Opening Statement of The Honorable Brett Guthrie
Subcommittee on Oversight & Investigations Virtual Hearing
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"
July 21, 2020

Thank you, Chair DeGette, for holding this critically important hearing. I appreciate our bipartisan approach to this hearing and believe this hearing is a great example of how the Energy and Commerce Committee works. We can come together— Republicans and Democrats—to solve vital issues presented by the Coronavirus pandemic.

The COVID-19 pandemic has been a tough challenge for our nation, but the incredible effort to develop safe, effective, and accessible COVID-19 vaccines gives me great hope that we are on a very promising path to solutions. The unified effort by vaccine manufacturers, the research community, and federal partners to work with each other is remarkable, and I am confident that through this unity of purpose, cooperation, focus, expertise, and the tremendous amount of resources, our vaccine efforts will prove successful.

Companies are using their own funds at their own financial risk to conduct research, develop vaccine candidates, and create more manufacturing capacity. Some companies are putting up to $1 billion at risk.

The federal government has poured billions more dollars into the vaccine effort. The U.S. government is supporting several initiatives to help accelerate the development of vaccines for COVID-19. Two key initiatives are Operation Warp Speed and the Accelerating COVID-19 Therapeutic Interventions and Vaccines, otherwise known as the ACTIV partnership. Operation Warp Speed was

established to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. The ACTIV public-private partnership also aims to speed vaccine and treatment options.

The testimony today from witnesses of leading COVID-19 vaccine candidates will be of vital interest to the American people. The companies represent a diverse portfolio of vaccine platforms with promising preliminary data. For example, Moderna's experimental COVID-19 vaccine reportedly provided all 45 of its healthy volunteers with immune responses to the virus in an ongoing early-stage study, with volunteers who received two doses showing antibody levels exceeding those found in people who have recovered from COVID-19 and were generally well tolerated.

The University of Oxford-Astra Zeneca candidate might complete human trials by September and agreements have been lined up to produce two billion doses by 2021. In addition, there reportedly is positive news on the responses seen from the antibodies and T-cells.

Last month, some vaccine experts expressed concerns that President Trump might exert political pressure to put a COVID-19 vaccine on the market before it's ready, and they wanted assurances from the FDA that a vaccine will not be authorized unless there are at least 30,000 people in each Phase 3 clinical study. It appears such assurance has been made. The leading vaccine candidates under the auspices of Operation Warp Speed are required to enroll 30,000 participants in Phase 3 trials. As Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, and Dr. Stephen Hahn, the Commissioner of the U.S. Food and Drug Administration,

testified before the Full Committee on June 23rd, there will be no shortcuts on safety and efficacy standards. The speed is being achieved through the financial risk of manufacturers accelerating their capacity to produce millions of doses, not at the expense of assuring safety and efficacy.

Concerns have also been raised about vaccine confidence, and whether there will be sufficient vaccination coverage to ensure herd immunity. We need to have a high enough percentage of the American people vaccinated to achieve the protective effect of herd immunity and to save American lives.

Regarding supply and manufacturing capacity, we will hear testimony of how these companies are working cooperatively to address potential supply concerns. These companies in the aggregate are committing to manufacture billions of doses. I look forward to hearing more about how each of the companies before us today are planning to scale up their manufacturing efforts to ensure an adequate supply of an authorized or approved COVID-19 vaccine.

Finally, on access and affordability, many manufacturers have told Committee staff that if their vaccine effort is successful, they do not want cost to be a barrier to accessing a COVID-19 vaccine. This is a welcome commitment, and we are eager to discuss it further.

The mission to get safe and effective vaccines has been a driving focus for Committee Republicans. At the beginning of this month, Leader Walden and I released the second pillar of its Second Wave Project with recommendations on how to better prepare production and distribution of vaccines and therapeutics.

I welcome all of our witnesses and look forward to their testimony and discussion of the issues.