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

DATE: July 19, 2023

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 Member: Angela M. Caliendo, M.D., Ph.D., FIDSA, FAAM

Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee

Meeting date: September 8, 2023

Description of the Particular Matter to Which the Waiver Applies:

Dr. Angela M. Caliendo, a special government employee, has been invited to participate in the September 8, 2023, Microbiology Devices Panel (MDP or "the Panel") meeting as a temporary non-voting member. The Panel will discuss and provide recommendations to FDA regarding topics related to in vitro diagnostic (IVD) devices used in pandemic preparedness and response consistent with the requirements under Section 3302 of the Food and Drug Omnibus Reform Act (FDORA) of 2022.

The topic of this session is a particular matter of general applicability. The MDP will discuss general topics. No specific marketing applications will be discussed, and the discussion will not focus on approval, ongoing approval, or conditions of approval of any specific product. The particular matter will affect entities that make, or are seeking to make, IVD medical devices used in pandemic preparedness and response.

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

Dr. Caliendo is serving as a temporary non-voting member of the MDP. The Panel's function is to review and evaluate data concerning the safety and effectiveness of marketed and

investigational in vitro devices for use in clinical laboratory medicine including microbiology, virology, and infectious disease, and make appropriate recommendations to the Commissioner of Food and Drugs. Dr. Caliendo is the President/Executive Director at Brown Physicians Inc. and an Infectious Diseases Consultant at Rhode Island Hospital in Providence, Rhode Island.

Dr. Caliendo reported financial interests in two manufacturers of IVD medical devices, namely (b)(4) and (b)(4) . Dr. Caliendo owns between $500,001 and $725,000 worth of stock in (b)(4) and between $2,500 and $5,000 worth of stock in (b)(4) Accordingly, the particular matter before the committee involving IVD medical devices used in pandemic preparedness and response will have a direct and predictable effect upon Dr. Caliendo's financial interests.

Under a regulatory exemption (5CFR §2640.202(c)(1)(b)) issued by the Office of Government Ethics, an employee may participate in any particular matter of general applicability in which the disqualifying financial interest arises from the ownership by the employee, his spouse, or minor children of securities issued by one or more entities affected by the matter if the securities are publicly traded, or are municipal securities, the market values of which does not exceed $50,000 in all affected entities. Because Dr. Caliendo's financial interest in stocks in affected entities exceed that amount, she has a disqualifying financial interest.

Basis for granting waiver

The upcoming MDP meeting on September 8, 2023, is a particular matter involving IVD medical devices used in pandemic preparedness and response. The discussion at that session will not focus on any IVD manufacturers or any particular devices but rather is intended to be a general discussion to provide feedback on future pandemics in general and how CDRH might sustain and strengthen national preparedness of IVDs for any future pandemics. A manufacturer's involvement in past pandemics (e.g., COVID-19) does not imply that those manufacturers would be impacted in any future pandemics as the response will likely depend on the particular emerging threat and that may include, and is not limited to, chemical, biological, radiological, and nuclear agents and those firms might not be involved in the development of IVDs for those particular agents of harm. No specific IVDs or manufacturers will be discussed at the upcoming pandemic session, and it is unlikely any specific firms will be directly impacted by their current involvement as it is unlikely a manufacturer is presently developing tests for an unknown future pandemic unless that firm specializes in pandemic preparedness and/or response.

In order to ensure a productive pandemic panel session, CDRH needs individuals with experience from past pandemics (e.g., COVID-19) to provide feedback and input on challenges faced during the pandemic and possible improvements that can be made next time to strengthen national preparedness of IVDs for any future pandemics. Such feedback can likely only be provided by individuals with direct involvement in past pandemics.

Dr. Caliendo has unique qualifications and specialized expertise needed for the IVD pandemic panel session.

Dr. Caliendo is an internist who specializes in infectious diseases, and her research interests include the development of molecular diagnostic tests for the detection and quantification of

various infectious diseases and establishing their clinical utility. She has extensive experience performing and developing molecular diagnostic tests for the detection and quantification of infectious diseases, including the design and execution of multi-center clinical studies. She has chaired working groups that have evaluated various Cytomegalovirus, Hepatitis C and Hepatis B viral load assays and her laboratory provided infrastructure and molecular testing for numerous multi-center clinical studies. Dr. Caliendo's leadership skills, expertise, and past service as Chairperson of this panel will make her a great nominee to serve at this session of the upcoming Microbiology Devices Panel meeting.

Dr. Caliendo holds a Medical Doctorate (MD) from Case Western Reserve University, a Doctor of Philosophy (PhD) from Case Western Reserve University, and a Bachelor of Science (BS) from Grove City College. She completed her internal medicine residency at the Brigham and Women's Hospital and has completed numerous fellowships including her fellowship in infectious disease at Massachusetts General Hospital.

Dr. Caliendo has unique qualifications and expertise needed to provide recommendations on how to further improve and strengthen CDRH's ability to respond to in vitro diagnostic devices (IVDs) testing needs in future pandemics. Dr. Caliendo's extensive experience is evidenced by her current and past appointments, her board certifications, her journal associations, her memberships, and her past publications. Examples of her expertise include: serving as an infectious disease consultant at the Rhode Island Hospital, previously serving as the co-chair of the COVID-19 Diagnostic Task Force for the Rhode Island Department of Health, currently serving as a member of the Laboratory Workgroup of the Advisory Committee to the Director, Centers for Disease Control and Prevention, serving on the editorial advisory board on the Journal of Infectious Diseases, and as a member of the American Society for Microbiology and Infectious Disease Society of America.

Dr. Caliendo has also been recognized as an effective leader and expert in this field as evidenced by her fellowship in Executive Leadership in Academic Medicine at Drexel University College of Medicine and her fellowship in Leadership Development for Physicians in Academic Health Centers at Harvard School of Public Health. Her current positions of leadership include co-chair of the COVID-19 Diagnostic Task Force for the Rhode Island Department of Health and Director and Creator of the Brown Physicians Leadership Course. She has previously lead various national committees on infectious diseases including serving as: Chair for the Diagnostics Task Force for Infectious Diseases Society of America, President of the Pan American Society for Clinical Virology, and as a past panel chair in microbiology panel meetings convened by FDA.

This expertise in infectious diseases, experience working in laboratories, experience in past pandemics, and demonstrated leadership skills make Dr. Caliendo uniquely qualified to discuss and provide recommendations on a future pandemic. Hearing from experts on what CDRH can do to strengthen the response in future pandemics to adequately prepare and ensure the availability of accurate and reliable IVDs is critical to the pandemic response in any future outbreak. The panel will likely discuss and provide recommendations on the validation of IVDs used in future infectious disease pandemics as well as offer an opportunity to collaborate with key stakeholders to proactively prepare for inevitable future challenges and threats to public

health. Dr. Caliendo's unique experience and qualifications include both infectious disease expertise as well as expertise working or consulting with laboratories, a combination which provides necessary expertise at the upcoming panel session.

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

The FDA Division responsible for conducting this meeting has struggled to find a qualified expert in infectious diseases who also has experience working in a laboratory environment as well as experience with IVDs in past pandemics who does not have similar disqualifying financial interests. In order to ensure a productive panel discussion, we need individuals with experience from past pandemics (e.g., COVID-19) to provide feedback and input on challenges faced during the pandemic and possible improvements that can be made next time to strengthen national preparedness of IVDs for any future pandemics. It is very likely that any similarly qualified individuals would have disqualifying financial interests based on their experiences. Several candidates have been removed from consideration due to either rescheduling conflicts or disqualifying conflicts of interest and this session must proceed as required by recent legislation. Dr. Caliendo's conflicts are also less critical, as this panel session discussion does not specifically impact any particular IVD manufacturers and none of those interests disclosed specialize in pandemic preparedness or suggest a likely future involvement in response to any outbreaks.

The particular matter is not sensitive.

No specific IVDs or manufacturers will be discussed at the upcoming pandemic session. Furthermore, this is not a voting session and there will be no binding decisions made, rather this is an open discussion forum with experts that have been involved in past pandemic responses to discuss and offer opinions on how to strengthen the Agency's response to future pandemics. This session is not considered sensitive as many different external parties have provided publicly available recommendations on the Agency's pandemic response and steps that could be taken to strengthen that response in future pandemics. This discussion is intended to discuss those recommendations further. In addition, this session is not considered controversial since no specific IVDs, or manufacturers will be discussed.

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

Dr. Caliendo's expertise in infectious diseases as well as experience in past pandemics is essential input that is needed at the upcoming panel as without involvement in past pandemics there would be no input for her or other panelists to provide to the Agency. Not only does Dr. Caliendo bring her experience from past pandemics, but she is a recognized expert in the field of infectious disease and also a practicing physician with laboratory experience which makes her uniquely qualified to provide feedback on how the Agency can strengthen its response in future pandemics to ensure that the public health is protected.

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

As the purpose of this panel session is to discuss IVDs in future pandemics, it is critical that the panel include experts in the field of infectious disease as well as panelists with past experience developing tests and involvement in past pandemics. In particular, past involvement is necessary in order for a panelist to know what steps the Agency took that were successful or unsuccessful as well as being able to share feedback on the perspective from laboratories who were developing and performing these tests.

We believe that the expertise Dr. Caliendo would bring to this panel session greatly outweighs any potential for a conflict of interest. Dr. Caliendo is expected to offer expertise based on IVD development in past pandemics and in her roles as serving in molecular laboratories in addition to her training and qualifications as an infectious disease specialist. Dr. Caliendo is a recognized expert in the infectious disease field and has extensive past involvement in pandemics including COVID-19. She has given numerous presentations and lectures on COVID-19 testing as well as infectious disease testing in general. In addition, her involvement with pandemics stretches back over a decade as evidenced by her 2011 publication in the Journal of Clinical Microbiology that discussed the characterization of the 2009 pandemic influenza A (H1/N1). Given that FDA needs experts with past pandemic experience, it is unlikely that there are other non-conflicted candidates with this level of experience available as nearly any manufacturer could develop an IVD in the future in response to an outbreak and it is likely that anyone with this level of experience in past pandemics has a potential for a conflict of interest.

Accordingly, I recommend that you grant Dr. Caliendo, a temporary non-voting member of the Microbiology Devices Panel of the Medical Devices Advisory Committee, a waiver from the conflict-of-interest prohibitions of 18 U.S.C. § 208(b)(3).

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:

____**X**___ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

/S/ **August 18, 2023**

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