Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: January 2, 2024

TO: Rachel Bressler
Acting Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

FROM: CDR Daniel Bailey, M.S., M.B.A., M.DIV, COR III
Assistant Director, Committee Management and Planning
Division of Management Services, Office of Management
Center for Devices and Radiological Health (CDRH)

Name of Advisory Committee Meeting Temporary Non-Voting Member: Jeffrey M. Feldman, M.D., M.S.E.

Committee: Anesthesiology and Respiratory Devices Panel (ARTDP) of the Medical Devices Advisory Committee (MDAC)

Meeting date: February 2, 2024

Description of the Particular Matter to Which the Waiver Applies:

On February 2, 2024, the Anesthesiology and Respiratory Devices Panel (ARTDP) of the Medical Devices Advisory Committee (MDAC) 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.

The topic for this meeting is a particular matter of general applicability (PMGA).

Type, Nature, and Magnitude of the Financial Interest(s):

Jeffrey M. Feldman, M.D., M.S.E., is being requested to serve as a temporary non-voting member for the ARTDP of the MDAC, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in

anesthesiology and respiratory therapy and makes appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Feldman reported a financial interest in (b)(4) a health sector mutual fund. This fund includes an underlying asset in four potentially affected/competing pulse oximeter firms, (b)(4) , representing (b)(4) respectively, of the holdings of the fund. The market value of Dr. Feldman's financial interest in the fund is between $75,000 and $125,000 as of the writing of this waiver, based on publicly available fund information.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter affecting one or more holdings in a sector mutual fund where the disqualifying financial interest in the matter arises because of ownership of an interest in the fund and the aggregate market value of interests in all funds in which there is a disqualifying financial interest, and which concentrates in the same sector does not exceed $50,000. Because Dr. Feldman's financial interests in the above listed sector fund exceeds that amount, he has a disqualifying financial interest based on the fund holdings of the above-mentioned firms.

In addition, Dr. Feldman's employer has submitted a grant application to the National Institutes of Health/National Heart, Lung, and Blood Institute (NIH/NHLBI) for a Prospective Observational Research project. The title of the grant is: (b)(4) which is a matter related to the general issues coming before the Panel. The intent of this federally funded project is to (b)(4) At present, (b)(4) , affected/competing pulse oximeter firms, are planned device suppliers for evaluation. Dr. Feldman's employer is requesting (b)(4) over a (b)(4) period from the NIH/NHLBI for the project, but no final decision has been made, and the expected timeframe for the project has not been determined. Dr. Feldman will serve as a co-investigator on the project and he is not expecting to receive any personal compensation. At this time no funds have been exchanged.

Basis for Granting the Waiver:

The upcoming February 2, 2024, meeting of the ARTDP will discuss highly specialized issues of tremendous public health importance regarding pulse oximeters. FDA will pose challenging questions to the Panel regarding the optimal premarket clinical study design and analysis for these devices as well as key aspects related to their over-the-counter (OTC) use for medical purposes. Pulse oximeters play a highly important role in the assessment and monitoring of oxygen saturation in a patient's blood. The devices are routinely used and depended upon by health care providers in settings ranging from routine office visits to monitoring of critically ill patients in the intensive care unit and operating room. Over the past several years, there has been increased recognition and concern regarding disparate performance of these devices among various groups of patients related to skin pigmentation, race, and ethnicity. These performance disparities can adversely impact important clinical treatment decisions such as hospital admission and oxygen administration. Thus, it is vital to have the very best clinical experts from

specific clinical backgrounds participate in the panel meeting and discuss the most appropriate way to address these issues that can result in healthcare inequities. Dr. Feldman possesses a unique combination of extensive training and experience in pediatric anesthesiology, research experience in patient populations affected by these issues, and training and expertise in medical device technology. We believe that any potential conflicts of interest are strongly outweighed by the benefit of him sharing his knowledge and judgement during the discussion of FDA's questions at the panel meeting.

Dr. Feldman has unique qualifications and specialized expertise needed for this particular matter.

Dr. Feldman has specialized expertise needed for this particular matter. Dr. Feldman received his medical degree from Albany Medical College and completed his residency in Anesthesiology at the University of Florida College of Medicine. Additionally, he completed a fellowship in Pediatric Anesthesiology at the Children's Hospital of Philadelphia (CHOP). He has many years of experience in academic medicine across numerous institutions (Yale University, University of Pennsylvania, Drexel University, and the University of Florida). He has published more than 70 research articles, many of which involve the role of medical devices in the monitoring and treatment of critically ill patients who would be impacted by the issues being discussed at the panel meeting (e.g., low flow ventilation techniques, the challenges related to designing displays and alerts for monitoring devices, depth of anesthesia monitoring, etc.). He has an unusual level of expertise in evaluating device technology due to his having also received a master's degree in Bioengineering from the University of Pennsylvania. Thus, his broad and highly specialized expertise is needed to address the complex issues regarding disparate performance of pulse oximeters due to skin pigmentation, race and ethnicity that will play a central role in the meeting.

There is limited expertise available and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.

As noted above, Dr. Feldman's expertise in pediatric anesthesiology and medical device design and technology, including specialized experience and research in monitoring displays, alarms, and monitoring approaches, is without precedent among the many SGEs we have reviewed across panels within CDRH and the Center for Drug Evaluation and Research. We have also attempted to recruit numerous clinicians with similar broad expertise, particularly in the pediatric anesthesiology field, but have been unsuccessful.

The particular matter is not sensitive

The issues that will be discussed at the February 2, 2024, panel meeting have been previously discussed at a panel meeting in November 2022. FDA will be presenting proposed changes to the design and analysis of premarket clinical studies for pulse oximeters largely based on the Panel's prior feedback and recommendations. The issue of disparate performance of pulse oximeters related to skin pigmentation, race and ethnicity has been known and described in the literature for at least two decades, although it has received increased attention due to the increased use of pulse oximetry during the COVID-19 pandemic. While there is some sensitivity with respect to the health equity concerns raised by this issue, they do not relate to Dr. Feldman's

clinical activities or background and should not adversely impact his candidacy for participation in the panel meeting.

Dr. Feldman's expertise in this particular matter is necessary in the interest of public health.

Dr. Feldman has specialized knowledge and expertise in several critical areas that will be discussed by the Panel. First, his knowledge of pediatric anesthesiology will be critical in understanding the necessary performance of pulse oximeters for pediatric patients with a variety of skin pigmentations and racial/ethnic backgrounds undergoing surgery. He will also understand the "form and fit" factors related to the sensor of the pulse oximeter that may influence oxygen saturation values, and how best to convey the performance characteristics and limitations of pulse oximeters to other clinicians. Additionally, his pediatric background will also be important as the role of and labeling for OTC pulse oximeters for medical purposes in pediatric patients will also be discussed. His bioengineering expertise will also be useful in discussing how the devices can best display information and alerts (if indicated) for users in the prescription and OTC device use settings.

Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Feldman's expertise in this matter.

Due to the high public health importance of the device issues being discussed, which could impact pediatric as well as adult patients in settings ranging from routine, standard care to the highest levels of criticality, it is essential to obtain a broad range of expert feedback and recommendations from the Panel regarding premarket clinical study design and analysis as well as issues related to OTC marketing of pulse oximeters. Dr. Feldman is uniquely well qualified to serve on this Panel due to his many years of training and experience in pediatric anesthesiology and his extensive research background and understanding of medical device technology. The CDRH staff have endeavored to find others with a similar strong background in these essential areas and have been unable to do so. Given the limited time left prior to the panel meeting, we believe Dr. Feldman's participation in the February 2, 2024, meeting will be essential to obtain feedback and recommendations on FDA's panel questions.

Accordingly, I recommend that you grant Dr. Jeffrey Feldman, a temporary non-voting member of the ARTDP of the MDAC, a waiver from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

X The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

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_____ Denied – The individual may not participate.

/S/ **January 16, 2024**

Rachel Bressler Date
Acting Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist