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

DATE: December 2, 2020

TO: (b) (6)

FROM: (b) (6)
Center for Biologics, Evaluation, and Research (CBER)

Name of Advisory Committee Meeting SGE Participant: **James Hildreth, M.D., Ph.D.**

Committee: Vaccines and Related Biological Products Advisory Committee (VRBPAC)

Meeting date: December 17, 2020

Description of the Particular Matter to Which the Waiver Applies:

Dr. James Hildreth, a Special Government Employee, has been invited to participate in the December 17, 2020, VRBPAC meeting to serve as a Temporary Voting Member (TVM). The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which the Food and Drug Administration has regulatory responsibility.

On December 17, 2020, the Committee will meet in open session to discuss Emergency Use Authorization (EUA) of the ModernaTX, Inc. COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years and older. EUA authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) needed during public health emergencies. Under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.

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

Dr. Hildreth has identified a financial interest of his employer, Meharry Medical College, which can be affected by the particular matter before the committee. This financial interest is imputed to him under the federal conflict of interest statute, 18 U.S.C. § 208.

Dr. James Hildreth is the President and Chief Executive Officer of Meharry Medical College. Currently, Meharry Medical College is the approved site for a Phase (b) (4) clinical trial using the (b) (4) COVID-19 vaccine candidate supported by the National Institutes of Health, National Institute of Allergy and Infectious Diseases, through Operation Warp Speed. Even though Dr. Hildreth is not the Principal Investigator (PI) on the trial, one of the faculty members, (b) (4) is the PI and Meharry Medical College will be receiving between $500,000 and $750,000 for conducting this clinical trial.

Additionally, Dr. Hildreth has expressed an interest in participating in the Phase (b) (4) clinical trial. He also will likely be offered compensation for his participation in the trial but he indicated his willingness to decline receiving payment as a trial participant.

Basis for Granting the Waiver:

Based on Dr. Hildreth's extensive experience in fields of critical importance to the discussion at the upcoming VRBPAC meeting, the need for his participation outweighs any potential conflict due to the financial interest described above.

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

Dr. James Hildreth, MD, PhD, is currently the President and Chief Executive Officer of Meharry Medical College. He graduated from Harvard University, *magna cum laude*, with a degree in chemistry, attended Oxford University as a Rhodes Scholar and received a Ph.D. in immunology, and he obtained his M.D. from Johns Hopkins University, where he later became an Assistant Professor. He was also appointed as a tenured professor in the Department of Cellular and Molecular Biology as well as a professor in the Department of Internal Medicine at the University of California at Davis, School of Medicine.

African-Americans present a population that are at increased risk of COVID-19 and are overrepresented among COVID-19 cases, associated hospitalizations, and deaths in the United States. Nevertheless, many have voiced skepticism and hesitancy concerning the uptake of COVID-19 vaccines. Considering the disproportionate burden of disease in communities of color, it is incumbent upon the FDA to convene a committee that includes experts on health issues of concern to minority populations. To this end, Dr. Hildreth is uniquely qualified to serve on the committee, both as an accomplished scientist/researcher with extensive experience in virology, immunology, pharmacology, and internal medicine, and also as an expert in health disparities.

Dr. Hildreth's strong scientific background in virology and immunology will be critical to the December 17, 2020, VRBPAC deliberations. It would be difficult to find a replacement for Dr. Hildreth given his unique qualifications in virology/immunology, internal medicine, and public

health. Excluding him from participation will have a deleterious impact on public confidence and committee deliberations.

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

Dr. Hildreth's strong and significant scientific background in virology and immunology will be critical to the December 17, 2020, VRBPAC deliberations on the EUA of the ModernaTX, Inc. COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years of age and older. It would be impossible to replace Dr. Hildreth (especially in view of previous multiple recusals of invited participants) and excluding him from participation will have a negative effect on the committee 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 does expect that the meeting is likely to receive significant public interest, (non-trade) press interest, and is considered highly controversial.

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

Dr. James Hildreth is well known and has been recognized as an accomplished scientist/researcher with extensive experience in virology, immunology, pharmacology, and internal medicine, and also as an expert in health disparities affecting minority communities. Given his exceptional scientific and public health background, his participation at this meeting will bring the synthesis of his expertise in multiple fields that are critical to VRBPAC's deliberations.

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

The strong need for Dr. James Hildreth's demonstrated expertise and diverse perspective that he can bring to this matter before the committee greatly outweighs any potential for a conflict of interest.

Accordingly, I recommend that you grant Dr. James Hildreth, a temporary voting member of VRBPAC, 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/ _____ ____12-3-2020_____

(b) (6)

Date

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