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

DATE: July 31, 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: Mr. Ian Burkhart

Committee: Patient Engagement Advisory Committee (PEAC)

Meeting date: September 6, 2023

Description of the Particular Matter to Which the Waiver Applies:

On September 6, 2023, the committee will discuss and make recommendations on the topic of "Advancing Health Equity in Medical Devices." The recommendations provided by the committee will address considerations for FDA and industry on these topics. The committee will consider ways to advance access to devices that allow for care outside a hospital or clinical care setting, for example, in the home setting. The committee will also discuss considerations for improving reach and comprehension of FDA's patient and caregiver communications, across diverse demographic groups. Additionally, the committee will discuss patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization.

The meeting type is a particular matter of general applicability. The PEAC will discuss general topics, no specific marketing applications will be discussed, and the discussion will not focus on approval, ongoing approval, or conditions of approval of any specific products. The particular matter will affect any medical device firms/products that allow for care outside a hospital or clinical care setting, for example in the home.

Type, Nature, and Magnitude of the Financial Interest(s):

Mr. Ian Burkhart, a voting member to the PEAC, reported that as President of the Ian Burkhart Foundation (IBF) he has fiduciary and fundraising responsibiities. IBF has a consulting contract with Blackrock Neurotech, a medical device firm for consulting on a brain computer interface control device that will be used in the home setting. These devices will hopefully be used by individuals with disabilities from all backgrounds. The total amount awarded to the IBF is between $50,001 and $70,000. This contractual agreement began in August 2022 and is expected to end in August 2023 with the option for renewal. The funds are used for general operations, for equipment grant programs, and consultant fees paid to Mr. Burkhart via an employment relationship with IBF.

Basis for Granting the Waiver:

Mr. Burkhart has unique qualifications and specialized expertise needed for this matter.

Mr. Ian Burkhart is the President of the IBF, a role in which he raises funds to provide accessible equipment for the independence of individuals with spinal cord injuries. Mr. Burkhart is a C5 tetraplegic from a 2010 driving accident. As a result, he has participated in several clinical trials using a brain-computer interface (BCI) to control muscle stimulation.

Mr. Burkhart is the vice president of the North American Spinal Cord Injury Consortium (NASCIC). NASCIC has the mission to bring about unified achievements in research, care, cure, and policy by supporting collaborative efforts across the spinal cord injury community. He is the chair of the NASCIC Project Review Committee. NASCIC's current advocacy efforts focus on research and the inclusion of people living with spinal injury as partners throughout the research process.

Mr. Burkhart is also a member of Unite 2 Fight Paralysis (U2FP). U2FP unites and empowers the international spinal cord injury (SCI) community to cure paralysis through advocacy, education, and support for research. U2FP's efforts involve working with state-level lawmakers to draft legislation to fund SCI research and require SCI consumers to be involved in all funded projects to ensure translation to maximize impact. This created funding for the Third Frontier Research Initiative for Spinal Cord Injury. Mr. Burkhart's advocacy and expertise, due to his personal use of several medical devices, will make him a valuable contributor to the deliberations at the advisory committee meeting.

There is limited expertise available, and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.

The CDRH division responsible for the advisory committee has struggled to find qualified patient experts with expertise in medical devices who were similarly qualified, without disqualifying conflicts of interest, and who could participate in the committee meeting. To date, multiple experts had to be eliminated due to unavailability and conflicts. Patients with severe disabilities, including those with spinal cord injuries, face additional challenges participating in clinical trials and managing their conditions at home and outside the clinic. There are very few patients with spinal cord injuries who have experience participating in BCI clinical trials and can

speak to the challenges involved. With limited expertise in this area, it is difficult to find experts that do not have some involvement with device companies. Mr. Burkhart's conflict is that he has a consulting contract with Blackrock Neurotech, a medical device firm in the BCI space. This conflict is less critical because his role is to provide user experience with the BCI device, and the committee topic is about general matters relating to medical device health equity, not specific to any individual BCI devices.

The matter is not sensitive.

There is no specific device being evaluated by the advisory committee for this meeting. This topic is not considered sensitive because Health Equity in Medical Devices has been a subject of concern for several years. The interest in this matter reinforces the need to have the appropriate experts on this committee to provide FDA with important insights and feedback. The committee discussion, deliberations, and recommendations will not focus on individual devices or manufacturers, but on the "Advancing Health Equity in Medical Devices" topic as a whole.

Mr. Burkhart's expertise in this matter is necessary in the interest of public health.

In the interest of public health, FDA is committed to working toward ensuring that all patients have access to high-quality, safe, and effective medical devices. This includes ensuring devices are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their healthcare and quality of life. Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. Mr. Burkhart's knowledge of spinal cord injury rehabilitation, neuroprosthetics and brain computer interface will provide the necessary expertise for this discussion.

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

The Committee is not evaluating any specific device. Mr. Burkhart's consultant role is primarily to provide user experience for Blackrock Neurotech, a medical device firm, who specific devices are not being evaluated during the meeting. Mr. Burkhart's qualifications include lived experience living with spinal cord injury which involves extensive use of a variety of assistive devices in the home use setting. His experience also includes participating in clinical trials and working in advocacy and patient-centered research roles to help advance patient access to devices designed to be safe and effective outside the clinic setting and to integrate these into the home setting, which makes his perspective highly relevant to the PEAC discussion topics. Therefore, it is essential that Mr. Burkhart be considered for participation as a voting member at this committee meeting. 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 Mr. Burkhart in the matter before the committee. In addition, the matters under consideration by the committee is

one of a general applicability and will not focus on any specific company, medical device, or application. Therefore, his substantial work and experience in the topics identified above will greatly contribute to the success of this advisory meeting.

Accordingly, I recommend that you grant Mr. Ian Burkhart, a voting Member of the Patient Engagement 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 21, 2023**

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

Date