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MEMORANDUM

December 16, 2020

TO: Tribal Health Clients
FROM: Hobbs, Straus, Dean & Walker, LLP
RE: *National COVID-19 Briefing Call with State, Local, and Tribal Officials*

On December 16, 2020, the White House held a COVID-19 briefing call for state, local, and tribal officials on the COVID-19 vaccine and COVID-19 therapeutic interventions. The call included officials from the White House and the White House's Coronavirus Task Force, Department of Health and Human Services (HHS), U.S. Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC).

Please note, the FDA's Vaccines and Related Biological Products Advisory Committee will meet on December 17, 2020, from 9:00 a.m. to 6:00 p.m. to discuss the Emergency Use Authorization (EUA) for the Moderna Vaccine. The meeting is open to the public and is available online.¹

COVID-19 Trends. Dr. Deborah Birx, White House Coronavirus Task Force Ambassador, said the rates of COVID-19 infection across the Great Plains region is improving but significant deterioration throughout the Coastal and Sun Belt regions is continuing. She said continued vigilance in following public health measures, such as wearing masks while indoors, in combination with the COVID-19 vaccines, will protect those most vulnerable to severe COVID-19 disease.

Vaccine Development. Paul Mango, HHS Deputy Chief of Staff for Policy, said approximately 100,000 individuals have participated in clinical trials for the COVID-19 vaccines. He explained that, by the end of January 2021, four COVID-19 vaccines could be available. He said the FDA will likely grant Moderna an EUA for its vaccine this week. He added that two other vaccines are in Phase 3 clinical trials, one of which will be available in a single dose. Deputy Chief Mango also said any American who wants a vaccine will be able to access one by the end of the second quarter of 2021.

COVID-19 Therapeutics. Deputy Chief Mango said two monoclonal antibody treatments are available to treat COVID-19 disease but noted there is some uncertainty regarding how and when to utilize these measures. He explained that, currently, it is

¹ Meeting registration, information, and materials are available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement>.

recommended that health care providers use monoclonal antibody treatments as soon as an individual tests positive for the virus. When taken early enough, he said, monoclonal antibody treatments will prevent the progression of COVID-19 disease and hospitalization. Dr. Birx said several hospitals have established monoclonal antibody infusion centers to treat those in the early stages of COVID-19 disease.

Vaccine Distribution and Administration. Deputy Chief Mango said 3 million doses of the Pfizer vaccine shipped during the week of December 14, 2020, and that 8 million doses will ship next week. Nancy Messonnier, M.D., Director of the National Center for Immunization and Respiratory Diseases for the CDC, added that the Pfizer vaccine has shipped to 5 federal entities and 61 jurisdictions (states and certain localities), and 55 jurisdictions have begun vaccinating health care personnel. She said there have been no reported issues with the initial distribution and delivery process.

Dr. Messonnier said the CDC has developed several tools to assist in the distribution and tracking of the vaccine. She said the CDC created a jurisdiction watch desk that is available 24 hours per day and 7 days per week to respond to questions about delivery and storage. She also said all jurisdictions have access to Tiberius, which monitors the geographic location of vaccine doses. She did not specify whether tribal health programs have direct access to Tiberius or whether they must request access from the jurisdiction through which they are receiving the vaccine (*e.g.*, states or Indian Health Service). Dr. Messonnier also said the CDC has created a vaccine clinical inquiry team to address complex questions from providers and frontline health care workers.

Dr. Messonnier emphasized the importance of communication in vaccine delivery and administration. She said the CDC has developed education and training materials for health care providers for vaccine storage and administration and issued best practice guidelines for immunizations. She explained that health care providers can immediately access new guidance when it is published by signing up for email alerts.

Dr. Messonnier also said the CDC will launch its Pharmacy Partnership for Long-Term Care Program using the Pfizer vaccine on December 21, 2020.² She said the program is scheduled to begin administering the Moderna vaccine on December 28, 2020.

Safety and Monitoring. Dr. Messonnier said the CDC's safety and monitoring activities have begun. She said the vaccine adverse events reporting system is working and noted that the system identified the first case of a severe allergic reaction to the vaccine in Alaska. She said the individual is recovering. Dr. Messonnier said the CDC has launched V-Safe, a smartphone-based tool that uses text messaging and surveys to

² The Pharmacy Partnership for Long-Term Care Program facilitates safe vaccination of long-term care residents at no cost to long-term care facilities. More information on the program is available at <https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html>.

communicate with patients after they have received the vaccine. She said 600 patients have thus far enrolled in V-Safe.

FDA Authorizations. Dr. Stephen Hahn, said that before issuing an EUA, the FDA thoroughly reviews the clinical trial and manufacturing data to ensure safety and efficacy. He explained that distribution occurred quickly because the FDA contacted federal partners and Pfizer before formally issuing the EUA for the Pfizer vaccine. He said the authorization is a significant milestone that is based on science and data.

Dr. Hahn emphasized that an EUA is not the final step in the process for FDA approval. Instead, he explained, the FDA expects Pfizer and other vaccine developers to collect additional data on vaccine safety and efficacy and prepare for the FDA approval and licensing processes. Commissioner Hahn noted that the Pfizer vaccine helps prevent COVID-19 disease and, at times, prevents severe COVID-19 disease. He said, however, the FDA does not know whether it prevents transmission of the SARS-CoV-2 virus.

Commissioner Hahn said the FDA's Vaccines and Related Biological Products Advisory Committee will meet on December 17, 2020, to discuss the EUA for the Moderna vaccine. Dr. Messionier said the CDC's ACIP will also meet the weekend of December 18 to review the safety and effectiveness information of the Moderna vaccine.

Commissioner Hahn also said the FDA has issued EUAs for over 200 COVID-19 tests. He said, for example, the FDA recently authorized the first consumer-direct test wherein consumers can collect their own nasal swabs at home and mail them to LabCorp for testing. He also said the FDA has issued an EUA for the first over-the-counter diagnostic COVID-19 test, the Ellume COVID-19 Home Test.³

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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).

³ More information on the Ellume COVID-19 Home Test is available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-antigen-test-first-over-counter-fully-home-diagnostic>.