

**Opening Statement of Republican Leader Greg Walden
Subcommittee on Oversight & Investigations Virtual Hearing
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will
Trust”**

September 30, 2020

As Prepared for Delivery

Thank you, Chair DeGette.

Americans should have high confidence that any COVID-19 vaccine that is approved or authorized by the U.S. Food and Drug Administration (FDA) will have gone through the most rigorous, independent and transparent trials, testing and review in the world.

In fact, the scientific and public attention focused on the COVID-19 vaccine process is itself unprecedented. For example, FDA has issued rigorous guidance for these vaccines, and each of the Phase 3 trials are enrolling at least 30,000 participants. In addition, FDA has multiple existing safeguards in place to ensure science-based decisions. These include standards for the vaccine review process, the Emergency Use Authorization review process, and the necessary evidence required to receive an approval that meets FDA’s gold standard.

Further, there are multiple safeguards outside of FDA. For example, each of the Phase 3 trials will be overseen by the Data and Safety Monitoring Board (DSMB). The DSMB is an independent, multidisciplinary group which includes individuals who are experienced with clinical trials, biostatisticians, bioethicists,

immunologists, vaccinologists, and virologists. The purpose of the DSMB is to oversee and monitor clinical trials to ensure participant safety and the validity and integrity of the data. In addition, all four companies in Phase 3 trials have published their clinical trial protocols to provide even more transparency.

There are also independent experts who serve on an FDA Advisory Committee who will scrutinize safety and efficacy data of the vaccine candidates. The evidence required for these vaccines is consistent with the FDA's gold standard that has made the vaccine supply in the U.S. reliable, safe, and effective.

Separately, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who are responsible for developing recommendations on the use of FDA approved vaccines for Americans, including how, when, and to whom a vaccine should be given.

It is critical that a life-saving, approved coronavirus vaccine gets to those most at risk to this deadly virus without delay once the FDA's independent scientists have cleared it for safety and efficacy.

However, some states have indicated that they plan to withhold distribution of vaccines while they conduct their own, unprecedented reviews of the data, potentially risking the lives of their own citizens.

Such reckless actions dangerously undermine the FDA, lead to greater vaccine hesitancy, delay and obstruct vaccine distribution, create public confusion with inaccurate and misleading information about vaccine safety and efficacy, and worst of all, jeopardize American lives.

These states have not provided any evidence of any expertise to conduct such a review nor have they cited any legal authority to prevent their citizens from accessing a vaccine approved by the FDA, especially during a national public health emergency.

The scientific collaboration throughout the COVID-19 vaccine research and development effort is extraordinary. That collaboration must continue through the complex vaccine distribution process, including the appropriate prioritization for distribution and all the logistics involved in distributing an approved or authorized vaccine.

American scientists are making remarkable progress towards a COVID-19 vaccine. Experts such as Dr. Anthony Fauci are optimistic that these efforts will lead to a life-saving vaccine and will benefit public health in our country and the world.

It is essential that all of us involved in public policy in this space stick to the facts and not falsely denigrate those doctors, scientists and public health officials who are working around the clock to save lives.