WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP
SUMMARY OF FINDINGS CONCERNING REPORTS OF ADVERSE EVENTS FOLLOWING RECEIPT OF THE MODERNA COVID-19 VACCINE IN SAN DIEGO

Recommendations of the Workgroup Concerning Resumption of Use of Moderna COVID-19 Vaccine Lot 041L20A in California

The Western States Scientific Safety Workgroup was asked by Dr Erica Pan, California State Epidemiologist, to meet on January 19, 2021 to provide advice concerning possible resumption of use in California of Lot 041L20A of the Moderna COVID-19 vaccine, which was paused on January 17, 2021 in response to reports of adverse events following administration of the vaccine to recipients at a drive-through clinic in San Diego, California on January 12 and 13, 2021.

For its discussion, members of the Workgroup were joined by allergy and immunology specialists Drs. Michael Welch, John Kelso and Stephanie Leonard; representatives of the San Diego County Health and Human Services Agency, including Dr. Eric McDonald, Medical Director, Epidemiology & Immunization Services, and Melissa Thun, Immunization Coordinator; and Dr. Francesca Torriani, UCSD infectious disease physician. Presentations were given concerning the drive-through vaccination site and its staffing and procedures; details concerning the distribution of other doses of the lot of Moderna COVID-19 vaccine in California and other states; and details concerning the seven individuals who reportedly had adverse events following receipt of the vaccine on January 12 (1 individual) and January 13 (6 individuals), including their signs and symptoms; the time intervals between vaccine administration and onset; the treatment they received and their outcomes; and any relevant histories of prior allergic or anaphylactic reactions.

On the basis of a lengthy discussion of the clinical findings among the seven vaccine recipients (all of whom received treatment and recovered), aided by the three guest experts in allergy and immunology, it was concluded that while one or more of the seven individuals had angioedema, anaphylaxis was not confirmed in any of them and none experienced a life-threatening adverse event following administration of the vaccine. No reason was identified as to why these adverse events occurred at that vaccine administration site on those dates. However, given that the fact that large numbers of individuals receiving the same lot of the

Moderna COVID-19 vaccine nationwide and at the drive through vaccination site in San Diego did not experience similar adverse events following immunization; given the continued use of the same lot of the vaccine in other states; and given the severity of the ongoing COVID-19 pandemic, together with the severe constraint on the number of available doses of COVID-19 vaccine, the Workgroup recommended that use of this lot of the Moderna COVID-19 vaccine could resume in California and continue in other states represented in the Workgroup, so as to maximize COVID-19 vaccination efforts.

The Workgroup noted that the rapid detection of and response to this cluster of adverse events following receipt of COVID-19 vaccine is important evidence that the systems put in place to monitor the safety of COVID-19 vaccines are functioning at a high level. They also noted the guidelines in place to ensure that COVID-19 vaccines, like all vaccines, be administered at locations and by staff fully equipped to monitor all vaccine recipients for 15-30 minutes following administration of vaccine doses and to respond quickly and effectively to any adverse events following immunization are important to adhere to fully. The Workgroup also reiterated the importance of using the CDC questionnaire to screen those being considered for COVID-19 vaccination to identify individuals who may be at elevated risk for an adverse event following immunization and who may benefit from a longer period of observation following vaccination. The Workgroup plans to continue to work with specialists in the field of allergy and immunology in the coming weeks to ensure that our advice regarding administration of COVID-19 vaccines to individuals with a history of selected forms of severe allergic reactions or anaphylaxis ensures maximum safety and that individuals who experience an adverse event suggestive of an allergic reaction receive appropriate testing and follow-up.

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Submitted by Art Reingold, MD, Chair, Western States Scientific Safety Review Workgroup on behalf of the Members of the Western States Scientific Safety Review Workgroup