



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

DATE: June 28, 2023

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: August 22-23, 2023

Description of the Particular Matter to Which the Waiver Applies:

On August 22, 2023, the Circulatory System Devices Panel (CSDP) will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the ReCor Paradise Ultrasound Renal Denervation System by ReCor, Inc. The proposed Indication for Use statement is as follows: the ReCor Paradise Ultrasound Renal Denervation System is indicated to reduce blood pressure in adult (≥ 22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications, which is intended to be used in renal arteries of diameters ranging from 3.0 to 8.0 mm.

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

On August 23, 2023, CSDP will discuss, make recommendations, and vote on information regarding the PMA for the Medtronic Symplicity Spyral Renal Denervation System by Medtronic, Inc. The proposed Indication for Use statement is as follows: the Symplicity Spyral multi-electrode renal denervation catheter and the Symplicity G3 RF Generator are indicated for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients in whom blood pressure lowering therapy is poorly tolerated.

The topic for this meeting is a PMISP.

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 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, Harvard Medical School, has an affiliate relationship with Massachusetts General Hospital, which receives funding from ReCor Medical Inc., the product sponsor for the PMISP discussion on Day 1 and a competing firm for Day 2. Massachusetts General Hospital is one of 58 sites for the RADIANCE-HTN SOLO study. There is one patient in follow-up for this study which started in August 2017 and is expected to end in January 2025. The total amount of funding Dr. Yeh's employer was awarded was between \$200,001 and \$300,000. There is no funding currently owed to the institution. Dr. Yeh 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 study at his institution. Dr. Yeh 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 is a Professor of Medicine at Harvard Medical School and an Attending Physician at Beth Israel Deaconess Medical Center. His expertise includes general cardiology and interventional cardiology, and he is a well-known clinical trialist. In addition, he is an expert in the design and analysis of post-market surveillance studies and real-world data. It will be critical at this panel meeting include a robust discussion on appropriate post-market surveillance plans for these important devices that address an important public health need. Novel analytical methods to assess real-world safety and effectiveness data will need to be utilized. Dr. Yeh will significantly contribute to such a discussion.

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 areas of hypertension, clinical cardiology, and interventional cardiology without disqualifying conflicts of interest and who is able to participate in the panel meeting. The Office has considered more than 10 other experts in this field, but many have participated in the sponsors' submissions or trials, have conflicting financial interests, or are unable to participate in the meeting due to scheduling conflicts.

The particular matter is not sensitive.

The devices being evaluated by the Advisory Panel are not considered sensitive because CDRH has previously had other similar meetings for vascular ablation catheters. CDRH did not consider past Advisory Panel meetings addressing vascular ablation catheters to be of "high visibility,"

and this meeting is no different. This subject technology has been a subject of research and investigation for several years and may impact the hypertension treatment field; however, at this point we cannot definitively state what that impact may be.

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

On August 22-23, 2023, the Circulatory Devices Panel meetings will discuss the clinical trial data and request recommendations regarding the benefit-risk profile for two premarket approval applications (PMA) for the ReCor Paradise Renal Denervation System and the Medtronic Symplicity Spyral Renal Denervation System. The two devices both have breakthrough device designations and would be the first device therapy to treat uncontrolled hypertension, an important public health problem. It is critical to include Advisory Panel members with comprehensive knowledge in the critical areas of hypertension and clinical cardiology. In addition, Dr. Yeh is well-known for analyzing complex clinical datasets. His knowledge of these fields will provide necessary expertise for the important panel discussion.

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

It is critical that the panel include leading experts in the field of hypertension and clinical cardiology who are familiar with the current challenges of the therapy and the current standard of care. Dr. Yeh is an ideal expert on this subject matter.

Dr. Yeh is a professor at Harvard Medical School, which is affiliated with the Massachusetts General Hospital, one of the clinical sites for the aforementioned devices. However, Dr. Yeh is not personally involved in this study and he has no management relationship with the principal investigator for this study.

We believe any potential conflict of interest created by this situation is greatly outweighed by the FDA's particularly strong need for the knowledge that Dr. Yeh will provide during 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:

 Non-voting

