U.S. FOOD & DRUG ADMINISTRATION

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

DATE: October 6, 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: Randall C. Starling, M.D., M.P.H., F.A.C.C.,

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):

Randall C. Starling, M.D., M.P.H., F.A.C.C., serves as a 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. Starling's employer, the Cleveland Clinic (Cleveland, Ohio) receives funding from Endologix LLC, the product sponsor for the particular matter involving specific parties discussion on Day 1 and an affected firm for Day 2, for the Post-Market Study to Assess Outcomes of Patients Treated with AFX System Compared to Other EVAR Devices (LEOPARD). The Cleveland Clinic is one of (b)(4) sites for this study of the AFX Endovascular System. There is one patient in follow-up for this study which started in November 2015 and is expected to end in March 2022. The total amount of funding Dr. Starling's employer was awarded is between $50,001 and $70,000. There are no outstanding amounts owed to the institution; funding for all trial-related activities have been paid. Dr. Starling reported that he is not involved in this study in any way and there is no management relationship between him and the principal investigators for the LEOPARD study at his institution. Dr. Starling does not receive any personal remuneration from the funds.

Basis for Granting the Waiver:

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

Dr. Starling has earned a Medical Doctorate from Temple University School of Medicine, a Masters of Public Health from the University of Pittsburgh School of Public Health, and his Bachelor's of Science in Biology from the University of Pittsburgh. He completed his internal medicine residency at the University of Pittsburgh Medical Center, and completed his cardiology fellowship at The Ohio State University.

Dr. Starling has unique qualifications and specialized expertise needed to consider the performance issues related to the AFX endograft system. Dr. Starling is a cardiologist with experience in the following areas: clinical cardiology including current standards of evaluation and care for AAA patients; clinical research study design, execution, and analysis; the use of registry and other real-world clinical data to inform clinical practice and advance medical science; and Public Health and Circulatory Systems Advisory Panel meeting responsibilities and processes. The panel deliberations for Day 1 will analyze clinical data to provide recommendations on the risk of Type III endoleaks for the AFX device, and the panel is in need of expertise in clinical research study design, execution, and analysis. Dr. Starling has experience with treatment of aortic disease and can provide this necessary expertise.

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

The Division has struggled to find a qualified expert in post-market surveillance of AAA devices, and interventional cardiology with experience with aortic devices, without disqualifying conflicts of interest and who could participate in the panel meeting. At least seven other experts were removed from consideration due to schedule conflicts or conflict of interests. Dr. Starling's conflict is less critical as he is not a site investigator on the LEOPARD Trial.

The particular matter is not sensitive.

The device 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. Furthermore, neither day of this meeting is a voting panel; therefore, there will not be any votes on binding decisions. CDRH is only seeking Dr. Starling's clinical opinion on the topics of this panel. On Day 2, the panel discussion, deliberations, and recommendations will not focus on individual devices or manufacturers, but the device class as a whole.

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

The November 2, 2021, CSDP meeting will discuss Type III Endoleaks Risk in the Endologix AFX Stent Graft System, an EVAR device. Day 2 will focus on 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 EVAR devices and management of aortic aneurysms that is consistent with the current standard of care.
Dr. Starling's expertise in cardiology including an understanding of the current standards of evaluation and care for AAA patients will provide the necessary expertise for this important discussion. In addition, Dr. Starling brings experience serving on a cardiovascular advisory panel in which he has analyzed clinical research data.

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

Dr. Starling is not personally involved in this study, and he has no management relationship with the principal investigators for this study at his institution. As the panel will be discussing issues with a particular EVAR device (Endologix AFX) and management/imaging of abdominal aortic aneurysms on Day 1 and discussing general issues with the device class as a whole on Day 2, cardiologists are critical for this panel. Dr. Starling is a highly-qualified cardiologist with expertise on current standards of evaluation and care for AAA patients; clinical research study design, execution, and analysis; the use of registry and other real-world clinical data to inform clinical practice and advance medical science; public health; and Circulatory Systems Advisory Panel meetings. Hence, we believe his expertise is crucial for the panel.

Dr. Starling is employed by one of the (b)(4) sites participating in the LEOPARD study with only 6 subjects recruited and with one subject still in follow up at his institution. He is not personally involved in this study and there is no management relationship between him and the principal investigators for the ongoing study at his institution. All allocated funding from Endologix has been paid and the study is expected to officially close on March 1, 2022. Endologix LLC. is a specific party to the particular matter under discussion regarding the AFX® Endovascular AAA Delivery System that will be discussed during the meeting on Day 1. Endologix and its AFX® Endovascular AAA Delivery System is affected by the particular matter discussed on Day 2 because it is part of the class of products at issue, but the actual post-market study or specific device is not part of the actual panel deliberations. In other words, the particular matter to be addressed by the panel on Day 2 is considered a particular matter that is focused on the interests of a discrete and identifiable class of persons but does not involve specific parties.

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. Starling in the matter before the panel.

Accordingly, I recommend that you grant Dr. Starling, a 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):

_____

_____

_____ Denied – The individual may not participate.

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

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