



State of California
Office of the Attorney General

ROB BONTA

ATTORNEY GENERAL

November 1, 2023

Via Electronic Mail and U.S. Mail

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

Today marks the one-year anniversary of the Food and Drug Administration's November 1, 2022, public meeting to address concerns related to pulse oximeters' race and color bias. This convening was a welcomed and much-needed first step in redressing the harms such medical devices have caused and continue to cause people of color. Since the convening, however, pulse oximeters continue to be sold without clear warning labels or other guidance to protect individuals from harm. We, the undersigned Attorneys General, write to encourage the FDA to act with urgency to address the inaccuracy of pulse oximetry when used on people with darker toned skin.

Blood oxygen level readings can be a crucial diagnostic indicator, especially for respiratory illnesses. Pulse oximeters are routinely used to determine blood oxygen levels for patients with conditions ranging from heart attack, heart failure, chronic obstructive pulmonary disease, asthma, lung cancer, and other diseases.¹ One such disease is COVID-19, which has had a disproportionately devastating impact on populations of color. In the early days of the pandemic, Black Americans were more than twice as likely to die of the disease as whites.² Research indicates that pulse oximeter errors due to technical inaccuracies in reading darker

¹ See e.g., Johns Hopkins Medicine, *Pulse Oximetry*, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/pulse-oximetry>.

² Lisa Cooper, National Urban League, *The Silver Lining in COVID-19's Dark Clouds, State of Black America*, <https://soba.iamempowered.com/silver-lining-covid-19%E2%80%99s-dark-clouds>; see also Nambi Ndugga et al., Kaiser Family Foundation, *COVID-19 Cases and Deaths, Vaccinations, and Treatments by Race/Ethnicity as of Fall 2022* (Nov. 17, 2022), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/covid-19-cases-and-deaths-vaccinations-and-treatments-by-race-ethnicity-as-of-fall-2022/>; Maritza Vasquez Reyes, *The Disproportional Impact of COVID-19 on African Americans*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7762908/> (December 2020) 299–307.

toned skin have caused Black patients and other people of color disproportionately increased time to diagnosis of illness, delayed hospital admissions, and delayed access to lifesaving treatment.³ As pulse oximeters were designed and calibrated using lighter skin tones,⁴ they tend to overestimate the oxygenation of blood for people with darker skin tones—leading to an underestimation of their need for healthcare and exacerbating already serious risks.⁵

It is imperative that the FDA act now to prevent additional severe illness and mortalities among darker skinned people resulting from inaccurate or misleading pulse oximeter readings as well as inadequate diagnostic and treatment protocols and procedures. This is particularly critical as the nation moves from a declared coronavirus public health emergency to a still-dangerous endemic phase.⁶

New Evidence Confirms Pulse Oximeters' Skin Color Bias

New evidence continues to confirm the skin tone bias inherent in pulse oximeters, and their potentially fatal unreliability in people with darker skin tones.⁷ One recent California study

³ See e.g. Usha Lee McFarling, *Inaccurate Pulse Oximeter Readings Tied to Less Supplemental Oxygen for Darker-Skinned ICU Patients*, STAT (July 11, 2022), <https://www.statnews.com/2022/07/11/inaccurate-pulse-oximeter-readings-tied-to-less-supplemental-oxygen-for-darker-skinned-icu-patients/>. Prior validation of these devices has (1) only required small studies of small numbers of patients, very few of whom were darker skinned, and (2) taken place in carefully controlled lab settings that do not correlate to how the devices actually are used with sick patients. Usha Lee McFarling, *FDA Panel Asks for Improvements in Pulse Oximeters*, STAT (November 1, 2022), <https://www.statnews.com/2022/11/01/fda-panel-asks-for-improvements-in-pulse-oximeters/>.

⁴ See Simar Bijaj, *Racial Bias is Built Into the Design of Pulse Oximeters*, Wash. Post (July 27, 2022), (describing technology history); Philip E. Bickler, John R. Feiner, and John W. Severinghaus, 102 *Anesthesiology* (Apr. 2005), pp. 715-719, <https://pubs.asahq.org/anesthesiology/article/102/4/715/7364/Effects-of-Skin-Pigmentation-on-Pulse-Oximeter>.

⁵ African American healthcare consumers are already at higher risk in healthcare settings given cognitive or implicit racial or cultural bias stemming in part from lack of physician-patient concordance and physician cultural competence. Megan Johnson Shen, et al., *The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature*, *J Racial Ethn Health Disparities* (Feb. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5591056/>; see also Patrick Boyle, *Do Black Patients Fare Better with Black Doctors?* (June 6, 2023), <https://www.aamc.org/news/do-black-patients-fare-better-black-doctors>.

⁶ See Center for Disease Control, *End of the Federal COVID-19 Public Health Emergency (PHE) Declaration* (updated Sept. 12, 2023), <https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html>; Lily Ramsey, *WHO Chief: World Must Prepare for Deadlier Outbreak than COVID-19*, *News Medical Life Sciences* (May 23, 2023), <https://www.news-medical.net/news/20230523/WHO-chief-World-must-prepare-for-deadlier-outbreak-than-COVID-19.aspx>.

⁷ Sylvia E.K. Sudat, et al., *Racial Disparities in Pulse Oximeter Device Inaccuracy and Estimated Clinical Impact on COVID-19 Treatment Course*, 192 *Am. J. of Epidemiology* 5, pp. 703-713 (May 2023) (pulse oximetry bias likely resulted in fewer hospital admissions and increased time to treatment for Black patients), <https://academic.oup.com/aje/article/192/5/703/6730981>; Ashraf Fawzy, et al., *Racial*

found that pulse oximeter errors likely led Black COVID-19 patients to face a 4.5 hour delay in access to supplemental oxygen, as well as a reduced likelihood of hospital admission and delays or reduced access to dexamethasone treatment.⁸ Moreover, this particular biased technology is just one piece in the larger context of “discriminatory medical research and technology [that] has resulted in worsening health disparities that harm African Americans” and other darker-skinned populations.⁹

We are additionally concerned about the risk of pulse oximeters’ incorporation into other diagnostic tools or medical technologies.¹⁰ Pulse oximeter readings help diagnose everything from sleep apnea to heart disease. In light of the “mass-scale digitization of data and the emerging technologies that use them,”¹¹ software or other tools that make predictions of future healthcare needs based on past pulse oximetry data with embedded color bias could end up reproducing health disparities based on race.

Finally, pulse oximeters’ widespread use in the maternal and infant health realm, where blood oxygen is a critical vital sign and determinant of health status for both mother and infant, is especially troubling.¹² It is unconscionable in a multi-racial, multi-ethnic nation with populations spanning the color, age, and medical vulnerability spectra that sub-optimal and

and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients with COVID-19 (May 31, 2022) (overestimation of arterial oxygen saturation levels by pulse oximetry occurs in patients of racial and ethnic minority groups with COVID-19 and contributes to unrecognized or delayed recognition of eligibility to receive COVID-19 therapies) <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653>.

⁸ See Sudat, supra n.7; Christina Jewett, *Faulty Oxygen Readings Delayed Care to Black and Hispanic Covid Patients, Study Finds*, <https://www.nytimes.com/2023/08/24/health/oxygen-covid-treatment-race.html> (citing Ashraf Fawzy, et al., *Clinical Outcomes Associated With Overestimation of Oxygen Saturation by Pulse Oximetry in Patients Hospitalized With COVID-19*, JAMA Netw. Open (Aug. 24, 2023)).

⁹ See California Task Force to Study and Develop Reparations Proposals for African Americans, Chapter 12, *Final Report*, (2023), p. 450, <https://oag.ca.gov/system/files/media/ch12-ca-reparations.pdf>.

¹⁰ See Larry Hardesty, Massachusetts Institute of Technology, *Study Finds Gender and Skin-Type Bias in Commercial Artificial-Intelligence Systems* (Feb. 11, 2018) (describing skin-color biases in other commercially available technology), <https://news.mit.edu/2018/study-finds-gender-skin-type-bias-artificial-intelligence-systems-0212>.

¹¹ Nicol Turner Lee et al., Brookings Institute, *Algorithmic Bias Detection and Mitigation: Best Practices and Policies to Reduce Consumer Harms* (May 22, 2019), <https://www.brookings.edu/articles/algorithmic-bias-detection-and-mitigation-best-practices-and-policies-to-reduce-consumer-harms/>.

¹² See e.g., UNITAID, *Next Generation Pulse Oximeters Have Great Potential to Reduce Maternal and Child Mortality, PATH and Unitaaid Report Says* (Sept. 12, 2022), <https://unitaid.org/news-blog/next-generation-pulse-oximeters-have-great-potential-to-reduce-maternal-and-child-mortality-path-and-unitaid-report-says/#en>; Alexandra L. Millman, et al., *Oxygen Saturation as a Predictor of Adverse Maternal Outcomes in Women with Preeclampsia* (July 2011), [https://www.jogc.com/article/S1701-2163\(16\)34955-6/pdf](https://www.jogc.com/article/S1701-2163(16)34955-6/pdf) (discussing the critical role of respiratory assessment by cardiorespiratory symptoms and/or oxygen saturation by pulse oximetry in predicting adverse maternal outcomes in women admitted to hospital with preeclampsia).

potentially harmful diagnostic technology such as the pulse oximeter is not calibrated to adjust for skin color. Such inaccuracy compounds maternal and infant mortality risks for darker skinned mothers and their infants, contributing to the current, avoidable crisis of maternal and infant mortality in the U.S. as well as other dimensions of health disparities.¹³

Proposed Urgent FDA Actions

As you know, regulation of medical devices such as pulse oximeters, including their “safety and effectiveness,” is the responsibility of the FDA. 21 U.S.C. § 360k(a). We therefore respectfully ask the FDA to take immediate action to ameliorate further unnecessary health risk to people with darker skin tones. Specifically, the FDA should immediately:

1. Require manufacturers and vendors of pulse oximeters to include clear, comprehensible, and evidence-based warning labels to all users about the reduced effectiveness of all pulse oximeter devices (both prescription and over-the-counter) based on skin tones. This information should include an appropriate, simple narrative and a pictograph indicating a warning for patients with darker skin tones.
2. Require inclusion of similar warnings in other medical devices that incorporate pulse oximeter readings, such as medical device software used for diagnosis or treatment of medical conditions.
3. Update the FDA’s November 2022 Safety Communication on “Pulse Oximeter Accuracy and Limitations”¹⁴ with a more clear and comprehensive statement of the latest information regarding the current evidence base (and its weaknesses) relating to pulse oximeters.
4. Issue a letter to healthcare providers about the risks and reduced efficacy of pulse oximeters for patient subgroups with darker skin tones. The letter should include reference to the National Institutes of Health’s March 6, 2023 updated treatment guidelines for COVID-19, which recommend ameliorative actions to counterbalance pulse oximeters’ known deficiencies by, for example, ensuring close monitoring of clinical progress in both clinical and home settings, the latter by video consultation, telephone calls, text messaging, or home visits.¹⁵

¹³ See Anuli Njok, et al., *Listen to the Whispers Before They Become Screams: Addressing Black Maternal Morbidity and Mortality in the United States* (February 3, 2023) (describing causes and consequences of maternal health disparities,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9914526/pdf/healthcare-11-00438.pdf>.

¹⁴ *Pulse Oximeter Accuracy and Limitations: FDA Safety Communication* (last updated Nov. 7, 2022), <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>.

¹⁵ National Institutes of Health, *Covid-19 Treatment Guidelines, Clinical Spectrum of SARS-CoV-2 Infection*, (Mar. 6, 2023) <https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/>.

5. Set an accelerated timeline for review of the Medical Devices Advisory Committee's recommendations, and for public release of the review. To facilitate public input, the FDA should indicate the range of additional required or recommended actions the FDA is considering.
6. Update and finalize regulations requiring demographically representative clinical trials for previously approved medical devices like pulse oximeters. Clarify and expand on guidance that clinical studies for these devices must be demographically representative, in order to ensure that studies have the necessary statistical power to detect differences in accuracy between demographic groups (particularly based on skin color).¹⁶

Ultimately, patients of color need and deserve technology that works as well for them, as it does for the predominantly white patient population with whom this tool was originally designed and tested. To this end, the FDA should support ongoing research to provide better calibration of existing pulse oximeter devices, and/or development of new tools that work accurately and equitably across a diversity of skin tones. The FDA should prioritize development of the research base to accomplish this goal, and should update its guidance as soon as improved technology has been tested and validated.

In this moment, our country faces multiple epidemiological and other public health, safety, and national security threats. The accuracy of diagnostic devices to ensure timely and potentially lifesaving access to healthcare should not be one of them. We welcome any other information you may wish to provide on any actions completed or planned relating to pulse oximeters and racial bias. We thank the FDA for previously convening a discussion of this important topic, and appreciate you as a powerful partner in the fight for health equity for all.

Sincerely,



ROB BONTA
California Attorney General



KRIS MAYES
Arizona Attorney General



PHILIP J. WEISER
Colorado Attorney General



WILLIAM TONG
Connecticut Attorney General

¹⁶ *FDA Safety Communication*, *supra* n. 14; see also UNITAID-World Health Organization, *Next Generation Pulse Oximeters: Technology and Market Landscape* (Sept. 2022), https://media.path.org/documents/MD_TIMCI_multimodal_ReportDevo_2022.pdf, p 33.



KATHLEEN JENNINGS
Delaware Attorney General



BRIAN L. SCHWALB
District of Columbia Attorney General



KWAME RAOUL
Illinois Attorney General




AARON M. FREY
Maine Attorney General



ANTHONY G. BROWN
Maryland Attorney General



ANDREA CAMPBELL
Massachusetts Attorney General



DANA NESSEL
Michigan Attorney General



KEITH ELLISON
Minnesota Attorney General



AARON D. FORD
Nevada Attorney General



MATTHEW J. PLATKIN
New Jersey Attorney General



RAÚL TORREZ
New Mexico Attorney General



LETITIA JAMES
New York Attorney General



JOSH STEIN
North Carolina Attorney General



DAVE YOST
Ohio Attorney General

The Honorable Robert M. Califf, M.D.

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ELLEN F. ROSENBLUM
Oregon Attorney General



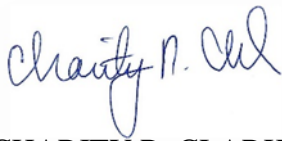
MICHELLE A. HENRY
Pennsylvania Attorney General



PETER NERONHA
Rhode Island Attorney General



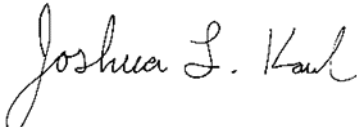
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Utah Attorney General



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Washington Attorney General



JOSHUA A. KAUL
Wisconsin Attorney General