U.S. FOOD & DRUG ADMINISTRATION

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

DATE: October 7, 2021

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 Member: Matthew J. Eagleton, M.D.

Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee

Meeting date: November 3, 2021

Description of the Particular Matter to Which the Waiver Applies:

On November 3, the Circulatory System Devices Panel (CSDP) will discuss and make recommendations on the continued safety and effectiveness of endovascular stent grafts and how to strengthen real-world data collection on long term performance of the devices, both for currently marketed devices and for future technologies. The FDA intends to request panel input on the clinical outcomes that are most relevant to capture in the real world, along with their frequency and duration. Additionally, the FDA intends to seek input on data collection platforms, and how to incentivize and optimize real world data collection.

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

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

Matthew J. Eagleton, M.D., serves as a temporary non-voting member of the CSDP, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory and vascular systems and makes appropriate recommendations to the Commissioner of the Food and Drug Administration.

Dr. Eagleton serves as the National Principal Investigator on the Terumo TREO multicenter trial for their endovascular aortic repair (EVAR) system and his current employer, Massachusetts General Hospital (MGH), is involved in the Phase II Clinical Study of the Safety and

Performance of the Treovance Stent-Graft with Navitel Delivery System for Patients with abdominal aortic aneurysm (AAA) for the EVAR system manufactured by Terumo Aortic. The TREO stent graft and its manufacturer Terumo Aortic are identified as affected product and firm for this meeting. Dr. Eagleton's employer, Massachusetts General Hospital, was awarded funding in the range of between $50,001 – $100,000 for the Terumo Phase II Clinical Study for the TREO device from Terumo Aortic. Dr. Eagleton does not receive any personal remuneration from the funds. In addition, Dr. Eagleton does not receive remuneration for his role as National Principal Investigator for this multicenter trial that is scheduled to end in June 2025.

Basis for Granting the Waiver:

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

Dr. Eagleton earned his Doctor of Medicine from the University of Rochester School of Medicine and Dentistry. He has practiced general and vascular surgery at several centers of excellence around the country. Dr. Eagleton is currently the Chief of Vascular Surgery at the Massachusetts General Hospital and Professor of Vascular Surgery at Harvard Medical School. For several years, he has been the program chair of the Society for Vascular Surgery Annual Meeting where he was responsible for all of the educational content presented at that meetings. With 20 years of experience with an academic focus on endovascular aortic aneurysm repair, Dr. Eagleton is regarded as a leading authority both nationally and internationally. He is an expert on the evolving standard of care for this treatment. The panel is in need of expert vascular surgeons knowledgeable of the most current standard of care for treating AAA. Dr. Eagleton is eminently qualified to provide this expertise.

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

It is difficult to find a qualified expert in the critical issues of endovascular surgery without disqualifying conflicts of interest and who could participate in the panel meeting.
The Division considered numerous other experts in this field, but many continue to serve in leadership positions in professional societies or ongoing clinical studies and are therefore disqualified. Additionally, five expert vascular surgeons were unable to participate in the meeting due to scheduling conflicts. Dr. Eagleton's individual endovascular AAA device trials are not going to be discussed at the meeting.

The particular matter is not sensitive.

The devices being evaluated by the advisory panel is not considered sensitive because CDRH has had other similar meetings for abdominal aortic endovascular stent grafts. This technology is well established, as there are at least eight currently marketed devices in this class. Previous advisory panels addressing such devices were not controversial, and this meeting is not expected

to be different. The panel discussion, deliberations, and recommendations will not focus on individual devices or manufacturers, but the device class as a whole.

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

The November 3, 2021 CSDP meeting will discuss the continued safety and effectiveness of endovascular grafts and how to strengthen real-world data collection on long-term performance of the devices. In the interest of public health, it is critical for the agency to review post-market safety signals that could potentially lead to injury or death. It is critical to include advisory panel members with comprehensive knowledge of the critical issues of endovascular devices that is consistent with the current standard of care. Dr. Eagleton's knowledge of this field will provide the necessary expertise for this important discussion. In addition, Dr. Eagleton's prominence in the international endovascular surgery community will give credibility to the recommendations from the panel's deliberations.

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

It is critical that the panel have leading experts in the field of vascular surgery who are familiar with the currently challenges of the therapy and the current standard of care. Dr. Eagleton is an ideal expert on this subject matter. There are few other endovascular surgery experts who are qualified to serve on this panel but are not conflicted by positions of leadership or ongoing involvement in individual device studies.

Dr. Eagle's professional expertise, experience and the Terumo TREO multicenter trial are related to some of the general topics that will be discussed during the panel. Dr. Eagleton does not receive remuneration for his role as National Principal Investigator. The particular matter of general applicability before the committee does not involve any premarket issues; rather, the topic involves issues with EVAR devices and management of abdominal aortic aneurysms. The questions to be addressed also do not focus on any specific product, device, or manufacturer. Dr. Eagleton's extensive knowledge and experience as a vascular surgeon is the reason that he is being sought as an expert. His very specialized expertise in endovascular therapy for aortic disease should enable him to significantly contribute to discussions on a variety of topics of interest to the panel.

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. Eagleton in the matter before the panel.

Accordingly, I recommend that you grant Dr. Eagleton, a non-voting member of the Circulatory System Devices Panel of the Medical Device 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:

____X___ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

_____/S/_____ ___**October 15, 2021**_____

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

Date