**Committee on Energy and Commerce**
**Subcommittee on Oversight and Investigations**

**Hearing on**
**"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"**

**July 21, 2020**

**Dr. Stephen Hoge, President, Moderna**

**The Honorable Brett Guthrie (R-KY):**

1. **Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?**

   At Moderna, we are currently focused on bringing a safe and effective vaccine for COVID-19 to patients as rapidly as possible. Once we have addressed this pressing challenge, Moderna would support an assessment of whether the traditional process for vaccine development should be reformed, either generally or for specific "fast-track" vaccine candidates.

2. **How did investments into platform technology help speed up the vaccine development process?**

   Moderna would not have been able to rapidly develop mRNA-1273 without our mRNA platform and the investment that supported it. Since 2010, we have built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body. At Moderna our "platform" refers to our accumulated knowledge and capabilities in basic and applied sciences across mRNA, the delivery of mRNA to target tissues, and the manufacturing processes for making potential mRNA medicines. We invest in basic science to discover foundational mechanistic insights, and we invest in applied sciences to invent technology that harnesses those insights. We use our platform to identify and develop new mRNA medicines. Our prior research and clinical trials taught us valuable lessons about designing vaccines—particularly how to manufacture mRNA that can be safely injected into people and induce an appropriate immune response. Without the benefit of this prior foundational work, we would not have been able to develop mRNA-1273 on the current timeline in order to meet this pandemic. That work on our platform was made possible by approximately $5.0 billion of investments from investors and partners.

3. **Do any of your companies have recommendations about how to further innovate clinical trials?**

At Moderna, we are currently focused on bringing a safe and effective vaccine for COVID-19 to patients as rapidly as possible. We are grateful to our government partners and their role in our clinical trials. Once we have all addressed this pressing challenge, Moderna would support an assessment of the clinical trial process and whether lessons learned from responding to this pandemic may be useful in innovating future trials.

4. **COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?**

   Since January, Moderna has worked tirelessly to understand COVID-19 and design a vaccine to combat it. We are continuing to collect data and evaluate the efficacy of the vaccine, and we are encouraged by the preliminary data. For instance, in August 2020, we announced that our vaccine generated a promising immune response in elderly patients. The study included 10 individuals between the ages of 56 and 70 and 10 individuals age 71 and older. Each participant received two 100 microgram doses of the vaccine 28 days apart. The study found that the participants produced neutralizing antibodies and T-cells and had a higher level of antibodies than seen in individuals who recovered from COVID-19. We at Moderna remain cautiously optimistic and hopeful that we are on track to create a vaccine that can help bring this global pandemic to an end.

5. **Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?**

   a. **If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?**

   b. **If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?**

   We have no current plans for human challenge studies.

6. **Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.**

   a. **If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?**

   We have no current plans to use an adjuvant with our mRNA-1273 COVID vaccine. Future modifications to our vaccine to strengthen the immune response would only be considered after the current vaccine is approved for use.

**The Honorable David B. McKinley (R-WV):**

1. **When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.**

   **Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?**

   We recognize the robust debate in this country regarding access to affordable drugs and other healthcare services. It is an important, complicated topic.

   As a relatively young biotechnology company, our goal is to develop a novel platform for designing and manufacturing a new class of mRNA-based vaccines. Over the past ten years, Moderna has invested over $5.0 billion in creating and developing our mRNA platform, which we believe offers an innovative new technique for discovering, developing, and manufacturing medicines. It is our hope that our platform could potentially help address not only the current COVID-19 pandemic, but other diseases that threaten lives and health around the world, including some for which there are currently no vaccines. Those diseases include Cytomegalovirus ("CMV"), Zika, and Respiratory syncytial virus ("RSV"), and are part of a pipeline of over 23 programs, of which 17 have entered clinical studies. Given the urgency of the pandemic, we have prioritized mRNA-1273, our vaccine candidate for SARS-CoV-2, over other development projects.

   We recognize and support the goal of improving access to life-saving drugs, and we are aware, as is this Committee, of many potential avenues to help achieve that goal. However, at this moment, we are focused on delivering our first product—a safe and effective pandemic vaccine—as quickly as possible. As we enter the commercial phase with an anticipated global launch of mRNA-1273 we will continue to study ways to bolster research and development while also increasing access to affordable drugs, and are happy to continue this conversation as the Committee considers H.R. 3 or similar legislation.

2. **Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?**

   a. **Are each of you on schedule and on budget?**

   We are currently in Phase 3 of the Coronavirus Efficacy ("COVE") study of mRNA-1273, which is being conducted in collaboration with the National Institute of Allergy and

Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH"), and the Biomedical Advanced Research and Development Authority ("BARDA"). Phase 3 began on July 27, 2020, and enrollment is on track to be completed in September 2020. Our expenditures for this Phase 3 study are consistent with the budgets of our current contracts for this study.

b. **If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development**?

When the threat posed by COVID-19 became apparent, Moderna rapidly focused on developing a COVID-19 vaccine. Moderna proceeded at-risk and without government funding. We are grateful to our government partners for their investment and support as we continued this work. So long as our vaccine candidate continues to show promising results, in the event that funds for manufacturing, clinical trials, or other developments were needed, we would continue to secure partners and manufacturing capabilities with our own resources. We would communicate with the government to discuss whether additional support would enable Moderna to bring a safe and effective vaccine to market as quickly as possible.

c. **If you are ahead of schedule and you have grant money left over, what are your plans for those funds?**

Moderna's BARDA awards represent a commitment to reimburse Moderna for allowable costs under our contracts. To the extent that we are able to fulfill our BARDA agreements under budget, the unused funds would remain with the federal government.