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

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Public Citizen's Health Research Group has a 50-year history of monitoring activities of the Food and Drug Administration (FDA) especially pertaining to the safety and effectiveness of medications and class II/III medical devices.

We believe this advisory committee topic — pulse oximeter accuracy given natural human variations in skin pigmentation levels — is one that exemplifies two ongoing challenges the FDA faces as the principal gatekeeper regarding the safety and effectiveness of medical devices. The first of these challenges is the issue of racial equity. The second is the deficiencies of the 510(k) pathway for clearing medical devices.

Concerning racial equity, we remind this committee and the FDA that the lack of diversity in FDA-regulated clinical trials has been a longstanding problem that can lead to inferior outcomes for patients of color. The fact that, for example, persons of color have not received proper care related to COVID-19 infections because of inaccurate pulse oximeters is unacceptable.

Regarding the 510(k) process, we have long been concerned that evidentiary standards for safety and effectiveness are too lax for many critical medical devices, thus giving manufacturers a reckless fast-track pathway to marketing.[1] In the case of pulse oximeters, we know that since the 1980s hundreds of such devices or their components have been cleared for marketing. In its briefing materials, the FDA reviewed a sub-sample from a total of 420 510(k) applications and found that clinical data was *not* required for approximately 35% (32/84) of such submissions

[1] Carome MA. Implanted Spinal Cord Stimulators for Pain Relief, https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf. June 10, 2020. Accessed October 31, 2022.

from 2000-2020.[2] FDA further reported that the measurement of skin pigmentation level was methodologically limited and variable across such device applications.[3]

Since at least 1991, researchers have observed that increasing levels of skin pigmentation correlate with overestimates by pulse oximeters of arterial oxygen saturation.[4] The FDA's briefing packet for this meeting tabulates at least 15 such studies,[5] with thousands of subjects, published just this year, including research that suggest treatments are withheld because of this medical device error.[6]

Accordingly, we agree with the FDA that more research is needed, and better device labeling may also be useful, but we would go decidedly further than that. We believe that there is now well-supported urgency that the FDA should do the following:

(1) Review all existing pulse oximeters for evidence that they accurately measure blood oxygen saturation levels in persons with increasing levels of pigmentation in their skin.
(2) Absent evidence, or with evidence of deficiencies, the manufacturers should be required to recall such devices until they can be corrected. (We are very concerned that FDA's briefing packet included little about the history of pulse oximeter recalls and safety communications. Therefore, this serious omission is inexcusable and must be remedied immediately.)
(3) Revise the 510(k) pathway standards to ensure that devices will only be marketed after they demonstrate reasonable safety and effectiveness in populations at least as diverse as the U.S. population, and as necessary in populations enriched to make sure relevant minority group issues are not neglected.

We hope the committee will urge the FDA towards these much-needed and long-overdue regulatory reforms.

[2] Food and Drug Administration. FDA executive summary: Review of Pulse Oximeters and Factors that can Impact their Accuracy. Prepared for 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.
[3] *Id*. PDF pp. 16, 18.
[4] Carome M. For Years, FDA Has Allowed the Marketing of Blood Oxygen Monitors that Contributed to Racial Disparities in Health Care. Public Citizen's Health Letter. August 2022. https://www.citizen.org/article/outrage-of-the-month-for-years-fda-has-allowed-the-marketing-of-blood-oxygen-monitors-that-contributed-to-racial-disparities-in-health-care/. Accessed October 31, 2022.
[5] Food and Drug Administration. FDA executive summary: Review of Pulse Oximeters and Factors that can Impact their Accuracy. Prepared for 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. 36.
[6] *Ibid.* Studies: Fawzy *et al*, 2022, Gottlieb *et al*, 2022, Sudat *et al*, 2022.