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

DATE: February 15, 2023

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

FROM: Byron Marshall
Director, Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

Name of Advisory Committee Meeting Temporary Voting Member: **Adaora A. Adimora, M.D.**

Committee: Antimicrobial Drugs Advisory Committee

Meeting date: March 16, 2023

Description of the Particular Matter to Which the Waiver Applies:

Adaora Adimora, M.D., is a temporary voting member of the Antimicrobial Drugs Advisory Committee (AMDAC). The Committee's function is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and make appropriate recommendations to the Commissioner of Food and Drugs.

On March 16, 2023, the committee will discuss new drug application (NDA) 217188, for Paxlovid (nirmatrelvir and ritonavir co-packaged tablets) for oral use, submitted by Pfizer, Inc. The proposed indication is treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID 19, including hospitalization or death. The topic of this meeting is a particular matter involving specific parties.

Type, Nature, and Magnitude of the Financial Interests:

Dr. Adimora is an overarching Data and Safety Monitoring Board (DSMB) member at National Institute of Health (NIH)/Research Triangle Institute (RTI) for a study titled *RECOVER (Researching COVID to Enhance Recovery)*. This is an NIH study of medications for treatment of post-acute sequelae of COVID. One of the drugs may be Paxlovid, the product at issue. This study has not started and is only in the protocol development stage. Dr. Adimora's role involves the usual

functions of a DSMB member, which is to monitor safety and progress of the trial. Her involvement has been ongoing since September 2022.

Dr. Adimora estimates receiving between $0 and $5,000 per year from NIH/RTI for her role in the study.

Basis for Granting the Waiver:

*Dr. Adaora Adimora has unique qualifications and specialized expertise needed for this particular matter.*

Dr. Adaora Adimora is a Sarah Graham Kenan Distinguished Professor of Medicine at the University of North Carolina (UNC) School of Medicine and professor of epidemiology at the UNC Gillings School of Global Public Health. She is Co-Director of the UNC Center for AIDS (acquired immunodeficiency syndrome) Research. Dr. Adimora earned her medical degree from Yale University School of Medicine and completed her Internship and Residency in Internal medicine at Boston City Hospital. She further pursued a Clinical and Research Fellowship in Infectious Diseases at Montefiore/Albert Einstein College of Medicine and also earned a master's in public health in Epidemiology at UNC.

She is a physician epidemiologist with more than 25 years of clinical experience in the treatment of patients with human immunodeficiency virus (HIV) disease. She has dedicated her career to investigating the epidemiology of HIV and sexually transmitted infections (STIs). Her work has helped characterize the epidemiology of heterosexual HIV transmission among African Americans, highlighted the role of sexual network patterns in the spread of HIV, and underscored the importance of macroeconomic and social forces in racial disparities in the US HIV epidemic.

Dr. Adimora serves as Principal Investigator of the UNC site of the Multicenter AIDS Cohort Study-Women's Interagency HIV Study Combined Cohort Study (MACS/WIHS CCS), the largest and longest-running cohort of persons with – and at risk for– HIV. She has served on the National Institute of Allergy and Infectious Diseases Advisory Council, the Presidential Advisory Council on HIV/AIDS, the Department of Health and Human Services Antiretroviral Guidelines Panel, the International AIDS Society's Governing Council and the NIH COVID-10 Treatment Guidelines Panel. In 2019, she became an elected member of the National Academy of Medicine in recognition of her contributions. The academy recognizes individuals who have demonstrated outstanding professional achievement and commitment to service throughout their careers. Dr. Adimora's extensive epidemiological, clinical and research experiences are essential to a productive discussion at the meeting.

*The particular matter is sensitive.*

The meeting topic is considered to be sensitive. The FDA Division responsible for review of Paxlovid expects the meeting to receive significant public and (non-trade) press interest, as there is a continued public health need for a safe and effective oral COVID-19 treatment for the prevention of progression to severe disease, including hospitalization or death. The product at

issue has been demonstrated to have efficacy in preventing progression to severe disease in high-risk patients in clinical trials; however, there continues to be significant interest from the press and public on understanding the use of Paxlovid under certain conditions. If approved, it will be the first COVID-19 oral therapeutic.

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

COVID-19 is a respiratory illness caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a coronavirus discovered in 2019. The virus spreads mainly from person to person through respiratory droplets and small particles produced when an infected person coughs, sneezes, or talks. The spectrum of COVID-19 in adults ranges from asymptomatic infection to mild respiratory tract symptoms to severe pneumonia with acute respiratory distress syndrome (ARDS) and multiorgan dysfunction. Adults 65 years and older and people of any age with underlying medical conditions are at higher risk for severe illness. According to the Centers for Disease Control and Prevention, there have been over 1 million deaths in the United States due to COVID-19. In 2023, weekly cases have been in the hundreds of thousands.

Current treatment options for non-hospitalized adults with mild-to-moderate COVID-19 at high risk for severe COVID-19 include Veklury (remdesivir) for injection, an FDA approved antiviral administered intravenously. Other products available through FDA's emergency use authorization include Paxlovid (nirmatrelvir and ritonavir), the product at issue, and Lagevrio (molnupiravir), both antivirals. Paxlovid would be the first oral approved treatment for mild to moderate COVID-19.

In the interest of public health, it is important that the Agency has the availability of Dr. Adimora to provide her unique expertise for the discussion of the particular matter before the committee.

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

The committee will discuss new drug application (NDA) 217188, for Paxlovid (nirmatrelvir and ritonavir co-packaged tablets) for oral use, submitted by Pfizer, Inc. The proposed indication is treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Due to the complexities of SARS-CoV-2 infection and disease, and the dynamic nature of the changing epidemiology, disease presentations and therapeutic interventions, the review division identified the need for multiple COVID-19 experts with clinical experience in treating COVID-19 patients with emergency use authorized (EUA) and approved products for COVID-19. Furthermore, patients with compromised immune system are particularly at high risk for severe COVID-19. Dr. Adimora's extensive research experience and management of patients who are immunosuppressed distinctly positions her to provide expert opinion and guide the advisory committee discussions on the management of immunocompromised patients with COVID-19.

Accordingly, I recommend that you grant Dr. Adaora Adimora, a temporary voting member of the Antimicrobial Drugs Advisory Committee, 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.

Russell Fortney -S Digitally signed by Russell Fortney -S Date: 2023.02.26 22:13:35 -05'00'

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

February 26, 2023
Date