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: Albert G. Hakaim, M.D., MSc, F.A.C.S.

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):

Albert G. Hakaim, M.D., MSc, F.A.C.S., serves as 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. Hakaim's employer, Mayo Clinic (Jacksonville, Florida) receives funding from Endologix LLC, the product sponsor for the particular matter involving specific parties discussion before the panel on November 2 and an affected firm for the November 3 discussion, for the Post-Market Study to Assess Outcomes of Patients Treated with AFX System Compared to Other EVAR Devices (LEOPARD). Mayo Clinic is one of (b)(4) sites for this study of the AFX Endovascular System and one patient was treated and is still in follow-up for this study which started in November 2016 and is expected to end in February 2022. Dr. Hakaim's employer was awarded between $25,001 and $50,000 in total funding from Endologix, which includes all compensation for anticipated future follow-up. The outstanding amount owed to the institution in standard process is between $0 and $1,000. Dr. Hakaim reported that he is not personally involved with the LEOPARD study at Mayo Clinic, and he does not oversee or have any relationship with the investigator's activities, including any clinical trial involvement. Dr. Hakaim does not receive any personal compensation from the study funds.

Basis for Granting the Waiver:

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

Dr. Albert Hakaim has a unique combination of qualifications and specialized expertise needed to consider the performance issues related to the AFX endograft system and endovascular devices in general.
Dr. Hakaim is the Chair of Vascular Surgery at the Mayo Clinic of Jacksonville, Florida. He is currently an editor for several renowned endovascular journals, including the International Journal of Vascular Medicine and the Journal of Vascular Surgery. He is a clinically-active vascular surgeon who is highly experienced in using EVAR devices and has published a number of peer-reviewed articles on management of aortic aneurysms. As the panel will be discussing device failures specific to endovascular AAA devices, there is a great need for expertise in vascular surgery on the panel. Dr. Hakaim has been practicing vascular surgery for approximately three decades, and hence is well-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 interventional cardiology with experience in aortic devices without disqualifying conflicts of interest and who could participate in the panel meeting. The Division has considered at least eight similarly qualified vascular surgeons who were disqualified due to conflicts of interest. In addition, at least five other vascular surgeons were unable to participate due to scheduling conflicts, and at least four were unresponsive to our

invitation or did not complete their paperwork. Dr. Hakaim's particular conflict is not as directly linked to his work as the other disqualified surgeons since he was not a site investigator with the LEOPARD Study.

***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, this panel is not a voting panel; therefore, there will not be any votes on binding decisions. We are only seeking Dr. Hakaim's clinical opinion on the topics of this panel. On Day 2, panel discussion, deliberations, and recommendations will not focus on individual devices or manufacturers, but the device class as a whole.

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

The November 2, 2021 Circulatory Devices Panel meeting will discuss Type III endoleak risk in the Endologix AFX Stent Graft System, an EVAR device. November 3's session 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. Hakaim's expertise in using EVAR devices 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. Hakaim's expertise in this matter.***

Dr. Hakaim is employed by one of the (b)(4) sites participating in the LEOPARD study with only 1 subject treated and still in follow-up at his institution. He is not involved in this study in any way, and he does not oversee or have any relationship with the investigator. The study is expected to officially close on February 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. Additionally, Endologix and its AFX® Endovascular AAA Delivery System are at issue during the discussion on Day 2 because it is part of a class of products, however, the actual post-market study or specific device will not be part of the panel deliberations. 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.

Dr. Hakaim was not a site investigator with the LEOPARD study. Any potential conflict of interest is greatly outweighed by the strong need for Dr. Hakaim's expertise in this matter for Day 1. As a panelist on Day 2, Dr. Hakaim will be asked to discuss the device class as a whole;

recommendations from the panel will apply to all devices in this class, so there is no opportunity for panelists to favor one device or manufacturer over another. As the panel will be discussing issues with a particular EVAR devices and management of abdominal aortic aneurysms, vascular surgeons are critical for this panel. As Dr. Hakaim is a highly qualified vascular surgeon with decades of experience in using EVAR devices and has published a number of peer reviewed articles on management of aortic aneurysms, Dr. Hakaim is an ideal expert on this subject matter.

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. Hakaim in the matter before the Panel.

Accordingly, I recommend that you grant Dr. Hakaim, 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):

_____

_____

_____ 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