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March 31, 2021

Jeffrey Shuren, MD, JD
CDRH Center Director
Via email: jeff.shuren@fda.hhs.gov

Michael Ryan
Director, Division of Health Technology 1C
Via email: michael.ryan@fda.hhs.gov

Dear Drs. Shuren and Ryan:

This correspondence is prompted by long-standing concerns regarding the accuracy of pulse oximetry across the spectrum of patient populations, particularly among those with darker skin color. Pulse oximetry is among the most common measures in healthcare, used either intermittently or continuously in millions of acutely and critically ill patients each year. Accurate measurement of arterial blood oxygen saturation via pulse oximetry is vital to the clinical management of patients. The universal use of these devices and the need for accuracy when caring for patients in intensive care make this both urgent and important for clinicians in critical care.

The technology underlying pulse oximetry has evolved since its inception, yet concerns have been raised for more than five decades about the potential inaccuracy of pulse oximetry in people with darker skin.[1,2] Studies have confirmed differences between arterial blood saturation and pulse oximetry for people with darker skin, sometimes in excess of 5%. These differences were greatest in the setting of hypoxemia—a situation in which accurate information is most important for clinical decision-making.[3,4] Most recently this finding was re-demonstrated by Sjoding et al, showing in a contemporary cohort of hospitalized patients a higher rate of occult and clinically significant arterial hypoxemia in Black compared to White patients (11.7%-17.0% vs. 3.6%-6.2%).[5]

We are aware of the FDA guidance on this subject issued February 19, 2021,[6] and we ask that the FDA directly engage the developers and manufacturers of FDA-regulated pulse oximeters to rectify this urgent situation in a timely manner. As noted in the FDA guidance, the agency has authority to regulate the pulse oximeters used in healthcare settings as medical devices. We urge you, through your agency's authority, to ensure that pulse oximeter manufacturers conduct the tests needed to ensure that the devices provide accurate and reliable readings for patients with diverse degrees of skin pigmentation.

We further note that pulse oximeters sold as consumer products are not medical devices and therefore are not subject to FDA oversight. As you know, many individuals have been directed to measure their oxygen saturation levels using consumer-grade pulse oximeters to gauge the severity of their COVID-19 symptoms as a guide for seeking medical help. We are concerned that the consumer-grade pulse oximeters may be giving inaccurate readings for patients with darker skin pigmentation—potentially underestimating the severity of their COVID-19 illness and thereby delaying essential medical intervention. This represents a clear racial health disparity that must be addressed.

We urge the FDA to use its considerable influence to encourage consumer-grade pulse oximeter manufacturers to also participate in the corrective efforts that the FDA seeks from medical device

manufacturers of pulse oximeters. Any response to the challenges with pulse oximeters that does not also include the consumer products would be incomplete.

Thank you for your consideration and your efforts to remove this barrier to high-quality equitable healthcare for all U.S. residents.

The Critical Care Societies Collaborative (CCSC) is a unique partnership comprising the four major professional and scientific societies whose members care for America's critically ill and injured patients. The CCSC leverages its collective and multiprofessional expertise through communication, education, research, and advocacy efforts. The CCSC speaks with a unified voice, representing nearly 200,000 critical care professionals to bring important issues to the forefront in public policy and the healthcare arena.

Sincerely,

Elizabeth Bridges

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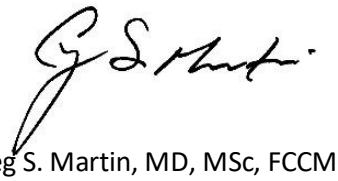

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