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FDA's Digital Health Committee Discusses AI Evaluation Methods

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Our Take & Next Up

The FDA has released guidance & is considering ways to standardize oversight of artificial intelligence (AI) enabled medical devices, with post market evaluation as a critical component. As usage proliferates and models improve, a two-day panel discussed pros, cons, and related issues. This week, the FDA held their inaugural Digital Health Advisory Committee Meeting to discuss total product lifecycle considerations for generative AI-enabled medical devices here. The agency is particularly focused on clinical and diagnostic tools that could be used in both hospital and home health settings to improve patient outcomes and improve workflow.

Please join us Weds Jan 15 @ 10:30 am PT at JPM25 to discuss the future of Diagnostics & Artificial Intelligence. We will discuss the regulation and oversight of Artificial Intelligence (AI) as it pertains to healthcare (and specifically Diagnostics) in 2025+. A new Administration & Congress will embark on a range of issues -- from FDA regulation to CMS coverage and payment -- in addressing the potential overreach and/or shortcomings of AI. Regulating AI is a bipartisan initiative, with an Executive Order (EO) enacted in 2023, as agencies roll out guidance and regulations to ensure safe usage of next generation technologies.

- Lee Fleisher, MD, former CMO, Centers for Medicare & Medicaid Services (CMS)
- Jennifer Leib, Principal, Innovation Policy Solutions
- Kate Sasser, Chief Scientific Officer, Tempus
- Troy Tazbaz, US Food & Drug Administration Office of Digital Health Lead

Key Points

The agency will apply a Lifecycle Management (LCM) approach, used to manage software. Earlier this year, the FDA released their AI report on how the different divisions are working together to regulate AI in drug development and medical devices and the agency has released guidance on AI enabled software functions (here). We expect the FDA's work in evaluating AI devices and software to continue. Under the new administration, the agency may provide a stronger push to create an appropriate regulatory system due to

potential benefits of AI predictive devices in treating chronic care and promoting earlier preventative measures for diseases.

Dr. Califf, outgoing FDA commissioner, sees potential for AI-enabled devices largely in home health. Califf and Michelle Tarver, head of CDRH, noted that AI offers ways to improve care access at home, but "tech must meet people where they are". AI may offer alternatives to traditional care as rural hospitals and care settings close down. The advisory committee members and presenters discussed the potential benefit to health outcomes and ways to measure those endpoints.

The FDA uses the total product lifecycle approach to evaluating AI devices, ranging from pre-market data requirements, risk management, to post-market performance monitoring. Regulatory issues for AI devices that were noted by CDRH officials include difficulty defining scope, an adaptive system, identification of hallucinations, adequacy of data sets, evaluating real world performance, and providing transparency for users. Advisor temporary committee member, Peter Elkin, noted that for every generative AI that is considered, the FDA should collect a significant amount of info (model card, demographic info of data, the exact data utilized, properties of the underlying foundational models) along with evaluation plans that should be in place.

Post-market oversight and clinical user population will need to be defined for AI devices/FDA review. How to ensure appropriate post-market oversight over evolving models is a key point of discussion. Committee members noted the need for surveillance of rare errors and a system for monitoring potential drift in accuracy of the model as data evolves. Blind preference testing (asking experts if they prefer human or AI report) was mentioned as a potentially acceptable evaluation method. The committee also noted that AI-enabled devices may not be suitable for the general population of providers, and the end use and end user labeling document should be clear. It remains difficult to quantify the "trust score" of the results generated by AI at this time. Clinical informaticians may play a role in developing recommendations for usage of AI enabled devices.

The FDA has already taken steps to standardize AI regulations with draft guidance on iterative improvement of machine learning-enabled device software functions (published in 2023).

- **The draft guidance provides recommendations on the information to be included in a Predetermined Change Control Plan (PCCP) for artificial intelligence/machine learning (AI/ML)-enabled devices**. A PCCP is the documentation describing what changes will be made to a device and how the modifications will be assessed. With this guidance, manufacturers can proactively specify and seek premarket authorization for intended modifications to an AI-enabled device.
- **Earlier this year, the divisions also jointly published a paper on the FDA's overarching approach to AI**. The paper highlights the FDA's risk-based regulatory framework in evaluating AI in medical products. The four focus areas discussed include: fostering collaboration to safeguard public health; advancing the development of regulatory approaches that support innovation; promoting the development of harmonized standards, best practices and tools; and supporting research related to the evaluation and monitoring of AI performance.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com
202.250.3741 I www.capitol-street.com
900 19th St NW 6th Fl
Washington, D.C. 20006
CAPITOL STREET