



1899 L Street, NW, Suite 1200
Washington, DC 20036

T 202.822.8282
F 202.296.8834

HOBBSSTRAUS.COM

MEMORANDUM

December 16, 2020

TO: Tribal Health Clients

FROM: Hobbs, Straus, Dean & Walker, LLP

RE: *National Institutes of Health: COVID-19 Research and Vaccines for AI/AN Communities*

On December 15, 2020, officials from the National Institutes of Health (NIH) hosted a Facebook Live discussion with Dr. Anthony Fauci, where they addressed tribal communities' frequently asked questions about the COVID-19 vaccines. We discuss the details of their conversation below.

Vaccine Candidates and Clinical Trials. Dr. Fauci said the federal government has invested in six vaccine candidates. He explained that Pfizer and Moderna have completed their Phase 3 trials. He said Pfizer recently received an Emergency Use Authorization (EUA) from the Food and Drug Administration for its vaccine. He also said the Moderna would be available next week after Moderna receives its EUA. Dr. Fauci said clinical trials are ongoing for the other four vaccine candidates. He said several vaccines must be developed to meet the demand to vaccinate individuals across the United States and throughout the world.

In response to whether the federal government and vaccine developers are using Native people as “guinea pigs” to test the vaccine, Dr. Fauci explained that all people are represented in the clinical trials. As a result, he said, the vaccines are being tested on a cross-section that represents the entire population. He said it is important to include Native people in the clinical trials so tribal populations have confidence that the vaccines are safe and effective in their communities.

Vaccine Development. Dr. Fauci addressed concerns about the speed with which the vaccines are being developed. He said, while this is an understandable concern, the fast development of the vaccines is a reflection of the scientific advances that have been made in vaccine platform technologies¹ and the billions of dollars the federal government

¹ A vaccine platform represents how the vaccine was developed and the method it uses to instruct the body to develop an immune response to a virus. See Laura Joszt, *Experts Highlight COVID-19 Vaccine Developments and Remaining Challenges*, AM. J. MANAGED CARE (Aug. 4, 2020), <https://www.ajmc.com/view/experts-highlight-covid-19-vaccine-developments-and-remaining-challenges>. There are several vaccine platforms in use today, however, the mRNA technology has shown the highest rate of efficacy against COVID-19 infection.

invested in the vaccine development. Dr. Fauci emphasized that the speed of COVID-19 vaccine development has not compromised scientific integrity.

Adverse Events. Dr. Fauci said no severe adverse events occurred during the Pfizer and Moderna clinical trials. He said the primary side effect of the vaccines is retrogenicity—the instance in which a person who has been vaccinated experiences very mild symptoms such as transient pain in the arm, body aches and pains, and, in some cases, fever. He said these symptoms last between 24 to 48 hours and can be managed with over the counter pain medication. Dr. Fauci said long-term adverse events typically occur between 30 and 60 days after vaccination. He explained that the FDA cannot grant an EUA for a vaccine until at least 60 days after 50% of the clinical trial participants received their last dose. By waiting 60 days, he said, the FDA would eliminate the risk of long-term adverse events by 90%.

Dr. Fauci explained that it is impossible for COVID-19 vaccines to alter or change human DNA. He said the Pfizer and Moderna vaccines use mRNA technology, which works by creating a protein that mimics the spiked shape of the SARS-CoV-2 virus. He said the body then creates an immune response to protein so that it can attack the virus.

Long-Term Efficacy and Continued Transmission. Dr. Fauci said the Pfizer and Moderna vaccines are 94% to 95% effective against COVID-19 disease and severe disease. Dr. Fauci said optimal protection from COVID-19 will occur between 7 and 14 days after a person receives their second dose of vaccine. He said, however, the long-term efficacy of the vaccine is currently unknown. To determine long-term efficacy, he said, vaccinated clinical trial participants will be followed for two years. He also said observational studies of people outside of clinical trials will be conducted.

Dr. Fauci said it is currently unknown whether the vaccine prevents SARS-CoV-2 transmission. He said, therefore, those who get vaccinated should still wear a mask, watch their distance, avoid indoor congregate settings, and wash their hands to prevent transmission of the virus to others. He also said those who have recovered from COVID-19 should continue to practice these public health measures. Dr. Fauci said communities can begin to lift public health measures when 75% to 85% of the population is vaccinated and the chances of getting infected become minuscule. Dr. Fauci emphasized that herd immunity only occurs when a large enough percentage of the population is vaccinated and, as a result, individuals should not wait to receive the vaccine.

Safety and Efficacy. Dr. Fauci addressed whether it is safe for those with underlying conditions to get vaccinated. He explained that the clinical trials included those with underlying, but stable, conditions. He also said the vaccine is safe for those with compromised immune systems but noted that the level of effectiveness for those individuals is not currently known.

Dr. Fauci said women of child-bearing age were also included in the clinical trials, and there was no evidence to suggest that the vaccine had any negative effect. He said the vaccine was not tested on pregnant women. He said, however, that problems with vaccinating those who are pregnant arise when they are vaccinated with live-attenuated vaccines. Dr. Fauci explained that the Pfizer and Moderna vaccines do not use this technology and instead use the pure-induction mRNA platform.

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If you have any questions or would like further information on the topics raised during this discussion, please contact Elliott Milhollin (emilhollin@hobbsstrauss.com or 202-822-8282); Geoff Strommer (gstrommer@hobbsstrauss.com or 503-242-1745); or Violet Rush (vrush@hobbsstrauss.com or 202-822-8282).