



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

DATE: May 25, 2018

TO: Rachel Sherman, MD, MPH  
Principal Deputy Commissioner  
Office of the Commissioner, Food and Drug Administration

THROUGH: Russell Fortney  
Director, 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 Meeting Member: Steven D. Nathan, M.D.

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

Meeting date: June 14, 2018

Description of the Particular Matter to Which the Waiver Applies:

The Panel will discuss, make recommendations and vote on the premarket approval application (PMA) submission for the PneumRx® Elevair™ Endobronchial Coil System (ELEVAIR System), which is a first of a kind implantable lung reduction coil for the proposed indication for use in patients with homogeneous and/or heterogeneous severe emphysema to improve quality of life, lung function, and exercise capacity. The sponsor is PneumoRx, Inc., a BTG International Group Company.

The ELEVAIR System consists of a sterile single-use Coil implant and a sterile, single-procedure (disposable) Delivery System comprised of a cartridge, catheter, guidewire and forceps. The Delivery System is intended to be used to deliver multiple Coils into one patient during an implantation procedure. The Coil is deployed using a bronchoscope.

The topic to be discussed during the meeting is a particular matter involving specific parties.

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

Dr. Nathan is serving as the temporary voting chairperson of the Anesthesiology and Respiratory Therapy Devices Panel. The function of the Anesthesiology and Respiratory Therapy Devices Panel is to review and evaluate data concerning the safety and effectiveness of marketed and investigational devices for use in anesthesiology and respiratory therapy and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Nathan reported a financial interest in (b) (4), a health sector mutual fund. This fund includes as an underlying asset shares in the parent company of a firm, (b) (4), that makes a product that competes with the device under review at the meeting. The market value of Dr. Nathan's financial interest in the fund is between \$50,000 and \$100,000. The value of the underlying asset is approximately (b) (4) of the holdings of the sector fund, which makes Dr. Nathan's interest in the company between \$0 and \$1,000.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter affecting one or more holdings of 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 concentrate in the same sector does not exceed \$50,000. Because Dr. Nathan's financial interest in the Invesco fund exceeds that amount, he has a disqualifying financial interest based on the fund's holding in the above-described company.

Basis for Granting the Waiver:

The upcoming June 14, 2018, Anesthesiology and Respiratory Therapy Devices Panel meeting will involve discussion and recommendation regarding a first of a kind implantable lung reduction coil device for the proposed indication for use in patients with homogeneous and/or heterogeneous severe emphysema to improve quality of life. A successful, robust discussion of this subject matter by the Panel requires participants with expertise in lung volume reduction, lung transplants and pulmonology. This subject matter requires more clinical experts than the Anesthesiology and Respiratory Therapy Devices Panel's current composition of pulmonologists, thoracic surgery and chronic obstructive pulmonary disease experts. Because this is such a unique area of discussion, there is a need for additional relevant expertise to supplement the standing members. As a result, CDRH is seeking to supplement the panel with experts in lung volume reduction and pulmonology, including Dr. Nathan. Without such experts, CDRH does not believe the panel will be able provide meaningful input and feedback to FDA. Therefore, it is essential that Dr. Nathan be considered for participation as a member 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 Health and Vascular Institute, Inova Fairfax Hospital, Virginia; 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 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, lung volume reduction, and critical care, Dr. Nathan is well acquainted with patients who have had lung volume reduction and the subsequent potential challenges such a procedure presents. These are significant issues for discussion during the upcoming panel meeting, and Dr. Nathan's expertise will be essential to that discussion.

Dr. Nathan 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 had previous involvement on another Medical Devices Advisory Committee 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.*

CDRH needs to draw on the expertise of a specific subset of pulmonologists. The device under review at this meeting is intended to treat patients with severe emphysema. The device reduces lung volume in hopes of preventing or delaying a need for lung volume reduction surgery or transplant. The experts needed to discuss this device must have experience in treating this specific patient population and experience with lung volume reduction surgery and transplant. The Center for Devices and Radiological Health (CDRH) division responsible for review of this device has been diligently seeking qualified experts (pulmonologists and lung transplantation experts) who have experience in treating these specific patients and experience with lung volume reduction surgery and transplant from various panels and past meeting rosters in CDRH, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research. Additionally, the division has pursued experts who work at NIH and who are in the academic community, and have not been successful in finding individuals with similar levels of expertise that can provide CDRH the input necessary to determine if this device is safe and effective.

Thus far, the division has eliminated approximately ten lung transplant and pulmonology experts due to unavailability and 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, resulting in a significant proportion of lung transplantation experts with direct involvement with the device sponsor or its competitors. Therefore, it is challenging to find an expert in this field who is not currently directly involved with the device sponsor or one of its competitors.

As a result, a significant proportion of lung transplantation experts have direct involvement with the sponsor, PneumoRx, Inc., and its competitors or work in the same institutional program as another SGE on the panel. Dr. Nathan is not currently involved in any clinical study with the affected firms.

*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. The clinical and patient communities are interested in this as a first of a kind device to treat severe emphysema patients that have few options beyond lung reduction surgery or lung transplant. CDRH has had other meetings for lung disease devices that treat the same type of patients, and the past meetings were not deemed to be controversial or sensitive. This meeting is not expected to be different.

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

In the interest of public health, it is critical for the agency to review new products that can potentially provide device advancements in the field of lung volume reduction for treatment of emphysema and lung disease. Dr. Nathan's knowledge of lung disease, lung volume reduction and pulmonology will provide the necessary expertise for this important discussion.

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

Dr. Nathan owns a health sector fund that holds as an underlying asset stock in the parent company of a firm with a competing product to the PMA device. The competitor is very well established with a diversified product line. The holding makes up approximately (b) (4) of the total value of the sector fund, making the value of Dr. Nathan's interest in the firm between \$0 and \$1000.

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.

