



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

DATE: April 18, 2017

TO: Janice M. Soreth, M.D.
Associate Commissioner for Special Medical Programs
Office of Medical Products and Tobacco
Office of the Commissioner, Food and Drug Administration

THROUGH: Jeffrey Anderson, MS, RAC
Director (Acting), Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Laura E. Bailey, M.S.
Chief, Committee Management Branch
Division of Workforce Management, OM
Center for Devices and Radiological Health (CDRH)

Name of Advisory Committee Member: Steven D. Nathan, M.D.

Committee: Gastroenterology and Urology Panel of the Medical Devices Advisory Committee

Meeting date: May 17, 2017

Description of the Particular Matter to Which the Waiver Applies:

The Gastroenterology and Urology Devices Panel of the Center for Devices and Radiological Health (CDRH) will meet on May 17, 2017, to discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics® Organ Care System™ (OCS) - Lung System, sponsored by TransMedics, Inc. The proposed indication for use, as stated in the PMA, is as follows: the TransMedics (OCS) Lung System is a portable organ perfusion, ventilation, and monitoring medical device intended to preserve donor lungs in a near physiologic, ventilated, and perfused state for transplantation.

The meeting's type is a particular matter involving specific parties.



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

Dr. Nathan is serving as a temporary voting member of the Gastroenterology and Urology Devices Panel (GU Panel). The Panel's function is to review and evaluate data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology and nephrology devices and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Nathan reported financial interests in three health sector funds: (b) (4); (b) (4); and (b)(4). Each of these sector funds includes as an underlying asset shares of a firm that makes a product which would compete with the device that is the subject of the PMA. The combined market value of Dr. Nathan's financial interests in the sector funds is between \$100,001 and \$200,000; the value of this underlying asset makes up approximately (b) (4) of the holdings of each sector fund.

Basis for Granting the Waiver:

The upcoming May 17, 2017 GU Panel meeting will involve discussion and recommendation regarding a device to preserve donor lungs for transplantation. A successful, robust discussion of this subject matter requires participants with expertise in lung transplantation and pulmonology. This subject matter is beyond the clinical expertise of the current GU Panel which is chiefly composed of gastroenterologists, urologists and nephrologists. Because this is such a unique area, there is a need for relevant experts to supplement the standing members of the committee who do not have the required specialized experience needed for the discussion. As a result, CDRH is seeking to supplement the panel with experts in lung transplantation and pulmonology, including Dr. Nathan. Without such experts, CDRH does not believe the panel will be able provide meaningful input and feedback to the FDA. Therefore, it is essential that Dr. Nathan be considered for participation at this panel meeting. We believe any potential conflict of interest is greatly outweighed by FDA's particularly strong need for the services of Dr. Nathan in the particular matter before the panel.

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

Dr. Nathan is Medical Director of the Advanced Lung Disease Program, Inova Heart and Vascular Institute, Inova Fairfax Hospital, VA; Co-Director of the NIH-Inova Advanced Lung Disease Program; and Professor of Medicine at Virginia Commonwealth University. He is also a Pulmonologist and Critical Care Medicine specialist, having done post-graduate fellowships in both pulmonology/critical care medicine and lung transplantation. Dr. Nathan is a graduate of the University of the Witwatersrand Medical School in Johannesburg, South Africa. He completed an Internal Medicine Residency at Long Island Jewish Hospital in New York City, New York, and then trained as a fellow in Pulmonary Medicine, Critical Care and Lung Transplantation at Cedars-Sinai Medical Center in Los Angeles, California. He maintains American Board Certifications in Critical Care Medicine and Pulmonary Diseases.



As a pulmonologist trained in lung transplantation and critical care, Dr. Nathan is well acquainted with patients who have had lung transplants and the subsequent potential challenges such a procedure presents. These are significant issues for discussion during the upcoming panel meeting; Dr. Nathan's expertise will be essential to that discussion.

Dr. Nathan has valuable expertise and is a long-standing internationally recognized expert within the lung transplantation clinical community. He has over 250 publications, including authorship of several chapters in well-recognized textbooks, research papers, case reports, abstracts, and monographs. Dr. Nathan has previous involvement on a similar advisory GU Panel meeting for a lung transplantation device where he was actively involved in the panel discussions and provided valuable feedback to the FDA. His academic and professional accomplishments, as well as his previous panel experience, uniquely qualify him to sit on the upcoming panel and provide FDA with valuable feedback.

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 review of this PMA has struggled to find qualified experts (pulmonologists and lung transplantation experts) with no disqualifying conflicts of interest or scheduling conflict who could participate in the panel meeting. The division had to eliminate two lung transplant and two pulmonology experts due to unavailability or conflicts. Because a limited number of clinical centers offer lung transplantation programs, there is much competition among lung transplantation studies to find sites and investigators to perform their medical research. As a result, a significant proportion of lung transplantation experts have direct involvement with TransMedics or its competitors. Therefore, it is challenging to find an expert in this field who is not currently directly involved with TransMedics, or one of its competitors. Dr. Nathan is not currently involved in any clinical study with the affected firms. His only conflict is ownership of health sector funds that have an underlying holding in a competing firm and the value of that holding makes up approximately  of the total value of each sector fund.

Further, in the interest of public health, it is critical for the agency to review new products that can potentially provide advancements in the field of lung transplantation, where approximately 80% of lungs offered for transplantation are turned down and discarded, and where the three-year survival rate is less than 70%. Dr. Nathan's knowledge of lung transplantation and pulmonology will provide the necessary expertise for this important discussion.

The particular matter is not sensitive.

The particular matter to be addressed by the Panel is not considered sensitive. This is an emerging technology that has been a subject of research and investigation for several years. CDRH has had other similar meetings for normothermic lung perfusion devices and the past meetings addressing



this technology were not deemed to be controversial or sensitive. This meeting is not expected to be different.

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

Dr. Nathan reported an ongoing investment in three health sector funds. These sector funds include, as an underlying asset, a firm that makes a product which would compete with the device that is the subject of the PMA. This competing product is similar to the product that will be evaluated at the panel meeting; however, there are important differences, including the (b)(4) and (b)(4). The competing product is indicated for the preservation of all comer lungs, which includes (b)(4) while the product going before the panel will be labeled, if approved, for standard criteria lungs. Also, the competing product is (b)(4) and it is (b)(4) while the product being reviewed by the panel is transportable and ambulatory. The value of this underlying asset makes up approximately (b)(4) of the total value of each sector fund; this is nominal compared to the overall value of each fund.

Any potential conflict of interest created by this investment is greatly outweighed by the need for Dr. Nathan's expertise in a field where such expertise is limited but imperative to the success of this panel meeting.

Accordingly, I recommend that you grant a waiver for Dr. Steven D. Nathan, a temporary voting member of the Gastroenterology and Urology Devices Panel, 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/_____
Janice M. Soreth, M.D.
Associate Commissioner for Special Medical Programs
Office of Medical Products and Tobacco
Office of the Commissioner, FDA

_____4/28/2017_____
Date