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FDA's Review of Pulse Oximeter Performance Continues a Trend in Addressing Biases in Digital Health Technologies

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***Update**: The FDA recently **announced a virtual meeting** of the CDRH Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee on November 1, 2022, from 9 a.m. to 6 p.m. ET*

The U.S. Food and Drug Administration (FDA) will schedule a public meeting of the Medical Devices Advisory Committee later this year to discuss study results, real-world data, and other evidence concerning the accuracy and performance of pulse oximeters. The planned meeting is consistent with the agency's recent efforts to evaluate the need for and options to address transparency and diversity in the design and development of artificial intelligence/machine learning (AI/ML) based software devices (see our **post** covering FDA's Transparency of AI/ML Enabled Medical Devices Workshop) and in clinical trial design. It is unclear whether or how the outcome of the planned meeting on pulse oximeters will affect prescription and over-the-counter (OTC) pulse oximeters currently on the market, but it is possible that the meeting could lead FDA to impose new testing or labeling requirements for pulse oximeters, and perhaps even other devices that use light-based sensors to evaluate certain biometrics.

The public meeting announcement follows FDA's safety communication from February 2021 informing health care professionals and the public that certain factors, including skin color, may cause inaccurate readings in pulse oximeters. Michael Sjoding and others wrote about the performance disparities in a **correspondence** published in the New England Journal of Medicine in December 2020. FDA warned that performance limitations and inaccuracies may extend to FDA-cleared prescription-use-only pulse oximeter models, as well as OTC models sold directly to consumers. In addition to discussing the data and other evidence relating to limitations in performance and accuracy, FDA's planned public meeting will explore possible recommendations for patients and health care professionals on using pulse oximeters and interpreting results and relevant data that should be provided to pulse oximeter manufacturers to enable further accuracy assessments.

Although prescription-use-only pulse oximeters are class II devices requiring 510(k) submission and review and clearance by FDA, it is not clear in many cases whether the manufacturers conducted human testing that incorporated diverse subjects of varying skin colors. Some pulse oximeter 510(k) summaries expressly state that human performance testing included multiple skin colors, but many do not, especially devices that are based on older predicates with only minor modifications. On the other hand, pulse oximeters sold OTC are class II device but are under FDA enforcement discretion, so there is little assurance that the manufacturers of such devices conducted rigorous performance testing. Thus, the information presented at the planned public meeting should prove useful in evaluating the actual performance limitations inherent in many pulse oximeters.

FDA's focus on pulse oximeter accuracy and the need for diversity and transparency in performance testing is consistent with FDA steps in recent years to address diversity and biases associated with medical device technology and clinical trials. Specifically, the agency has issued guidances on improving clinical trial diversity, including the ***Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials*** draft guidance in April 2022 and the ***Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs*** final guidance in November 2020. In addition, a major topic of FDA's AI/ML workshop in October 2021 was the need for data relating to gender, race, ethnicity, age, disabilities, and comorbidities in clinical testing and human factors analyses of AI/ML-based software to improve consistency and transparency.

Device manufacturers should pay attention to the outcome of this public meeting and FDA's subsequent actions as they could indicate the agency's approach to diversity and transparency in other medical

devices and digital health technologies. It is possible that discussion during the planned public meeting could lead FDA to establish new requirements for pulse oximeter labeling or even performance testing. Furthermore, FDA's consideration of the pulse oximeter accuracy may even cause the agency to take a close look at the limitations of other devices with light-based sensors, including photoplethysmography functions for smart watches.

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Benjamin advises pharmaceutical, medical device and biotech companies on the FDA regulatory process to identify the correct regulatory pathway, assisting with FDA communications and strategy.

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