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

DATE: September 30, 2020

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

Name of Advisory Committee Meeting: **Jeannette Lee, Ph.D.**

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

Meeting date: October 22, 2020

Description of the Particular Matter to Which the Waiver Applies:

Dr. Jeannette Lee, a Special Government Employee who is a current voting member with CBER's Cellular, Tissue and Gene Therapies Committee (CTGTAC), has been invited to participate as a Temporary Voting Member (TVM) in the October 22, 2020 VRBPAC meeting. The VRBPAC 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 October 22, 2020, VRBPAC will meet in open session to discuss the development and licensure of vaccines to prevent COVID-19. Although no specific product applications will be discussed at this meeting, the VRBPAC recommendations pertaining to COVID-19 vaccine development and licensure will be considered, as applicable, by FDA in regulatory decision making on specific products. Therefore, for conflicts purposes, the agency is regarding this meeting as one that involves one or more particular matters involving specific parties and is applying the regulatory standards that are applicable to such matters. See 5 C.F.R. § 2640.202(a).

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

Dr. Lee has identified a financial interest in Philip Morris International, which owns approximately one-third of (b) (4), a company which can be affected by the particular matters

before the committee. Her stock holding in Philip Morris International is valued between $25,000 and $50,000.

Because Philip Morris owns a minority interest in (b) (4) , the two companies are not deemed to be the same "person" under regulations issued by the Office of Government Ethics (OGE). See 5 C.F.R. § 2635.102(k). Nevertheless, OGE guidance does not definitively state that a conflict of interest for purposes of 18 U.S.C. § 208 is not created when there is a financial interest in a parent company that holds a minority ownership interest in a subsidiary that can be affected by a particular government matter. See *Memorandum dated February 23, 2007, from Robert I. Cusick, Director, U.S. Office of Government Ethics, to Designated Agency Ethics Officials Regarding Waivers Under 18 U.S.C. § 208*. Dr. Lee's stock holding in Philip Morris International exceeds the regulatory exemption de minimis amount of $15,000 described in 5 C.F.R. § 2640.202(a). Accordingly, out of an abundance of caution, a waiver under 18 U.S.C. § 208(b)(3) is requested to permit Dr. Lee's participation in the upcoming VRBPAC meeting.

Basis for Granting the Waiver:

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

Dr. Jeannette Lee has unique qualifications and specialized expertise needed for this particular matter.

Dr. Jeanette Lee is currently a Professor in the Department of Biostatistics at the University of Arkansas for Medical Sciences (UAMS). She serves as Director of the Statistical Center for the AIDS Malignancies Clinical Trials Consortium and the Director of the Biostatistics Core of the UAMS Winthrop P. Rockefeller Cancer Institute.

Dr. Lee holds an A.B. in Mathematics from Boston University and a Ph.D. in Biostatistics from Johns Hopkins University.

The VRBPAC will be asked to deliberate on the clinical development of COVID-19 vaccines. In addition to experts in the fields of epidemiology and infectious diseases, the VRBPAC must consider biostatistical issues critical to the framework of clinical trials conducted to demonstrate the safety and efficacy of COVID-19 vaccine candidates, such as randomization and blinding and ensuring adequate trial design including setting prespecified statistical success criteria for clinical trial endpoints. Dr. Lee has unique and specialized competencies in biostatistics specifically for clinical trials and can opine on such issues before the VRBPAC.

Dr. Lee's extensive background in biostatistics is critical to the VRBPAC deliberations. Agency staff believe that it will be difficult to find a replacement for Dr. Lee and excluding her from participation will have a negative effect on the committee deliberations.

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

Dr. Lee's statistical skills will be critical to the October 22, 2020, VRBPAC deliberations on the development and licensure of vaccines to prevent COVID-19. It will be difficult to find another individual with equivalent expertise who is not conflicted either by a consulting/research relationship or by a disqualifying financial interest. It would be impossible to replace Dr. Lee in view of the previous multiple recusals of invited participants and excluding her from participation will have a negative effect on the committee's deliberations.

The particular matter is sensitive.

The meeting topic 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. Lee's expertise in this particular matter is necessary in the interest of public health.

Dr. Jeannette Lee is a well-established statistician. She has provided meaningful analysis of data at previous advisory committee meetings. She also is experienced in the design of clinical trials and survival analysis. Her expertise in this particular matter is necessary for the discussions and recommendations at the upcoming VRBPAC meeting.

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

Dr. Lee's stock holding in Philip Morris International is only marginally above the regulatory exemption amount described at 5 C.F.R. § 2640.202(a). In addition, Philip Morris International has only a minority ownership interest in (b) (4) and is not otherwise affected by the particular matter before the VRBPAC. However, Dr. Lee's extensive background in biostatistics and clinical trial design is critical to the VRBPAC deliberations. It will be very difficult to find a replacement for Dr. Lee and excluding her from participation will have a negative effect on the committee deliberations. Therefore, any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Lee's expertise in this matter.

Accordingly, I recommend that you grant Dr. Jeannette Lee, a temporary voting member of VRBPAC, a waiver from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

_____ 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/ _____ _____Oct 5, 2020_____

(b) (6) Date

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