January 7, 2021

To: Governors of California, Nevada, Oregon, and Washington State
- Governor Gavin Newsom, California
- Governor Steve Sisolak, Nevada
- Governor Kate Brown, Oregon
- Governor Jay Inslee, Washington

From: Arthur Reingold, MD, Chair
Western States Scientific Safety Review Workgroup

SUMMARY OF FINDINGS:

After reviewing the state of the COVID-19 pandemic in our states and the beginning of wide scale COVID-19 vaccination efforts, the Western States Scientific Safety Review Workgroup:

- Continues to endorse implementation of COVID-19 vaccination, as the benefits of vaccination substantially outweigh any known risks associated with receipt of the COVID-19 vaccines currently available under Emergency Use Authorization;

- Continues to recommend that COVID-19 vaccination be carried out in settings equipped to respond to anaphylaxis and following CDC guidelines concerning COVID-19 vaccination;

- Recommends that our respective states' health agencies, along with this Workgroup, continue monitoring FDA and CDC's reporting and study of adverse events following COVID-19 immunizations;

- Recommends continued adherence to the two dose regimens of the Pfizer/BioNTech and Moderna COVID-19 vaccines authorized by the FDA under Emergency Use Authorization;

- Recommends expanded resources be mobilized to ensure that doses of COVID-19 vaccines be administered expeditiously; and

- Recommends continued monitoring of the supply of COVID-19 vaccines available for use and frequent re-visiting of these recommendations.

Since the Western States Scientific Safety Review Workgroup provided its recommendations concerning the use of Pfizer/BioNTech and Moderna COVID-19 vaccines on December 13 and 20, 2020, respectively, its members have monitored closely the evolving pandemic in the U.S. and in our respective states, and the initiation of wide scale COVID-19 vaccination. Because of evidence that the epidemiological situation regarding transmission of SARS-CoV-2 and resultant illnesses, hospitalizations, and deaths from COVID-19 appears to be worsening in recent weeks and because of calls to alter how COVID-19 vaccines are administered to vaccinate more people faster, the Workgroup met on January 4, 2021 to review COVID-19 dosing schedule issues. These increases in illnesses, hospitalizations and deaths are likely the result of a combination of factors, including increased travel for the holidays; relaxation of social distancing measures by individuals; and the arrival of colder weather, limiting outdoor activities and promoting increased exposure to and transmission of the SARS-CoV-2 virus in indoor settings. The Workgroup also recognized that the arrival in the U.S. and in our respective states of one or more variants of the SARS-CoV-2 virus that may be more readily transmissible could lead to more rapid and widespread transmission and illnesses, although evidence is insufficient at this point to judge whether such variants are contributing substantially to the recent surge in cases of COVID-19 in our states.

The Workgroup also discussed the reasons for the slower than anticipated roll out of COVID-19 vaccines. Similar delays in using available doses of the two COVID-19 vaccines have been seen in other countries and have been attributed to diverse reasons, including the winter holidays, winter storms, and shortages of staff, among other constraints. In this context, there have been calls by some public health experts in the U.S. and other countries to make changes to the initial recommendations for use of the two currently available COVID-19 vaccines. Such proposed changes have included giving only half the dose of vaccine assessed in the clinical trials and delaying administration of the second dose of the vaccine beyond the three- or four-week intervals tested in the phase 3 trials. The latter two changes are intended to increase the number of individuals who can be

vaccinated quickly, given a fixed supply of vaccines, relying on limited available evidence concerning the efficacy of either a two doses regimen using only a half a dose of the vaccine each time or of a single full dose of the vaccine and acknowledging that the duration of vaccine - induced protection from various regimens is not yet known.

The Workgroup discussed all of these issues, informed by public health officials from our respective states concerning roll out of vaccination efforts and the extent to which limitations in the number of doses of COVID-19 vaccine have been a constraint. While very concerned about the current numbers of illnesses and hospitalizations for COVID-19 and the likelihood that the pandemic situation will not improve in the coming weeks, the Workgroup concluded that the scientific data available to support the proposed changes are extremely limited and that, at this time, it would be premature to adopt any of the proposed changes to how the currently available COVID-19 vaccines are used. This conclusion is in line with a January 4, 2021 statement by the FDA concerning such proposed changes in COVID-19 vaccination schedules.

The Workgroup was particularly concerned about the very limited data concerning the efficacy and duration of protection of either one dose of a COVID-19 vaccine or two half doses, especially in high-risk individuals, such as the frail elderly in long term care facilities. Furthermore, the evidence available at this point suggests that, thus far, inadequate vaccine supply has not been the primary cause of the slower than anticipated roll out of vaccination efforts in the U.S. and in our respective states, as substantial amounts of vaccine are available. Rather, limitations in staffing and other resources in both healthcare and public health settings, as well as the administrative complexity of setting up and implementing a mass vaccination program targeting adults, with a focus on reaching high risk groups and also assuring equity, have yet to be overcome.

The Workgroup also expressed concern regarding both a possible increase in confusion and a decrease in confidence in the COVID-19 vaccination program and in COVID-19 vaccines that might result from making changes to the vaccination schedule at this time, and particularly, if these changes lead to COVID-19 illness in vaccinated individuals. However, the Workgroup acknowledged that the situation regarding both the availability of sufficient numbers of doses of COVID-19 vaccines and the ability of our respective states to vaccinate large numbers of

individuals quickly could change in the coming weeks. The Workgroup therefore believes that close monitoring of the situation is essential. If constraints on the first dose supply begin to limit our ability to expand vaccination efforts, policy makers may wish to allow use of second dose allocations (which are currently being held in reserve) to more rapidly expand the number of individuals receiving their first dose.

The Workgroup also briefly reviewed the current situation with regard to the safety of the two COVID-19 vaccines that are currently in use in the U.S. The Workgroup reviewed the recently published revised guidelines from CDC regarding who should not receive the currently available COVID-19 vaccines because of a concern regarding an increased risk of anaphylaxis. It also re-affirmed its strong support for the administration of COVID-19 vaccines (like all vaccines) in locations equipped to deal with anaphylaxis and the importance of having individuals remain under observation for 15 minutes or 30 minutes for those with a history of allergic reactions following vaccine administration. It further emphasized the need to continue close monitoring and investigation of reports of adverse events following receipt of COVID-19 vaccine. The Workgroup re-affirmed its judgement that under the current COVID-19 pandemic circumstances, the benefits of COVID-19 vaccination substantially outweigh any known risks of vaccination.

The Workgroup will continue to monitor COVID-19 disease and vaccination in our respective states and in the U.S., and will meet expeditiously as needed to re-assess and, if needed, revise its recommendations.