

**Hearing Before the House Energy and Commerce Committee
Subcommittee on Oversight & Investigations**

**Testimony of Dr. Stephen Hoge
President, Moderna, Inc.**

February 23, 2021

Chairwoman DeGette, Ranking Member Griffith, and distinguished Members of the Subcommittee, thank you for the opportunity to appear before you today. My name is Stephen Hoge, and I serve as the President of Moderna, Inc. (“Moderna”). Since we last spoke in July, the collaborative effort to end this pandemic has made remarkable progress. We have also confronted new challenges and continued human suffering and hardship. We know that much work remains. Today, I will update you on the status of our continued efforts at Moderna to help stop this pandemic.

When I testified before this Subcommittee in July, Moderna was just four days away from dosing the first participant in our Phase 3 clinical trial. We did not yet have proof that our vaccine was effective against COVID-19. Despite that, we were preparing for the future. With the support of the U.S. government, Moderna had begun to modify our facilities, procure supplies, hire and train staff, and establish partnerships with leading pharmaceutical manufacturing companies to give us a head start on producing our vaccine if the Food and Drug Administration (“FDA”) determined it was safe and effective.

We have made significant progress since then. In November, we announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19 and a 100% efficacy rate against severe COVID-19. In December, after robust review, the FDA granted an emergency use authorization (“EUA”) for our vaccine. By the end of 2020, we had delivered 17.8 million doses to the federal government. To date, we have delivered over 45 million doses of our vaccine, with tens of millions more at different stages of the production process. We are on track to meet our commitment to deliver 100 million doses by the end of March. We have doubled our monthly deliveries since late 2020, and we are aiming to double them again by April to more than 40 million doses per month. Based on this progress scaling up manufacturing, we recently agreed to move up our delivery timeline: we now are aiming to deliver a second hundred million doses by the end of May and a third hundred million doses by the end of July.

This work could not be more pressing. The pandemic continues to have a devastating impact. Nearly half a million people have died in the United States alone. Many more have been ill, some severely. As you all know, the pandemic has also cost jobs, shuttered businesses, closed schools, burdened families, and disrupted countless traditions and routines. All of us have been profoundly impacted by this. We also know that communities of color and essential workers have disproportionately borne the burdens of COVID-19. We must bring this pandemic to an end.

We understand the significant interest in Moderna’s vaccine, along with the vaccines and vaccine candidates of other companies, including those testifying today. We also understand how important it is that large quantities of every approved vaccine be produced rapidly—with

robust commitment to safety and quality—and that vaccines be made available widely, transparently, and equitably. I hope that my testimony today will provide useful information to this Subcommittee as you continue your oversight over these important matters.

Over the past year, Moderna has been pleased to collaborate with the U.S. government in accelerating the development, production, and delivery of our vaccine. As we continue these efforts, we remain committed to ongoing dialogue with key U.S. government agencies to ensure that our work proceeds as quickly and safely as possible.

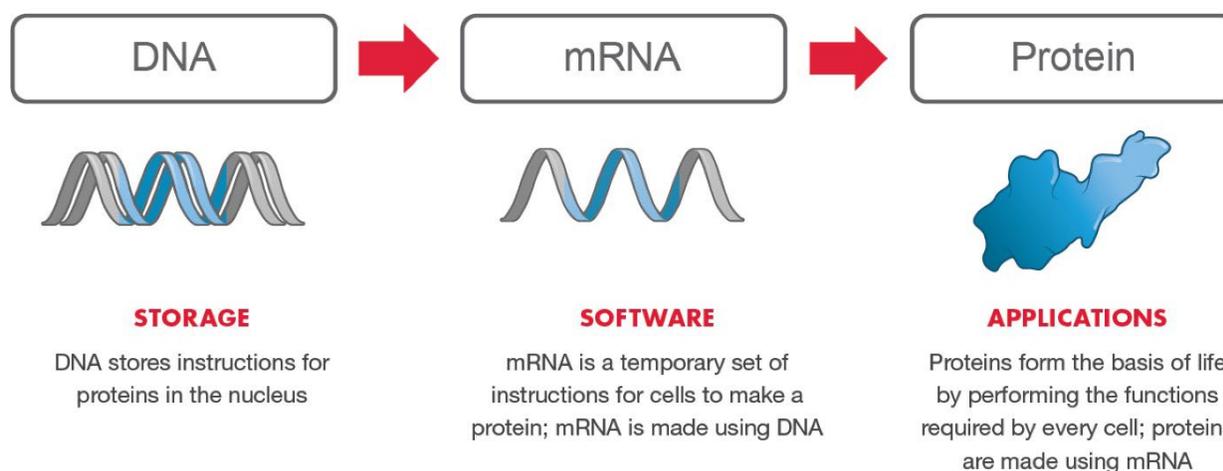
In my testimony today, I will provide an update on our work. *First*, I'll give you a brief overview of our company and mRNA technology. *Second*, I'll explain the process we used to create our COVID-19 vaccine. *Third*, I'll provide an update on the clinical trial process and the FDA's issuance of an EUA for our vaccine. *Fourth*, I will provide an overview of the manufacturing process and update you on our work to manufacture the vaccine.

I deeply appreciate the opportunity to appear before you today, and we at Moderna are profoundly grateful for the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic.

I. Moderna is an Innovative Company That Has Built Unique mRNA Technology

Moderna is a young, innovative biotechnology company that seeks to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA ("mRNA"). Founded in 2010, we are proud to be an American company, with our headquarters and a major manufacturing facility in Massachusetts. Moderna has grown over the past decade into a dynamic company with over 1,300 employees. This exceptional team—which has worked in collaboration with leading biopharmaceutical companies, U.S. government agencies, and private organizations focused on public health—has disclosed twenty-four therapeutic and vaccine development programs to date. These programs span a wide range of diseases and conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases.

At Moderna, we create medicines by using mRNA, which plays a fundamental role in human biology. All human genetic information is stored in DNA located in a cell's nucleus. In order to access that information, cells need to make a working copy of it—that is mRNA. Unlike DNA, mRNA molecules move out of a cell's nucleus; once outside the nucleus, mRNA molecules transfer the information they encode to the cellular machinery that make all the proteins required for life. Each mRNA molecule contains the instructions to produce a specific protein with a distinct function in the body. mRNA thus plays a central role in all biological processes, including in human health and disease, which is why we call it the "software of life."



Our approach fundamentally differs from traditional approaches to medicine. Rather than introduce a protein or chemical to the body, we send tailored mRNA into cells to instruct them to produce specific proteins. We built Moderna on the guiding premise that if mRNA can be used as a medicine for one disease, it could work for many diseases. Instead of starting from scratch for each new vaccine or therapy, our mRNA approach leverages the technology and fundamental components that we have been researching and developing since our founding. By building off our prior research and learning, we believe we can improve how we discover, develop, and manufacture medicines.

We designed our strategy and operations to realize the full potential value and impact of mRNA over a long time-horizon. 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. Our prior research and clinical trials taught us valuable lessons about designing vaccines—particularly how to manufacture and formulate mRNA that can be safely injected into people and induce an appropriate immune response. We believe this platform can be used to pursue mRNA medicines for a broad spectrum of diseases.

Creating a new generation of medicines is a challenging endeavor. Over the past ten years, Moderna raised over \$5 billion in funding from our strategic collaborators and investors who recognize the potential of our unique mRNA approach. We are also grateful for approximately \$58 million in grant funding from the Defense Advanced Research Projects Agency (“DARPA”) and the Biomedical Advanced Research and Development Authority (“BARDA”). And in April, BARDA committed to fund up to \$483 million to accelerate the clinical development and manufacturing scale-up of our coronavirus vaccine candidate. In July, we amended our agreement with BARDA to provide for an additional commitment of up to \$471.6 million to support late-stage clinical development of Moderna’s COVID-19 vaccine candidate, including the execution of a 30,000-participant Phase 3 study in the United States. In August, we signed a contract with the U.S. government to provide millions of doses of our prospective vaccine to the American people.

II. Moderna Used its mRNA Platform to Create an Effective COVID-19 Vaccine

Our mRNA technology is flexible and quickly adaptable; that allowed Moderna to step forward and pursue the rapid development of a COVID-19 vaccine candidate named mRNA-1273. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (“NIAID”), a part of the National Institutes of Health (“NIH”), in January 2020 to try to accelerate our vaccine candidate.

The story of mRNA-1273 really begins before any of us had ever heard of COVID-19. Since 2015, Moderna has worked to develop mRNA vaccines for coronaviruses, such as the SARS and MERS viruses. And in 2016, we began building our U.S. manufacturing facility, based on our early clinical data, and our belief that the mRNA platform would be necessary to address diseases in the future. Those experiences, and Moderna’s own proprietary technologies developed through years of research, put Moderna in a unique position to respond to the current pandemic.

For example, a key challenge in developing mRNA vaccines and treatments has been to develop a vehicle for getting the mRNA into the body’s cell—in other words, the “packaging” for shipping the mRNA software into the cell. You need technology that both protects the mRNA in transmittal and will not be targeted by the body’s natural defenses. After years of effort, Moderna has developed a proprietary lipid nanoparticle delivery system that enhances safety and tolerability. We have also invested significantly in the manufacturing process to invent the technological capabilities necessary to manufacture our potential mRNA medicines.

We were able to research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines and other mRNA-based medicines. In addition to the technology described above, this prior knowledge included our understanding of the safety of our platform and our experience producing over 100 batches of mRNA for use in human clinical trials in the two years before the COVID-19 virus emerged.

In our prior work on coronavirus mRNA vaccines, we identified a key protein on the surface of coronaviruses, called the Spike protein, as a good vaccine candidate. The identified Spike protein has two primary functions: it (i) facilitates the attachment of the coronavirus to the host cell in an individual; and (ii) contributes to the entry of the coronavirus into the host cell by fusing viral and host membranes. We began to develop mRNA-1273 by reviewing the genetic sequence of the SARS-CoV-2 Spike protein. Based on the sequence for the Spike protein, we designed and synthesized a corresponding mRNA sequence—in other words, the genetic software that instructs a human cell to create the Spike protein. Using our validated mRNA vaccine platform, we have been able to formulate this mRNA by incorporating lipid nanoparticle technology into a vaccine that can be administered directly to a patient. Once injected, the mRNA molecule causes the patient’s cells to produce the Spike protein; the body’s immune system then attacks that protein, triggering a protective immunological response.

Our approach to a COVID-19 vaccine differs from traditional vaccine development because we are not injecting into the body a dead or weakened version of the novel coronavirus or one of its components. Instead, we use the information from the virus to teach the cells in a

patient's body how to make the virus's Spike protein, which itself provokes a protective immune response. Using this novel approach, we progressed from genetic sequencing to a vaccine ready for human testing in just 63 days—a testament to the 10 years of investment and hard work on our platform.

III. Clinical Trials Led to the FDA Emergency Use Authorization for mRNA-1273

Working closely with the government, Moderna put mRNA-1273 through a rigorous set of clinical trials to test its safety and efficacy. This process began extraordinary quickly. We began work on mRNA-1273 immediately after the genetic sequence of the novel coronavirus was released on January 11, 2020. Only 25 days later, on February 7, 2020, Moderna completed its first clinical batch of mRNA-1273. The Phase 1 study, led by NIH, dosed its first participant on March 16, 2020. On May 18, 2020, we announced positive interim results from the mRNA-1273 Phase 1 study, showing the generation of neutralizing antibody titer levels in all eight initial participants. In July 2020, the NIH and other authors published a fuller set of interim data and results of the Phase I study in the *New England Journal of Medicine*. Those results indicated that the vaccine produced neutralizing antibody titers in all forty-five participants evaluated.

The first participants in our Phase 2 study were dosed on May 29, 2020, and we completed enrollment of all 600 subjects in our Phase 2 study on July 8, 2020. While the Phase 2 study was pending, we began our Phase 3 study in July 2020. We enrolled 30,000 participants in a randomized and placebo-controlled study, which was conducted in collaboration with NIAID. Recognizing the importance of including a representative population in this important study, we and NIAID made a concerted effort to enroll participants from communities that have historically been under-represented in clinical research and have been disproportionately impacted by COVID-19. The study ultimately included more than 11,000 participants from communities of color, representing 37% of the study population. On November 30, 2020, we announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19. Efficacy was consistent across age, race and ethnicity, and gender demographics. The interim results from the Phase 3 trial were later published in the *New England Journal of Medicine* and confirmed the efficacy and safety of the vaccine. The data from our Phase 3 trial also suggest that our vaccine prevents severe cases of COVID-19, with no severe cases of the disease occurring in the trial participants who received the vaccine.

On December 18, 2020, the FDA authorized Moderna's COVID-19 vaccine for distribution under an Emergency Use Authorization. The next day, the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices unanimously voted to recommend the use of Moderna's COVID-19 vaccine in people 18 years of age and older. In the days and weeks that followed, additional countries authorized the use of Moderna's vaccine. Canada authorized the use of our vaccine shortly before the end of the year, while Israel, the European Union, and the United Kingdom authorized the vaccine in the first days of 2021.

IV. Moderna Is Working with Partners to Produce and Deliver mRNA-1273

We are now focused on working closely with our manufacturing partners and the federal government to produce, fill, and deliver vaccine doses rapidly, with robust commitment to safety and quality. I will provide a brief overview of our production process and give you a status update.

A. Overview

Producing and delivering a vial of mRNA-1273 is a multiple-stage process. The first stage is to create large batches of the drug substance: mRNA encapsulated in a lipid nanoparticle. For the U.S. supply line, this stage takes place in two places: Moderna's manufacturing facility in Norwood, Massachusetts, and a facility in Portsmouth, New Hampshire operated by our contract manufacturing partner, Lonza Ltd. ("Lonza"). The use of such partners is common in the biopharmaceutical industry, and Lonza is one of the world's leading contract manufacturers. This first stage is itself a multistep process that requires the availability of raw materials and consumable supplies, such as the custom-made plastic bags that line the tanks in which the drug substance is made.

The second major stage of the production process is filling vials with the drug substance. As is common in the industry, we have partnered with a contractor, Catalent, Inc. ("Catalent"), that specializes in this "fill-finish" process. Catalent is filling vials with our vaccine at its biologics facility in Bloomington, Indiana. We are in the process of onboarding another fill-finish partner with a U.S. facility to expand our capacity at this stage of the process. As with the first stage, putting mRNA-1273 into vials is itself a multistep process that depends on the availability of supplies.

The third major stage of the production process is inspecting, testing, and packaging the filled vials for delivery. Catalent also manages this multistep stage, and our capacity will be supplemented when we fully onboard an additional fill-finish partner.

On any given day, millions of doses of mRNA-1273 will be at different stages of this process. Over time, the buildup of the product and other necessary supplies generally allows subsequent stages to operate more efficiently. The pace of production also increases as the process gets refined and the highly skilled and experienced personnel operating that process gain greater familiarity with it.

I want to be clear that, throughout this process, Moderna and its partners are committed to maintaining the highest standards of safety and quality. That commitment requires careful planning and specialized learning; it can also extend the production timeline. It is essential, however, to maintain public confidence in biopharmaceutical products like our vaccine.

B. Production Update

Moderna and its partners began to raise additional investor capital to modify and expand our manufacturing and distribution chains for mRNA-1273 well before the FDA authorized the vaccine for use in the United States. Those efforts were complimented by additional funding from BARDA, which also facilitated our agreements to collaborate with Lonza in May 2020 and

with Catalent in June 2020. Working with those partners, we began to scale up the production process and manufacture doses for potential distribution under our supply agreement with the U.S. government.

We began delivery to the federal government promptly after the FDA issued its EUA. By the end of December, we had delivered 17.8 million doses to the federal government. To date, Moderna has delivered over 45 million doses of our vaccine to the federal government. Tens of millions of doses are at different stages of the production process. We are on track to meet our original commitment of delivering the first 100 million doses to the federal government by the end of March.

Less than two weeks ago, we reached an agreement with the federal government to accelerate the delivery of the second hundred million doses and to deliver a third hundred million doses on an advanced schedule. We are now planning to deliver the second hundred million doses by the end of May, rather than the end of June. We plan to complete delivery of the third hundred million doses by the end of July, moved up from the end of September. We plan to ship doses as they are released. We are able to accelerate these delivery timelines—while maintaining a robust commitment to safety and quality—thanks to the highly-skilled and experienced workers at our Massachusetts facility, our raw material suppliers, our contract manufacturing partner Lonza, and our fill-finish contractor Catalent.

Since the end of 2020, we have doubled our monthly deliveries to the U.S. government, and we are working to double them again by April to more than 40 million doses per month. As we work to meet these goals, we are continually learning and working closely with our partners and the federal government to identify ways to address bottlenecks and accelerate our production. For example, one of the recently identified constraints on our production process has been the capacity of the fill-and-finish process. To reduce this constraint, we studied the possibility of adding more doses to each vial of vaccine. Doing so would improve output because it allows us to complete manufacturing runs more quickly; it also reduces the need for consumable materials in high demand. The FDA has given us positive feedback on our proposal, and we are pursuing a plan that may allow up to 15 doses to be drawn from each vial. This will allow us to produce and deliver more doses more quickly. We will continue to collaborate with our manufacturing partners and the federal government to increase the efficiency of our production process without compromising quality or safety.

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During this period, Moderna is continuing research and development efforts to address the COVID-19 pandemic. For example, we are closely monitoring emerging variants and testing the performance of our vaccine against them. We are also studying potential booster shots, either of the existing vaccine or of a version that has been adjusted to address significant variants. We are also conducting a trial of the safety and efficacy of our vaccine in younger populations, with the hope of being authorized to provide our vaccine to adolescents aged 12 to 18 by the fall.

This pandemic remains a challenge unlike anything that we have faced in recent memory. At Moderna, we are grateful for the opportunities we have had to collaborate with the

government on our efforts to deliver a safe COVID-19 vaccine. We are also grateful for the many companies around the world, including my colleagues testifying today, that are working to deliver COVID-19 vaccines and treatments.

Finally, I would like to thank this Subcommittee for its commitment to this cause, as well as the diligent work of your staff. We deeply appreciate the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic, and we remain committed to collaborating with the U.S. government in this fight.

Thank you, and I look forward to your questions.