Additional Questions for the Record of a Hearing Titled
"Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations"

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

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Dr. Anthony S. Fauci, Director, NIAID, NIH

The answers to these questions for the record are accurate as of the date of the hearing.

The Honorable Diana DeGette (D-CO)

1. **What do we know about the effectiveness and safety of the three COVID-19 vaccines currently authorized for people living with HIV?**

NIAID response: The available COVID-19 vaccines authorized for emergency use by the U.S. Food and Drug Administration (FDA) meet FDA's rigorous standards for safety and effectiveness as well as manufacturing quality. Although further study is needed, no safety concerns have been observed to date in the almost 1,600 people with HIV (PWH) who were included in Phase 3 clinical trials of the three FDA-authorized COVID-19 vaccine candidates. Efficacy data for these vaccines in PWH may become available after further analysis, and additional studies to evaluate COVID-19 vaccines in PWH are in planning. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices notes that PWH can receive any of the FDA-authorized COVID-19 vaccines, and the Department of Health and Human Services guidelines for HIV/AIDS recommend PWH receive COVID-19 vaccines because the potential benefits outweigh the potential risks. Individuals with HIV who have a weakened immune system may not mount as robust an immune response to the vaccine, and so, as with all individuals, it is important for PWH to continue to practice effective public health measures such as wearing a mask, physical distancing, and avoiding congregate settings until the risk of SARS-CoV-2 transmission is low in their community.

In addition, the National Institutes of Health (NIH) is working to better understand the effects of COVID-19 on PWH through the support of large-scale cohort studies. The National Institute of Allergy and Infectious Diseases (NIAID) is supporting the Corona infectious virus epidemiology team (CIVETs), which will leverage the previously established North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) to better understand the clinical epidemiology of SARS-CoV-2. CIVETs will be able to evaluate the natural history and treatment history of SARS-CoV-2 in hospitalized and non-hospitalized patients, including those with HIV. NIAID, along

with other Institutes and Centers at NIH, also supports the Multicenter AIDS Cohort Study and Women's Interagency HIV Study (known as the MACS/WIHS Combined Cohort Study), which studies the long-term outcomes and co-morbidities of people with, or at risk for, HIV. This observational cohort study has been expanded to explore risk and resilience for COVID-19 outcomes in this population. NIAID also will continue to support research to prevent and treat SARS-CoV-2 and COVID-19, including among PWH.

The Honorable Kathleen Rice (D-NY)

1. **Two weeks ago, the Administration announced a pilot initiative, Vaccine CommunityConnectors, a partnership with a dozen health insurers that aims to vaccinate two million seniors in vulnerable communities.**

    a. **How will this new partnership help this population access the vaccines?**

    NIAID Response: The Biden Administration is committed to an equitable distribution of COVID-19 vaccines available under emergency use authorizations by the FDA, including for older adults, and has encouraged the private sector to use their expertise and talents to work to help address the COVID-19 pandemic. The Vaccine Community Connectors program is a partnership of more than a dozen health insurers that aims to help adults ages 65 and older from the most vulnerable communities overcome barriers to accessing COVID-19 vaccines. Health insurance providers will work to increase vaccine access to these individuals by providing education, facilitating vaccine registering, and coordinating transportation to vaccination sites.

    While the NIH does not fund Vaccine Community Connectors, this program complements ongoing NIH efforts to promote equitable access to vaccines by reducing vaccine hesitancy. For example, NIH established the Community Engagement Alliance Against COVID-19 Disparities (CEAL) initiative, led by the National Heart, Lung, and Blood Institute and the National Institute on Minority Health and Health Disparities. CEAL brings together trusted community leaders to serve as champions who share information about the importance of participating in COVID-19 research and communicate data on the safety and efficacy of FDA authorized COVID-19 vaccines. Efforts undertaken through CEAL are expected to increase rates of vaccination in communities hit hardest by COVID-19, such as African Americans, Hispanics/Latinos, and American Indians/Alaska Natives, including among older members of the community.

The Honorable Morgan Griffith (R-VA)

1. **Are the projections of herd immunity at 70-85 percent vaccination rate assuming thatsome children under 16 are getting vaccinated?**

NIAID Response: As with adults, children and adolescents can transmit SARS-CoV-2, the virus that causes COVID-19, to others, even if they are asymptomatic. Therefore, estimates of herd immunity should also account for children under 16 years old. While taking in the totality of what we know about this virus and other similar pathogens, a rate of 70-85 percent of the U.S. population with immunity to COVID-19, including adolescents and children, has been considered a reasonable estimate of what is needed to lower the risk of infection from SARS-CoV-2. It is important to note that estimates of herd immunity are affected by the evolving properties of the virus that may impact vaccine effectiveness and the changing dynamics of an outbreak. The emergence of SARS-CoV-2 variants of concern, which appear to have higher rates of transmission, may alter the ability of vaccination or natural infections to achieve effective levels of herd immunity. In addition, the level of adherence to public health measures, such as masking, physical distancing, and avoiding congregate settings as well as the durability of immune responses to SARS-CoV-2 infection and vaccination against COVID-19 can impact herd immunity estimates.

To ensure an effective level of herd immunity is achieved, the Administration is working to get as many people vaccinated as quickly as possible. Studies are currently underway to test COVID-19 vaccine candidates in both adolescents and children, in addition to those COVID-19 vaccines that are already available for adults under emergency use authorization (EUA) from the FDA. Based on initial results from a Phase 3 clinical trial of the Pfizer/BioNTech COVID-19 vaccine candidate that showed 100 percent efficacy and robust immune responses in adolescents 12-15 years of age, the company has requested an expansion of the current EUA to include this age group. With multiple trials to evaluate COVID-19 vaccines in children and adolescents currently ongoing, it appears likely that several vaccines will be authorized for emergency use in adolescents by Fall 2021 and in children younger than 12 years of age by Spring 2022.

2. **Is it possible for the U.S. to reach herd immunity without children under 16 being vaccinated?**

NIAID Response: As mentioned in response to question 1, children and adolescents can transmit SARS-CoV-2 to others, even if they are asymptomatic. Therefore, it is likely that to achieve an effective level of herd immunity against SARS-CoV-2 infection, individuals under 16 years of age also would need to be included in our vaccination programs. As noted in the response to question 1 above, there are several ongoing clinical studies to evaluate the safety and efficacy of COVID-19 vaccines in children and adolescents.

3. **For this projection of herd immunity, are you only looking at the percentage of the population that is vaccinated, or does your projection include the percentage of the population that is unvaccinated but was previously infected with COVID-19? Pleaseexplain why the percentage does or does not include those who have been previouslyinfected with COVID-19.**

NIAID response: For most individuals, infection with SARS-CoV-2 appears to generate an immune response that would be expected to prevent the development of severe COVID-19 disease upon subsequent exposure to the virus. These individuals may contribute to the overall level of herd immunity; however, it is important to note that not all individuals develop a strong immune response following SARS-CoV-2 infection. In addition, we still do not know how long protection resulting from SARS-CoV-2 infection persists. For these reasons, it is recommended that all individuals receive an FDA-authorized COVID-19 vaccine when it is available to them, regardless of their prior infection status.

4. **What is the assumed efficacy of the vaccines in the herd immunity projection?**

NIAID Response: As noted in the response to question 1, estimates of herd immunity are not static – they are affected by the evolving properties of the virus and the changing dynamics of an outbreak. In general, a vaccine with a higher level of efficacy could be expected to lower the level of vaccination needed to develop herd immunity. The available and FDA-authorized COVID-19 vaccine candidates meet FDA's rigorous standards for safety and effectiveness. However, the estimates of herd immunity being reached at a 70-85 percent immunity rate were developed prior to the emergence of SARS-CoV-2 variants of concern. These SARS-CoV-2 variants of concern appear to have higher rates of transmission and may ultimately increase the level of immunity required to achieve herd immunity in a given population. To ensure that we are providing sufficient protection against SARS-CoV-2 and COVID-19 at the individual and community levels, we are working to exceed the estimated levels of vaccination needed to obtain herd immunity and vaccinate as many individuals as possible.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. **For decades, the National Institutes of Health (NIH) has provided grant dollars to the EcoHealth Alliance, which studies emerging diseases caused by human and animal interactions. In 2014, EcoHealth Alliance was granted federal dollars specifically for,"Understanding the Risk of Bat Coronavirus Emergence." In addition to EcoHealth Alliance, sub-awardee grant dollars were also approved for the Wuhan Institute of Virology, which worked with EcoHealth Alliance. How have these NIH grant dollarshelped the United States understand the emergence and origins of the COVID-19 virus?**

NIAID Response: The National Institutes of Health (NIH) is not currently supporting any research at the Wuhan Institute of Virology (WIV). As you have noted, the NIH previously awarded a grant to EcoHealth Alliance in which the WIV was a sub-awardee. It is important to note that the project period of this grant largely predates the emergence of SARS-CoV-2, and as approved, the project was not designed to examine the origins of SARS-CoV-2, the virus that causes COVID-19. The approved research of EcoHealth Alliance scientists and their collaborators under the grant focused on improving the understanding of coronaviruses, animal reservoirs of the viruses, and the

potential for spillover of viruses from animals to humans. As published in a *Nature* article describing research funded in part by the NIAID grant, NIH-supported scientists at EcoHealth Alliance and their collaborators reported that they identified in 2017 a novel pig coronavirus, swine acute diarrhea syndrome coronavirus (SADS-CoV), in Guangdong Province, China. The investigators reported that they then traced the virus back to bats by testing specimens that were collected in the same province as the affected pig farms. 11.9 percent of the bat specimens tested positive for SADS-CoV. To confirm whether transmission of SADS-CoV from swine to humans had occurred, the researchers reported that they also tested farm workers in close contact with the sick pigs and none tested positive. Through this coronavirus research, EcoHealth Alliance investigators indicated that they identified a novel coronavirus present in swine and bats while further developing research collaborations with investigators at the WIV, Duke-National University of Singapore Medical School, and other organizations in the region. For further information, see Zhou, P., Fan, H., Lan, T. *et al.* Fatal swine acute diarrhoea syndrome caused by an HKU2-related coronavirus of bat origin. *Nature* 556, 255–258 (2018). https://doi.org/10.1038/s41586-018-0010-9.

Research to characterize and monitor the diverse population of viruses in animals may help identify potential geographic areas where emergence of a novel infectious disease is most likely to occur. Once these areas are identified, surveys of local human populations for evidence of infection by viruses normally found in animals may allow for early identification of a virus that has evolved to be able to infect humans. This could lead to a potential outbreak if the virus evolves to be able to spread easily from human to human, as was the case with SARS-CoV-2. Investigations on the origin of SARS-CoV-2 by appropriate authorities are ongoing.

a. Have these grant dollars helped us understand the structure and operations ofthe Wuhan Institute of Virology?

NIAID Response: It is important to note that NIH research grants are competitively awarded to support the most meritorious research to answer pre-specified scientific questions and are not awarded for the purpose of gaining insight into the structure and operations of grant recipients and their sub-awardees. The WIV operated under a sub-award from EcoHealth Alliance and has not received funding directly from the NIH. NIH's relationship is with the primary recipient of NIH funding (the grantee), and the grantee is required to oversee subrecipients' compliance with the terms and conditions of subawards. NIH defers to the Office of the Director of National Intelligence and other appropriate authorities on the structure and operations of the WIV.

2. In April of 2009, the first case of H1N1 was detected in California. The Centers for Disease Control and Prevention began researching a vaccine, completing the gene sequences of the virus by the end of April, during which the Federal Government promised up to 160 million doses of a vaccine by October. This did not happen. In fact, only 23 million doses were available by the expected date. Where there any lessons learned from the H1N1 vaccine development and administration

response, andhow were these lessons applied to Operation Warp Speed?

NIAID response: One of the lessons learned from the 2009 H1N1 pandemic is the importance of developing flexible, broadly applicable technologies for the development of medical countermeasures, especially vaccines, to be able to respond quickly to emerging infectious diseases. Since the emergence of 2009 H1N1 pandemic influenza, there have been a number of advances in the field of vaccinology that have significantly accelerated the vaccine development process. The development of highly adaptable vaccine platforms and structural biology tools enabling the design of immunogens that stimulate the immune system were essential research advances that have helped usher in a new era of vaccinology.

The NIAID Vaccine Research Center has played a key role in both the development of novel vaccine platforms – many of which do not require the lengthy, egg-based production methods used for most influenza vaccines – and the design of the stabilized prefusion spike protein immunogen used in all three of the COVID-19 vaccines currently authorized under an EUA from the FDA. The development in record time of these highly efficacious vaccines with the potential for saving millions of lives was only possible through an extraordinary multidisciplinary effort leveraging decades of basic, preclinical, and clinical science. This is an important reminder of the societal value of sustained and robust support for the U.S. biomedical research enterprise, which continues to accelerate the development of vaccines to protect against emerging and re-emerging infectious diseases.

In addition to the need for accelerated vaccine development, another lesson learned from the emergence of 2009 H1N1 pandemic influenza was the need to move beyond chasing the different viral strains or variants that emerge with strain-specific vaccine approaches. NIAID is leading efforts to develop "universal" influenza vaccines to protect against multiple strains of seasonal and pandemic influenza viruses. NIAID also is conducting early-stage research on the development of pan-coronavirus vaccines designed to provide broad protective immunity against multiple coronaviruses, especially SARS-CoV-2 and others with pandemic potential. New viral threats will continue to emerge, and the development of universal influenza vaccines and pan-coronavirus vaccines will help us be better prepared for future infectious disease threats.

The Honorable John Joyce, M.D. (R-PA)

1. **Dr. Fauci, would you commit to your colleagues on the White House COVID taskforce as well as at HHS to make sure that long-term care pharmacies' efforts to vaccinate our seniors in long-term care facilities can be sustained?**

NIAID Response: The Administration is committed to the equitable distribution of COVID-19 vaccines authorized for emergency use by the FDA and has made tremendous progress on vaccinating older adults, with over 80 percent of people in the

United States over 65 years old receiving at least one dose of a COVID-19 vaccine. I agree that pharmacies have, and should continue to, play an important role in ensuring access to COVID-19 vaccines for older adults. Older adults, especially residents of long-term care facilities (LTCFs), are at an increased risk of SARS-CoV-2 infection and severe illness from COVID-19. As a result, the Centers for Disease Control and Prevention (CDC) recommended that healthcare personnel and LTCF residents be among those offered the first doses of COVID-19 vaccines available under EUA from the FDA. The Pharmacy Partnership for Long-Term Care Program is a partnership between CDC and retail pharmacies to facilitate on-site vaccination of residents and staff at LTCFs. NIAID defers to CDC to provide additional information on the Pharmacy Partnership for Long-Term Care Program.

The NIAID immediately began working to ensure that older adults were included in the evaluation of COVID-19 candidate vaccines when it became clear early in the pandemic that this population was particularly vulnerable to COVID-19. NIAID, in collaboration with Moderna, Inc., worked quickly to expand the Phase 1 clinical trial of the mRNA-1273 vaccine to include adults ages 56 and older in April 2020. As candidate vaccines progressed to advanced stages of testing, older adults were prioritized for inclusion in these studies and have been included in all Phase 3 clinical trials of investigational COVID-19 vaccines supported by the ongoing partnership between the Department of Health and Human Services and Department of Defense to develop COVID-19 medical countermeasures. The results of these studies have supported EUAs from the FDA for the use of three vaccines to date in adults, including older individuals.