U.S. FOOD & DRUG ADMINISTRATION

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

DATE: October 5, 2022

TO: Russell Fortney
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 Standing Voting Member: Steven D. Nathan, M.D.

Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

Meeting date: November 1, 2022

Description of the Particular Matter to Which the Waiver Applies:

Steven D. Nathan, M.D., serves as a standing voting member, Chairperson of the Anesthesiology and Respiratory Therapy Devices Panel (ARTDP), 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.

On November 1, 2022, the Panel will discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations. The advisory panel will discuss factors that may affect pulse oximeter accuracy and performance, the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, the amount, and type of data that should be provided by manufacturers to assess pulse oximeter accuracy and to guide other regulatory actions as needed. The topic for this meeting is a particular matter of general applicability.

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

Dr. Nathan reported that he has financial interests in (b) (4) healthcare sector mutual funds (b) (4) [redacted]

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

(b) (4) The aggregate market value of his holdings in the funds is between $200,000 - $300,000. As of the writing of this waiver, based on publicly available fund information:

- (b) (4) sector fund contains underlying assets in (b) (4) potentially affected/competing firms, (b) (4) respectively, of the holdings of the fund.
- (b) (4) sector fund contains underlying assets in (b) (4) potentially affected/competing firms, (b) (4) respectively, of the holdings of the fund.
- (b) (4) sector fund contains underlying assets in (b) (4) potentially affected/competing firms, (b) (4) respectively, of the holdings of the fund.
- Regarding (b) (4), no entity that is likely to be affected by the particular matter before the Panel has been identified as a holding in these (b) (4) sector funds. However, due to the changing nature of sector funds' holdings where underlying assets could include potentially affected or competing entities, in the interest of caution funds, (b) (4) are included in this waiver that is being sought to ensure there is no recusal requirement on the day of the advisory Panel meeting.

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. Nathan's financial interests in the above listed sector funds exceeds that amount, he has a disqualifying financial interest based on the fund holdings of the above-mentioned firms.

Basis for Granting the Waiver:

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

Steven Nathan, M.D., is currently a Professor of Medical Education at the University of Virginia and serves in other roles as Medical Director for the Pulmonary Service Line at Inova Fairfax Hospital, Professor of Medicine at Virginia Commonwealth University and as an Affiliate

Professor of Biomedical Science at George Mason University. He received his M.B.B.cH degree from the University of Witwatersrand Medical School in Johannesburg, South Africa. He completed a residency in Internal Medicine at Long Island Jewish Hospital and two fellowships, one in Pulmonary and Critical Care Medicine and one in Lung Transplantation at Cedars-Sinai Medical Center in Long Angeles, CA. Since his training he has served in clinical and academic leadership roles at various prestigious tertiary care facilities across the country in the areas of lung and heart transplantation, critical care medicine, and thoracic immunology. In these roles, he has treated the "sickest of the sick": critically ill, complex patients in intensive care units and provides a unique and invaluable perspective on the physiological monitoring of these critically ill patients. He will provide an essential, unique viewpoint regarding the clinical impact of pulse oximeter inaccuracy on the clinical care and outcomes of these patients, particularly for the vulnerable, complex transplant patient population. His high level of expertise is reflected by his status as a reviewer for over 30 clinical journals including the New England Journal of Medicine, Lancet Respiratory, JAMA, Chest, BMJ, and the Cochrane Review. He has authored over 150 papers directly or indirectly related to patient populations who may be directly impacted by the pulse oximeter issue being discussed at the panel meeting.

In summary Dr. Nathan has the unique and critical training and experience in highly specialized areas that the advisory committee requires to make informed recommendations to FDA about the relationship of skin pigmentation to inaccuracy of pulse oximetry readings in high acuity patient populations. His expertise as an intensivist with unique training and experience in the lung/heart transplant patient population will make him an invaluable contributor to the deliberations at the advisory committee meeting.

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

The CDRH division responsible for the advisory committee has struggled to find a qualified expert in the areas of heart and lung transplantation and critical care medicine without disqualifying conflicts of interest and who could participate in the committee meeting. This is a highly specialized area of critical care medicine, and we have been unable to identify any other clinicians with this unique combination of transplantation medicine and critical care medicine experience, as there are very few clinicians with this level of training and experience. Therefore, despite our efforts, we have been unable to find an expert in this field without a disqualifying financial interest.

The particular matter is not sensitive.

This panel meeting topic is not considered sensitive because it involves a matter of general applicability across an entire device/technology type, i.e., a general issues panel meeting regarding pulse oximeters. Thus, there is no specific device being evaluated by the advisory panel for this meeting. Rather, the Panel will address the potential inaccuracy of these devices in patients with deeply pigmented skin, and the potential for racial disparities in device performance related to this issue. The strong public interest in this matter by clinicians, professional societies, Congress, and the press reinforces the need to have the appropriate experts on this panel to provide FDA with important insights and feedback.

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

The November 1st virtual meeting of the ARTDP will discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations. The Panel will also discuss factors that may affect pulse oximeter accuracy and performance, the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, and the amount, and type of data that should be provided by manufacturers to assess pulse oximeter accuracy and to guide other regulatory actions as needed. Dr. Nathan's unique knowledge of critical care medicine, pulmonology, and transplantation medicine, and how patients in these areas may be impacted by pulse oximeter accuracy is clearly in the interest of public health. In particular, this panel topic will involve an important public health discussion of racial disparities in the performance of an FDA regulated medical product, and how to address such disparities, which is an area of great public health interest for the Agency's Office of Minority Health and Health Equity and the FDA leadership.

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

FDA was unable to find any other individual with Dr. Nathan's unique level of expertise across clinical specialties (critical care medicine, pulmonology, and transplantation medicine) which are heavily dependent upon and impacted by the performance of pulse oximeters. He is the only panel member with such essential background who is available to participate. Furthermore, he is the current Chair of the ARTDP and has outstanding knowledge and experience regarding the regulation of medical devices. His extensive experience and excellent past performance as a panel chair will ensure smooth and efficient guidance of the panel process throughout the panel deliberations and discussion of FDA's important questions regarding the discussion of the pulse oximetry performance concerns. With his unique and essential clinical background as well as his experience and his adept administration of the panel process, he is ideally suited to serve as panel chair as well as a key subject matter expert and discussant on the panel topic. We believe any potential conflict of interest issue related to Dr. Nathan's investments in healthcare sector mutual funds is highly unlikely to impact his input during the panel meeting and is greatly outweighed by the FDA's particularly strong need for his services during this general issue panel meeting which does not focus on any specific company, medical device or application before the Agency.

We believe any potential conflict of interest created by this situation is greatly outweighed by the FDA's particularly strong need for the services of Dr. Nathan in the matter before the Panel.

Accordingly, I recommend that you grant Dr. Steven D. Nathan, standing voting member, Chairperson of the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee, 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:

_____ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

/S/ **October 13, 2022**

Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

Date