U.S. FOOD & DRUG ADMINISTRATION

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

DATE: 9/03/2021

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)

Member of Advisory Committee Meeting Temporary Member: Shelby D. Reed, Ph.D., RPh.

Committee: Patient Engagement Advisory Committee (PEAC)

Meeting date: October 6, 2021

Description of the Particular Matter to Which the Waiver Applies:

Dr. Shelby D. Reed, a special government employee, has been invited to participate in the October 6, 2021, PEAC meeting as a temporary non-voting member. The committee will discuss and make recommendations on the topic ‘‘Medical Device Recalls.’’ Once a medical device is available in the U.S. marketplace and in widespread use, unforeseen problems can sometimes lead to a recall. When a device is defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public. A company may recall a device after discovering a problem on its own, or after FDA raises concerns. In rare cases, FDA may require a company to recall a device. When a device is recalled, FDA reviews the company’s strategy for resolving the problem by assessing the relative degree of risk associated with the product and making sure the strategy effectively resolves the problem with the device. FDA provides transparency and communicates information when the public needs to be alerted to a serious hazard, as well as once the recall has been appropriately resolved. The recommendations provided by the committee will address factors FDA and industry should consider to effectively communicate medical device recall information to patients and the public, including but not limited to content, format, methods used to disseminate the message, and timing of communication. The committee will also consider concerns patients have about changes to their device in response to a recall and will discuss ways

patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider and patient decision-making process related to a recalled medical device, including implanted devices.

The topic of this meeting 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 product. The particular matter will affect entities that make, or are seeking to make, medical devices.

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

Shelby D. Reed, Ph.D., RPh. is being requested to serve as a temporary non-voting member for the PEAC, which provides advice to the Commissioner of Food and Drugs on complex, scientific issues related to medical devices, the regulation of devices, and their use by patients.

Dr. Reed reported financial interests in medical device firms (b) (4) (b) (4) . Dr. Reed cumulatively owns between $50,000 to $70,000 worth of stock holdings in these affected entities. Accordingly, the particular matter before the committee involving recalls of medical devices will have a direct and predictable effect upon Dr. Reed's financial interests.

Basis for granting waiver:

The upcoming October 6, 2021 PEAC meeting is a particular matter involving medical device recalls, with a focus on incorporating patient concerns and perspectives, and more effectively communicating with patients. A successful, robust discussion of this subject matter by the committee requires participants with expertise in Preference Elicitation. This particular matter requires additional experts than the PEAC's current composition of patient expertise in Health Policy, Patient Advocacy, Total Joint Replacement, Diabetes, Rheumatology, Spine and Scoliosis Surgery, Arthritis, Women's Health, Geriatric Medicine, Cognitive Aging and Clinical Medicine. As a result, CDRH must supplement the panel with experts in Patient Engagement and Preference Elicitation, including Dr. Reed. Without such experts, CDRH does not believe the panel will be able to provide meaningful input and feedback to FDA. Therefore, it is essential that Dr. Reed participate as a temporary non-voting member at this meeting. We believe any potential conflict of interest is greatly outweighed by FDA's particularly strong need for the services of Dr. Reed in the particular matter before the committee.

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

Dr. Reed has specialized expertise needed for this particular matter. Dr. Reed is a Professor in Population Health Sciences and Medicine and Director of the Preference Evaluation Research (PrefER) Group at the Duke Clinical Research Institute at Duke University in Durham, North

Carolina. She is also Core Faculty and serves on the Executive Committee at the Duke-Margolis Center for Health Policy at Duke University. Dr. Reed is a Doctor of Philosophy: Pharmacy Administration, which she received from the University of Maryland. She holds a Bachelor of Science in Pharmacy from the University of Maryland-Baltimore and she also completed Pre-Pharmacy from North Carolina State University. Her expertise is essential for the committee meeting due to her experience in patient engagement and eliciting patient preference. As the Director and Co-Founder of PrefER Group at Duke University, Dr. Reed is well experienced with evaluating and understanding patient preferences. Over the last several years, her research has increasingly focused on stated-preference studies to evaluate benefit-risk tradeoffs, patient-centered value, and their application in comparative effectiveness research and clinical decision making. These issues are key for the upcoming committee meeting, and Dr. Reed's expertise will be important as FDA engages the committee and asks them questions regarding patient care as it pertains to medical device recalls. Without the participation of a patient preference elicitation and patient outcomes expert such as Dr. Reed, CDRH does not believe the panel will be able provide meaningful input and feedback to FDA.

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

The Center attempted to find other qualified individuals with the appropriate expertise by conducting a search on the Federal Advisory Committee Act (FACA) database, FDA's other advisory committees, and the NIH employee listing. Because a limited number of individuals with expertise in this area are in the Center's pool of special government employees, we were unsuccessful in finding the range of expertise and depth of understanding equivalent to that of Dr. Reed, who is available for this meeting, in such a short timeframe. No other individuals could be found for this particular meeting to replace Dr. Reed's experience.

The particular matter is not sensitive.

The particular matter to be addressed by the panel is a particular matter that is focused on the interests of a discrete and identifiable class of persons but does not involve specific parties. It may be considered sensitive because of public interest in medical device recalls. At this time, it is not possible to predict who has a device that will be part of a medical device recall. The interest in this matter reinforces the need to have the appropriate experts on this panel to provide FDA with important insights and feedback.

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

The October 6, 2021 PEAC meeting will discuss and make recommendations on the topic of medical device recalls. Further, in the interest of public health, it is critical for the agency to find ways to effectively communicate medical device recall information to patients and the public. It is important that the Agency has available the unique expertise that Dr. Reed will provide for the discussion of the particular matters before the committee.

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

Dr. Reed is the only meeting participant with expertise in patient preference elicitation that FDA needs to ensure a thoroughly informed and robust discussion of issues associated with this particular matter before the committee. With such short notice, CDRH was unable to find any other individual with Dr. Reed's level of expertise who was available to participate. Therefore, it is essential that Dr. Reed participate as a temporary non-voting member at this committee meeting. Without the participation of a patient preference elicitation expert such as Dr. Reed, CDRH does not believe the committee will be able to provide meaningful input and feedback to FDA.

Accordingly, I recommend that you grant Dr. Reed, a temporary non-voting member of the Patient Engagement Advisory Committee, a waiver from the conflict-of-interest prohibitions of 18 U.S.C. § 208(b)(3).

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:

_____X___ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

_____/s/_____ _____9/20/2021_____
Russell Fortney Date
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist