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

DATE: September 29, 2022

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 Temporary Non-Voting Member: Matthew B. Bloom, M.D., M.S.E.E., FACS

Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (MDAC)

Meeting date: October 26, 2022

Description of the Particular Matter to Which the Waiver Applies:

Mathew B. Bloom, M.D., MSEE, FACS, is a temporary non-voting member of the General and Plastic Surgery Devices Panel (GPSDP), which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general and plastic surgery devices and makes appropriate recommendations to the Commissioner of Food and Drugs. On October 26, 2022, during the afternoon session, the Panel will discuss and make recommendations on the classification proposals for wound dressings with animal-derived components, absorbable synthetic wound dressings, and hemostatic wound dressings with or without thrombin, or other biological products, which are all currently unclassified preamendments devices, to be class II (general and special controls).

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

Matthew B. Bloom, M.D., M.S.E.E., FACS is being requested to serve as a temporary non-voting member for the GPSDP of the Medical Devices Advisory Committee, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general and plastic surgery devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Bloom reported a financial interest in (b) (4) an affected firm for wound dressings with animal-derived materials, absorbable synthetic wound dressings products and for hemostatic wound dressings products. Dr. Bloom owns between $25,001 and $50,000 worth of stock in this non-publicly traded company. Accordingly, the particular matters before the panel involving classification proposals for these unclassified devices will have a direct and predictable effect upon Dr. Bloom's financial interests.

Basis for Granting the Waiver:

The upcoming October 26, 2022, GPSDP meeting is a particular matter involving classification of wound dressings. A successful, robust discussion of this subject matter by the panel requires participants with expertise in trauma surgery. This particular matter requires additional experts beyond the GPSDP's current composition of wound management expertise in dermatology, general surgery, plastic surgery, materials science, polymer engineering, biochemistry, vascular surgery, and nursing. As a result, CDRH must supplement the panel with experts in trauma surgery, including Dr. Bloom. 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. Bloom participate as a temporary non-voting member at this meeting. We believe any potential conflict of interest is greatly outweighed by FDA's strong need for the services of Dr. Bloom in the particular matter before the panel.

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

Dr. Bloom has the specialized expertise needed for this particular matter. Dr. Bloom is an Associate Professor of Surgery at Cedars-Sinai Medical Center in Los Angeles, California and Director of the Minimally Invasive Surgery Laboratory at Cedars-Sinai Medical Center. Dr. Bloom also serves on the Trauma Improvement Committee and Trauma Research Committee at Cedars-Sinai Medical Center. He earned both a Bachelor of Science (Electrical Engineering) and a Masters of Science (Electrical Engineering and Computer Science) from the Massachusetts Institute of Technology, before earning his Doctor of Medicine from Duke University. He has completed a residency in General Surgery at Stanford University Medical Center, as well as a clinical fellowship in Surgical Critical Care at Cedars-Sinai Medical Center. His expertise is essential for the panel meeting due to his experience in caring for trauma patients. Dr. Bloom's expertise will be important as FDA engages the panel and asks them questions regarding classification of wound dressings containing animal-derived materials, synthetic absorbable wound dressings, and hemostatic wound dressings (with and without thrombin). Without the participation of a trauma surgery expert such as Dr. Bloom, 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. Bloom, who is available for this meeting, in such a short timeframe. No other individuals could be found for this particular meeting to replace Dr. Bloom's experience.

The particular matter is not sensitive

The devices being evaluated by the Advisory Panel are not considered sensitive because wound dressings containing animal-derived materials, synthetic absorbable wound dressings, and hemostatic wound dressings (with and without thrombin) have been reviewed by FDA/CDRH and widely available for decades, and do not represent an emerging technology. The benefits and risks of these devices have been consistent over time, and these dressings represent no controversial or new complex issues. Further, CDRH has publicly stated the intention to classify all wound dressings for many years (the most recent panel was in September 2016 on classification of wound dressings combined with drugs), so this Advisory Panel meeting is expected and not anticipated to raise concern by the public.

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

The October 26, 2022, GPSDP meeting will discuss and make recommendations on the topic of classification of wound dressings containing animal-derived materials, synthetic absorbable wound dressings, and hemostatic wound dressings (with and without thrombin). In the interest of the public health, it is important that the Agency has available the unique expertise that Dr. Bloom 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. Bloom's expertise in this matter.

Dr. Bloom is the only meeting participant that is available with expertise in trauma surgery 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. Bloom's level of expertise who was available to participate. Additionally, one expert trauma surgeon was unable to participate in the meeting due to scheduling conflicts. Therefore, it is essential that Dr. Bloom participate as a temporary non-voting member at this committee meeting. Without the participation of a trauma surgery expert such as Dr. Bloom, CDRH does not believe the committee will be able to provide meaningful input and feedback to FDA.

Accordingly, I recommend that you grant Dr. Matthew Bloom, a temporary non-voting member of the General and Plastic Surgery 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/ **October 4, 2022**

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

Date