Improving the Performance of Pulse Oximeters Taking into Consideration Race, Ethnicity, and Differences in Skin Pigmentation

Testimony Before the Food and Drug Administration's Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

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I am Michael Abrams of Public Citizen's Health Research Group. I have no conflicts of interest on this matter.

Public Citizen is a consumer advocacy group with a 50-year history of monitoring Food and Drug Administration (FDA) activities including those pertaining to class II/III medical devices. In 2022, we testified before this advisory committee about the inaccuracy of pulse oximeters related to race, ethnicity and differences in skin pigmentation. Our concerns remain.

Documented pulse oximetry deficiencies in persons with darker skin pigmentation date back to at least 1991, when Zeballos and Weisman observed in 33 Black men that oximeter-measured oxygen levels were several percentage points higher than corresponding levels measured by direct blood gas readings.[1]

By the time of this committee's 2022 meeting, the FDA had collected at least 15 additional studies revealing similar concerns about the accuracy of pulse oximeters related to skin pigmentation. These studies included thousands of subjects; several studies found that needed hospital-based respiratory care was delayed or denied because of low sensitivity pulse oximeter readings.[2] The FDA materials for today's meeting add 13 studies to those collected earlier; seven of these studies confirm bias related to race and ethnicity.[3] For example, the Fawzy et al.

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[1] Zeballos RJ, Weisman IM. Reliability of noninvasive oximetry in Black subjects during exercise and hypoxia. Am Rev Respir Dis. 1991 Dec;144(6):1240-4.

[2] Abrams MT. Review of Pulse Oximeters and Factors that can Impact their Accuracy, Especially Including Skin Pigmentation Levels. Testimony Before the Food and Drug Administration's Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee. November 1, 2022. https://www.citizen.org/wp-content/uploads/2644.pdf. Accessed January 31, 2024.

[3] U.S. Food and Drug Administration. FDA Executive Summary: Performance Evaluation of Pulse Oximeters Taking into Consideration Skin Pigmentation, Race and Ethnicity. Prepared for the February 2, 2023 meeting of the

2023 study of over 24,000 COVID-19 hospitalizations observed that occult hypoxemia rates (Sp02 - Sa02 discrepancies of at least 4%) were evident in nearly 20% of Black or Hispanic patients, compared to 13% of White patients.[4]

Premarket analysis from the FDA shows that most applications for clearance of pulse oximeters include little or no information about race, ethnicity, or skin pigmentation effects, including applications cleared as late as 2022.[5] I confirmed this deficiency by reviewing the last 19 cleared applications of 2023 in the FDA's 510(k) database.[6] Only nine of those applications mentioned pigmentation categories, most frequently characterized as "light and/or dark," while two used the (more standardized) Fitzpatrick scale. Only one application disclosed point estimates regarding bias that clearly contrasted "light and dark" categories. All 19 devices were cleared because they were deemed "substantially equivalent" to prior ("predicate") devices, which likely involved even less (or no) data on skin pigmentation, as previously described by the FDA during the earlier advisory committee meeting.

Surprisingly, adverse event reports or recalls for pulse oximeters have not recently increased,[7] despite this committee's meetings and a 2021 FDA communication about device inaccuracies.[8] The FDA's briefing materials for today's meeting confirm the lack of an expected increase in adverse event reports. Using data compiled by Madris Kinard with her Device Events software, I independently confirmed that there has been no noticeable increase in adverse event reports or recalls.[9] The Device Events data show not only that the recent adverse event signal was low, but also that recalls were infrequent. Moreover, race/ethnicity was not reported in essentially all the more than 12,000 adverse event reports in the Device Events data.

This advisory committee is considering more rigorous clearance standards for pulse oximeters, including more racially- and ethnically-representative subject pools.[10] Such changes will only suffice if the required sub-samples are large enough to generate between-group point

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Anesthesiology Devices Advisory Committee Center for Devices and Radiological Health. https://www.fda.gov/media/175828/download. Accessed January 31, 2024. PDF p. 41.

[4] *Id.* PDF *p.* 45.

[5] U.S. Food and Drug Administration. FDA executive summary: Review of Pulse Oximeters and Factors that can Impact their Accuracy. Prepared for the November 1, 2022, meeting of the Anesthesiology Devices Advisory Committee Center for Devices and Radiological Health. https://www.fda.gov/media/162709/download. Accessed October 28, 2022. PDF p. 14, 16, 17.

[6] U.S. Food and Drug Administration. 510(k) Premarket Notification Database. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed February 1, 2024.

[7] U.S. Food and Drug Administration. FDA Executive Summary: Performance Evaluation of Pulse Oximeters Taking into Consideration Skin Pigmentation, Race and Ethnicity. https://www.fda.gov/media/175828/download. Accessed January 31, 2024. PDF pp. 25-27.

[8] *Id.* PDF p. 4.

[9] Device Events Homepage. https://deviceevents.com/. Accessed February 1, 2024.

[10] U.S. Food and Drug Administration. Pulse Oximeters 2. Panel Questions. https://www.fda.gov/media/175827/download. Accessed February 1, 2024.

estimates that give clinicians a true sense of the skin pigmentation bias inherent in the devices they are using. Through your deliberations, we urge the committee to clarify that underlying statistical power consideration.

Enhanced pulse oximeter testing standards should be implemented for new and existing devices. At the same time, all pulse oximeter labeling should be immediately revised to educate and caution clinicians about skin pigmentation bias,[11] as called for in a November 2023 letter sent by Attorneys General in 24 states and the District of Columbia to FDA Commissioner Robert M. Califf. Devices that demonstrate unreasonable error, or otherwise fail to comply with the testing requirements, should be recalled (or removed) from the market.

[11] Attorneys General Letter to U.S. Food and Drug Administrator Robert M. Califf. Regarding Concerns Related to Pulse Oximeters. November 1, 2023.