



**FDA CDRH**  
**Anesthesiology and Respiratory Therapy Devices Panel**  
**of the Medical Devices Advisory Committee**

**February 2, 2024**  
**\*\*\*Virtual\*\*\***

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*The Committee will discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentation. The Committee will discuss an approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters submitted for premarket review, taking into consideration a patient’s skin pigmentation, and patient-reported race and ethnicity. The Committee will discuss the type and amount of data that should be provided by manufacturers to FDA to evaluate the performance of pulse oximeters submitted for premarket review, including prescription and over-the-counter indications, and labeling considerations.*

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9:00 a.m.	Call to Order Panel Introductions	Hugh A. Cassiere, M.D. Panel Chair
	Conflict of Interest Statement	Candace Nalls Designated Federal Officer
9:15 a.m.	FDA Opening Remarks	Jeff Shuren, M.D., J.D. Center Director, Center for Devices and Radiological Health (CDRH) and Christine Lee, Pharm.D., Ph.D. Acting Associate Commissioner for Minority Health (OMHHE)
9:30 a.m.	FDA Presentations: Pulse Oximeters: Technology, Accuracy Limitations, and Regulations	James Lee, Ph.D., OHT1, CDRH
	A Systematic Literature Review of the Real-World Performance of Pulse Oximeters	Allison O’Neill, Ph.D., OHT1, CDRH

9:50 a.m.	<p>FDA Presentations: Considerations for Study Design and Acceptance Criteria for Non-Disparate Performance</p>	<p>Kumudhini Hendrix, M.D., OHT1, CDRH          Josh Pfefer, Ph.D., OSEL, CDRH          Gene Pennello, Ph.D., OSEL, CDRH</p>
	Proposed Approach to Premarket Clinical Study	
	<p>Assessment of Skin Pigmentation          Statistical Considerations</p>	
10:40 a.m.	Break	
10:50 a.m.	<p>Invited Speakers:          MST Scale and Pigmentation</p>	<p>Ellis Monk, Ph.D., Harvard University          Philip Bickler, M.D., Ph.D., UCSF-CERSI          Carolyn Hendrickson, M.D., M.P.H., UCSF-CERSI          Christopher Almond, M.D., Stanford-CERSI</p>
	Real-World Evidence and Pulse Oximetry	
	<p>Patient Perspectives:          Adult Perspective</p>	<p>Edward McClure, Right2Breathe          Ryan Jolly, International Children's Advisory Network</p>
	Pediatric Perspective	
	Industry Perspectives	<p>Tara Federici, Advanced Medical Technology Association          Steven J. Barker, Ph.D., M.D., Masimo, Medical Device Manufacturers Association</p>
12:00 p.m.	Panel Deliberations	<p>Hugh A. Cassiere, M.D.          Panel Chair</p>
1:00 p.m.	Lunch	
1:30 p.m.	<b><i>*Open Public Hearing</i></b>	
3:30 p.m.	<p>Invited Speakers:          Collaborative Community</p>	<p>Michael Lipnick, M.D., Open Oximetry Project</p>
	<p>Professional Societies' Perspectives on Pulse Oximetry</p>	<p>American Academy of Sleep Medicine, Indira Gurubhagavatula, M.D., M.P.H.</p>

American College of Chest Physicians, Aaron Baugh, M.D.  
 American College of Surgeons, Ann G. Rizzo, M.D., F.A.C.S.  
 American Medical Association, Jesse M. Ehrenfeld, M.D., M.P.H.  
 American Thoracic Society, Nirav Bhakta, MD  
 Anesthesia Patient Safety Foundation, Meghan Lane-Fall, M.D., M.S.H.P., F.C.C.M.  
 Society of Technology in Anesthesia, Garrett W. Burnett, M.D.  
 American Association of Critical Care Nurses, Theresa M. Davis, PhD, RN, NE-BC, CHTP, FAAN  
 American Academy of Pediatrics, Joseph Wright, M.D., F.A.A.P.

4:10 p.m.	Break	
4:15 p.m.	FDA Questions to the Panel	Hugh A. Cassiere, M.D. Panel Chair
6:20 p.m.	Panel Summation	Hugh A. Cassiere, M.D. Panel Chair
6:30 p.m.	Adjourn	Hugh A. Cassiere, M.D. Panel Chair

**\* Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.