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Abstract

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Artificial intelligence (AI) is rapidly transforming the healthcare landscape, with AI-enabled medical devices offering unprecedented opportunities to improve diagnostics, treatment, and patient care. However, with these advancements come new challenges, particularly the risk of algorithmic bias. Biased AI algorithms can perpetuate or even exacerbate existing health disparities, leading to inequitable patient outcomes. Recognizing this critical issue, the U.S. Food and Drug Administration (FDA) has taken a proactive stance in addressing AI bias in medical devices. This article explores the FDA's multifaceted approach to ensuring the safety, effectiveness, and equity of AI-enabled medical technologies.

The FDA's authority to regulate medical devices, including those incorporating AI, is well-established. The agency has been actively developing a regulatory framework that is both flexible enough to accommodate the rapid pace of innovation in AI and robust enough to ensure patient safety. The FDA has authorized over 1,000 AI-enabled devices through its existing premarket pathways, including premarket clearance (510(k)), De Novo classification, and premarket approval (PMA) [1].

The FDA has issued a series of guidance documents and action plans to guide developers in creating and validating AI-enabled medical devices. A cornerstone of this effort is the "Artificial Intelligence and Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan," published in January 2021 [2]. This plan outlines a multi-pronged approach to regulating AI/ML-based SaMD, focusing on a risk-based framework and a total product lifecycle (TPLC) approach.

More recently, in January 2025, the FDA released a comprehensive draft guidance titled "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" [3]. This document provides developers with a clear set of recommendations for the entire lifecycle of an AI-enabled device, from initial design and development to postmarket performance monitoring.

A key focus of the FDA's guidance is the mitigation of bias in AI algorithms. The agency emphasizes the importance of a proactive approach, encouraging developers to consider potential sources of bias throughout the device's lifecycle. The draft guidance provides specific recommendations for sponsors to demonstrate that they have addressed risks associated with bias. These recommendations include:

Data-centric approaches: *The FDA stresses the importance of using high-quality, representative data for training and testing AI models. This includes ensuring that datasets are diverse and reflect the intended patient population to avoid underrepresentation of certain demographic groups.* **Transparency:** The FDA advocates for greater transparency in AI algorithms. The agency encourages manufacturers to provide clear, user-friendly labeling that explains the AI's functionality, limitations, and instructions for use. This transparency is crucial for healthcare professionals to understand how the device works and to make informed decisions. **Postmarket monitoring:** *The FDA recognizes that the performance of AI algorithms can change over time. Therefore, the agency requires manufacturers to have a plan for postmarket monitoring to detect and address any performance degradation or new biases that may emerge after the device is on the market.*

The FDA's approach to regulating AI in medical devices is grounded in a commitment to ensuring that these innovative technologies are safe, effective, and equitable for all patients. By providing clear guidance to developers, promoting transparency, and emphasizing a lifecycle approach, the FDA is working to build a future where AI in healthcare is a force for good, reducing health disparities and improving outcomes for everyone.

References

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[3] U.S. Food and Drug Administration. (2025, January 6). FDA Issues Comprehensive Draft Guidance for Developers of Artificial Intelligence-Enabled Medical Devices*. FDA. https://www.fda.gov/news-events/press-announcements/fda-issues-comprehensive-draft-guidance-developers-artificial-intelligence-enabled-medical-devices