

January 21, 2025

**Re: Docket No. FDA-2024-N-3924**

**“Digital Health Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments”**

The Radiological Society of North America (RSNA) is a non-profit organization representing over 48,000 medical imaging professionals spanning the full breadth of radiologic subspecialties in more than 150 countries around the world. Our mission is to promote excellence in patient care and healthcare delivery through education, research, and technological innovation.

Radiology and medical imaging are data-intensive specialties at the forefront of grappling with the numerous ways that artificial intelligence (AI) and machine learning (ML) are transforming the practice of medicine and the delivery of healthcare. No medical specialty has been impacted by this transformation more than radiology, which has seen greater development and application of AI-enabled tools and platforms than any other medical field. Notably, of the over 950 algorithms currently cleared for use by the FDA, more than 76 percent are for use in radiology.

Thus, radiologists are the end users of many of the medical devices requiring premarket approval or notification, whose development will be significantly impacted by the FDA’s regulatory framework for AI-enabled medical devices. As a leading medical society representing radiologists and bringing expertise in the use of AI in medical imaging and practice, RSNA appreciates this opportunity to provide comments to the Public Docket established as part of the first meeting of the FDA’s Digital Health Advisory Committee (DHAC), held November 20-21, 2024.

Given the leading role that radiologists play in integrating AI-enabled tools into medicine and patient care, RSNA was pleased to see radiologists well-represented among the technical experts invited by the FDA to present to the committee. Speakers such as Drs. Dryer, Bitterman, and Kottler highlighted the deep knowledge and real-world experience radiologists bring to the implementation of AI-enabled tools in clinical practice. Their presentations underscored the significant contributions that radiologists have made in advancing these technologies and articulated some of the unique challenges associated with the evolving nature of AI-enabled tools that FDA must address as part of its regulatory approach. Throughout the meeting, several DHAC members acknowledged the extensive experience of the radiology field in addressing the challenges and opportunities associated with deploying AI-enabled tools in medical imaging and patient care.

Given this, RSNA is disappointed that the DHAC panel itself does not include one or more radiologists as members. Radiologists possess expertise in the development, evaluation, and deployment of AI tools and can offer invaluable insights to guide the committee’s work. Moving forward, RSNA looks forward to collaborating with the FDA and the DHAC to ensure radiology expertise continues to inform the committee’s deliberations as it navigates this critical and rapidly evolving area of healthcare.

As was highlighted by numerous speakers and DHAC members, the ecosystem around the use of AI-enabled tools in healthcare settings brings unique challenges to the FDA’s current regulatory framework. Many radiology practices report that AI algorithms do not perform as expected on their specific patient population, necessitating rigorous testing and validation prior to implementation. Radiology practices have also learned that AI models must

be monitored closely to prevent “diagnostic drift,” where even minor algorithmic changes can lead to significant diagnostic discrepancies. Given the lack of standardization across AI tools and technologies, different algorithms may yield varied outputs; therefore, any modifications to these tools must be transparent and readily available for revalidation by end users to ensure they meet clinical expectations. Thus, to enhance overall transparency, we recommend that FDA consider requiring AI tool vendors to adopt standards that would govern algorithmic outputs and identify and address potential biases as part of their testing and modification protocols.

RSNA strongly recommends that FDA require vendors to document and disclose all changes to AI tools, with clear version histories and detailed modification notes. This transparency would enable radiology practices to compare versions, validate updates, and troubleshoot issues, especially as AI tools from multiple vendors may need to work in tandem within complex clinical workflows. Long-term access to prior software versions is critical to confirm diagnostic consistency and address any discrepancies that may arise post-update.

Rigorous validation criteria would ensure that AI models are safe, effective, and equitable. Given the diverse patient populations AI tools serve, validation protocols should explicitly include criteria for detecting and mitigating biases in datasets. We encourage the FDA to mandate developers to disclose their data sources, data composition, and methodologies for bias detection and correction. This approach will help to prevent unintended disparities in AI tool performance across different demographic groups and empower healthcare providers to deliver safe, high-quality, and equitable care to all patients.

Several speakers highlighted the role of Predetermined Change Control Plans (PCCPs) as a tool that assists both developers and the FDA in managing changes to AI-enabled medical devices. While RSNA understands that FDA emphasizes vendor self-monitoring for adherence to PCCPs, we have concerns that self-monitoring alone may be insufficient for AI tools in radiology, where practices often rely on multiple AI systems from various vendors. These tools, each with unique functions and outputs, may interact in complex ways that individual vendors are not able to fully anticipate or detect. Given this environment, solely relying on vendors to self-report deviations could leave safety issues unaddressed, potentially impacting patient care.

A dual-reporting mechanism would strengthen the oversight process, allowing both vendors and end users, like radiologists, to report deviations in AI tool performance directly to the FDA. Furthermore, we recommend that the FDA establish a formal process allowing radiologists to request modifications or updates to PCCPs based on real-world experience. Radiologists may encounter unique clinical scenarios or identify data-related nuances that were not considered during initial testing but that could significantly impact tool safety and effectiveness (e.g. use of an AI-enabled tool on a patient population when that same population was not well represented in the algorithmic training data). Creating a pathway for radiologists and other end users to provide feedback and request updates would foster collaboration between developers, end users, and regulators, helping to ensure AI tools continue to meet evolving clinical needs while prioritizing patient safety.

RSNA looks forward to supporting the work of FDA’s Digital Health Advisory Committee in the coming months. For additional information or questions, please contact RSNA’s director of government relations, Libby O’Hare ([eoahare@rsna.org](mailto:eoahare@rsna.org)).

Sincerely,



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Chair of the Board  
Radiological Society of North America