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

DATE: June 23, 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: Julia B. Lewis, M.D.

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):

Julia B. Lewis, M.D. serves as a consultant to the Cardiovascular and Renal Drugs Advisory Committee at the Center for Drug Evaluation and Research. She is being requested to serve as a temporary 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. Lewis' employer, the Vanderbilt University Medical Center (VUMC), Nashville, Tennessee receives funding from ReCor Medical Inc., the product sponsor for the PMISP discussion on Day 1 and a competing firm for the PMISP discussion for Day 2. The funding VUMC receives is for data from the RADIANCE-II (R-II) study, RADIANCE-HTN-SOLO (RHTN SOLO) study and RADIANCE-HTN-TRIO (RHTN TRIO) study that supports the PMA being discussed on Day 1. VUMC is one of 68 sites for the RADIANCE-II study. Currently there are two patients in follow-up for this study which started in July 2019 and is expected to end in September 2026. As for the other two studies, the RHTN SOLO one patient is expected to complete follow-up in December 2024, and RHTN-TRIO one patient is expected to complete follow-up in February 2024. The total amount of funding Dr. Lewis' employer was awarded for activities associated with these three studies is between $500,001 and $700,000. There is no money currently owed to VUMC for these studies.

Dr. Lewis reported that she is not involved in the studies in any way and there are no managerial responsibilities between her and the principal investigators for the studies conducted at her institution. Dr. Lewis does not receive any personal remuneration from the funds.

Basis for Granting the Waiver:

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

Dr. Julia Lewis is a Professor of Medicine at Vanderbilt University School of Medicine. Her expertise is in internal medicine, hypertension, and nephrology, for which she completed two postdoctoral fellowships in 1985 and 1986. As an experienced medical consultant and advisor, she has participated in collaborative study groups and advisory boards for multiple medical organizations and pharmaceutical companies. Dr. Lewis is an accomplished researcher, having conducted more than 50 clinical nephrology trials over her career. She sits on the Editorial Board for the Journal of the American Society of Nephrology and has authored and co-authored more than 200 book chapters and peer-reviewed journal articles. Given her 32 years of experience as a clinician, advisor, and researcher, the Office of Cardiovascular Devices has selected Dr. Lewis to serve on this Advisory Panel.

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 and nephrology without disqualifying conflicts of interest and who is able to participate in the panel meeting. CDRH has considered numerous other experts in this field, but many have participated in the sponsors' submission or have conflicting financial interests. Several other expert nephrologists were 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. Lewis'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 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 of the areas of hypertension and nephrology because these devices have the potential to negatively impact kidney function. Dr. Lewis'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. Lewis's expertise in this matter.

It is critical that the panel include leading experts in the fields of hypertension and nephrology who are familiar with the current challenges of the therapy and understand the standard of care. Dr. Lewis is an ideal expert on this subject matter. There are few other available nephrologists who are also experts in hypertension treatment. FDA was unable to find any other individual with Dr. Lewis' level of expertise available to participate who did not have a more significant conflict of interest.

Dr. Lewis is employed at Vanderbilt University Medical Center, one of the clinical sites for ReCor, Inc.'s PMA being discussed on Day 1. She does not have any involvement or oversight with the study itself. Dr. Lewis does not oversee or have any relationship with the studies investigators at VUMC. In addition, ReCor, Inc. is a competing firm for Medtronic, Inc.'s PMA being discussed on Day 2.

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. Lewis will provide during the

Advisory Panel meeting. Her substantial work and experience in hypertension and nephrology are imperative to the success of this panel meeting.

Accordingly, I recommend that you grant Dr. Lewis, a temporary 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