24 Hour Summary of the Anesthesiology and Respiratory Therapy Devices

Panel Meeting

November 1, 2022

The Anesthesiology and Respiratory Therapy Devices Panel of the Medical Device Advisory Committee met on November 1, 2022, to discuss concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentation. The Panel heard presentations related to this topic from FDA, clinicians, researchers, eight professional societies, patients, and industry. During the Open Public Hearing, the Panel heard nine presentations from academia, industry, patient advocacy and research groups. Twenty-five comments were submitted to the public docket for the meeting as of October 31, 2022 and were provided to the Panel for review. The Panel was asked to discuss the available real-world evidence concerning the accuracy of pulse oximeters, factors that may affect pulse oximeter accuracy and performance, tools to assess skin pigmentation, the amount and type of accuracy data that should be provided by manufacturers, and labeling recommendations for these devices.

The Panel agreed that the available clinical evidence from real-world studies demonstrated a reduction in the accuracy of pulse oximeter devices in individuals with darker skin pigmentation, which may lead to increased health risks in this population. The Panel also noted that skin perfusion (as reflected by the perfusion index), and the tightness, form, fit, and location of the pulse oximeter sensor may also be important factors impacting device accuracy. The panelists noted the need for additional studies of patients in health care settings, to better reflect real-world performance of these devices. The panel was supportive of the two FDA-funded real-world evidence studies at UCSF-Stanford *Center for Excellence in Regulatory Science and Innovation* (CERSI), which will prospectively evaluate the performance of pulse oximeters in adults and children.

The Panel discussed tools for the assessment of skin pigmentation, including subjective scales (e.g., from Fitzpatrick, von Luschan color scales), objective scales (e.g., melanometer measurement), and self-reported race/ethnicity. The panel recommended that future studies should evaluate the full spectrum of skin pigmentation with an adequate sample size to ensure sufficient accuracy of the pulse oximeters for all patients and to ensure equity in the performance of pulse oximeters. Regarding FDA's current assessment of pulse oximeters using A_{rms} (root mean square of pooled data pairs), the Panel recommended that the Agency explore additional metrics regarding device performance to assist clinicians in understanding the accuracy of pulse oximeters.

Finally, the Panel discussed labeling for prescription use pulse oximeter devices and recommended that specific information regarding the accuracy of devices across various levels of skin pigmentation be included. The panelists also recommended that pulse oximeter products that are currently available over-the-counter (OTC) should clearly indicate in their packaging that they are not intended for medical use or clinical decision making to mitigate the misuse or misapplication of produced measurements. The Panel recommended further efforts aimed at providing education to health care providers and patients regarding the appropriate (non-medical) intended use and limitations of OTC pulse oximeters.

Contact: Akinola Awojope, Designated Federal Officer,

(301) 636- 0512

Akinola.Adwojope@fda.hhs.gov

Transcripts may be downloaded from:

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Freedom of Information Staff (FOI)

5600 Fishers Lane, HFI-35

Rockville, MD 20857

(301) 827-6500 (voice), (301) 443-1726