

United States Senate

WASHINGTON, DC 20510

January 25, 2021

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

Dear Dr. Woodcock:

We write to request that the U.S. Food and Drug Administration (FDA) quickly conduct a review of the accuracy of pulse oximeters across racially diverse patients and consumers. The ongoing coronavirus disease 2019 (COVID-19) pandemic has had disproportionate consequences for communities of color, who have mortality risks that are significantly higher than those for white Americans.¹ The use of pulse oximeters to monitor blood oxygen levels has increased during the pandemic, but a new study suggests that devices measuring blood oxygen levels are less accurate in Black patients with undetected low levels of oxygen in their blood when compared to white patients.² The authors concluded that “reliance on pulse oximetry to triage patients and adjust supplemental oxygen levels may place Black patients at increased risk for hypoxemia,” a finding with “major implications...during the current [COVID-19] pandemic.”³ Therefore, we are seeking information from the FDA on their clearance or approval of pulse oximetry measurement devices that may be biased against patients with “darkly pigmented” skin.⁴

Pulse oximeters measure a patient’s blood oxygen saturation (SpO₂) levels, an important measurement in determining patient’s basic treatment needs, including the administration of supplemental oxygen.⁵ Sales of pulse oximeters began increasing this year, with many retail

¹CNBC, “CDC quietly adjusted Covid death data, shows higher relative toll on Black, Hispanic people,” Will Feuer, December 4 2020, <https://www.cnbc.com/2020/12/04/revised-cdc-data-shows-higher-relative-black-hispanic-covid-death-rate.html>.

² New England Journal of Medicine, “Racial Bias in Pulse Oximetry Measurement,” Michael W. Sjoding, M.D., et al., December 17, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMc2029240>; NPR, “Devices Used In COVID-19 Treatment Can Give Errors For Patients With Dark Skin,” Richard Harris, December 16, 2020, <https://www.npr.org/sections/health-shots/2020/12/16/947226068/dark-skin-can-lead-to-errors-with-pulse-oximeters-used-in-covid-19-treatment>.

³ New England Journal of Medicine, “Racial Bias in Pulse Oximetry Measurement,” Michael W. Sjoding, M.D., et al., December 17, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMc2029240>; NPR, “Devices Used In COVID-19 Treatment Can Give Errors For Patients With Dark Skin,” Richard Harris, December 16, 2020, <https://www.npr.org/sections/health-shots/2020/12/16/947226068/dark-skin-can-lead-to-errors-with-pulse-oximeters-used-in-covid-19-treatment>.

⁴ 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>.

⁵ New England Journal of Medicine, “Racial Bias in Pulse Oximetry Measurement,” Michael W. Sjoding, M.D., et al., December 17, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMc2029240>; The Washington Post, “What is a pulse oximeter, and does the coronavirus pandemic mean you need one?,” Laura Daily, May 19, 2020,

pharmacies selling out amid reports that the devices “give you valuable information about your health during a bout of COVID-19.”⁶ Some emergency departments and outpatient testing centers are even discharging some COVID-19 patients with a home pulse oximeter to be used for self-monitoring.⁷

Despite the widespread purchases of pulse oximeters and the advice by some in the medical field that they be used with suspected cases of COVID-19 infection, the medical community has long acknowledged that there may be racial bias in pulse oximetry measurement devices.⁸ In a 2005 publication, three pulse oximeter brands were tested on 11 Black participants and 10 white participants.⁹ The study found that all three assigned higher pulse oxygen saturation (SpO₂) levels to the Black individuals—notably finding the effect of skin pigment on inaccuracy in the pulse oximeters increased linearly as SpO₂ levels decreased.¹⁰ A low SpO₂ means a patient is more critically ill, and the fact that the pulse oximeters become less accurate the more sick a patient becomes is unacceptable. The study noted that “[m]ost pulse oximeters have probably been calibrated using light-skinned individuals, with the assumption that skin pigment does not matter.”¹¹ Skin pigment does appear to matter to pulse oximeter measurements, as demonstrated by the 2005 study,¹² a 2007 study,¹³ and a recent 2020 study¹⁴ which found that low levels of oxygen in the blood of Black patients was nearly three times as likely to be undetected than it was in white patients. Simply put, pulse oximeters appear likely to provide misleading measures of blood oxygen level to patients of color—indicating that patients are healthier than they actually are and increasing their risk of negative health impacts from diseases like COVID-19.

In order to reduce health disparities and restore trust among communities of color, we must reevaluate the ways in which current practices and clinical tools themselves potentially worsen outcomes for people of color. It is unacceptable that the efficacy of these devices may have a direct negative correlation with a patient’s amount of skin pigment, and that the clinical

https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad_story.html.

⁶ CNN, “People are buying pulse oximeters to try and detect coronavirus at home. Do you need one?,” Harmeet Kaur, April 26, 2020, <https://www.cnn.com/2020/04/26/health/pulse-oximeters-coronavirus-wellness-scen-trnd/index.html>; The New York Times, “What’s a Pulse Oximeter, and Do I Really Need One at Home?” Tara Parker-Pope, Dec. 22, 2020, <https://www.nytimes.com/2020/04/24/well/live/coronavirus-pulse-oximeter-oxygen.html>.

⁷ Academic Emergency Medicine, “Novel use of home pulse oximetry monitoring in COVID-19 patients discharged from the emergency department identifies need for hospitalization,” Sonia Shah, et al., August 2020, <https://doi.org/10.1111/acem.14053>.

⁸ Anesthesiology, “Effects of Skin Pigmentation on Pulse Oximeter Accuracy at Low Saturation,” Philip E. Bickler, M.D., Ph.D., John R. Feiner, M.D., and John W. Severinghaus, M.D., April 2005, <https://pubs.asahq.org/anesthesiology/article/102/4/715/7364/Effects-of-Skin-Pigmentation-on-Pulse-Oximeter>.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*; Anesthesia & Analgesia, “Dark skin decreases the accuracy of pulse oximeters at low oxygen saturation: the effects of oximeter probe type and gender,” John R. Feiner MD, John W. Severinghaus, MD, Philip E. Bickler MD, PhD, December 2007, <https://doi.org/10.1213/01.ane.0000285988.35174.d9>.

¹⁴ New England Journal of Medicine, “Racial Bias in Pulse Oximetry Measurement,” Michael W. Sjoding, M.D., et al., December 17, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMc2029240>.

significance of this racial bias, recurring in study after study, simply remains unknown.¹⁵ With an ongoing pandemic disproportionately affecting communities of color, it can be a matter of life or death that the very device that could help these communities and their health care providers detect the need for urgent care is less likely to alert them to risks simply because of the color of their skin. Racial disparities in health care stem from a wide variety of factors, and it is particularly disturbing that racism may be embedded in key clinical tools. Additionally, if these tools are creating erroneous data, the racism can be perpetuated through use of the data in clinical trials or epidemiologic studies.

The *FDA is tasked with* regulating medical devices in the U.S., including pulse oximeters. We therefore ask the FDA to conduct a review of the interaction between a patient's skin color and the accuracy of pulse oximetry measurements. We also ask that you provide answers to the following questions no later than February 8, 2021:


- 1) Has the FDA reviewed data on the inaccuracy due to skin color of pulse oximeters, including those used in professional and at-home settings? If so, what has the FDA concluded, and what is the clinical significance of this inaccuracy?
- 2) For current pulse oximeters being used clinically and over-the-counter, before the product received FDA clearance or approval, did the FDA collect data on the accuracy of the product among subgroups for example, by sex, age, race, and ethnicity?
 - a. Was data shared on the test subjects among whom the product was calibrated?
 - b. If so, were the test participants representative of the U.S. population in sex, age, 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) During the COVID-19 pandemic, sales of many over-the-counter pulse oximetry devices have sky-rocketed, though some of these devices are not considered medical devices and are not FDA cleared or approved pulse oximeters.
 - a. Has the FDA be monitoring these devices to ensure they are being marketed appropriately under the *Federal Food, Drug, and Cosmetic Act* (FDCA)?
 - b. If these devices are being monitored, has the FDA identified any accuracy issues with these over-the-counter devices?
 - c. Has the FDA seized or requested a recall of any products from the market due to their inaccuracy in pulse oximetry measurements? If so, what are those products?
- 4) To what degree are different cleared or approved pulse oximeters efficacious across racial and ethnic groups? Is one group consistently producing more accurate measures? Is one group consistently producing less accurate measures?
 - a. If so, why were these products cleared or approved?

¹⁵ *Id.*

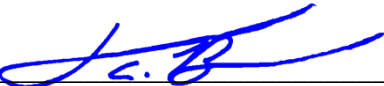
- b. Were the producers of these products required to inform those purchasing of the differences in accuracy?
- 5) FDA guidance on pulse oximeters from 2013 recommends that applicants conduct a study in healthy volunteers that includes “subjects with a range of skin pigmentations, including at least 2 darkly pigmented subjects or 15% of your subject pool, whichever is larger.”¹⁶
- a. From where did this recommendation of 15% originate? Is the suggested number of as few as 2 people considered normal for studies like these?
 - b. When was the last time this guidance was reviewed?
 - c. Has the COVID-19 pandemic encouraged the review and a potential update of this guidance?
- 6) Does the FDA plan to adjust accuracy requirements of future pulse oximeters seeking clearance or approval to ensure they are accurate on all patients regardless of skin color?
- 7) Is there evidence that other infrared medical devices that interact with a patient’s skin pigment, such as vein visualization devices or thermometers, also vary in efficacy by the patient’s race and ethnicity?

Thank you for your prompt attention to this matter.

Sincerely,


Elizabeth Warren
United States Senator


Ron Wyden
United States Senator


Cory A. Booker
United States Senator

¹⁶ 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>.