U.S. FOOD & DRUG ADMINISTRATION

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

DATE: October 5, 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: Robert W. Yeh, M.D., M.Sc, M.B.A.

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:

The Circulatory System Devices Panel 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):

Robert W. Yeh, M.D., M.Sc, M.B.A. serves as a voting member of the Circulatory System Devices Panel (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. Yeh's employer, Beth Israel Deaconess Medical Center (BIDMC), has a research grant funded by (b)(4) unaffected entities, to conduct an analysis of the Endologix AFX endovascular grafts. (b)(4)

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(b)(4) BIDMC's research grant is (b)(4) The Endologix AFX graft and its manufacturer, Endologix LLC were identified as an affected product and firm for this meeting.

Dr. Yeh's employer was awarded between $200,001 and $250,000 from April 2021 to April 2022 in funding for the Endologix AFX device study. Dr. Yeh, (b) (6) for the study, does not receive any personal remuneration from the funds.

Basis for Granting the Waiver:

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

Dr. Yeh has earned a Medical Doctorate from Harvard Medical School, a Master of Business Administration (MBA) with distinction from Oxford University, a Master of Science in Health Policy, Planning, and Financing from the London School of Economics, and a Certificate in Clinical Research, Epidemiology and Biostatistics from the University of California, San Francisco. His broad educational background is rare in the field of cardiovascular surgery and is valuable for this panel's deliberations on questions at the intersection of medicine and business. He is currently a professor at the Harvard Medical School and practices at the Beth Israel Deaconess Medical Center.

Dr. Yeh is a nationally recognized researcher whose work focuses on the evaluation of cardiovascular devices and therapies in both clinical trials and observational studies, with an emphasis on using insurance claims data to assess long-term outcomes following cardiovascular treatment. This is critical expertise needed for the panel meeting, as the topic of discussion will be post-market surveillance mechanisms for AAA device outcomes. It is important to emphasize that Dr. Yeh is a critically important speaker for this meeting where only general issues (not individual or specific device performance) pertaining to endovascular aneurysm repair will be discussed.

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 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. Yeh uniquely has expertise and experience using post-market claims sources for research but does not currently serve in a leadership role on a board of a potential surveillance source.

The particular matter is not sensitive.

The device technology 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.

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

The November 3, 2021, CSDP meeting will discuss mechanisms to gather post-market data on AAA 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 methods for collecting post-market safety data. Dr. Yeh's knowledge of the strength and limitations in collecting post-market safety data for the purpose of evaluating long-term device success will provide the necessary expertise for this important discussion. As such, he is viewed as an essential participant.

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

While Dr. Yeh is serving as (b) (6) on a device-specific study, the meeting topic does not focus on evaluating the safety and effectiveness of any specific device. Instead, Dr. Yeh is expected to provide his perspective on how post-market sources such as claims data can be used to collect data on long-term device performance. This perspective has nothing to do with his association with a single manufacturer. Dr. Yeh is uniquely familiar with both cardiovascular treatment outcomes and how claims data can be used successfully to track device outcomes. There are no other non-conflicted candidates with this expertise. 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. Yeh in the matter before the panel.

Accordingly, I recommend that you grant Dr. Yeh, 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
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

Date