

Congress of the United States

Washington, DC 20515

August 12, 2022

Dr. Robert M Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf,

We write to follow up with the U.S. Food and Drug Administration (FDA) about the accuracy of pulse oximeters across racially diverse patients and consumers. Recent studies suggest that pulse oximeters, medical devices that monitor blood oxygen saturation (SpO₂) levels, overestimated SpO₂ in patients of color which contributed to unrecognized or delayed COVID-19 treatment and potentially worse health outcomes.¹ We appreciate that, last year, the FDA put out a safety communication about pulse oximeter accuracy and limitations to inform patients and providers of these risks, and we welcome the recent news that the FDA is planning to convene a public meeting of the Medical Devices Advisory Committee later this year.² There are decades of research showing inaccurate results when pulse oximeters are used to monitor people of color, particularly patients with darker skin.³ Therefore, we are seeking information from the FDA on your clearance of pulse oximeters and urge the FDA to initiate a post market study for these devices to understand what improvements to the technology will make the devices effective on the full range of human skin pigmentation.

Our January 2021 letter expressed concerns about how pulse oximeters, which are cleared medical devices, may be unreliable solely based on a patient's skin pigment and can worsen health outcomes for people of color.⁴ That is because pulse oximeters “work by

¹ Wall Street Journal, “Pulse Oximeters Are Less Accurate Among Black, Hispanic and Asian Covid-19 Patients,” Dominique Mosbergen, May 31, 2022, <https://www.wsj.com/articles/pulse-oximeters-are-less-accurate-among-black-hispanic-and-asian-covid-19-patients-11654009236>; NPR, “When it comes to darker skin, pulse oximeters fall short,” Craig Lemoult, July 11, 2022, <https://www.npr.org/sections/health-shots/2022/07/11/1110370384/when-it-comes-to-darker-skin-pulse-oximeters-fall-short>.

² FDA, “Pulse Oximeter Accuracy and Limitations: FDA Safety Communication,” February 19, 2021, <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>.

³ Wall Street Journal, “Pulse Oximeters Are Less Accurate Among Black, Hispanic and Asian Covid-19 Patients,” Dominique Mosbergen, May 31, 2022, <https://www.wsj.com/articles/pulse-oximeters-are-less-accurate-among-black-hispanic-and-asian-covid-19-patients-11654009236>.

⁴ Senator Elizabeth Warren, “Senators Warren, Booker and Wyden Urge FDA to Address Concerns about Dangerous Pulse Oximeter Inaccuracies for Patients of Color,” <https://www.warren.senate.gov/oversight/letters/senators-warren-booker-and-wyden-urge-fda-to-address-concerns-about-dangerous-pulse-oximeter-inaccuracies-for-patients-of-color>.

shooting light onto a person’s skin and observing how much bounces back,” and “flawed readings are the result of how light is absorbed on different skin shades.”⁵ The device’s inequitable results can have life threatening consequences for patients, which may have been exacerbated by the COVID-19 pandemic.⁶ The medical community’s use and reliance on pulse oximeters may have contributed to the inequitable use of COVID-19 treatments as patients of color were deemed ineligible because of those SpO₂ overestimations.⁷

Recent studies revealed the impact of inaccurate pulse oximeter measures in COVID-19 patients and acknowledged that it may have contributed to lower quality health care. One study determined that “[p]ulse oximeter measurements among Black, Hispanic and Asian Covid-19 patients were less accurate than measurements for white patients,” and that “[t]he discrepancies may have led to some patients of color with severe disease receiving delayed or no treatment.”⁸ Black patients were almost 30 percent and Latino patients were over 20 percent less likely than white patients to be recognized as eligible for COVID-19 treatments⁹ during a pandemic that has disproportionately impacted communities of color and in which Black and Latino patients have a significantly increased mortality risk than their white counterparts.¹⁰ Another study found that, because of pulse oximeters’ inaccurate measurements, patients of color received less supplemental oxygen than their white counterparts.¹¹

The *FDA is tasked with* regulating medical devices in the U.S., including pulse oximeters. We therefore urge the FDA to initiate a post market study for pulse oximeters to ensure they are accurate on the full range of human skin pigmentation. We also ask that you provide answers to the following questions no later than August 26, 2022:

- 1) Since issuing its safety communication, has the FDA reviewed data on the inaccuracy of pulse oximeters due to skin pigmentation, including those used in clinical settings?

⁵ Politico, “Flawed oxygen readings may be behind Covid-19’s toll on people of color,” Ben Leonard, July 1, 2022, <https://subscriber.politicopro.com/article/2022/07/flawed-oxygen-readings-impact-minorities-00043282?source=email>.

⁶ NPR, “When it comes to darker skin, pulse oximeters fall short,” Craig Lemoult, July 11, 2022, <https://www.npr.org/sections/health-shots/2022/07/11/1110370384/when-it-comes-to-darker-skin-pulse-oximeters-fall-short>.

⁷ *Id.*

⁸ Wall Street Journal, “Pulse Oximeters Are Less Accurate Among Black, Hispanic and Asian Covid-19 Patients,” Dominique Mosbergen, May 31, 2022, <https://www.wsj.com/articles/pulse-oximeters-are-less-accurate-among-black-hispanic-and-asian-covid-19-patients-11654009236>.

⁹ Stat, “Faulty oxygen readings delayed Covid treatments for darker-skinned patients, study finds,” Usha Lee McFarling, May 31, 2022, <https://www.statnews.com/2022/05/31/faulty-oxygen-readings-delayed-covid-treatments-darker-skin-patients/>.

¹⁰ CDC, “Hospitalization and Death by Race/Ethnicity,” <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>.

¹¹ NPR, “When it comes to darker skin, pulse oximeters fall short,” Craig Lemoult, July 11, 2022, <https://www.npr.org/sections/health-shots/2022/07/11/1110370384/when-it-comes-to-darker-skin-pulse-oximeters-fall-short>.


- a. If yes, what was the scope of those reviews? What did they conclude?
 - b. If not, why not?
- 2) For current pulse oximeters being used clinically, before the product received FDA clearance, did the FDA collect data on the accuracy of the product among subgroups, for example, by race and ethnicity?
 - a. Did the FDA collect demographic data on the test subjects among whom the product was calibrated?
 - b. If so, were the test participants representative of the U.S. population in race and ethnicity?
 - c. Were there enough test subjects for an adequately powered study of differences between groups?
 - d. Did these products reflect differences in accuracy among test subjects by their race and ethnicity?
 - e. If so, were these differences significant?
- 3) To what degree are different cleared pulse oximeters accurate on the full range of human skin pigmentation?
 - a. If there was variation in performance, why were these products cleared?
 - b. Were the manufacturers of these products required to inform purchasers of the differences in accuracy?
- 4) FDA guidance on pulse oximeters from 2013 recommends that applicants conduct a study in healthy volunteers that includes “subjects with a range of skin pigmentations, including at least two darkly pigmented subjects or 15 percent of your subject pool, whichever is larger.”¹²
 - a. From where did this recommendation of 15 percent originate? Is the suggested number of as few as two people considered normal for studies like these?
 - b. When was the last time this guidance was reviewed? Have you considered increasing the pool?
- 5) Does the FDA plan to adjust accuracy requirements of future pulse oximeters seeking clearance to ensure they are accurate on all patients regardless of skin color?
 - a. If so, are you looking at updating the 510k process so devices that have shown bias through peer-reviewed studies or clinical practice may not use the substantial equivalence pathway?
- 6) Is there evidence of other medical devices that interact differently with the full range of human skin pigmentation?
 - a. If so, how many?


¹² FDA Center for Devices and Radiological Health, "Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff," March 4, 2013, <https://www.fda.gov/media/72470/download>.

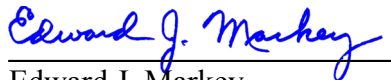
- b. Do you plan to release a safety communication for these products? If not, how are you notifying patients and health care professionals about inaccuracies?

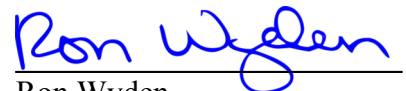
Thank you for your prompt attention to this matter.


Sincerely,


Elizabeth Warren
United States Senator


Cory A. Booker
United States Senator


Edward J. Markey
United States Senator


Ron Wyden
United States Senator


Tammy Duckworth
United States Senator