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

DATE: June 7, 2022

TO: (b) (6)

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

Name of Advisory Committee Temporary Voting Member: **James Hildreth, M.D., Ph.D.**

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

Meeting date: June 14-15, 2022

Description of the Particular Matter to Which the Waiver Applies:

Dr. James Hildreth, a Special Government Employee, has been invited to participate in the June 14-15, 2022, VRBPAC meeting as a temporary voting member. 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 June 14-15, 2022, the VRBPAC will meet in open session to discuss the recent requests to amend the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA vaccine to include the administration of a primary series to infants, children, and adolescents 6 months through 17 years of age, and also to amend the EUA of the Pfizer-BioNTech COVID-19 mRNA vaccine to include the administration of a primary series to infants and children 6 months through 4 years of age. The topic before the committee is a particular matter involving specific parties.

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

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

Dr. Hildreth is the President and Chief Executive Officer of Meharry Medical College. Currently, Meharry Medical College is the approved site for an ongoing 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 since the summer of 2020. (b) (4) is an affected firm/entity for this meeting. In addition, the meeting will likely have a direct and predictable affect on Meharry Medical College's funding. Even though Dr. Hildreth is not the Principal Investigator (PI) on the trial, one of Meharry Medical College's faculty members, (b) (4) , is the PI and Meharry Medical College is still due to receive between $1,500,000 and $2,000,000 for conducting this clinical trial. Meharry Medical College has also enrolled (b) (4) participants in Moderna's Pediatric COVID-19 Vaccine Trial, with a goal of enrolling up to (b) (4) participants. (b) (4) is also the PI on this trial, and Meharry Medical College will be receiving between $400,000 and $600,000 from Moderna for conducting this clinical trial (between (b) (4) per enrollee) from June 2021 to December 2022. Dr. Hildreth will not receive any personal remuneration from either of these two trials.

Additionally, Dr. Hildreth will participate in the (b) (4) Phase (b) (4) COVID-19 vaccine clinical trial noted above to encourage minority participation and will accept compensation in the range of between $0 and $5,000 from the National Institutes of Health for his participation.

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 interests described above.

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

Dr. James Hildreth, M.D., Ph.D., 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 June 14-15, 2022, VRBPAC discussions. 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 the committee's deliberations and may potentially affect public confidence in those 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 June 14-15, 2022, VRBPAC deliberations on the recent requests to amend the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA vaccine to include the administration of a primary series to infants, children, and adolescents 6 months through 17 years of age, and also to amend the EUA of the Pfizer-BioNTech COVID-19 mRNA vaccine to include the administration of a primary series to infants and children 6 months through 4 years of age.

It would be extremely difficult and unlikely within the limited time allotted to find an equally accomplished individual 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's 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 the 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 conflicts 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-_____ __June 8, 2022_____

(b) (6) Date