Opening Statement of The Honorable Brett Guthrie
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, for holding this important hearing about the COVID-19 vaccine pathway.

Ultimately, it will be a vaccine that offers us the best chance to finally end this pandemic, allowing our nation to fully reopen. But it is not just the vaccine itself. In addition to an approved or authorized vaccine, we will need widespread acceptance, distribution, and immunization to successfully combat this virus.

The purpose of this bipartisan hearing should be to increase public confidence in the U.S. Food and Drug Administration (FDA) and its process for authorizing and approving vaccines through science-based decisions so that there is greater vaccine acceptance and confidence among Americans.

Congress, through this Committee, created the emergency-use authorization pathway as part of the Project BioShield Act in 2004, and later expanded that pathway in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 on a bipartisan basis. Through those efforts, we provided special authority to FDA to be used in a public health emergency prior to a full approval, when the scientific evidence is available to support such a use.

To receive an Emergency Use Authorization (EUA), a drug company must demonstrate, that based on the totality of scientific evidence the drug's known or potential benefits outweigh the known and potential risks. The FDA can apply that standard appropriately to different settings, such as requiring more-rigorous evidence for treatments used on healthier populations than for seriously ill hospitalized patients. For COVID-19 vaccines, the FDA has announced it is using an "EUA plus approach," through a guidance setting a much more stringent standard than for other EUAs.

Unfortunately, I have grave concerns that some are trying to score political points by irresponsibly criticizing the FDA and its vaccine review and approval process, potentially undermining trust in an FDA-authorized vaccine, especially during this global pandemic and national health emergency. It is understandable in this politicized environment that many in the public would be concerned or confused about the vaccine development and approval process and whether corners are being cut with these unfounded criticisms circulating.

The truth of the matter is that the review and approval stages of the vaccine will be controlled throughout the process by non-political, independent, scientific experts, not politicians. The data produced during the vaccine clinical trials are reviewed and evaluated by a Data Safety Monitoring Board, which is composed of independent scientific experts.

In addition, there is an FDA Vaccines and Related Biological Products Advisory Committee composed of independent, leading medical experts who are expected to review and evaluate data on the vaccines in public meetings.

Indeed, even Congress has contributed to getting assurances on a science-based decision from the FDA. It was this Committee's full Committee hearing in June, and other Committee hearings over the past few months, where Congress and the American people received assurances from FDA Commissioner Stephen Hahn that he would support his career scientists and that FDA would not cut corners on the safety or efficacy of COVID-19 vaccines.

The intense scrutiny has led to other extraordinary pledges from highly respected public health officials. Dr. Peter Marks, the Director of FDA's Center for Biologics, said that he will resign his position if the FDA were to green light an unproven coronavirus vaccine. In addition, the Director of the National Institutes of Health, Dr. Francis Collins, and the Director of the National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci, have said they will only back a vaccine that has the science behind it.

Further, nine drug companies have already pledged that they will not submit vaccine candidates for FDA review until their safety and efficacy is shown in large clinical trials. In addition, each of the four companies who are now in Phase 3 clinical trials have published their clinical trial protocols.

For vaccine distribution, two independent committees will provide guidance: The National Academies of Sciences, Engineering and Medicine; and CDC's Advisory Committee on Immunization Practices.

I urge each of us to put politics aside in order to deliver one unified, life-saving message that Americans can trust that the FDA's vaccine approval process and that it will be driven by the science and will result in a science-based decision.

And lastly, a reminder for everybody to get your flu shot. It has never been more important.

I look forward to the testimony from these esteemed witnesses and welcome them to this hearing. I yield back.