



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

DATE: June 1, 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: Bohdan M. Pichurko, MD

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 sponsored by PneumRx (a BTG International Group Company) 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 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. Pichurko is serving as the temporary voting member 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. Pichurko's employer, Cleveland Clinic Foundation (CCF), is one of (b) U.S. clinical sites for the PneumRx's Elevair Endobronchial Coil System study, the *Lung Volume Reduction Coil Treatment in Patients with Emphysema (ReNEW)* trial. Data from ReNEW trial supports the PMA for the Elevair Endobronchial Coil System, which is the particular matter under review by the Panel at this meeting. CCF treated 10 patients, or (b) of the total treated in the study. The clinic is no longer enrolling patients; it is in the ongoing follow-up phase of the trial, which is expected to continue until April 2021. Funding to CCF from the start of the trial in 2014 to the present was between \$500,001 and \$700,000. CCF will be awarded between \$100,001 and \$200,000 to fund the remaining years of ReNEW trial-related activities.

Dr. Pichurko is not personally involved with the ReNEW trial at CCF. He is one of over 150 pulmonary members of the CCF Respiratory Institute and serves as the Medical Director of the Pulmonary Function and Blood Gas Laboratories within the Respiratory Institute. The ReNEW trial has been the exclusive responsibility of five trial investigators in the Respiratory Institutes' Interventional Pulmonary section. Dr. Pichurko does not work in the Interventional Pulmonary section, and he does not oversee or have any relationship with the trial investigators' activities. Dr. Pichurko had no role in the implementation of the study protocol, has no knowledge of the study particulars, and is not familiar with preliminary or final results from the study protocol.

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. Because this is a unique area of discussion, there is a need for relevant experts to supplement the standing members. 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. As a result, CDRH must supplement the panel with experts in pulmonology, including Dr. Pichurko. Without such experts, CDRH does not believe the panel will be able to provide meaningful input and feedback to the FDA. Therefore, it is essential that Dr. Pichurko be

considered for participation as a temporary voting 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. Pichurko in the particular matter before the panel.

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

Dr. Pichurko is the Medical Director of Pulmonary Function and Blood Gas Laboratories at Cleveland Clinic Foundation with extensive experience as a Pulmonologist and Critical Care Medicine specialist. Dr. Pichurko is a graduate of Loyola University, Stritch School of Medicine. He trained as the Clinical Fellow in Pulmonary Medicine and as the Parker B. Francis Fellow and Shipley Institute Research Fellow in Pulmonary Medicine at Harvard Medical School and Brigham and Women's Hospital in Boston. His expertise is essential for the panel meeting due to his dual experience with lung volume reduction and the care of lung volume reduction patients. As a pulmonologist, he is well acquainted with patients who have had lung volume reduction and with the issues present after such a procedure. These issues are key for the upcoming panel meeting, and Dr. Pichurko's expertise will be important as FDA engages the panel and asks them questions regarding patient care. Dr. Pichurko is a long-standing internationally recognized expert within the lung volume reduction clinical community. He has over 50 publications, including authorship of several chapters in well-recognized textbooks, research papers, case reports, abstracts, and monographs. Without the participation of a pulmonology expert such as Dr. Pichurko, CDRH does not believe the panel will be able provide meaningful input and feedback to the FDA.

*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 submission has struggled to find qualified expert pulmonologists without disqualifying conflicts of interest and who could participate in the panel meeting. To date, approximately seven lung volume reduction and pulmonology experts had to be eliminated due to unavailability and conflicts. Therefore, Dr. Pichurko will be the only expert in his specialty area able to participate in the meeting. Because a limited number of clinical centers offer lung volume reduction programs, there is much competition among lung volume reduction studies to find sites and investigators to perform their medical research, resulting in a significant proportion of lung volume reduction 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 involved in the study, or employed by an institution receiving funding related to the study or a study of a competing product. Dr. Pichurko is not involved in any clinical study with the affected firms; his only conflict is that he works at the Cleveland Clinic Respiratory Institute which is one of (b) U.S. clinical site for the PMA sponsor's device study.

*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. Pichurko'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 to improve quality of life. Dr. Pichurko's knowledge of pulmonology and Critical Care medicine 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. Pichurko's expertise in this matter.*

Dr. Pichurko is not personally involved in the study, and does not supervise anyone who is involved in the study. His participation in the meeting will not involve him reviewing his own work during panel deliberations or the work of his subordinates at CCF. Dr. Pichurko is the only pulmonologist with the expertise in chronic obstructive pulmonology disease that FDA needs to ensure a thoroughly informed and robust discussion of issues associated with this PMA submission. FDA was unable to find any other individual with Dr. Pichurko's level of expertise who was not more conflicted or who was available to participate. Therefore, it is essential that Dr. Pichurko 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. Pichurko in the particular matter before the panel.

Accordingly, I recommend that you grant a waiver for Dr. Bohdan M. Pichurko, temporary voting member of the Anesthesiology and Respiratory Therapy Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

