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

DATE: April 18, 2024

TO: Rachel Bressler
Acting Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

FROM: Prabhakara Atreya, Ph.D.
Director, Division of Scientific Advisors and Consultants
Center for Biological Evaluation and Research

Name of Advisory Committee Meeting Voting Member: Evan Bloch, MBChB, MS

Committee: Blood Products Advisory Committee

Meeting date: May 9, 2024

Description of the Particular Matter to Which the Waiver Applies:

Dr. Evan Bloch is a voting member of the Blood Products Advisory Committee (BPAC). The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and as required, any other product for which the FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents.

On May 9, 2024, the Committee will meet in open session to discuss general strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure. This will include the discussion of a licensed product manufactured by Roche used to test for malaria in donated blood and recommendations from the Committee on all potential future products that may be used for testing for malaria in blood. The Committee will also discuss FDA’s guidance recommending donor deferral to reduce the risk of transfusion transmitted malaria.

This meeting involves a Particular Matter Involving Specific Parties (PMISP) and a Particular Matter of General Applicability (PMGA). The presentation of the Roche product before the Committee and the discussion of blood (a regulated biologic product) deferral creates separate PMISPs for the two products. The open class of potential future malaria testing products for blood donation, that will all be affected equally, create a PMGA.

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

Dr. Bloch's employing institution, John Hopkins University School of Medicine, is participating in a study titled *The Malaria Transfusion Risk Study*, funded by National Institutes of Health (NIH). Dr. Bloch is a Principal Investigator for this study and received a career development award from NIH for his role in the study. The study began on April 1, 2020, with an anticipated end date of March 31, 2025. Johns Hopkins anticipates receiving between $750,000 and $1,000,000 from NIH for this study. Dr. Bloch is using a (b) (4) kit as a molecular assay for this study. (b) (4) is an affected firm and the (b) (4) kit is an affected product related to the matter coming before the Committee.

Dr. Bloch also serves as a co-investigator on a Department of Defense (DOD) Johns Hopkins Peer Reviewed Medical Research Program using (b) (4), a strategy to reduce the risk of transfusion-transmitted malaria in blood. The study began in September 2018, with an anticipated end date of September 2024. Johns Hopkins anticipates receiving between $5,000,000 and $7,500,000 from DOD for this study. (b) (4) is an affected firm relative to matters coming before the Committee.

Additionally, Dr. Bloch will likely be a co-investigator in an upcoming (b) (4) study of malaria in blood donors in (b) (4) using a (b) (4) molecular test. The study is under negotiation and has not started yet, nor has it been funded. The study dates are also currently unknown.

Basis for Granting the Waiver:

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

Evan Bloch, MBChB, M.S., currently serves as an Associate Professor in the Department of Pathology, Johns Hopkins University School of Medicine, Director, Post-graduate Fellowship Blood Banking/Transfusion Medicine, Medical Director, Hemapheresis and Transfusion Service, and Physician Advisor, Department of Pathology, Johns Hopkins Hospital, Baltimore, Maryland,

Dr. Bloch received his medical degree from the University of Cape Town, Cape Town, South Africa, and did his post-graduate residency in Anatomic and Clinical Pathology at Tufts University, Boston, MA. He also did a post-graduate fellowship in Transfusion Medicine at the University of California, San Francisco (UCSF). Dr. Bloch subsequently earned a M.S. degree in Global Health at UCSF. He has published extensively; more than 120 publications and several review articles, case reports, books, editorials, and guidelines related to the transfusion medicine field. Dr. Bloch is well respected and a leader in this area of science. He has received several honors and awards and given many national and international talks and presentations. Dr. Bloch is highly qualified to serve on this committee due to his extensive and relevant expertise in the

subject matter and prior experience on the Committee, which will bring valuable insights to the discussions and recommendations on the topics before the Committee.

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

Dr. Bloch's strong scientific background in transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure will be critical for the May 9, 2024, BPAC discussions. It would be difficult to find a replacement for Dr. Bloch, given his unique qualifications in transfusion-transmitted malaria and blood banking. Excluding him from participation will have a deleterious impact on the Committee's deliberations and may potentially affect public confidence in those deliberations.

The particular matter is sensitive.

The meeting topic for this session is considered sensitive and the FDA Review Division with responsibility for these products expects that the meeting is likely to receive significant public interest, and (non-trade) press interest.

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

Dr. Evan Bloch has been recognized as an accomplished scientist/researcher with extensive experience in blood banking and transfusion-transmitted malaria. Given his exceptional scientific and public health background, his participation at this meeting will bring the unique combination of his expertise in multiple fields to the BPAC's deliberations.

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

The strong need for Dr. Evan Bloch's demonstrated relevant expertise and diverse perspective that he can bring to the matter before the Committee outweighs any potential for a conflict of interest.

Accordingly, I recommend that you grant Dr. Evan Bloch, a voting member of the Blood Products Advisory Committee (BPAC), 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*-- **April 18, 2024**

Rachel Bressler
Acting Director, Advisory Committee Oversight and
Management Staff, Office of the Chief Scientist

Date