients are able to verify the systems' recommendations.

There are certain AI practices that are prohibited under the act, specifically in systems involved in health care sensitive medical decision making.

This act will likely have significant implications for health care organizations and AI developers operating within the EU.

Developers of AI systems used in health care will need to adhere to the regulations, undergo rigorous assessments and ensure the responsible use of AI to protect patient safety and privacy while harnessing the potential benefits of AI in improving health care outcomes. Failure to comply will lead to substantial fines and penalties.

Takeaways

- AI and machine learning medical devices have and can continue to assist health care providers in making better clinical decisions and ultimately delivering better patient care.

- There is potential for the U.S. and the EU to align regulatory frameworks, at least in some areas, as both appear to have the same underlying principles.

- As technology and regulatory frameworks advance, players in the space should continue to be aware of the impact of harmful bias and the importance of protecting patient privacy without limiting the interoperability of software systems.

- Companies, researchers and health care providers should continue to voice concerns during the development of legislation to align regimes and allow for easier medical device approval globally.

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