



Roots Community Health Center Issues Letter to Manufactures of Pulse Oximeters

Roots Community Health Center is extremely concerned that despite research showing that pulse oximeters do not properly measure oxygen levels in people with darker skin, there does not appear to have been corrective action taken to remedy this problem.

The profound harms posed by Pulse Oximeters to communities of color were clear by the study Roots co-authored with Sutter Health. The study determined that diagnoses based on Pulse Oximeter readings resulted in delayed treatment for African Americans.



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October 27, 2022

Via U.S. Mail

Dear Purveyors of Pulse Oximeters,

We are writing on behalf of Roots Community Health Center, a non-profit organization headquartered in the City of Oakland that as part of its mission provides medical care to low-income patients, primarily people of color.

Roots Community Health Center is extremely concerned that despite research showing that pulse oximeters do not properly measure oxygen levels in people with darker skin, there does not appear to have been corrective action taken to remedy this problem. The result is that pulse oximeters continue to provide readings that often overestimate the amount of oxygen in the blood of people with darker skin. In other words, people with darker skin are at risk of seeming to be healthier than they are actually due to inaccurate pulse oximeter readings. The difference is enough to be catastrophic because it can result in a failure to provide life-saving oxygen treatment, for instance to treat Covid-19.

Most recently, on September 29, 2022, the American Journal of Epidemiology published an article entitled “Racial Disparities in Pulse Oximetry Device Inaccuracy and Estimated Clinical Impact on COVID-19.” One of the authors is the Chief Executive Officer of Roots Community Health Center, Dr. Noha Aboelata. The article described the results of a study on non-Hispanic Black/African American and non-Hispanic white patients in a large healthcare system in northern California. The study found that pulse oximeters overestimated blood oxygenation in Black patients. This overestimation in turn led to underestimation of the need for hospital admission and treatment. For instance, Black patients were more likely to have hypoxemia (low levels of oxygen) go undetected than white patients.

An earlier study reported in the December 17, 2020 New England Journal of Medicine compared instances where actual oxygen saturation was less than 88 percent with pulse oximeter readings in the range of 92 to 96 percent. For Black patients who had oxygen saturation of 92 to 96 percent on pulse oximeters, the actual oxygen saturation was less than 88 percent approximately 11.5 percent of the time. For white patients who had oxygen saturation of 92 to 96 percent on pulse oximeters, the actual oxygen saturation was less than 88 percent only 3.6 percent of the time. That is, Black patients were more than three times as likely as white patients to obtain the inaccurate pulse oximeter oxygen reading of less than 88 percent. Although this earlier study did not look at admission and treatment differentials, it is well known in this Covid era that the difference between an oxygen level of 88 percent and 96 percent (or even 92 percent) can be the difference between being rushed to the hospital and staying at home and between receiving oxygen treatment or not.

As one of many purveyors of pulse oximeters to whom we are sending this letter, these results should cause you to re-design your product to eliminate the disparities or at least, as an interim measure, to provide sufficient warning about this problem so corrective steps can be taken by health providers and the general public. As far as Roots Community Health Center can tell, you have done neither. We invite you to respond to this letter with any steps you have taken and any suggestions you have about how to resolve this issue.

Failing that, Roots Community Health Center and potentially others intend to bring a lawsuit raising the following three claims: First, a claim under California Business and Professions Code §17200, *et seq.*, for unlawful business acts and practices for misbranding FDA-approved pulse oximeters in violation of California Health & Safety Code §111330, which provides: “Any drug or device is misbranded if its labeling is false or misleading in any particular.” Labeling that fails to adequately explain the discrepancies in measurement for people with darker skin is false or misleading. Second, with respect to pulse oximeters that are not FDA approved, a claim under California Business and Professions Code §17200, *et seq.*, for unfair business acts and practices based on the same issue. Third, also with respect to pulse oximeters that are not FDA approved, a claim under California Business and Professions Code §17500, *et seq.*, for untrue or misleading statements based on the same issue.

The lawsuit will seek an injunction prohibiting any further sales of the devices at issue and requiring distribution of accurate information, among other relief.

Thank you for your attention to this important matter. We believe this matter should be able to be resolved without the need for litigation. Please respond by November 16, 2022, if you agree; if not, we will begin preparation of a lawsuit. The best way to contact us is by e-mail to jonathan@weissglass.com and dnahealthlaw@gmail.com.

Sincerely,



Jonathan Weissglass



Daniel N. Abrahamson