

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

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

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Chairwoman DeGette, Ranking Member Guthrie, 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”). I am proud to work for a company that is developing one of the vaccine candidates, mRNA-1273, for the treatment of SARS-CoV-2, the novel strain of coronavirus causing the devastating global COVID-19 pandemic.

We recognize the extraordinary harm the pandemic has done to millions of Americans. Our hearts go out to those who have lost loved ones or have been sick themselves. Millions of Americans are out of work. Others, like my wife and I, work to balance parenting with our professional obligations. My wife is a practicing physician, as are several members of my family, and I have seen how profoundly healthcare providers have been challenged by COVID-19. The pandemic has postponed weddings, cancelled graduations, and kept people away from funerals. All of us have been profoundly touched by this in some way. We also know that communities of color and the working class have disproportionately borne the burdens of COVID-19. We must do everything we can to stop this pandemic.

I understand there is significant interest in the work of Moderna and the companies who have witnesses testifying today. People all over the world want to know when we might be able to return to some sense of normalcy. People want to know how they can best protect their relatives and others. People want to go back to work. Others miss the ability to easily see their friends or family. Parents want their kids to continue their education, and their children want to play with their classmates. People also want to know that the taxpayer funds invested in potential vaccine candidates will pay off. I hope that my testimony today will provide further information about how Moderna—like the other companies testifying today and others not present here—is working as hard as it can to fight the COVID-19 pandemic. This may provide comfort to people in America and around the globe.

I feel fortunate to be in a company that is now working toward a scientific response to this current crisis. I joined Moderna eight years ago to do something like this and meet significant scientific challenges. My background is in medicine. I attended medical school at University of California San Francisco and briefly served as a resident in the emergency medical department at a New York City hospital. A decade later, while consulting for companies in the healthcare sector, I learned about a ten-person start-up pursuing a revolutionary approach to

treating disease: Moderna. If it worked, the vision and technology driving the company could unlock new frontiers for medicine. The chance to pursue that future is why I joined Moderna.

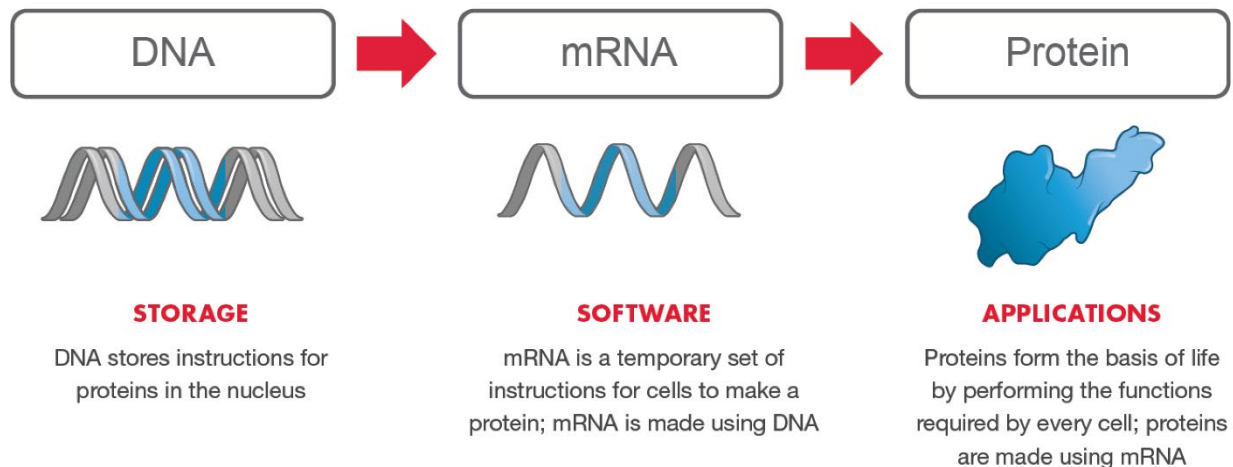
Over the past few months, Moderna has been pleased to collaborate with the U.S. government during the development of our vaccine candidate. This collaboration includes not only working together to test a possible COVID-19 vaccine, but also to build the manufacturing and distribution capacity needed to deliver a safe and effective vaccine to the American people. As we move into Phase 3 of our mRNA-1273 clinical trials, we remain committed to maintaining an ongoing dialogue with key U.S. government agencies to ensure that our work proceeds as quickly and safely as possible.

I'd like to take this opportunity to describe Moderna and our efforts to develop a vaccine that will be effective against COVID-19. *First*, I'll give you a brief overview of our mRNA technology and how it works. *Second*, I'll explain the process we used to develop our COVID-19 vaccine. *Finally*, I'll provide an update on the current status of our efforts. I appreciate deeply 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 800 employees—a far cry from the ten-person startup that I first encountered. 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 messenger RNA, or 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 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.

II. Moderna Has Used its mRNA Platform to Develop a Promising COVID-19 Vaccine

As the spread of COVID-19 across the globe has shown, the virus will not wait for the development of a vaccine. Lives depend on finding multiple safe, effective vaccines as soon as

possible. Because our mRNA technology is flexible and quickly adaptable, we stepped forward and pursued the rapid development of a COVID-19 vaccine candidate named mRNA-1273, focused always on making it as safe and tolerable a candidate as possible. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (“NIAID”), which is part of the National Institutes of Health (“NIH”), in January 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. That experience, 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 cell—in other words, the “packaging” for shipping the mRNA software into the cell. You need technology that both protects the mRNA in transit and will not be mistakenly 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 have been 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 includes our understanding of the safety of our platform and our experience producing over 100 batches of mRNA for use in human clinical trials in just the last two years.

In our prior work on betacoronavirus 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 will instruct 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, which the body’s immune system then attacks, 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 coronavirus or one of its components. Instead, we used the information from the virus to teach the cells in a patient’s body how to make the virus’s spike protein, which then 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. Now, just over six months from the sequencing of the virus, Moderna is about to become one of the first U.S. companies to enter a Phase 3 trial for a vaccine candidate, with 30,000 participants. While we pursue this mission with speed, we have been, and remain committed to, prioritizing safety and effectiveness. I am grateful for the hundreds of scientists and other Moderna employees whose hard work and sacrifice have made our rapid progress possible.

III. Moderna's Progress Toward a Vaccine

I would like to give you an update on the current status of our work. Right now, we are focused on two important tasks: *First*, testing mRNA-1273 in clinical trials to assess its safety and efficacy. *Second*, developing and scaling our manufacturing and distribution capacity for mRNA-1273. I will first describe the status of our clinical trials.

As I noted above, 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, which showed the generation of neutralizing antibody titer levels in all eight initial participants. A fuller set of interim data and results of the Phase I study were recently published by the NIH with other authors in the *New England Journal of Medicine*, which are consistent with and expanded on the interim results disclosed by Moderna on May 18, 2020. The vaccine showed neutralizing antibody titers in all forty-five participants evaluated.

The first participants in our Phase 2 study were dosed on May 29, 2020. We completed enrollment of all 600 subjects in our Phase 2 study on July 8, 2020. The Phase 2 study is ongoing.

We are set to begin our Phase 3 trial this month. 30,000 participants are expected to enroll in a randomized and placebo-controlled study, conducted in collaboration with NIAID. Each participant receiving mRNA-1273 will be dosed at 100 µg, the level Moderna has selected as the optimal dose to maximize the immune response while minimizing adverse reactions. Like the earlier Phase 1 and Phase 2 trials, the Phase 3 is a two-vaccine regimen with the doses delivered 28 days apart. The primary focus of our Phase 3 trial is determining whether mRNA-1273 can prevent symptomatic COVID-19 diseases, along with other secondary considerations, such as whether the vaccine can prevent severe COVID-19 disease.

We, along with the rest of the world, will eagerly await the results from these trials. If our vaccine is proven to be safe and effective, the Food and Drug Administration (“FDA”) will be responsible for determining whether, when and under what conditions mRNA-1273 is approved.

We have also been working to develop and scale our manufacturing and distribution chains for mRNA-1273. These efforts have been partially facilitated by a \$483 million grant awarded from BARDA, as well as \$1.3 billion of recent investment from our shareholders. These have helped to lay the foundation for, if mRNA-1273 is proven safe and effective, the efficient manufacture of the vaccine and transfer into the appropriate distribution channels for the vaccination of Americans. Recognizing the need to have a robust manufacturing capability that can be executed at scale quickly, we announced a long term agreement with Lonza Ltd., a Swiss-based company with manufacturing sites in the U.S. and elsewhere, which should allow us to reach an annual manufacturing capacity of more than 500 million doses for worldwide usage.

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As the COVID-19 pandemic spread across the world, Moderna hoped and believed our groundbreaking technology could make a positive difference. With the support of our dedicated team of employees, our Board of Directors, our shareholders, and our collaborators in the U.S. government, we stepped forward to pursue the safe and rapid development and manufacture of our vaccine candidate, mRNA-1273.

This is an unprecedented challenge, and no one has ever done anything like this before—not Moderna, not the NIH, and not any of the other companies working to stop this pandemic. While these are trying times, we are dedicated to creating a safe, effective vaccine that can help bring an end to the global pandemic. We remain committed to collaborating with the U.S. government in this process.

Thank you, and I look forward to your questions.