U.S. FOOD & DRUG ADMINISTRATION

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

DATE: July 19, 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: Patrick H. Nachman, 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., a unit of Otsuka Holdings Co., Ltd. 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 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 G3 RF Generator is 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):

Patrick H. Nachman, M.D., serves as a consultant to the Cardiovascular and Renal Drugs Advisory Committee at the Center for Drug Evaluation and Research. He 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. Nachman is a Councilor at Large for the American Society of Nephrology (ASN), which is an equivalent position to a Member of the Board of Directors for ASN. Dr. Nachman has a fiduciary responsibility in his role as Councilor at Large for ASN. ASN received contributions from Otsuka Pharmaceutical, Inc., an unaffected unit of Otsuka Holdings Co., Ltd., parent firm of ReCor Medical Inc., the product sponsor for the PMISP discussion on Day 1 and a competing firm for the PMISP discussion on Day 2. ASN also received contributions from Medtronic plc, a competing firm for the PMISP discussion on Day 1 and the product sponsor for the PMISP discussion on Day 2. From January 2022 to date, ASN received funds from Otsuka Pharmaceutical, Inc. totaling between $1,000,000 and $1,500,000, and from Medtronic plc totaling between $100,000 and $200,000. Dr. Nachman does not receive any personal remuneration from the funds, and he is not compensated for his services to ASN.

Basis for Granting the Waiver:

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

Dr. Patrick Nachman is a Professor of Medicine and Director of the Division of Renal Diseases and Hypertension at the University of Minnesota. He received his M.D. from Boston University School of Medicine, and completed his Internal Medicine and both a clinical and research Nephrology fellowship at the University of North Carolina, Chapel Hill. His specialty areas and interests include glomerular disease, vasculitis, polycystic kidney disease and clinical trials. His qualifications and expertise in teaching, research, and publications in peer-reviewed journals in the field of nephrology identify him as highly qualified to serve as a consultant of the Cardiovascular and Renal Drugs Advisory Committee. Dr. Nachman's training and experience will provide invaluable expertise in understanding the disease being treated (hypertension), the devices' proposed mechanisms of action, the clinical implications of adverse events associated with the invasive procedures associated with these devices, and the potential impact of renal denervation on kidney function.

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. The Office has considered numerous other experts in this field, but many have directly participated in the sponsors' submissions or have conflicting financial interests. Several 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 technology has been a subject of research and investigation for several years and may impact hypertension treatment. However, at this point we cannot definitively state what that impact may be.

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

On August 22-23, 2023, the CSDP meetings will discuss clinical trial data and request recommendations regarding the benefit-risk profile for two premarket approval applications (PMAs) for the ReCor Paradise Renal Denervation System and the Medtronic Symplicity Spyral Renal Denervation System. These two devices have breakthrough device designations and would be the first device therapy to treat uncontrolled hypertension, a critically important US public health problem. Inclusion of Advisory Panel members with comprehensive knowledge of hypertension and nephrology is needed because these devices have the potential to negatively impact kidney function. Dr. Nachman's renal training and experience will provide the necessary expertise for this important discussion. In addition, Dr. Nachman previously participated in the Advisory Panel meeting on general issues of hypertension device therapies, and his continued participation would be highly valued.

Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Nachman' 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 attaining blood pressure control with currently available therapies and the risks associated with renal damage. It will be critical to include multiple experts in the field that treat hypertensive patients in order to have a robust discussion for these important topics. Dr. Nachman is a subject matter expert on this issue. There are few other available nephrologists who are also experts in hypertension treatment.

Dr. Nachman's imputed interests based on his position at the American Society of Nephrology (ASN) that received funding from Medtronic and Ostuka Pharmaceutical Inc. (an unaffected unit of the parent, Otsuka Holdings Co., Ltd) represent a conflict of interest. However, it is common for medical professional societies to receive some funding support from a wide range of stakeholders, including industry sponsors, healthcare providers, and patient groups. Dr. Nachman did not receive any contributions or pay related to this activity.

Therefore, we believe that any potential conflict of interest created by this situation is greatly outweighed by the FDA's particularly strong need for the knowledge that Dr. Nachman will provide during the Advisory Panel meeting.

Accordingly, I recommend that you grant Dr. Nachman, 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/ **August 4, 2023**

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

Date