U.S. FOOD & DRUG ADMINISTRATION

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

DATE: October 8, 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: Alexander D. Shepard, M.D.

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

Meeting date: November 2- 3, 2021

Description of the Particular Matter to Which the Waiver Applies:

On November 2, 2021, the Circulatory System Devices Panel (CSDP) will discuss and make recommendations on information about the benefit-risk profile of the Endologix AFX endovascular graft system with regards to the risk of Type III endoleaks. FDA requests panel input regarding the totality of data collected on AFX devices and whether further actions are necessary.

The topic for this meeting is a particular matter involving specific parties.

On November 3, 2021, the 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. 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, 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):

Alexander D. Shepard, 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 Food and Drugs.

Dr. Shepard's employer, Henry Ford Health System, has a contract sponsored by (b)(4) for a post-marketing surveillance project titled, (b)(4) The (b)(4) abdominal stent graft and its manufacturer (b)(4) are identified as a competing product and competing firm for the matters before the CSDP on November 2nd, and as affected product and affected firm for the matters before the CSDP on November 3rd.

Dr. Shepard's employer was awarded funding in the range of between $5,001 and $10,000 from (b)(4) for the one patient that is enrolled in the study of the (b)(4) abdominal stent graft. The study started in March 2021 and the estimated completion date is July 31, 2027. Dr. Shepard reported that all members of his group in the Division of Vascular Surgery are eligible to participate in this study. His role is to enroll any patients in whom he implants one of these grafts. To date, only his junior partner has implanted these grafts in one patient. If any additional patients are enrolled in the (b)(4) abdominal stent graft study, then Henry Ford Health System will receive funding in the range of $5,001 to $10,000 per enrollee from (b)(4)

Basis for Granting the Waiver:

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

Dr. Shepard received a Medical Doctorate from the Johns Hopkins University School of Medicine. He has trained in and practiced vascular surgery at several centers of excellence around the country. Among his previous appointments, Dr. Shepard served as the head of the Division of Vascular Surgery at the Henry Ford Hospital. He currently serves as a clinician and professor at the Wayne State University School of Medicine. Dr. Shepard is also currently involved with the Vascular Quality Initiative (VQI) Patient Safety Organization within the Society for Vascular Surgery (SVS).

Dr. Shepard has unique expertise in post-market surveillance registries due to his experience with VQI, professional relationships with health insurers to gather real-world data, and involvement in the world's first vascular registry (the Henry Ford Vascular Registry). Additionally, he has practiced vascular surgery since the inception of endovascular aortic repair (EVAR), so he is familiar with the evolving learnings on the benefits and challenges of EVAR. The purpose of the panel is to provide recommendations on how to strengthen real-world data collection, so the panel is in need of vascular surgeons who are familiar with current real-world surveillance frameworks, such as VQI. Dr. Shepard is one of the most experienced leaders in this field.

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

It has been difficult to find a qualified expert in post-market surveillance of AAA devices without disqualifying conflicts of interest and who could participate in the panel meeting. There is a very small pool of candidates with this expertise, and many are currently serving in leadership positions in surveillance organizations or ongoing device trials and are therefore conflicted.

The particular matter is not sensitive.

The devices being evaluated by the advisory panel are 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. Shepard's expertise in this particular matter is necessary in the interest of public health.

The November 2 and 3, 2021 CSDP meeting 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. 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 current state of real-world data collection and how these capture outcomes of AAA treatment consistent with the current standard of care. Dr. Shepard's knowledge of the current real-world data collection mechanisms 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. Shepard's expertise in this matter.

This particular conflict is not critical in the context of this panel discussion, in part because Dr. Shepard has not enrolled any subjects in the (b)(4) post-approval study to date. Additionally, outcomes discussed will be considered for the device class as a whole, and recommendations for post-market surveillance will apply to all AAA devices. The outcome of the November 3 panel meeting will not favor one manufacturer over another, so Dr. Shepard's institution's involvement with one manufacturer is not expected to affect his contributions to panel deliberations. The Agency will ask the panel to comment on how post-market data collection may be strengthened, so it is critical that the panel include experts on current surveillance mechanisms, such as VQI, insurance claims-based registries, and single center registries. Dr. Shepard possesses such expertise and also has extensive experience in treating AAA using endovascular devices. There are very few other candidates qualified to provide this expertise, as many individuals are conflicted due to involvement in ongoing studies.

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. Shepard in the matter before the CSDP.

Accordingly, I recommend that you grant Dr. Shepard, a temporary non-voting member of the Circulatory System 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:

____X___ Non-voting

_____ Other (specify):

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_____ Denied – The individual may not participate.

_____**/S/**_____ **October 14, 2021**

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

Date