



State of California
Office of the Attorney General

ROB BONTA
ATTORNEY GENERAL

March 10, 2025

Filed Electronically

Sara Brenner, MD, MPH
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

RE: Docket No. FDA-2023-N-4976, Pulse Oximeters for Medical Purposes – Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submissions Recommendations, Draft Guidance for Industry and Food and Drug Administration Staff

Dear Acting Commissioner Brenner:

Thank you for the opportunity to submit a comment to the Food and Drug Administration (FDA) regarding the agency's "Draft Guidance for Industry and Food and Drug Administration Staff for Pulse Oximeters for Medical Purposes – Non Clinical and Clinical Performance Testing, Labeling, and Premarket Submissions" (Draft Guidance), published on January 7, 2025.

Pulse oximeters are routinely used to measure blood oxygen levels, which inform medical care for a wide range of illnesses. Blood oxygen is often called the "fifth vital sign" and is usually measured along with other vitals. However, the accuracy levels of pulse oximeters vary depending upon the level of pigmentation or melanin in the skin. Use of pulse oximeters on highly pigmented skin results in inaccurate measurements of blood oxygen levels due to the way the medical device functions. Therefore, blood oxygen levels obtained with a pulse oximeter may make some people appear healthier than they are. Importantly, the Draft Guidance includes recommendations for manufacturers on how to gather clinical data to help improve the efficacy of pulse oximeters on people with a wide range of skin tones.

The FDA's release of the Draft Guidance on pulse oximeters is an important step to address urgent concerns related to pulse oximeters' racial and color bias. The Proposed Guidance comes after a 2021 safety communication from the agency about the devices, a several days-long advisory board meeting, a detailed white paper, and extensive studies conducted at the FDA's directive in a specialized lab. All of these aforementioned actions by the FDA unequivocally

show that pulse oximeters do not work for everyone. Any further delay in finalizing and enforcing the FDA's recommendations for clinical testing and warning labels would be unconscionable. All patients need better pulse oximeters now.

The FDA's Draft Guidance comes almost thirty-five years after a study¹ showed that these widely used devices work less effectively on people with darker skin and more than four years after new research on the problem arose as a result of the Covid-19 pandemic, when the devices were integral to determining whether patients should be admitted to the hospital and provided with supplemental oxygen.² Subsequent studies have shown that faulty pulse oximetry caused some patients to be denied care in emergency rooms for severe cases of COVID-19,³ or refused supplemental oxygen while being treated in intensive care units,⁴ and likely also led to cases of organ failure and death for patients with darker skin.⁵ One additional study showed that in the Veteran's Affairs system, pulse oximeters accounted for 80,000 incorrect measurements of hypoxemia, or low oxygen, in one year.⁶ Better devices are urgently needed to avoid the continuation of these harms.

While the guidance is a necessary first step, the FDA should additionally require manufacturers to test pulse oximeters in a variety of real-world settings where patients are known to have low-oxygenated blood. One of the reasons that incorrect readings from pulse oximeters have persisted for so long is because of a lack of testing on patients in real-world settings. The guidance should be expanded to provide details on how manufacturers could collect data from real patients outside of a clinical testing environment and not simply on healthy individuals.

Additionally, the proposed guidance asks manufacturers to gather clinical data showing the efficacy of these devices on all skin tones and submit that data and a new label showing the device performs well on all skin tones in a new 510(k) submission. For the Draft Guidance to have its intended effect, the FDA must continue to demand that manufacturers provide clinical data and proof of efficacy.

¹ Amal Jubran, M.D., et al., *Reliability of Pulse Oximetry in Titrating Supplemental Oxygen Therapy in Ventilator-Dependent Patients*, *Chest Journal* (June 1990), [https://journal.chestnet.org/article/S0012-3692\(16\)32029-3/abstract](https://journal.chestnet.org/article/S0012-3692(16)32029-3/abstract).

² Michael Sjoding M.D., et al., *Racial Bias in Pulse Oximetry Measurement*, *New England Journal of Medicine* (Jan. 16, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMc2029240>.

³ Eric Gottlieb, et al., *Assessment of Racial and Ethnic Differences in Oxygen Supplementation Among Patients in the Intensive Care Unit*, *JAMA Network* (July 11, 2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2794196?guestAccessKey=e4b8e496-5dfb-495b-b3fa-4bcd505bb482&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tf1&utm_term=071122.

⁴ See supra, n. 2

⁵ See supra, n. 3

⁶ Theodore Iwashyna, et al., *Lest a Smoky Haze of Doubt Suffocate Progress Towards Better Pulse Oximeter*, *American Thoracic Society* (Nov. 21, 2024), <https://www.atsjournals.org/doi/abs/10.1513/AnnalsATS.202411-1213ED>.

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Lastly, the proposed guidance would maintain a list of devices that have been shown to work equally well on all skin tones on its website “to further promote transparency.” This proposal is essential to inform healthcare professionals and protect the general public. Providers ordering pulse oximeters in a healthcare setting should be able to check the website and order from the list of devices that work equally well on all patients. In California, healthcare professionals have repeatedly stated they want more information about which pulse oximeters they should be using and prescribing to their diverse patients. And too often, healthcare professionals are still unaware that a device that is instrumental in their work is faulty. The FDA should continue to raise awareness through public advisories and other campaigns so that the general public is aware of this important issue.

The Proposed Guidance is a crucial step towards better medical technology for all. We urge the FDA to finalize it expeditiously.

Sincerely,



ROB BONTA
Attorney General