U.S. FOOD & DRUG ADMINISTRATION

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

DATE: June 14, 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: 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: 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 and 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, the Circulatory System Devices Panel (CSDP) will discuss and 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 Renal Denervation System is indicated for the reduction of blood pressure in patients with hypertension, alone or in combination with other blood pressure-lowering therapy.

The topic for this meeting is a PMISP.

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 ReCor Medical Inc., the product sponsor for the PMISP discussion on Day 1 and a competing firm for the PMISP discussion on Day 2. The Cleveland Clinic is one of 68 sites for the RADIANCE-II study. There are two patients in follow-up for this study which started in December 2021 and is expected to end in March 2028. The total amount of funding Dr. Starling's employer was awarded is between $50,001 and $70,000. The outstanding amount owed to the institution is between $0 and $5,000. 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 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 is board-certified in internal medicine, cardiovascular medicine, and advanced heart failure and transplant cardiology. He is a cardiologist and Professor of Medicine at the Kaufman Center for Hearth Failure and the Heart, Vascular, and Thoracic Institute at the Cleveland Clinic. He has served on numerous national committees, including for the American College of Cardiology and the Heart Failure Society. With his experience in clinical medicine and public health, Dr. Starling has an excellent grasp of cardiovascular clinical trial design and analysis. He has authored numerous authoritative cardiology papers. At prior meetings of the Circulatory Systems Devices Advisory Panel, he has demonstrated an outstanding ability to analyze complex cardiovascular clinical trial design and analyses and provide important recommendations to the Agency.

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, cardiology and intervention cardiology without disqualifying conflicts of interest and who is able to participate in the panel meeting. CDRH has considered more than 10 other experts in this field, but many have participated on 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 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. Starling'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. Dr. Starling's knowledge of this field 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. Starling' s expertise in this matter.

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

Dr. Starling's employment at the Cleveland Clinic, one of the clinical sites for the aforementioned devices, is imputed to him, but he did not participate as an investigator in the study. 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.

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:

_____ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

/S/ **July 20, 2023**

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

Date