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**Opening Statement**  
**Chairman Raja Krishnamoorthi**  
**Briefing on “Guardrails to Ensure a Safe and Effective COVID-19 Vaccine”**  
**Subcommittee on Economic and Consumer Policy**  
**July 14, 2020**

Today’s briefing is about the extraordinary effort underway to develop a vaccine to prevent COVID-19. A safe and effective vaccine will protect the most vulnerable, slow the spread, and, if potent enough, may hasten the end to this disastrous epidemic. But, the herd immunity that will end COVID 19 once and for all requires all of us to get vaccinated. For that, we need public trust in the vaccine project.

Around the globe, nearly 200 vaccine candidates are being developed, and over twenty have entered human clinical trials—five here in the United States, with large-scale phase 3 trials scheduled to begin this month.

With intensive public investment and an historic all-hands-on-deck effort underway, the timeline to develop a vaccine may be compressed from as many as 10 to 20 years down to just 12 or 18 months. However, moving with this amazing speed does not—and must not—require cutting any corners.

Today, we will hear how we must place our trust in the Food and Drug Administration’s tried and tested vaccine review process. We will learn how this process remains the best in the world and will be able to clear a COVID-19 vaccine in record time while retaining its rigorous standards.

While the nation’s scientific workforce spends late nights in their labs to produce a vaccine, we in Congress must do our part to protect their work from meddling, so that they can uphold their profession’s utmost standards of scientific analysis and ethics.

We are not here today to place bets on the vaccine horse race. We leave the careful assessment of individual vaccines to the experts. We must entrust science to the scientists, not politicians.

I want to highlight two guardrails that protect the integrity of vaccine development and will ensure the safety and efficacy of a COVID-19 vaccine:

First, phase 3 trials must include at least 30,000 people. This is the mark endorsed by National Institutes of Health Director Francis Collins and our top infectious diseases authority Dr. Anthony Fauci. All NIH-approved trials meet that key metric.

Second, FDA must receive and consider advice from the Vaccine and Related Biological Products Advisory Committee, or “VRBPAC.” In the area of vaccines, VRBPAC has a sterling reputation, and for decades it has played a central role in FDA’s process for assessing new vaccines. Review of a COVID-19 vaccine by this body of vaccine experts from academia and industry will add transparency, public accountability, and deliberative insight to the approval decision—critical values for a vaccine that will undergo immense scrutiny and require full public participation to be deployed.

However, FDA has failed to commit to these two guardrails. With fellow oversight chairs Maloney and Clyburn, I wrote to FDA Commissioner Stephen Hahn asking for commitments on 30,000 trial participants and engagement with VRBPAC. A month later, we have received no response.

Two weeks ago, FDA Commissioner Hahn testified to Congress that he would maintain his independence and the high standards of the FDA. Commitments to these two guardrails would be concrete ways to guarantee that independence and rigor.

We must remain vigilant to the risk that politics will infiltrate the regulatory process. This Subcommittee showed how that risk manifested with antibody tests. After the FDA chose not to regulate antibody tests following criticism of its handling of diagnostic tests, hundreds of junk tests flooded the market.

The virus does not yield an inch to political tactics or media campaigns. It does not follow consumer sentiment polls or approval ratings. The impending election, the stock market, and the yearning for a return to normalcy must not distort the decision whether to approve a vaccine.

Today, I look forward to hearing from our country's top experts on vaccines. They will assure us that there is a community of talented scientists who are putting 110% into this extraordinary effort, and we can all trust this dedicated group to produce a safe and effective vaccine for COVID-19.

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