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TAXPAYERS PAID BILLIONS FOR IT: SO WHY WOULD MODERNA CONSIDER QUADRUPLING THE PRICE OF THE COVID VACCINE?

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE MODERNA CONSIDERING QUADRUPLING THE PRICE OF THE COVID VACCINE

MARCH 22, 2023

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C O N T E N T S

STATEMENTS

WEDNESDAY, MARCH 22, 2023

TAXPAYERS PAID BILLIONS FOR IT: SO WHY WOULD MODERNA CONSIDER QUADRUPLING THE PRICE OF THE COVID VACCINE?

Wednesday, March 22, 2023

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room 216, Hart Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Murray, Casey, Baldwin, Murphy, Kaine, Hassan, Smith, Luján, Hickenlooper, Cassidy, Paul, Collins, Braun, Marshall, Romney, Tuberville, and Mullin.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. The Senate Committee on Health, Education, Labor, and Pensions will come to order. Let me begin by thanking Mr. Bancel, the CEO of the Moderna, for being with us today, and all the other panelists who will be joining us. Mr. Bancel very early on agreed to be here voluntarily, and I appreciate that very much.

I also want to take this opportunity, so there is no confusion, to congratulate Moderna, Pfizer, other companies, and the great scientists at the National Institute of Health, and other Federal agencies for their extraordinary work in rapidly producing COVID vaccines that have saved millions of lives.

We should be grateful to all those in Government and in the private sector who worked so hard to save lives. This hearing, to my mind, is about several enormously important and interrelated issues that are on the minds of the American people. In the pharmaceutical industry today, we are looking at an unprecedented level of corporate greed, and that is certainly true with Moderna.

Today, according to a recent survey, 37 percent of the American people could not afford the prescription drugs their doctors prescribe. Got that? Over one-third of the American people can't fill their prescription drugs that the doctors prescribe.

Meanwhile, 10 major pharmaceutical companies made over $100 billion in profit in 2021, 137 percent increase from the previous year. In these same corporations, the 50 top executives made over $1.9 billion in total compensation in 2021 and are in line to receive billions more in golden parachutes once they leave their companies.

In other words, all over this country, in Vermont and in every state represented here, people are getting sicker and, in some cases, dying because they cannot afford the outrageous cost of prescription drugs while these companies make huge profits and their executives become billionaires.

Furthermore, and many Americans don't know this, the taxpayers of our Country have spent many tens of billions of dollars over the past decade to research and to develop lifesaving medicine. And in my view, that is a good investment. Yet, despite that huge amounts of money and the vitally important work done by the National Institute of Health scientists, the citizens of the United States pay far more for prescription drugs than do the people of any other country on Earth, in some cases, 10 times more for the same exact drug.

Unbelievably, there are important lifesaving drugs on the market today that literally cost hundreds of thousands of dollars, cancer drugs and other types of drugs. And my simple question is, what does a lifesaving drug mean for a person who cannot afford that drug? You have all the great drugs out there in the world, but if you can't afford it, what does it mean?

Now, in terms of Moderna, the focus of our attention this morning, let us be clear, the NIH and other Federal agencies worked with Moderna to research, develop, and distribute the COVID vaccine that so many of our people have effectively used. While Moderna may wish to rewrite history, it is widely acknowledged that both Moderna and the NIH created this vaccine together.

According to a letter I received from the NIH on March 17th, and which has been distributed to all Members of the Committee, three scientists at the NIH, "are co-inventors" and "of this vaccine" who are "integral members of a collaborative team of scientists working to design and produce the vaccine."

In other words, this vaccine would not exist without NIH's partnership and expertise, and the substantial investment of the taxpayers of this country. As a matter of public record, U.S. taxpayers spent $12 billion on the research, development, and procurement of the NIH, Moderna COVID vaccine.

Here is the thank you that the taxpayers of this country received from Moderna for that huge investment. They are thanking the taxpayers of the United States by proposing to quadruple the price of the COVID vaccine to as much as $130 once the Government's stockpile runs out, at a time when it costs less than $3 to manufacture the vaccine—$3 to manufacture it, $130 on the market.

What this means is that Moderna will be charging Medicare, Medicaid, the VA, the Department of Defense, the Indian Health Service, and insurance plans, private insurance plans on the Affordable Care Act, billions of dollars more for the COVID vaccine. So, all of us who are concerned about the deficit, the national debt, billions more goes to Moderna.

Meanwhile, Moderna has already made $21 billion in profits off the COVID vaccine during the pandemic, and four of Moderna's executives and investors collectively became more than $10 billion wealthier as a result of the massive taxpayer investment into that

corporation. As soon as Moderna started to receive billions of dollars from the Federal Government, Mr. Bancel literally became a billionaire overnight and is now worth over $4 billion.

He was also able to secure a golden parachute for himself, worth another $926 million after he leaves the company. But let's be clear, Mr. Bancel is not alone. One of Moderna's co-founders, Noubar Afeyan, is now worth $1.8 billion. And another co-founder, Mr. Langer is now worth $1.7 billion.

One of the founding investors in Moderna, Tim Springer, is now worth $2.2 billion. None of these four individuals were billionaires before the taxpayers of our Country funded the COVID–19 vaccine. This type of profiteering and excessive CEO compensation is exactly what the American people, whether they are Republicans, Democrats, or Independents, are sick and tired of.

That is why this morning I will be asking Moderna and Mr. Bancel to reconsider their decision to quadruple the price of this vaccine and not raise the price at all. Let me mention that after this hearing was announced, Moderna pledge that its, "vaccines and boosters will continue to be available at no cost for the vast majority of people in the United States" through the creation of a patient assistance program.

That is good news. The bad news is that most patient assistance programs are poorly designed and extremely difficult. And I will be asking. Mr. Bancel to make certain that this patient assistance program is simple, non-bureaucratic, and in fact gets out to the people who need it.

Let me pose, if I might, a moral question that we ask to rarely, but that I hope that this Committee will address in the months in front of us, and that is above and beyond the COVID vaccine, should people in our Country and around the world get sicker and sometimes die because they cannot afford the outrageous prices that the drug companies are charging?

Is it morally acceptable to say, I have a drug here that can cure you, save your life, but I am sorry, you can't afford the $50,000 that it costs. Is that the moral values of the United States of America? And I would contrast that attitude that we see today from Moderna and virtually all the other drug companies with what Jonas Salk said when he invented the polio vaccine that had such a profound impact—and you know what he got for inventing the polio vaccine?

He got nothing and he was proud of it. He gave a gift to the world that saved God knows how many lives. So, I think we need to do some moral thinking about the role of the drug companies in our society, and I hope this Committee will get into that.

With that, let me give the mic over to Senator Cassidy.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Chair Sanders. You know, I am a physician. I worked for over two decades in a hospital for the uninsured and those poorly insured on Medicaid, so I am very familiar with this issue.

We share the concerns, Americans pay too much for prescription drugs and the medicines we depend upon. So today we are asking questions of Mr. Bancel, what price does Moderna plan to charge when the vaccine goes to the commercial market, and how did the company arrive at that price?

Why is it different than the price that the Government charged—that the Government was charged? Now Moderna announced recently it will provide the vaccine at no cost to patients. How will the company implement this? They are fair questions and hopefully at the end of this hearing we will have a better understanding of these issues.

But I am also—let's just kind of think about the process here. The title is, taxpayers paid billions for it, so why would Moderna consider quadrupling the price of the COVID vaccine. Now, frankly, this presumes guilt in its title before we have learned. I am a physician.

I don't leap to a diagnosis before I take a careful history and physical. This is more like a show trial and a public shaming than a fact-finding mission. And it should be the goal of this Committee to first fact find before we attempt to hold someone guilty.

The Chair speaks of corporate greed in the context of over 1 million Americans who tragically died during the pandemic. I don't see the link. I just don't. The vaccine was available. As soon as it was available, it was implemented and lives began to be saved. It is hard to say that corporate greed was implicated before the vaccine was actually passed.

It is important for us not to allow rhetoric to distort our analysis of the situation. This should be a fact-finding hearing. I do see a link between millions of lives saved because of the quick development of a vaccine made here in the United States. COVID–19 cost the U.S. economy an estimated $26 billion dollars a day between 2020 and 2021.

In this light, a study by the International Monetary Fund shows that Operation Warp Speed and the taxpayer dollars spent to support the vaccines would have paid for itself had it cut the duration of the pandemic by 12 hours. By 12 hours. We got a bargain here. An expensive bargain?

No, a cheap bargain relative to that which it costs us every day. And considering that the initial estimates for the development of a vaccine were 3 to 10 years, thanks to Operation Warp Speed, private industry, American capitalism, things that we had done as a Committee on a bipartisan basis to give tools to FDA and BARDA, the world leading COVID vaccines were developed and distributed in less than 1 year, and taxpayer returns on investment were incalculable.

Now, it is easy to criticize and decry capitalism, but it is the reason that we developed multiple world leading vaccines in 10 months and is a reason that hundreds of thousands, if not millions of Americans are still alive today. This would not be had it not been for this process and for these vaccines. But cost is an issue.

Let's just not paper over that. I can criticize the process, but I agree, cost is an issue. And during my decades treating the unin-

sured, I had patients who could not afford the drugs prescribed. And my nurse and I would sit on the phone for sometimes hours with insurance companies trying to get the authorization so that they could get their drugs.

But I have also seen when a drug has not been invented, so to speak, where there are no other options. When there was a death sentence or a life of chronic disease, because a medicine to treat the chronic illness or condition did not exist.

Then, maybe a few years later, maybe many years later, I would be with a different patient in a different exam room with the same diagnosis, but now that drug had been invented and a formerly fatal disease was now treatable and a relic of the past. Why? Because in the interim, treatment was developed for their condition.

Now, it is easy to put the COVID vaccine as one of the success stories, but it happened over 10 months. At first, we had no way to prevent, 10 months later, there it was. It seems like we in this Committee need to keep the bigger picture in mind. We have got an ecosystem of innovation that is leading to lives being saved.

There are people in this room who would not be alive today were it not for capitalism interfacing with the pharmaceutical and medical device industry that allows you to be alive today. And a crowd this size, that is absolutely the case.

Now we can disturb that ecosystem and assume there is no harm, but there are literally lives, future lives at stake. And so, for decades, this Committee has passed legislation knowing that at one point we would have to ask companies to step up and do something quickly and put everything aside.

Moderna was one of those companies. We authorized grant funding. We set the groundwork for public, private partnerships. We stood up new institutions, all with the purpose that if something like a pandemic happened, something would be quickly developed. Well, when we did it in 2020, Moderna responded to their credit.

I am not defending any salaries, I am not defending any profit. What I am defending and pointing out is the great benefit our Country and the world received from this technology that was translated out of the lab into clinical practice.

Now, others did not make the same choice as Moderna, and I will say, it is important that through this hearing and otherwise that we do not send a hostile signal to future prospective partners that if you do something and you do it well and you profit after it happens, we may come right back at you.

You saved a million lives, but hey, buddy, we don't like your management decisions. We are coming back at you. That would mean a future company would not work closely with the Government. They would run away from that quick response. Now there are legitimate policy questions to ask how Moderna will price their vaccine post-commercialization. We are interested in that.

We have never been in this situation before where a company has taken the reins back from the Federal Government after the Federal Government controlled distribution of the product. But this is not the time to discuss eliminating intellectual property rights or destroying business models of those whom our Country will need

to respond to the next pandemic and to develop the next life changing cure.

We can't live in a fantasy world and pretend that what we do in this Committee will not affect those future decisions. I want people to know that this Committee is doing whatever it can to encourage cures for cancer, Alzheimer's, ALS, and other devastating disease. And if they do, and if a private company does it, they shall be rewarded.

Lives depend upon it. Senator Sanders, we have pledged to work together, but I will say that if the purpose of the hearing is to demonize capitalism, we should not hate the thought of a person or a company making a profit, that we lose sight of the ideas and accomplishments that their profit is rewarded.

We can't be a country that encourages citizens and companies to succeed and step up and make a difference and then shames them when they do. If we want to consider real policies that work to lower the cost Americans pay for medicines. Let's work together. Thanks, and I look forward to hearing from our witness.

The CHAIR. Thank you very much, Senator Cassidy. We will now turn to our witness. Mr. Stéphane Bancel is the Chief Executive Officer of Moderna. Mr. Bancel, thank you very much for being with us. You may proceed with your testimony.

STATEMENT OF STÉPHANE BANCEL, M.B.A., M.ENG., M.S.C., CHIEF EXECUTIVE OFFICER AND DIRECTOR, MODERNA, INC., CAMBRIDGE, MA

Mr. BANCEL. Chairman Sanders, Ranking Member Cassidy, distinguished Members of the Committee, good morning. My name is Stéphane Bancel, and I am the CEO of Moderna. While I speak with an accent, I lead a company that is an American success story.

After losing money for 10 years, Moderna created a vaccine that helped end the pandemic. We were able to move quickly because of a decade of private investment in our mRNA platform and because of a decision in 2016 to build a manufacturing plant in Massachusetts.

We made these investments before most people had heard of mRNA. Over Christmas break 2019, I read about an outbreak of pneumonia like illness in Wuhan, China. I immediately reached out to the U.S. Government because I believed our mRNA technology could make a difference. Two days after Chinese scientists put the genetic sequence online, our team created mRNA 1273 of COVID vaccine.

As we were shut down in March, we moved faster. Every day brought new pressure as case counts and deaths rose in the country and around the world. I am so grateful for all teams who worked relentlessly, including Saturdays and Sundays, locked down from home, and from our lab and our factory.

In the spring of 2020, we worked through Operation Warp Speed to develop a vaccine faster than we could have done alone. The U.S. Government gave us and four other vaccine companies fund-

ing to accelerate clinical trials. We thank our partners in the Federal Government for their support.

We built our mRNA platform before the pandemic with $3.8 billion of private investments. In mid–2020, we raised an additional $1.3 billion from shareholders for manufacturing scale up for the pandemic.

In November, I received the long-awaited news, the results of our phase 3 study showed that our vaccine was 94 percent effective at preventing COVID. I literally cried tears of joy and relief. We had that complete in 10 months what would normally take 10 years. After a decade of building our mRNA platform, we are changing the future of medicine.

Vaccine brought relief in our hospital system, put children and teachers back in classrooms, reopened our economy, and made it safe to reconnect in-person. We are under no obligation to do so, but recognizing the U.S. Government's investments, our company decided to provide the Government a discount versus the other mRNA vaccine.

While the Government provided $1.7 billion in grant funding, Moderna returned at $2.9 billion. The U.S. vaccination program is responsible for an estimated $5 trillion of economic value, prevention of 18 million hospitalization in this country, and 3 million American lives saved.

Innovations like our vaccine can only happen in America. The public private, partnership of Operation Warp Speed enabled a world leading response to a crippling pandemic. We at Moderna, along with the people of this country and the people of the world, owe the U.S. Government a debt of gratitude.

Let me now address the transition from pandemic to endemic. First, we are committed to ensuring anyone who wants a vaccine can get one without the price being a barrier. Until now, the U.S. Government has purchased and distributed the vaccine.

Now, Moderna, a small company, must ensure that anyone who wants a vaccine can get one at a location convenient to them. With this role comes increased complexity and increased risk. In the pandemic market with one customer, the U.S. Government.

In the endemic market, we are going to have 10,000 customers. In the pandemic markets, the U.S. Government took the risk for wasted doses. In the endemic market, Moderna will take that risk and that cost. In the pandemic markets, we only had to deliver to three CDC warehouses.

In the endemic market, we are going to have to manage logistic to deliver to 60,000 pharmacies, doctors' office, and hospitals. In a pandemic market, we had 1 vial with 10 doses in there. In the endemic market, where the market requires a single dose vial, or even better prefilled syringe.

On top of all this, we are expecting 90, 9–0, reduction in demand. As you can see, we are losing economies of scale. We must deal with supply chain complexity. And we must assume the wasted risk and costs that the U.S. Government used to assume. So, what's next for Moderna?

This year, we are investing $4.5 billion in R&D. We are working hard on developing medicines to treat cancer, cystic fibrosis, multiple sclerosis, and very—all very important diseases. Thank you for your opportunity to share our story and perspective.

[The prepared statement of Mr. Bancel follows:]

PREPARED STATEMENT OF STÉPHANE BANCEL

Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for the opportunity to appear before you today. My name is Stéphane Bancel, and I am CEO of Moderna, Inc. ("Moderna").

I was born and raised in Marseilles, France, where my formative years were shaped by Jesuit teachings. Jesuit values—the continuous pursuit of excellence, service of the greater good, and social responsibility—have informed my life and leadership of Moderna. I grew up with a keen interest in math, science, and computers, and dreamed of a career in STEM. I first moved to the U.S. in 1994 when I received a need-based scholarship that allowed me to study biochemical engineering in graduate school at the University of Minnesota. I returned to the U.S. in 1998 to go to business school. My experiences as an immigrant and an entrepreneur have taught me the importance of diversity of people and ideas. These values are central at Moderna, where our mission is to deliver the greatest possible impact to people through mRNA medicines.

Moderna is built around the promise of medicines (vaccines or therapeutics) that leverage mRNA technology. Unlike DNA, mRNA molecules move out of a cell's nucleus. Each mRNA molecule contains 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 diseases. Our approach fundamentally differs from traditional approaches to medicine; we are a platform company, not a traditional biopharmaceutical company. Rather than introduce a protein or chemical into the body, we send tailored mRNA into cells to instruct them to produce specific proteins. Our mRNA technology is highly adaptable; our platform is uniquely suited to tackle global health's biggest challenges with speed, scale, and flexibility.

We are not a big pharmaceutical company, but we are growing based on these scientific ideas. Since our founding in 2010, we have grown to approximately 4,000 employees globally, including around 3,200 in the U.S. This year alone, we plan to hire 2,000 new employees, around 1,600 of whom will be based in the U.S. To deliver the greatest possible impact to people through mRNA medicines, we are rapidly expanding and investing in people, science, and manufacturing.

Moderna's Beginnings: An American Success Story

While I speak with an accent, I lead a company that is a true American success story.

In 2011, a Moderna co-founder shared preliminary data that showed how mRNA technology could work and asked my opinion. I told him that what he was showing me was not possible, that mRNA could never make human medicines. He then asked what it would mean for medicine if the technology could work. I told him that, if we could get medicinal mRNA technology to work, we could make medicines that had previously been unimaginable. In other words, it would transform the future of healthcare.

I spent weeks debating whether to take the role of Moderna's CEO. My wife asked me what the chances were that Moderna would receive Food and Drug Administration ("FDA") approval for a product. I told her the chance of success was around 5 percent. But the more I thought about it, the more I became convinced that I had to do it. The technology could, on paper at the time, change medicine forever. It could help treat children with rare genetic diseases for which there was no hope of treatment with traditional pharmaceutical and biotechnology approaches. It could help the millions of people with heart disease and could produce vaccines for infectious diseases. And over time, it could work on many other diseases, maybe even cancer, an illness that has touched my life as it has so many others, perhaps even yours.

In 2011, I resigned from my job as CEO of a well-established global company with 6,000 employees and took a significant pay cut to become Moderna's CEO and its second team member. I took a risk on an untested medical technology when the rate of failure in the pharmaceutical industry is around 90 percent. I knew I had to give

the company and the technology my best shot because the consequences for the health of so many people were on the line.

When we started operations in 2011, we only had about $2 million in funding—enough to get us through our first 6 months. I hired the first few scientists, secured lab and office space, bought machines from a company that had gone bankrupt to save money, and moved us into our office and lab over a weekend. I watched Moderna double in size repeatedly during my first several years on the job. Over the next decade, there were many encouraging signs around the potential of our mRNA platform. But there were many setbacks as well; while we tested several mRNA applications in clinical trials, we were unable to bring a commercial product to market. We lost money every year from our founding until 2021.

Year after year, even when we were losing money, I bought Moderna stock with money my wife and I had saved because I believed in the company. About half of my Moderna shares I purchased as an investor, separate from my CEO compensation. I traveled the world raising money in exchange for shares to keep the dream of mRNA medicines alive.

With support from investors and strategic collaborators, we invested heavily in research and development for our mRNA platform. We built our mRNA platform and funded it through private investment. We took risks and made large investments to develop our corporate infrastructure, including over $100 million beginning in 2016 to construct our Norwood, MA manufacturing facility. Norwood, an integrated plant capable of full-scale development production, was operational by summer 2018, well before the COVID–19 pandemic.

The early investments we made in our manufacturing capabilities prepared us to rapidly scale our production when the COVID–19 pandemic hit. We did this without support from the Federal Government and before turning a profit. Over the years, we have partnered with the U.S. Government when pressing global health crises have emerged—like Zika and COVID–19—to develop specific medicines enabled by our privately funded mRNA platform.

Clinical Development of our COVID–19 Vaccine

Over Christmas break 2019, I read about an outbreak of pneumonia-like illness in Wuhan, China. I reached out to the U.S. Government because I believed our mRNA technology could make a positive impact. In parallel, I directed my team to begin leveraging our proprietary mRNA platform that we had invested in for 10 years.

We started working on our vaccine as soon as Chinese scientists posted the virus' genetic sequence online. Our mRNA platform and prior work on coronaviruses enabled us to develop our COVID–19 vaccine in a matter of days. We did all this work before the first case was reported in the U.S. and months before the World Health Organization ("WHO") declared a global pandemic. We did this because we felt a responsibility to do what we could to address the human suffering. Through my prior work on infectious disease outbreaks, I saw how viruses can grow exponentially. I knew every day and every hour mattered in the fight against COVID–19.

On March 11, 2020, the WHO declared COVID–19 a global pandemic. As the world shut down, we continued our work. Each day brought new pressures as we saw case counts and death tolls rise. Our team worked tirelessly, in our homes, lab, and wherever we could. We worked long hours every day, including weekends. My executive team and I worried a lot about how we were going to keep such a pace for a year.

We started Phase 1 clinical trials in March 2020. The first patient received our vaccine in Seattle just 2 months after COVID–19's genetic sequence became available. By way of comparison, this process took 20 months for the SARS vaccine. We were able to move 10 times faster because of our decade of investments in our mRNA platform and our decision years ago to invest in our Norwood manufacturing plant. We received emergency use authorization from the FDA on December 15, 2020. At each step in the process, we were proud to partner with the Federal Government, through Operation Warp Speed, to answer the call and deliver an effective vaccine.

We worked at an extraordinary pace to bring our vaccine to people as quickly as possible. However, we made sure to slow down when circumstances required. For example, recognizing COVID–19's disproportionate impact on people of color, we slowed enrollment in our Phase 3 clinical trial to ensure diverse representation following discussions with the U.S. Government. This effort enrolled 11,000 people of color in our trial, or 37 percent of our study population. This was a tremendous out-

come when you consider that historically, only 6 percent of all clinical trial participants in the U.S. are people of color. We built a diverse study population to ensure that the outcomes reflected the country's population and to help build public trust in our vaccine.

As our team continued our round-the-clock work on our vaccine, COVID–19 was taking its toll on society. Our hospitals were overrun with sick patients, people were dying alone, and essential workers risked their lives every day to stock food on store shelves and keep us safe. The experiences of our team in those dark days of the pandemic mirrored the rest of the world. We were separated from our families, our children went to school on Zoom, and we suffered the loss of loved ones without being able to say goodbye. Feeling the pain of our fellow citizens gave us the energy and motivation to keep working at an accelerated pace; we knew every hour we worked would get us closer to saving lives. The U.S. Government teams also did a remarkable job in those difficult times, and we at Moderna are grateful for their efforts.

Finally, on a Sunday in November 2020 while I was working from home, I received long-awaited news: the results of our Phase 3 clinical trials showed that our vaccine was 94.1 percent effective at preventing symptomatic COVID–19. When I finished the video conference, I called to my wife and daughters, and we hugged and cried tears of joy and relief. Our accomplishment started to sink in: we had achieved in 10 months what would normally take 10 years. After 10 years of building our mRNA platform, we had developed a tool that would save lives today and change medicine for the future.

Collaboration with BARDA

As outlined in previous sections, we built our mRNA platform and funded it through private investment, including $3.8 billion before the pandemic. We have partnered with the U.S. Government when pressing global health crises have emerged—like Zika and COVID–19—to develop specific medicines built from our mRNA technology platform.

The U.S. Government gave us $1.7 billion in funding to accelerate clinical trials for our COVID–19 vaccine at the scale and speed it required through grants from the Biomedical Advanced Research and Development Authority ("BARDA"). This was particularly important for us because we are a small company and, unlike big pharmaceutical companies, could not self-fund robust clinical trials.

Grant funding and advance purchase orders from the U.S. Government allowed us to accelerate development of our COVID–19 vaccine and enabled us to deliver our vaccine to the public at a speed we could not have accomplished on our own. We at Moderna, along with the people of this country and the world more broadly, owe the U.S. Government a debt of gratitude for its important investment.

We were under no obligation to do so but, recognizing the U.S. government's investment in the later stages, we provided the government a discount versus the other mRNA vaccine. While the government provided $1.7 billion in funding, we returned $2.9 billion.

Innovations like our vaccine can only happen in America. We thank our partners in the Federal Government for their support and the vote of confidence they cast for our mRNA technology.

Scaling up the Manufacturing of the COVID–19 Vaccines

At the same time, while working through all of the challenges of the clinical trials, we were preparing for manufacturing so that we would be ready to supply quickly in the event that our vaccine was successful in clinical trials. We needed to scale up our manufacturing capacity exponentially. In our 10 years of business before the pandemic, we had never produced more than 100,000 product doses per year across our entire pipeline portfolio. By late January 2020, I became convinced that COVID–19 would be a pandemic like the 1918 Spanish Flu. I challenged Moderna's head of manufacturing to come up with a plan to produce a billion doses for distribution in 2021, a daunting 10,000 times more doses than we had produced ever before.

Given the magnitude of the required manufacturing scale-up and the risk of doing so before we knew if our vaccine worked, we solicited outside funding. In May 2020, when our positive Phase 1 clinical trial data went public, our board approved raising $1.3 billion through the capital market (NASDAQ). These private funds raised through the sale of new shares enabled us to hire new employees, buy new equipment and raw materials, set up facilities that met rigorous FDA standards, and es-

tablish protocols and processes to keep our employees safe while producing our vaccine in the midst of a global pandemic.

Facilitated by the early investments in our mRNA platform and manufacturing facility, we delivered 300 million doses of our vaccine to the U.S. Government in 2021. Our team knew that each dose we produced represented an additional life protected. Vaccines brought relief to our overwhelmed hospital system, put children and teachers back in classrooms, reopened our economy, and made it safe to re-build in-person social networks.

While much progress has been made, it remains a top priority for us to continue supporting efforts to fight COVID–19 and advancing the most efficacious vaccine. To date, our COVID–19 vaccine has been distributed to more than 70 countries and has helped protect the lives of hundreds of millions of people around the world. We partnered with Gavi's Vaccine Alliance to distribute more than 170 million doses to low-and middle-income countries. However, as demand shifted, Gavi asked to be released from its purchase commitment, which we did. When doses were declined, we recognized write-downs of approximately $1 billion in non-standard costs.[1] Notwithstanding this loss, we have offered Gavi up to 100 million more doses in 2023 at our lowest-tier price.[2]

Our Commitment to Vaccine Access

A lot will change for our company as we step into the shoes of the U.S. Government to ensure that everyone who wants a vaccine has access in a convenient location. One thing that will not change is our commitment to delivering the greatest possible impact to people through our mRNA medicines.

We are committed to ensuring anyone who wants a vaccine can get one, without price posing a barrier. Our vaccine will continue to be available at no out-of-pocket cost to insured people. For the uninsured (or underinsured), our free drug program will ensure access by providing COVID–19 vaccines at no cost.

We remain steadfast in our commitment to protecting as many people as possible across the world. To that end, we are building a manufacturing facility in Kenya capable of producing up to 500 million vaccine doses per year. Through this facility we hope to ensure sustainable access to transformative mRNA medicines in Africa and positively impact public health.

Our Approach to Pricing

We are committed to pricing that reflects the impact our vaccine has on patients and healthcare systems. This impact includes lives saved and hospitalizations avoided. The U.S. vaccination program is responsible for an estimated $5 trillion in societal economic value.[3] The Commonwealth Fund estimates that the U.S. vaccination program prevented 18.5 million additional hospitalizations and 3.2 million COVID–19 deaths.[4]

In addition to helping protect the lives of millions of people around the world, our COVID–19 vaccine has also dramatically lessened the pandemic's economic burdens. For example, according to a study published at the end of 2021, COVID–19 vaccines had already saved the U.S. economy approximately $438 billion.[5]

As the pandemic has ended and we move to an endemic phase, the U.S. Government will wind down its role as the sole purchaser and distributor of COVID–19 vaccines. We will be offering our vaccine as a commercial product for the first time.

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[1] *See* Moderna 2023 Proxy Statement (March 15, 2023), *https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/a3589eb3-e49a-4135-a05c-746fe30f466a.pdf*.

[2] *See* Moderna Announces Update to 2022 Supply Agreement with Gavi that Secures Access to Updated Variant-Specific COVID–19 Vaccines for Low-and Middle-Income Countries (Oct. 17, 2022), *http://investors.modernatx.com/news/news-details/2022/Moderna-Announces-Update-to-2022-Supply-Agreement-with-Gavi-that-Secures-Access-to-Updated-Variant-Specific-COVID-19-Vaccines-for-Low-and-Middle-Income-Countries/*.

[3] Noam Kirson et al., The Societal Economic Value of COVID–19 Vaccines in the United States, Journal of Medical Economics (Jan. 20, 2022), *https://www.tandfonline.com/doi/pdf/10.1080/13696998.2022.2026118*.

[4] Meagan C. Fitzpatrick et al., Two Years of U.S. COVID–19 Vaccine Have Prevented Millions of Hospitalizations and Deaths (Dec. 13, 2022), *http://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations*.

[5] Anusuya Chatterjee et al., Economic Savings in America: A Story of Public-Private Partnership in Rapid COVID–19 Vaccine Development and Deployment, Heartland Forward (Dec. 18, 2021), *https://heartlandforward.org/wp-content/uploads/2021/12/Economic-Savings-in-America-7.pdf*.

Some people may be asking—why does this matter? During the pandemic, we had guaranteed sales to one customer (the U.S. government); moving forward, we are expecting to work with about 10,000 customers. Challenges of endemic distribution include:

- Assuming the cost of producing vaccines that we may not be able to sell given uncertainty in demand for fall of 2023, both in the U.S. and globally;
- Distributing to approximately 60,000 pharmacies, doctors' offices, and hospitals throughout the country, rather than three warehouses;
- Transitioning from 10 dose vials to single dose vials or pre-filled syringes;
- Providing some customers with a "right of return" in which we give them back their money for some purchased product if they can't sell it; and
- Moving from a single 500 million dose contract with the government to a commercial market with demand for perhaps 30–50 million doses, creating more than a 90 percent volume decrease.

Notwithstanding these challenges, we are committed to a fair price, which will be similar to other vaccines. Notably, our price will be less than two times the cost of enhanced flu vaccines,[6] whereas COVID–19 causes three times as many deaths as the flu.[7]

Looking Ahead to the Next Decade and Beyond

We have worked tirelessly to build the industry's leading mRNA platform. We did this while losing money for over 10 years so we could make mRNA medicines a reality for the world. This work allowed us to play a leading role in the fight against COVID–19. The success of our COVID–19 vaccine is funding more research to continue transforming the future of medicine, including for cancer and cystic fibrosis.

In 2023, we will invest $4.5 billion in research and development. We are committed to this investment even though analysts expect Moderna to report a loss in 2023. And last year our research and development investment was $3.3 billion—almost 40 percent of our net revenues, which is about twice the pharmaceutical industry standard.[8] We continue to make these significant research and development investments even as we face declining profits.

Our commitment to broad research and development is illustrated by our development pipeline. We are working to address a wide range of diseases and conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases. We have 48 therapeutic and vaccine candidates in development. We are in dialog with the WHO and the Coalition for Epidemic Preparedness Innovations ("CEPI") to develop 15 vaccines against priority pathogens that pose a threat to public health. Moderna's clinical portfolio already includes vaccines targeting COVID–19, HIV, Nipah, and Zika. Moderna's expanded global health strategy will advance programs against the remaining pathogens by 2025.

We are working on personalized cancer vaccines, treatments for cystic fibrosis, and a cytomegalovirus ("CMV") vaccine, in addition to the tools to fight future pandemics. Our personalized vaccine for melanoma, a cancer that is expected to kill 8,000 people in the U.S. this year, has the potential to transform outcomes for high-risk resected melanoma patients. Results from a recent Phase 2 clinical trial show that when combined with Merck's KEYTRUDA® cancer drug, our vaccine reduced the risk of cancer recurrence and death by 44 percent. In partnership with Vertex, we are developing an mRNA therapeutic to treat the underlying cause of cystic fibrosis, a rare genetic disease that causes degeneration of lung function and often death, for which there is no cure. Addressing the root cause of cystic fibrosis with an mRNA medicine could profoundly improve quality of life for the approximately 5,000 people who live with the disease and do not respond to existing treatments.

For ultra rare diseases—those that impact fewer than 100 people globally—we understand that the cost of therapeutics can put treatment out of reach for many pa-

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[6] The CVS list price for enhanced flu vaccines is $95. See CVS Minute Clinic Price List, available at *https://www.cvs.com/minuteclinic/services/price-lists*.

[7] Sarah Zhang, The 'End' of COVID Is Still Far Worse Than We Imagined, The Atlantic (Sept. 22, 2022), *https://www.theatlantic.com/health/archive/2022/09/covid-pandemic-end-worse-than-flu/671514/*.

[8] The U.S. government's twenty-year average shows that pharmaceutical companies have invested 19 percent of their net revenue into research and development. Congressional Budget Office, Research and Development in the Pharmaceutical Industry, at 5 (Apr. 2021), *https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf*.

tients. We are committed to considering patient access in our pricing decisions. In the case of Crigler-Najjar Syndrome Type 1 ("CN–1"), rather than commercialize the product, in September 2021, we committed to making the intellectual property available for free through a partnership with the Institute for Life changing Medicines at the University of Pennsylvania. Through this partnership, we have committed to providing the medicine for free for pre-clinical and clinical testing. If the medicine receives regulatory approval, we will supply the medicine to families for free forever.

Commitment to Our Community

At Moderna we care deeply—about our patients, our employees, the environment, and our communities. We recognize that we have an opportunity to change medicine for all, and we will continue to make corporate responsibility a critical part of who we are and what we do.

Last year we launched the Moderna Charitable Foundation ("Moderna Foundation" or "the Foundation"). We are proud to extend our social impact and support the causes our employees care most about as we work relentlessly to improve human health with our mRNA technology.

The Moderna Foundation's work reflects our continued commitment to communities impacted by COVID–19. The Foundation provides grants to local and global organizations, makes event-driven philanthropic gifts, and matches employee gifts to certain organizations. Our grant program provides financial support to organizations that focus on healthcare quality and access, mental health, STEM education, food insecurity, and child development.

Conclusion

We at Moderna are grateful for the actions you and your colleagues have taken to support and fund efforts to combat the COVID–19 pandemic. Thank you, and I look forward to your questions.

The CHAIR. Mr. Bancel, thank you very much for your testimony. You sent us a, I think it is a nine-page, single spaced document longer than your testimony. We appreciate that. But in these nine pages, as I read it, you do not mention the National Institute of Health, the NIH once, nor the research that they did.

As I mentioned earlier, according to a letter I recently received from the NIH, distributed to all Members, what the NIH says is that three scientists at the NIH, "are co-inventors and were integral members of a collaborative team of scientists working to design and produce it."

That is the scientists at the NIH, not to mention the many billions of dollars the Federal Government that came to Moderna in order to produce the vaccine and do the clinical trials. How come—in your judgment, what role did the NIH play in co-authoring and developing this vaccine?

Mr. BANCEL. Thank you, Mr. Chairman. Let me start by saying that we have a lot of respect, great respect for the NIH team. And we believe what the NIH was for this country and for the world is really important within science that industry might not fund.

What happened when the sequence came online is our team at Moderna, were working on the technology, but the way one needs to think about Moderna is like an operating system. What we spent 10 years doing is developing all the tools to make products——

The CHAIR. I don't mean to be rude, but isn't it absolutely true that the NIH was also doing that, had done research for many years on that same area?

Mr. BANCEL. What is correct, sir, Mr. Chairman, is that the NIH has worked on the virus and on the protein. So, what our team did is develop the mRNA molecule. What the NIH did, which was a great confirmation, is they designed the same protein, then our team did, in parallel, but the design of the mRNA vaccine was done by our team. This is our technology.

The CHAIR. The NIH considers themselves to be co-authors of the vaccine. Do you disagree?

Mr. BANCEL. Our team have been working through that discussion for quite a while. We have agreed to disagree. The team is following U.S. IP law, which is very important. And what we have done to close the matter is we actually have decided to abandon that patent. We have abandoned that patent.

The NIH is aware of it and we are moving on because we cannot agree on what happened. The mRNA molecule was designed by the Moderna team. That is our technology.

The CHAIR. Mr. Bancel, in terms of the role that the U.S. Government and taxpayers of this country had in terms of the success of Moderna, let me read to you a quote from Boston Magazine, June 4th, 2020.

The quote says, "the U.S. Government announced that it was funding Moderna with nearly half a billion dollars. The news sent Moderna's stock price so high that Bancel became a billionaire overnight." Comment?

Mr. BANCEL. What the Government has done through Operation Warp Speed was a moment that can only happen in America. We were facing a virus. This was the common enemy. This did not come out of Europe or other Governments.

What the U.S. Government did was say, we need to fund six different companies, six different technologies to be able to get at least one or two vaccine working. That was really what the Government did——

The CHAIR. I don't mean to interrupt you. I just don't have a lot of time. Everybody else is going to want to ask the question. But here's the point, it was announced that the Federal Government would put money into Moderna and you became—the stock market soared. You became a multi-billionaire overnight.

It is hard for me not to believe that the Federal Government played a major role in the development of this drug. But here is the main point. I don't want to talk about what happened 3 years ago. We are here today.

You are a multi-billionaire. Other people, top executives in your company are multibillionaires, all developed as a result of the vaccine. And now we have a situation where you are proposing to quadruple the price of the new—of the vaccine once the Government stockpile runs out.

That will mean that not only, and we will talk about later on the patient assistance program, but in terms of Government, in terms of Medicare and Medicaid, other Government agencies, taxpayers are going to have to spend substantially more money.

My question to you is, given the fact that you have made billions of dollars, that your company has made huge profits on behalf of

the taxpayers of this country, will you reconsider your decision to quadruple the price of the vaccine?

Mr. BANCEL. Chairman Sanders, what we have to do is to deal with a complexity I described, and I am happy to go into more detail for this hearing. This is not the same product. We used to have ten doses in each vial. Now we are going to have—every vial will have a different dose. This is not the same——

The CHAIR. I understand it, but quadrupling the price is huge, and I will hope—I would hope very much that you will reconsider that decision. It is going to cost the taxpayers of this country billions of dollars. That is something you can do.

Mr. BANCEL. The volume we had during the pandemic gave us the economies of scale we won't have anymore. That is what is different.

The CHAIR. Okay.

Senator Cassidy.

Senator CASSIDY. I defer to Senator Paul.

Senator PAUL. Mr. Bancel, Moderna recently paid NIH $400 million. Do you believe it creates a conflict of interest for the Government employees who are making money now off of the vaccine to also be dictating the policy about how many times we have to take the vaccine?

Mr. BANCEL. Good morning, Senator. Indeed, we recently made, before Christmas last year, a $400 million payment to the NIH for an old patent that they had developed not related to COVID, but useful in the development of a COVID vaccine, to pay them for their work. It is for the U.S. Government to assess how that money should be——

Senator PAUL. Do you think it creates a conflict of interest for the same people deciding the policy of how often we have to take the vaccine to also be making money the more times we take the vaccine, yes or no?

Mr. BANCEL. This is for the Government to decide, Senator.

Senator PAUL. You have no opinion on whether or not it creates a conflict of interest. Is there a higher interest or a higher incidence of myocarditis among adolescent males 16 to 24 after taking your vaccine?

Mr. BANCEL. Thank you for the question, Senator. First, let me say we care deeply about safety and we are working closely with the CDC and the FDA——

Senator PAUL. It is pretty much a yes or no. Is there a higher incidence of myocarditis among boys, 16 to 24, after they take your vaccine?

Mr. BANCEL. Data have shown actually—I have seen sorry from the CDC actually showing that there is less myocarditis for people to get the vaccine versus who get COVID infection.

Senator PAUL. You are saying that for ages 16 to 24, among males who take the COVID vaccine, their risk of myocarditis is less than people who get the disease.

Mr. BANCEL. That is my understanding, Senator.

Senator PAUL. That is not true. And I would like to enter into the record six peer reviewed papers from the Journal of Vaccine, the Annals of Medicine that say the complete opposite of what you say.

I also spoke with your President just last week, and he readily acknowledged in private that, yes, there is an increased risk of myocarditis. The fact that you can't say it in public is quite disturbing. Do you think it is scientifically sound to mandate three vaccines for adolescent boys?

Mr. BANCEL. This is for the public health leaders to decide.

Senator PAUL. You have been advocating for it. You have been interviewed and you have been advocating for boosters. Do you know when the myocarditis is most common among these adolescent boys?

After the second dose. When I spoke with the President, he readily acknowledged in private, yes, that maybe there ought to be a discussion whether we ought to have one vaccine versus two versus three.

If 90 percent of the myocarditis comes after the second dose, why don't we have a rational discussion about one? Marty Makary, a physician from Johns Hopkins, has said exactly the same thing. It has been discussed. And yet we have this ridiculous notion from the CDC. So, the CDC says, and I will ask you this question, let's start it as a question.

Your 16-year-old has had COVID. Your 16-year-old gets better and now has recovered from COVID. You vaccinate them and they get myocarditis. Are you going to give them two more vaccines, your child, give them two more vaccines?

Mr. BANCEL. I am not a clinician. I would have to discuss——

Senator PAUL. You have children.

Mr. BANCEL. I do.

Senator PAUL. Have you vaccinated your children?

Mr. BANCEL. I have.

Senator PAUL. How many times?

Mr. BANCEL. Three or four times.

Senator PAUL. Three or four times. So, the CDC recommends this, and you are obviously someone who is self-interested in the outcome here—but the CDC says that if you are a 15, 16-year-old, gets COVID, recovers, takes a vaccine and gets myocarditis, is hospitalized with elevated heart enzymes, and is very sick.

The CDC says, as soon as he gets better, vaccinate him again. Do you know how many American parents think that is a rational, reasonable thing to do? Do you know how many countries don't do this for children?

Sweden doesn't offer the vaccine for kids under 12 unless they are at risk for severe disease. And I agree with that. I am not saying never on any of this. I think it is a very reasonable position to say kids at risk or have some diseases, that there may be a reason for vaccinating some children.

Finland doesn't recommend it for under 12 months and Norway also. England as well. France, Poland, Germany, Switzerland all

vaccinate 12 and up. So, we have got half the world who have looked at these studies.

There is a study in Israel of thousands of patients, and yet you sit here and act as if you have never heard of myocarditis and you don't think it is an increased risk for young adolescent males when all of the studies who isolate out people by age have found that, yes, there is an increased risk after taking your vaccine. Pfizer, too, but worse with Moderna.

Mr. BANCEL. There is an increased risk, and that is always comparing it to somebody who gets COVID.

Senator PAUL. Well, that is also not true either, but there is an increased risk of getting it. But even when they compare it to the disease, there are many papers out there who do show that there is more of a risk of mercados after vaccination. So, you have to weigh the risk and balances.

You are right, you are going to make less money, because you are going to try—they are already trying. The CDC has got it on their schedules. They are going to try to force all the kids in America to do this through school. But guess what, parents aren't going to do it. They have seen that COVID is not deadly in children. And you are right, it has become less deadly over time.

Your market is going down, so you aren't going to make as much money. I am all for you making money in an honest way, but I don't like the idea that the people making the decisions in Government are also receiving money and are now conflicted in their interest.

The CHAIR. Thank you, Senator Paul.

Senator Casey.

Senator CASEY. Mr. Chairman, thanks very much. Mr. Bancel, great to be with you and thanks for your testimony. I wanted to get right to the heart of the matter that we are exploring today, among other issues, and that is the question of price.

But I wanted to start with, by way of a predicate, that we are certainly grateful for the work of Moderna and the other companies working in concert with the Federal Government, both Federal appropriations, as well as agencies like NIH and others to develop these vaccines in short order and to be able to provide the benefit, as you outlined in your testimony, to save millions of lives.

We are grateful for that. We are also grateful for the ongoing work that is done every day to save lives. I wanted to explore, though, this question of this partnership between not only Modena, but other entities in the Federal Government that you might call it a public, private partnership. I would argue that partnership, which yielded such great benefits for our Country and the world, should not be extinguished because the pandemic is over.

I would argue there are ongoing obligations, and I think even practical reasons to continue that kind of partnership, maybe in a different form, maybe with different outcomes and different dynamics, as you have outlined on page nine of your testimony, when you go from the earlier version of a partnership to commercial application of the vaccine.

But I would ask you this, and I noted in your testimony on page one, you said in the second paragraph about the Jesuit teachings. I went to a Jesuit high school in college. I am somewhat familiar with these teachings.

You said, "Jesuit values, a continuous pursuit of excellence. Service of the greater good, No. 2. And third, social responsibility, you say have informed my life and leadership of Moderna."

I want to juxtapose those values, which I think are commendable, and I think they are—we hope they are American values as well. Next to this, what I would argue is an ongoing obligation to have this partnership.

Shouldn't there be an ongoing obligation with regard to a product that was developed in partnership with the Federal Government to ensure that it remains both inexpensive and accessible? Don't you believe that is your obligation and Moderna's obligation?

Mr. BANCEL. Thank you, Senator, and good morning. So first, thank you for the kind words that you shared about our teams and all the other companies, and the Government personnel was—helped fight this pandemic.

First, on access. As I shared in my testimony and in a written one, we care deeply about access and we are working hard with our team and IP to spend more time on that topic, I know it is important for the Chairman as well, to make sure that people that are uninsured or underinsured have access to the vaccine.

We want to make sure that cost and out of pocket cash is not a barrier to access to vaccine. And on the topic of price, it is important, as we move into the endemic market, that we price to value of a vaccine. What value does it bring in terms of healthcare dollars? As you know, vaccines are one of the best investments we can make with healthcare dollars in terms of a return.

This has been documented for many, many years because it is better to prevent disease than to have to pay the cost of somebody being hospitalized, and that is a very expensive cost, without even adding the economic burden, obviously. So that is very important. If you look at the interesting comparator is flu.

The CVS price of a high dose flu vaccine use for the elderly is around $95 in this country. If you look at the COVID, they are 2 to 3 times more hospitalization right now of COVID. So, when you look at the price in that range seems to make sense, because it is a value that has been assigned already to flu over years. And you can look at the other vaccine, pneumonia, the CVS price of the vaccine is around $250.

Senator CASEY. I would ask you this, just by way of follow-up, and I realize that you are making that comparison with flu vaccine, but for a lot of my constituents, most of my constituents, no matter what their insurance status is, the cost of prescription drugs is like a bag of rocks on their shoulder every single day.

What may not seem like a lot of money to you or a lot of other people, $130, $150, or whatever the number ends up, is a lot of money. And I would ask you, and I will ask you for the record in writing, to ensure that anyone can get a vaccine, they won't have to apply through some tedious process and then wait for approval,

or apply for some kind of reimbursement, or have to drive a long distance.

That, I believe, is your obligation as a company. And I know I am out of time, but we will ask that in writing. Thank you.

The CHAIR. You can answer that, Mr. Bancel, if you would like.

Mr. BANCEL. Yes, Senator. And I am happy to spend time later on the topic, on the access program. We want to make sure we have a simple program that is in multi-language. We are also trying to learn from what is not working from current programs done by larger companies.

For example, we want to make sure we can partner with rural of community hospitals, potentially homeless shelters, to make it much easier. So, I am happy to spend more time on that topic. It is very important.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. Yes, I will allow Senator Romney to go next.

Senator ROMNEY. Thank you. Senator Cassidy. Thank you, Mr. Chairman. I am one of those Americans who is concerned about the fact that Americans tend to pay a lot more for drugs than do people in other countries, and have looked for ways to see if we couldn't have some kind of global recognition of the prices that are available in other countries and limiting our drug prices to those that may be consistent with a basket of other countries that purchase and honor our patents.

That being said, I reject the idea of a, if you will, an ex post facto effort on the part of some to say, oh, we provided some money in research, a lot of money in research to Moderna, and therefore we want to take the ownership of this product. That would simply be unfair and contrary to our system of law.

I would also note that the U.S. investment in Moderna's effort, I would comprise a portion that went to research and fast tracking the vaccine versus actually purchasing vaccine that was being manufactured by Moderna.

The latter was the great bulk of what the U.S. Government invested, if you will—and actually the wrong word is invested. We purchased a lot of product from Moderna. I am glad we did. I would also note this, which is this is a global demonstration that the world can look at as to the comparison between socialism and capitalism.

Free enterprise created vaccines that saved millions of lives. And the history of Moderna, I think, is pretty interesting. You indicated the company started 10 years before COVID, 10 years. It had no products during that time, no revenues at all. The investment you said, if I get it right, was $3.8 billion.

That meant individuals responsible for investing money put $3.8 billion into a new technology that might or might not work. I recall—understand that at one point you indicated to your family that you thought there was a 5 percent chance it would work, this technology would work.

If I am an investor putting $3.8 billion in an enterprise that has a 5 percent chance of working, I got to expect that if it does work, I am going to make an awful lot of money. Now, I have heard people say, well, that is corporate greed.

Yes, that is kind of how the free enterprise system works, which is people who start enterprises say, I am going to take a huge risk, invest my life savings, my career, and if it works, I get a huge return. If it doesn't, I lose it all. There are right now in our Country, hundreds of startup businesses with—trying to develop drugs that will cure diseases.

I happen to know that because I invested in some in my prior life. I lost my money in every single one. Studied them as well as we could, we lost our money. That is the nature of it. But we thought if it works, we are going to really get a huge return for ourselves and for our investors.

I don't know how much money is the right amount of money, but the idea that somehow corporate greed has just been invented in America is absurd. It has been there for the beginning of free enterprise individuals investing, hoping that if it succeeds, they will do very well financially, extraordinarily well.

I want to applaud the example we have—by the way, the socialist countries, China, and Russia and Northern Europe, did they come up with a vaccine that saved lives? No, no, they didn't. Pfizer got technology from a German company, free enterprise company, Moderna, and saved lives.

It is a stark demonstration of the comparison between free enterprise and socialism. And free enterprise works, and socialism doesn't, when it comes to saving our lives. Now, I look at the technology which you are proposing to continue to develop in other areas, and I guess I want to ask, what are the kinds of things that you are working on now? What are the prospects that you believe for some of these to make a real difference in saving lives or improving lives? Is this a one-off technology man?

mRNA, which is something which is really just effective for vaccines or does it have broader application? And what will you do with the money that the company is making? By the way, I noted that you are a billionaire now. Did the company pay you a salary of billions of dollars?

Mr. BANCEL. No, Senator.

Senator ROMNEY. You are a billionaire because the stock that you got when you started the company, you kept some of it I presume, that stock is now worth a lot of money because your technology has been proven to actually work. Is it going to work beyond vaccines, and what kinds of things are you working on?

Mr. BANCEL. Thank you, Senator. So, we are very excited because this is a platform that we have worked on for 10 years. We shared just before Christmas exciting data in cancer, which we are very excited because of course, all of us have been touched or are being touched right now by cancer.

We show a 44 percent reduction in recurrence of disease for melanoma cancer or deaths. We are working very quickly to get this with the FDA, in a phase 3 study this year.

We are also working with our partners at Merck to try this—and we are going to want to explore as many tumor type as we can to

see where can we help people, because if we—if that results translate to have a tumor type, which we believe should happen—we have to be careful and of course, wait for the clinical data.

That could be helpful to a lot of people. We are still working on rare genetic disease. One of the reasons I got excited about Moderna in the early days is, I have children——

The CHAIR. I am sorry. Senator Romney's speech on socialism took up the bulk of the time. We have to go to Senator Murray right now.

Senator ROMNEY. As did our Chairman.

Senator MURRAY. Thank you very much, Mr. Chairman, for holding this hearing. Mr. Bancel, welcome to the Committee. I understand that shifting from a single Federal contract to a multilayered payer market is adding complexity to distribution claims.

But we are talking about a vaccine that taxpayers invested $12 billion in, a vaccine that was once $15, and now you are planning, of course, to price it at $130, despite the fact that it just costs about $3 to make.

That, as we know, that cost is going to get passed on to consumers, whether it is through higher premiums or higher administration fees. So, I want to know, what is your answer to this Committee and really to the public about the need for such a drastic quadrupling of the cost?

Mr. BANCEL. Thank you, Senator, for the question. So first, just to be precise some numbers. The U.S. Government invested $1.7 billion in the vaccine development. The rest of the amount that you mentioned was actually purchase of products, not investment in the development.

As I said in my oral testimony, we decided, and this was because of us—this was not asked of us by the Government. We in the letter I wrote to the Government when we started discussing about procuring the vaccine in September 2020, we proposed with the discount. It was not asked of us.

We discussed we were bold and we said if the vaccine works—in September 2020, we had no idea. The phase 3 came in November, the data. So, if the vaccine works, we think it is our responsibility to return the capital to taxpayers.

We returned, as I mentioned, $2.9 billion in discount versus the other vaccine that the Government procured. So, despite the vaccine having three times more mRNA in it out of microgram, versus the other one was 30 microgram, we discounted our product to return $2.9 billion to the U.S. taxpayer.

We felt that was the right thing to do to say thank you for Government. In addition, the Government got $5 trillion of economic value, $18 million hospitalizations less, the impact on humans and the cost of it, and three millions lives saved.

In the endemic setting, the challenge that we have is, as I mentioned in my opening testimony, the wastage we are going to have to take care of. So first we have to make more product than we think we will sell because we cannot have patients going to pharmacies and having no supply.

This is a very hard business, very complex because it is a seasonal product. The FDA currently plans to tell us they think late May, early June, what they want in a vial. We are going to spend the whole summer making as much as we can. And what we know is the forecast is going to be wrong.

The forecasts are always wrong. And so, the question, to protect people, we need to make more than we think is going to be needed. That is waste. We are going to have to pay for it. What happened in the fall of 2022, which I think is an important way to think about it. The U.S. Government purchased 160 million doses.

To the last number I got from CDC, around 50 million doses got in the arms. But the Government bought everything. So, the difference, 110 million doses might go to waste in the garbage.

Saying that the cost of a vaccine before was $20, I don't think is the right way to do because it is not a cost to the U.S. taxpayer. The U.S. taxpayer pays for everything. If you do the math, it is around $80 the cost in the fall of 2022, still with five products in the vial——

Senator MURRAY. Okay. Well, I understand that. And I just have a minute here left. I want to ask some questions. You are talking about having a vaccine accessible to the uninsured. What I am concerned about is people hear $130, and they just don't get it because they think it is expensive. How are you going to make sure people know that you do have this program to help the uninsured?

Mr. BANCEL. Thank you for the question. And I care deeply about access and protecting people. That is why we started the company, is to help protect people. We will advertise it and communicate about it as we get into the fall.

As you know, as of today, the Government is still in charge of vaccine distribution, so we don't want to confuse things for the U.S. consumer. But as we get closer to the fall, we will make sure we get the word out.

As I mentioned, we want to work with rural hospitals, community hospital, homeless shelters because I really believe there is a better way to give access to people that are uninsured. We have heard loud and clear that the system set up by big companies is too complicated. Too much paperwork, takes too much time——

Senator MURRAY. Okay, I just want a commitment that you are going to make sure the public understands that there is a way to get this if you are uninsured, correct?

Mr. BANCEL. Senator, we are going to work really hard to make sure that the public understand the process.

Senator MURRAY. Okay. And my final question really is about the COVID–19 vaccine trials that excluded pregnant populations, which left moms and their doctors with very little information to guide them. It caused a lot of confusion. And we know that pregnant patients with COVID are at greater risk if they are infected.

Last week, actually, the CDC released some new data showing that 40 percent increase in maternal deaths compared with 2020. And a recent GAO report found that COVID–19 related deaths accounted for this increase.

Can you just talk to us about your decision to exclude pregnant patients from trials?

Mr. BANCEL. Yes. Thank you. That is a very important question that I care deeply about having children. The challenge really in 2020, and the guidelines from the FDA, is to be very careful, which you understand that in clinical trials the safety of a participant is the No. 1 priority.

There was a lot we didn't know about the safety of a vaccine until November 2020. Except for the pediatric setting. We did those studies much later, which was parents having the ability to have a vaccine for children because we wanted the FDA to go slow to understand the safety.

Senator MURRAY. I am getting gaveled. Can you just tell me that you will include a pregnant patient in continuing trials?

Mr. BANCEL. Yes, Senator, we want to include pregnant women, and also pediatric for the children.

The CHAIR. Senator Cassidy

Senator CASSIDY. I will defer to Senator Tuberville.

Senator TUBERVILLE. Thank you, Senator Cassidy, Chairman. Mr. Bancel, thanks for being here today. Thank you for what you did for my State of Alabama, our Country, and the world. And to your employees. Sometimes we overlook the people who actually do the big work. But thanks for being here today and answering these questions. I hope my Alabama accent and your French accent get along here pretty well.

Mr. BANCEL. I am sure it would.

Senator TUBERVILLE. Yes. I understand that Moderna was founded in 2010 in Cambridge, Massachusetts, and you have been the CEO since October 2011. And I also understand that you are from France originally. Could you speak about why Moderna was founded in the U.S. instead of somewhere else in the EU?

Mr. BANCEL. That is a great question, Senator. There is no better country than this country for science and entrepreneurship. People are willing to take a risk. As Senator Romney mentioned, much more capital is available to take risk. We started in the U.S. because the core technology was initially from Harvard Labs and then MIT labs, like you have seen a lot of those stories.

A great VC firm from Boston where only those health care work. Very innovative, very risky type of work, but that could change the world. And that is one reason I decided to join the team that was being formed to start this enterprise. You need to know, when I was—talked about the idea of using mRNA to treat people, I first looked at them and say, are you kidding me?

This will never work. But the more I spent time thinking about it, looking at the data, talking to experts—as Senator Romney said, I had to tell my wife, it was a 5 percent chance of working. She is not a scientist and she was asking, how risky is it?

But because if it was going to work, it was going to be a new platform, it was going to be a new way to make medicine. And that is why I took that risk with my career, is to say, it might fail me. I will have to find another job.

It is going to be Okay. But I have to try to make this work because it could save so many people. Of course, we never thought there would be a pandemic in our lifetime. But while working on infectious disease vaccine—we are running 13 clinical trials right now, which is one of the largest number in the industry, as I mentioned, working with cancer, genetic disease, heart disease, the team is working on an autoimmune disease. It is still in a lab but is coming soon.

This is a really—it is a platform. For 100 plus years of the pharma industry has been an analog industry where every drug is different, we have to agree on everything. This is a platform that is going to enable so many medicines in helping people. And as we saw during the pandemic, because it is a platform, we can go much faster to the clinic, much faster to approval, so we can help save lives.

Senator TUBERVILLE. Thank you. Kind of reminds me of my former profession which was a coach, and I used to tell my players, this country owes you nothing but an opportunity, and you came here, took the opportunity, and made a success out of it, so I want to thank you for that.

Again, a lot of people I want to thank for that. We are hearing a lot today about how much the Government spent on vaccine development and how much risk pharmaceutical companies took themselves.

I wasn't here in the Senate when Operation Warp Speed was getting started, but I do recall hearing a lot of criticism on the other side of the aisle about whether partnering with pharmaceutical companies like this was a good idea and whether we would get any successful vaccines.

Seems like it worked out pretty well for all of us. Can you speak about Operation Warp Speed and how it brought the vaccines to patients, and what the overall impact of our health care system and overall deaths would have been without this investment?

Mr. BANCEL. Thank you, Senator. I think the world owes so much gratitude to the U.S. Government and to Operation Warp Speed.

I think the idea to say, we have no idea which technology is going to work, we are fighting this enemy, the virus, but we don't know which technology is going to work, so let's bet on three technologies.

Protein technology, very mature, but much slower. Adenovirus technology. And the mRNA technology. And to do it even better, the Government said, let's not bet on one company. Let's bet on two companies per technology versus the six-company portfolio, two in the portfolio to hedge for risk.

Then Congress, and I want to really thank Members of Congress for the budget that was appropriated to bother to be able to fund this work, allowed this. This did not happen in Europe.

This did not happen in Asia or anywhere else. This country helped change the course of this pandemic through the public, private partnership, which is why when the Government called for help, we raised our hand.

We made the 10 years' worth of investments in science and technology platform available. Say, we are going to make the technology available. We make the plant available. We delayed products. We have commercial products, including for—cancer, that have been delayed because we prioritize our resources to the pandemic because it was the right thing to do for the country.

Senator TUBERVILLE. Thank you. And I would just like to make this statement, we did a lot of research on this, and the U.S. taxpayer paid $30 billion for the successful vaccines and received $1.15 trillion in direct benefit back from that $38 billion. Pretty good investment to me. Thank you very much.

The CHAIR. Thank you, Senator.

Senator Smith.

Senator SMITH. Thank you, Mr. Chairman. And thank you, Mr. Bancel, for being with us today. So, I want to start by just saying that the COVID–19 vaccine is safe and effective in preventing hospitalizations and deaths from COVID–19, and the process for developing and distributing this vaccine is a tribute to the innovation in the technology and the perseverance of the scientists and researchers and manufacturers, and also the Federal, state, tribal, and local agencies that delivered shots into arms.

I include Moderna in that group. I mean, it is also critical that Americans continue to have access to these vaccines. Now, we are not talking economic theory today, but I want to say I am a capitalist. I went to business school. I started my own business, though I did not make as much money as you have made, Mr. Bancel.

I understand the concepts of return on investment and risk reward. But it is difficult for me to accept that the profits that you are reaping on the backs of American taxpayers are necessary or reasonable.

It feels like a bonanza to me. So, I want to just understand a little bit about what is going to happen next. You tell us that you expect the Moderna—expect Moderna to offer its vaccine at a list price of about $130, up from $26.23.

Yet it is extremely confusing for Americans to understand what the price is that they will actually pay. It feels a little bit like a lottery and too often we lose rather than win. So, if a Minnesotan gets their insurance through Medicare, their vaccine will be free thanks to the Inflation Reduction Act.

Will Moderna negotiate with Medicare on the price, or will you demand $130 sort of take it or leave it?

Mr. BANCEL. Good morning. Thank you, Senator, for the question. So indeed, and maybe I should start there, regardless of insurability status of people in this country, where you are insured by a company, insured for Government program, or uninsured, we want that this is a no out-of-pocket costs for the American people.

That is really, really important to us, which is why, as I shared, that we already set up that program for the uninsured. For people that are insured, it is through the law, because it is a vaccine, there would be no co-pay. And we will make sure for the summer that the American people are aware, if you are insured or uninsured, there would be no co-pay. We can work——

Senator SMITH. But some—I am sorry, but somebody will be paying. And what I am trying to understand with Medicare or Indian Health or veterans, the Veterans Administration, will you negotiate with the Federal Government of those agencies beyond $130, or is that the price sort of take it or leave it?

Mr. BANCEL. Like it is usually traditionally in the industry or teams, and those discussions are happening as we speak. We will be discussing with all those agencies following the law——

Senator SMITH. Okay. So, you will be negotiating——

Mr. BANCEL [continuing]. And the process—yes.

Senator SMITH. Then thanks to the Affordable Care Act, Americans who receive their health insurance through private insurance or through the exchanges will also get a vaccine for free. Do you expect that you will be negotiating with those insurance companies or the PBMs or others on the ultimate price?

Because, again, even though it is free to—it might be free to those folks based on their insurance, somebody is going to pay. And that could, of course, contribute to increased rates for everybody.

Mr. BANCEL. That is a very important question, Senator. So first, one piece that is important for the vaccine is if you look at the vaccine in that price range, and that is why we looked at it very carefully, the cost savings in some hospitalization costs that year for people who will not get the vaccine ending up in hospital is a tremendous return.

The cost is estimated to be in several hundreds of dollar for the direct cost of hospitalization and medical costs, not even talking economic impact and things like that. And so, the benefit to the health care system is going to be in the reduction of health care spend in hospitals.

Senator SMITH. Yes, that is—I, of course, understand that. The question, though, is still whether or not there is—I am hearing you say that you expect to be negotiating on what the ultimate price is. And I want to just note, Mr. Chairman, that thanks to the Affordable Care Act and the Inflation Reduction Act, Americans will be not paying a cost for this, but there still is a cost to the system, to taxpayers.

Now, let me ask you one last question just the minute I have left. So, if I am uninsured and I go to my local pharmacy, and I need—I want to get the vaccine, I hear you saying that you don't have all the details worked out yet on what that will be like, but what would that be like for that American?

I mean, are they going to be asked to pay something upfront and then try to figure out the paperwork for reimbursement later, for example.

Mr. BANCEL. Thank you for our question, Senator. We want to make it as easy as possible. What would be really bad, I think we can agree on this point, if somebody walks into a pharmacy and decide they don't want the vaccine.

We want those people who want to be vaccinated to have access to the vaccine. So, where we are trying to work with a team is on all the learnings of the other programs that sometimes don't work so well. Which is why I am a big proponent with our teams of hav-

ing those discussions as we speak, to think about those people, what are they associated to. Is it a rural community hospital?

Then, is there a way for Moderna to do a partnership with a hospital so that people will go to that hospital. If the hospital is certified, they are uninsured, those individuals don't have to do the paperwork.

We are trying to work on things like these because we want people who want to be vaccinated to get access to vaccine. We care deeply about that.

Senator SMITH. Thank you, Mr. Chairman. Thank you.

The CHAIR. Point of privilege, if I might. Do I understand, in response to Senator Smith, that you are in fact prepared to negotiate a $130 price with Medicare, Medicaid, and other Federal agencies?

Mr. BANCEL. Senator, our teams are going and having discussions with all the different customers. As I said, we used to have one customer, the U.S. Government. We have ten thousands now. So, our teams, as we speak——

The CHAIR. But you have a Federal Government, which is basically one. Are you prepared to negotiate that price with the Federal Government?

Mr. BANCEL. Yes, different agencies work differently, so we are working with all of those.

The CHAIR. Senator Cassidy.

Senator CASSIDY. I will defer to Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. Thank you, Ranking Member. This is indicative of a much bigger problem facing health care. You are one small part of it which looms huge because everyone sooner or later ends up with a prescription, even a vaccination now and then.

The issue that most of us are confronted with, if you don't own a health care business, is that—I listened carefully to Senator Sanders' opening remarks. You can probably take those as being representative of anyone that wrestles with the health care system that does not own a business in the system.

It has gotten to be such a huge part of our GDP, unlike anywhere else in the world. So, you get into something extra normal like we have just gone through, it raises all kinds of issues. And I have been the Senator most outspoken on I think you run like an unregulated utility across the board. You don't embrace competition.

You don't embrace transparency. And you are a small part of it. Hospitals now have gotten up to where they are close to 35 to 40 percent of the health care dollar, and that is even harder to find out how much things cost, how it is working.

If you are in the business of free enterprise, which I think many on our side make excuses for, and that means no barriers to entry, that means full transparency, full competition, and don't try to business with the Federal Government and then want more from it when you are not performing well in the first place.

Let's look at a narrow issue here. You are claiming that you need more because of the cost of distribution. Well, in any other field,

and I did it for 37 years, it is very simple. You have a network of distributors, dealers.

You don't have PBMs in there that make it confusing. You need an MBA to look at that flow chart. When are you going to start making it easy for all of us to see what things cost, and then not look to Government when they were part of this formulation in terms of how we got the vaccination, and then want more from it.

You are involved in a taxpayer—you are involved in a lawsuit where you have got two smaller companies, Abutus and Genevant, that are making a claim that you had a patent infringement.

I am hearing that not only here, but patent tweaking, patent infringements when it comes to where we spend even more money on biologics and biosimilars. Point being, whether it is the Government paying for it or the private sector, it is a broken system and you need to get better at it or you are going to get solutions in the long run that you don't like.

Your distribution system, why is it something that you sound like you have got to recreate it? Where has it been up to this point? How do you describe your flu vaccines? Why do you need this much money? A 400 percent price increase is preposterous, especially when you have been given all this Government largesse that is even going to protect you from these lawsuits.

What is the nature of your current distribution system to where you can't just put this into it, and why is this that much different from what you have done for years in distributing a flu vaccine? Because it looks like we are headed more to where this is going to be like the flu than it is going to be something extra normal.

Mr. BANCEL. Thank you, Senator, for your question. So just to clarify, we do not have a flu vaccine on the market yet. We have one in clinical study. We should have a phase 3 data soon and hopefully——

Senator BRAUN. You may not have one on the market, but there is a distribution network for them from your competitors, why wouldn't you be able to get into that? Why do you have to justify creating a new distribution network? No one would ever do that.

Mr. BANCEL. Indeed, Senator. We are going to use—but we have to set up a distribution network. I am not saying that we are going to be the only warehouses like other companies do.

We are going to work with companies, but we have to set up those contracts. During the pandemic, we only shipped trucks to three warehouses in the U.S., when the CDC was taking the responsibility and the cost of getting the vaccine to hospitals, pharmacies——

Senator BRAUN. Is the Government requiring you to do something different here that would cause you to use a different network—what do McKesson and Cardinal and the others do? There is a network to get this stuff to pharmacies already in the places they need to go. Why can't you blend it into that? Keep the costs down. Be a little entrepreneurial in what you are doing.

Mr. BANCEL. It is part of a solution we are going to be doing, Senator, as we are going to use existing networks. But we have to set up everything because we never had a commercial product be-

fore. We just have to go, which we are doing right now, through all the contracting and negotiating of all those rights and so on, to set up the distribution capability so that we can get the vaccines to pharmacies——

Senator BRAUN. I ran out of time. You cannot, as well as the rest of the industry, including hospitals, have the best of both worlds where you want Government to be in there helping you when it is tough, and to where for the private side, most of us are not happy with the fact that we are lucky if your health insurance plan only goes up 5 to 10 percent, which incorporates hospitals, pharma, and maybe the Darth Vader of it all, the insurance business. Something has got to give or you are going to get more Government involved in health care. Thank you.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chairman. Mr. Bancel, thank you for coming in and testifying before us. It really is a remarkable, if you look at the arc of what happened, and you look at it, actually take it all the way back to when Moderna was founded in 2010 and you came on board in 2011.

I look at so many moments of risk and how many times, I don't want to alarm anyone, but the company could be at risk. Your margins were so thin you didn't have sufficient money to invest.

I think the notion of what the Federal Government did during a time of crisis, where we made, I think a decision baked in wisdom to pursue six different solutions. Talk about multiple working hypotheses.

In your case, the Federal Government, BARDA provided, I think it was $1.7 billion, in your statement, you said. And that was money that really was, after the earlier investments, which were largely in research and those are public, private partnerships that have—that money is invested.

We do that. The Government does that in all different levels. In this case, the $1.7 billion, you actually returned $2.9 billion, $2.8 billion?—$2.9 billion. What was part of your motivation in that?

Mr. BANCEL. Thank you, Senator, for the comments and for the question. It is actually quite simple. As we were starting—so there is really two moments during the pandemic, in the partnership with the Government. First, focus on the vaccine development and accelerate it. That is what the BARDA funding provided.

Then we started to discuss with the Government toward the end of the summer of 2020 about purchasing vaccine in case the FDA would approve them. And as we sat to have those discussions, we had to discuss with a board.

It became very clear, like family discussion at the board meeting, that we had to find a way to give the money back to the U.S. Government because we all felt very grateful that thanks to that funding, we were able to accelerate the vaccine. I believe more that I would have got the vaccine approved without the funding, but it would not have been by the end of a year.

Americans' life would have been impacted by that delay without the support. And so, when we looked at, we were like, if we are going to get the vaccine to work, we should provide a discount.

The board said in 5 minutes, and that is what I put in my letter that I sent to the Government in our first discussions for procurement.

Senator HICKENLOOPER. Well, it would be an interesting calculation, look at how many lives were saved by accelerating that process with that $1.7 billion, and was paid back, almost not quite doubled, but certainly more than just paying it back.

I am sympathetic to some of the issues as you look at pricing going forward, that this is something that needs to be kept at a cold temperature. You are going from one customer to thousands of customers.

You are looking at a 90 percent or 95 percent reduction in what you are producing, so all your manufacturing is going to have to be reconfigured. I am not an expert in pharmaceutical, so I can't address that, but I think it is a complex issue that we need to spend more time looking at.

In these kinds of public, private partnerships, we want to get to the alignment of interests. And I guess my question is, you can comment on that, but I also—what do you think, going forward, how can we do a better job of creating these public, private partnerships so that both sides feel they know exactly what they are getting and what is—there is an alignment of that self-interest.

Mr. BANCEL. Thank you, Senator. Actually, the way we think about the price during the pandemic was actually a discount. We are talking here today about an increase in price. But if you think about what happens in any of our industry, when you get to a very large volume, you get a very big discount.

That is actually what we do. With $500 million, all there from the U.S. Government. This year if we get 30, 50, that would be great. Actually, this year, if you look at any consensus, the company might be at a loss this year.

Senator HICKENLOOPER. I know, and then you made the—I get it and I am sympathetic to that. I am not sure all the other Senators are sympathetic as I am, but we will have the discussions. But I do want to get, because I have only got 40 seconds left and maybe we will get an extra 20 seconds, what would be—what would you suggest in terms of going forward, in terms of improving public, private partnerships?

Mr. BANCEL. Thank you, Senator. I think making sure that the terms are clear. As you know, in enterprise, we are making decisions every day. And what we are trying to do is to allocate our resources to the best projects that we can do.

I think being clear about what are the rules and making sure that the rules don't change later, that is what is really important. And when we discussed about the BARDA funding, there was no discussion about commercial pricing.

The focus was, accelerate the study, get the vaccine to American people to save lives. And as you said, this was a great return for U.S. taxpayers.

Senator HICKENLOOPER. No, again, I think it is—you can't measure the success and the savings. I haven't added it up to figure out that discount, how much savings that was and the benefit to the

economy, you do mention—you did mention in your remarks, it is just, it is a remarkable story. So anyway, I feel gratitude that you were there and able to step up and play such an important role in addressing really the worst medical crisis of certainly my lifetime.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Well first, I want to pass my Ranking Member seat right now to Senator Mullin, while I walk across and ask in another Committee, and then I will defer to Senator Marshall for questions.

Senator MARSHALL. All right. Thank you, Senator Cassidy. Thank you, Chairman. I want to, first of all, submit for the record a couple of Op-Eds, the first one written by a Senator from Democrat—Democrat from Indiana, and my hero, Bob Dole from Kansas.

This is an editorial just talking about Bayh-Dole law, which encourages and has been so successful, encourages Federal Government to work with the private sector.

Also, an Op-Ed that I wrote, goodness mine was in 2022, about how fixing prices kills innovation. So, we will submit both of those for the record if it is Okay, Mr. Chairman.

[The following information can be found on page 139 in Additional Material:]

Senator MARSHALL. Well, Mr. Chairman, let the record show that you and I agree on something again. This is my goal. Every one of these hearings is for you and me to agree on something. And I agree that charging Americans $130 for this vaccine is outrageous. But where we always disagree is the cure. How do we get there?

I know one of your biggest concerns is the cost of insulin, as it has been mine. And I presented this graph that shows what the cost of insulin has done as competition is being introduced in the market.

With two biosimilars coming on board now, the cost, and I checked with one of my pharmacies back home, the amount supply of insulin, $400 6 months ago, now a biosimilar for $120. And I am not satisfied. And I also want to point out, though, this big difference between the gross cost, the list price versus the net cost and how pharmacy benefit managers work in that margin for their rebates is something we need to tackle yet as well.

Okay, let's go to the next graph here, Charlotte. Again, this is what happens in America when we have innovation and competition that the U.S. leads the world in access to miracle drugs. And we will go to this last one as well, just showing how certainly the Americans paying too much for medicines, but at least we have access to these miracle drugs.

I would ask everybody, which miracle drugs do you want to give up? Which one of these would you give up? Would you give up Car T-cell therapy, the miracle cures we have in cancer, which ones would we give up?

We got to be careful we don't throw the baby out with the bathwater, if you will. Mr. Bancel you guys have been working on mRNA technology, I think, since at least 2010, 2011, and you had a lot of patents you issued. Were most of those patents in that era around mRNA development, vaccine development?

Mr. BANCEL. Good morning, Senator. Thanks for the question. Yes, the company only works on mRNA because we believe if we invest in the platform and improve it, we can do more application of more medicine across therapeutic areas. So, it is mRNA focused.

Senator MARSHALL. Right. I bet you expected when you invented this vaccine, you would come to Congress and get a hero's welcome, that you get a Nobel Prize even for this. You had no idea that you were going to be castigated because of your success as well. So that is—the two sides of this coin that we are concerned about. I want to back up to your time with your previous company, Biomerieux.

Mr. BANCEL. Yes, Biomerieux.

Senator MARSHALL. At that time, the Wuhan laboratory, the BSL–4, biosafety level 4 lab was being made, and your predecessor had something to do with that. Did you keep track of the Wuhan lab being—going up? And were you concerned about it?

Mr. BANCEL. That is all—Biomerieux had no involvement with the Wuhan lab. I was aware, of course, because Biomerieux is the leading company in infectious disease diagnostic. I was aware there was a new high security lab being built in China, but I had zero involvement. My company had zero involvement.

Senator MARSHALL. Okay. This is a pretty complex question. Is Moderna or did Moderna executives have agreements with organizations in China, including the Wuhan Institute of Virology or with Eco Health? And if so, what are the terms and does Moderna owe any of those people any moneys?

Mr. BANCEL. We never had any agreements with Chinese labs or Wuhan labs, Senator.

Senator MARSHALL. Or Eco Health?

Mr. BANCEL. I am not aware of that lab.

Senator MARSHALL. Okay. Were you aware in September 2019 when the Wuhan lab and the Chinese took down their DNA lab bank, were you aware of that pretty much in sequence when that occurred?

Mr. BANCEL. I was not, Senator.

Senator MARSHALL. Okay. In September 2019 is when that occurred. In December 2019, you took your mRNA corona vaccine candidates to the University of North Carolina at Chapel Hill to work with Senator Ralph—not Senator—Dr. Ralph Baric as well. What was the impetus to do that?

Mr. BANCEL. Thank you for the question, Senator. It was actually a vaccine for candidates against MERS, the Middle East Respiratory Syndrome, which is of the corona family, but of course, not SARS-CoV–2. It is a different one.

Senator MARSHALL. You had no idea that what was exploding in China already, probably since September?

Mr. BANCEL. No, I was made aware of a first time, as I said during my testimony, at the Christmas break by reading the newspaper. There was a little article saying there was pneumonia like symptom cases that were really in Wuhan, which is why I directly contacted the NIH at that time to say, are you aware about this?

Because we had been working together on the coronavirus, as you mentioned, because we believe that the highest risk of pandemic——

Senator MARSHALL. You never worked with China, never worked with WV.

Mr. BANCEL. At Moderna? No, sir.

Senator MARSHALL. What about not in Moderna?

Mr. BANCEL. When I was running Biomerieux, we had a team in China. The company was in 40 plus countries. So, we were selling product in China, yes, sir.

Senator MARSHALL. Okay. Thank you so much.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. This week, I am proud to once again introduce my bipartisan Fair Drug Pricing Act with my colleague, Senator Braun. This would require drug companies to provide transparency and justification report when they increase the price of a drug above a certain threshold, or when the drug costs more than the median household income in the U.S.

Today's hearing demonstrates exactly why we need more transparency. While big drug companies have taken in record profits, more than one-quarter of Americans struggle to pay for their prescription medications.

These same Americans are the taxpayers who are footing the bill for research and drug development that companies like Moderna are benefiting from. Researchers have estimated that prior to the pandemic, the Federal Government and taxpayers invested more than $337 million in mRNA vaccine technology and development.

Mr. Bancel, I didn't read your mention of those numbers in your written testimony. I believe that when drug manufacturers significantly increase the price of their drugs, that they should have to provide information to the public that justifies these increases, including research and development expenditures derived from Federal funds.

My bill, the Fair Drug Pricing Act, also requires that companies provide information on all stock-based performance metrics used to determine executive compensation associated with price increases or high initial launch prices.

Mr. Bancel, your stock compensation is, I understand, based on performance metrics set by your board. And last year it's reported that you earned salary and stock compensation worth nearly $400 million.

This is despite the fact that your board apparently found that you actually underperformed the company's target for sales income generated by the COVID–19 vaccine. So, I want to ask, the decision to increase the price of the vaccine is—it appears tied to the impact of your personal performance assessment on your bonus and how much you would stand to gain personally from increasing the price of the COVID vaccine.

Can you talk about how much of that decision to increase the price is related, as I just suggested.

Mr. BANCEL. Thank you, Senator, for the question. It is not related. When we look at price, we look at value for any product. We look at what is the value of a product to the health care system, how much money can be saved.

That is how the price is determined. And that is why, as I mentioned initially, if you look at the price, the cost of a flu vaccine at CVS, it's on $95 for a high dose flu vaccine used for the elderly.

Given there is 2 to 3 times more hospitalization of COVID versus flu, that was one of the metrics we looked at as looking at price. The other one, as you might be aware of, the cost of a pneumonia vaccine is around $250. So that is kind of how we looked at that price.

Senator BALDWIN. Well, let me ask you another question. Moderna's most recent annual report stated that the company repurchased $3.3 billion worth of stock in 2022 and over $800 million in 2021 to, "return capital to shareholders." Mr. Bancel, you are one of, if not the largest shareholder in Moderna.

Yet despite spending significantly to buy back stock over the last 2 years, Moderna's share price has actually declined. If you had not spent nearly $5 billion on buybacks when your stock was at the highest price it has ever been, do you think you would be under less pressure to raise the price of the COVID vaccine now?

Mr. BANCEL. Thank you, sir. So, the price is not linked to the company's performance. The price is linked to the value of a product, to the patient, and to the impact on the patient. That's how we set the price. I yield back.

Senator BALDWIN. Thank you. I yield back.

The CHAIR. Senator Mullin.

Senator MULLIN. Thank you, Chairman. The Government overshot the number of vaccines needed in 2022 by over 100 doses. What were the challenges of estimating the number of doses needed for 2023, and how does that impact your cost?

Mr. BANCEL. Thank you, Senator, for the question. That is sort of a very complex issue with this transition from the pandemic to endemic. I have never managed a company going from pandemic to pandemic, and it has not happened since, of course, the pandemic flu of 1918. And so, we are trying to guess how much volume is needed, which is a manufacturing challenge we have, especially as a small company. We do not do with filling in the vials ourselves.

We have to contract out to outside companies. And what we are trying to do is to not undershoot it, because as I said earlier, we care deeply about having enough products available for patients when somebody walks into a pharmacy.

We know by design we are going to have to over make products and we are going to have to take the returns and destroy them at the end of a season. But that is part of a cost of running a seasonal respiratory vaccine franchise, which is why it is necessary for us to increase the cost versus the discount that we had during the pandemic, where the Government took all of our risk, managed the waste.

Senator MULLIN. Buying the unused doses, you have to factor that back into the cost because you had to repurchase them and then dispose of them correctly. Is that correct?

Mr. BANCEL. We have to do two things, and that is correct. One is we have to pack more than we need to make sure it is available across the country when needed.

If you think about just the supply chain and distribution, we need much more to make sure you have everywhere at any time.

Then there is the returns, which is if a pharmacy gets more than they thought they needed, they will return it to us and then we have to, of course, incur that cost obviously.

Senator MULLIN. What will need to change within your company to accommodate the demand for single bottle versus prefilled syringes rather than ten those files that were purchased by the Federal Government?

Mr. BANCEL. We have to move to single dose vial because that is what the pharmacists and the doctors want. And we understand that. That is what the commercial market needs, because it is simpler, there is less wastage. Somebody walks in——

Senator MULLIN. You have to factor that into the cost too? Is that cheaper to do ten at a time versus one at a time?

Mr. BANCEL. Exactly. It is much more expensive to do ten because just if you look at the cost of a glass of vial—you need ten vials versus just one right, and then you use a lot of capacity and——

Senator MULLIN. I am talking about per dose though.

Mr. BANCEL. Yes. And then you use a lot of capacity as the manufacturer. So, while the number of doses go down, the number of vials goes up.

Senator MULLIN. Right. Pfizer has also noted that they are going to intend to increase the price of their vaccine to $130 per dose. How does the market competition factor into changing cost?

Mr. BANCEL. We look at value and price. And of course, like in any market, we want to be competitive as an enterprise and so we look at that as well.

But the key driver, as I was sharing with Senator a minute ago, is really value, which is what is the value of a vaccine in terms of health care costs, and then how can we create a product to extract some value for the company but leave some value in the health care system?

We want to make sure that there is a lot of value left for Medicare and the payers.

Senator MULLIN. Your company decided to take funding as part of the Operation Warp Speed. Can you discuss how Moderna chose to take the loan from HHS and the difference in business structure between you and other manufacturers?

Mr. BANCEL. Thank you, Senator. So, we decided to take the loan from BARDA, because it will accelerate the vaccine development. If you go back in time, those discussions were happening in January—end of January, February, March, until April grant, and

whether the company we wanted to insure is a vaccine going to clinical trial as fast as possible.

At the time, Moderna was losing money, and so if we had developed the vaccine without Government funding, the development would have been much slower because we would not have been able to take a similar financial risk that we took thanks to the Government money like making product ahead of a study. And so that is why we decided to take the money because we felt it was going to save lives.

Senator MULLIN. Thank you. With that, I yield back.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Thank you, sir. I am going to lead into my first question, kind of repeating some of the things I said in my opening statement. For decades, this Committee has passed legislation knowing that we would have to ask companies to step up at perhaps a pandemic time and do exactly what Moderna did during this time.

Others didn't make the same choices of Moderna to collaborate with the Government. So, the question is, if we send a hostile signal to future and prospective partners that Moderna is now being singled out for its decision to work more closely with the Government, what signal would that send to that future prospective partner?

Now related to that, there are folks who have spoken of marched-in, where the intellectual property which has been developed by Moderna or Pfizer or another, would be, if you will, marched in by the Federal Government and shared worldwide to those who had no role in its development.

What would that do to the willingness of a future prospective partner to work in a public, private partnership with the Federal Government to find a solution as hastily as it had to be found?

Mr. BANCEL. Thank you, Senator. So first, let me say, we were very proud to partner with the U.S. Government. And when the call came, we raised our hand and we said, of course we will help and do our best work.

I think what is key for any enterprise, not only in the pharmaceutical industry but across different fields, is to know what is going to happen. Companies needs to plan based on what our hypothesis or how we are going to work together during the crisis and also after the crises.

I think what we need as industry is clear rules that do not change. So, for example, during the BARDA discussions, there was no discussion on commercial price. It was assumed, never discussed, to the best of my knowledge——

Senator CASSIDY. I have limited time. So, the question is, if the Government were to exercise its march-in rights and take the IP from the company and distribute it worldwide without compensation for the company, what would that do to—what can you imagine it would do to a company, a future company's willingness to work with the Federal Government in a public, private partnership?

Mr. BANCEL. I always say that it will really impact the willingness of those companies to partner with the Government. And I think patients will suffer.

Senator CASSIDY. Okay. Now, let me ask you in your—it is a different question, different set. In your patient assistance program, while I assume that will also apply to the short-term limited duration programs, because to be clear, under current U.S. law, if you are commercially insured, if you are federally or state insured through Medicaid, Medicare, etcetera, you don't have to pay for this vaccine, at least as the patient.

You are paying indirectly through premiums, but you are not paying directly. And you are going to make through your patient assistance program available for the uninsured. Two questions about that.

Will that also include limited—a limited, short term, limited duration policies which do not—are not under the Federal mandate to provide vaccines at no cost? That is a question. I don't know if you know that.

Mr. BANCEL. I don't know the answer, but I would make a note to follow-up with my team and make sure we follow back with you after.

Senator CASSIDY. Please. And I would ask that those folks be afforded the same as the uninsured, because effectively for vaccine, they are uninsured. Second, as regards the vaccine itself, will your patient assistance program also include the administration fee?

Mr. BANCEL. This is something we have to look into——

Senator CASSIDY. I will say for the uninsured, just as a doc who treated the uninsured, it is not just the cost of the vaccine, it is the administration fee. And obviously, that is something you can limit. You can make it an x amount of dollars. It doesn't have to be astronomical. But we—but I agree with Senator Sanders.

We want that PAP to be something that works for patients and is not just kind of like, oh, yes, we have it, but no one can use it. Now, I also want to clarify a couple other things. It was suggested that the IRA is what has resulted in the coverage of the COVID vaccine, but indeed that was the CARES Act, just to make that clear.

I also want to make something else clear, that there has been a lot of discussion about pharmaceutical costs, but this has nothing to do with the cost of a drug. The cost of a drug is related to pharmacy benefit managers. It is related to the initial price of the of drugs. It is related to scarcity, you name it.

But that is a separate topic from this. And I look forward, Mr. Chairman, to that future discussion in which we do discuss the high cost of pharmaceuticals, but that is a separate issue from this vaccine. And I think I wanted to make that clear because it was not perhaps not as clear as it could be. And with that, I yield.

The CHAIR. Thank you, Senator Cassidy.

Senator Hassan.

Senator HASSAN. Thank you very much, Mr. Chairman and Ranking Member Cassidy, for this hearing. Mr. Bancel, thank you

for being here. I want to follow-up a little bit on what Senator Cassidy was just trying to get at.

Moderna has said that his patient assistance program will provide low cost and no cost COVID–19 vaccines to the uninsured and underinsured. This program cannot simply be a public relations exercise that provides cover for the company to hike prices on families seeking COVID–19 vaccines.

How quickly, after the launch of its patient assistance program, will Moderna start providing publicly available data on the number of individuals it has covered and typical out-of-pocket costs under the program?

Mr. BANCEL. Thank you, Senator, for that question. We care deeply about patient access, and so I will work with a team to figure out what is the right frequency for sharing that data. But we want to find ways for people to get access to a vaccine. We still have 250 people dying every day of COVID in this country. And we have a tool, so we want to make them available.

Senator HASSAN. I understand that. Congress and the public are going to need information so that as you all proceed, if you are still planning to hike the price, that we can make sure that really the uninsured and underinsured are getting meaningful access to this in a timely way.

Another piece of this is that uninsured individuals seeking COVID–19 vaccines are going to need to be able to access this program that you have, and they shouldn't have to fill out pages of forms with fine print in order to get access to your patient assistance program. So how long will the application for your program be, and how much documentation will you require from applicants?

Mr. BANCEL. Thank you, Senator. We have heard that feedback as we have talked to patients, to doctors, to Members of Congress.

The team is working diligently to figure out how do we use technology to make it simpler, how do we make sure we have access to enough languages so it's easy for people who are not English as a first language. And also, we are trying to be creative, as we have done over the history of a company.

For example, of our partnerships we can do directly between Moderna and the rural hospital or community hospital in your state, and of course, across the country. Whereas we do a partnership, the doctors agree that they will certify that the people will get a vaccine that we send to them for free, will be uninsured so that individuals don't have to all do the form.

We are trying to figure out all those mechanisms to make it easier for people, including we are also working, for example, with homeless shelters for the same thing.

Senator HASSAN. I think that is really important. I think it is also going to be important that you all release the application for your patient assistance program before its launch so that the public can see what you are requiring from uninsured families. And just a note on the rural issue, one of the other things to be aware of, of course, is that a lot of rural communities don't have uniform access to high-speed internet, right.

We need to have processes that are meaningful for people who don't have that kind of access. I also just want to talk about the impact of the price increase on vaccine uptake. The fact remains that hiking prices and requiring families to fill out forms will likely decrease vaccine uptake and set back the public health effort to combat COVID–19.

What are your plans to quantify and publicly disclose the consequences of your price hike for vaccine uptake among the uninsured and underinsured?

Mr. BANCEL. Thank you, Senator, for the question. So, I will work with my team and we are very happy to follow-up with your office in terms of what would be all disclosure moving forward. The plan is still being work on.

What we want to make sure is that the plan is set up and announced way ahead of a vaccine availability in the fall so that somebody was uninsured has access at the same time as somebody who was insured.

Senator HASSAN. Well, I understand that. But I also think it is going to be really important for us to see what the uptake looks like in light of these increases, because I think all of us who have constituents, family and friends who deal with access to lifesaving medications, every time there is some sort of bureaucratic hurdle, as well as every time there is a cost hurdle, there is an impact on uptake.

Moderna needs to kind of own its public health responsibility and disclose the effects of its price hikes so that the public and Congress can hold the company accountable, if the price hike discourages millions of Americans from getting vaccines.

I know you want to work on that, too, but this—we really are going to need data here, and I am looking forward to seeing the company produce it. Thank you.

Mr. BANCEL. Thank you, Senator.

The CHAIR. Thank you.

Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman, very much. Welcome, sir. In the dark days of 2020, it was the partnership between the Federal Government and state Government research centers and companies like Moderna that made it possible for us to make a huge medical breakthrough.

It was places like the National Institutes of Health and health systems, and companies, communities, and getting people vaccinated, that was the real triumph. People young and old at every income got their shots for free. We helped to lift the weight off of hospitals and brought the innovation of Cambridge to community health centers in communities around the world.

But now the list price of COVID vaccines may more than quadruple, and the cost of high drug prices is that families may need to pay higher health care premiums, health care providers may struggle to afford doses for their patients, and uninsured people may not get vaccinated at all. And even one person not getting vaccinated because they can't afford is a health system failure.

Biopharmaceutical innovation can cure disease, extend lives, and epidemics, and they should be praised for that. But the real power of that innovation comes from guaranteeing that every community, no matter of their income or zip code, has access. So, during the height of the crisis, it cost about $26 per patient for the Federal Government to vaccinate an individual.

For a family of four, that is $104. The price you are now talking about of $130 times four for a family of four brings that price out to $520 for a family of four, up from $104. So, you can see why we are so concerned. That is a huge price increase. It is clearly going to be limiting access for many people in our society. And so, my question to you is, do you have a way of lowering that price even further?

Have you finished all of your calculations? Because just by pricing it at that level, our Country is going to see millions of people unable to be able to afford it. And if they can afford it, it is only because insurance premiums are going to be going up for them and for Americans across the country. Can you lower it any further?

Mr. BANCEL. Thank you, Senator, for your question. So let me start with access. Because of how things are set up in the country, people that are insured, will have no out of pocket. People that are not insured, we are currently working on the program and want to make sure it is as easy as possible to access it so that people who are not insured also have access to a vaccine at no cost.

That is very, very important to us. The big unknown for us as we move forward is the unknown and the complexity. We do not know what volume will be required in the fall of 2023. We do not know how much wastage there will be in the country. If you look at the fall of 2022, I think this is interesting data to think about and reflect upon.

U.S. Government bought 160 million doses, 50 only million went into arms. So, the true cost to the U.S. taxpayer was way above $26 because they paid for all the doses that ended up going to waste.

This does not include the costs of distribution, which now we are going to have to bear. So over time we would have to see where things stabilize in terms of volume——

Senator MARKEY. I appreciate that. It is only that as time goes on, identifying where the waste is becomes easier and easier because of experience. So obviously that was an absolute rush that we were in.

But as time goes on, you get better in terms of efficiencies in logistics and making sure that the number of people who we think are going to be wanted are matched up within a logistical system that gets it to them.

I guess what I would say to you is that it is important to be looking at additional efficiencies, additional ways you can lower this price, because it is going to be critical to making Americans feel they can afford it. And following on that, Moderna announced that you have develop a potential cancer treatment for melanoma using mRNA technology, which is an exciting development in cancer treatment.

But Merck's cancer drug list price is $175,000, $175,000. And it generated $21 billion in revenue while patients skip treatment or take on significant medical debt. So, Mr. Bancel, how can you use your role to ensure that the cancer drugs you are developing are affordable for people who are going to need them?

Mr. BANCEL. Thank you, Senator, for your question. That is something we will look into it as time goes by, closer to launch. At this time, our focus is to start the phase 3 study as fast as we can, because we believe, as you said, the data is very encouraging. 44 percent reduction of recurrence of disease or melanoma or deaths.

It is a big impact on patients. And as we get closer to launch, we will have to figure out—we have to even invent how to manufacture those drugs. Because unlike the vaccine which we make in larger batches, this is an individualized medicine.

We make a different one for you or for me if we have cancer, because we have to adapt to the general disease. So, we will have to figure all those things out.

Senator MARKEY. A drug that is unaffordable is a hallucination to ordinary people in our Country. So, it has to be made more affordable. Thank you, Mr. Chairman.

The CHAIR. Senator Luján.

Senator LUJÁN. Thank you, Mr. Chairman. And Mr. Bancel, thank you for being with us today. We have heard a lot of numbers thrown around today. So, my goal here is to try to shed some light on that one and see if we can clear some things up. I have a series of yes or no questions for you, sir. Before the COVID vaccine, Moderna had never had a vaccine approved. Is that correct?

Mr. BANCEL. That is correct, Senator.

Senator LUJÁN. Yes or no, BARDA provided Moderna $1.7 million to support clinical trials related to COVID vaccine?

Mr. BANCEL. That is correct, Senator.

Senator LUJÁN. Yes or no, the Federal Government promised and provided $10 billion in guaranteed advance purchase orders if Moderna successfully developed a vaccine?

Mr. BANCEL. That discussion happened later, Senator. It was different from the BARDA discussion.

Senator LUJÁN. That sounds like a long way of saying yes. Is the answer to that question, yes, or no?

Mr. BANCEL. Can you repeat the question, please, sir?

Senator LUJÁN. Yes or no, the Federal Government promised and provided $10 billion in guaranteed advance purchase orders if Moderna successfully developed a vaccine?

Mr. BANCEL. It was actually in tranche, Senator. It was not $10 billion at the beginning. The Government started by ordering 100 million and had the rights to——

Senator LUJÁN. We can have a disagreement there. I think if I go back and look at the facts here, the Federal Government guaranteed $10 billion. We can—if you would like some time to clear that up, I can submit a question to the record. Yes or no, that deal allowed Moderna to secure early supplies of component parts to speed up production.

Mr. BANCEL. Actually no, Senator. We had to raise capital in the public market in May 2020, $1.3 billion——

Senator LUJÁN. Will getting a $10 billion guarantee help you raise more money from the market?

Mr. BANCEL. We do not have that guarantee—the purchase agreement——

Senator LUJÁN. Okay. I am going to move on. I appreciate that. So, you disagree with the question that I asked?

Mr. BANCEL. Yes.

Senator LUJÁN. Okay. Despite the Federal Government investing early and heavily in Moderna, the Federal Government has been repeatedly asked to increase its payment per dose. Yes or no, the Federal Government most recently bought boosters from Moderna at about $26?

Mr. BANCEL. I think that is correct, sir.

Senator LUJÁN. For the record, the $26 price represents a 73 percent increase in the price per dose compared to the last purchase the general Government made in June 2021 when it was $16.52 per dose.

Mr. BANCEL. This is because of a discount. As I mentioned, we provided a discount for the initial purchase, equivalent to $2.9 billion that of discount to reimburse BARDA. It is why the initial price in 2020 was much lower.

Senator LUJÁN. I appreciate you sharing that response, Mr. Bancel. I have heard it a few times today. Pharmaceutical companies set the price. There has been a whole conversation about this. There is a low price and there is a lowest price, and then there is a broken price, and then there is a discount price.

But you still make money. So, I would like to have another hearing maybe on that, Mr. Chairman, so that we understand indeed what the lowest price is, because if there is a low price and then there is a discount offered, the company agrees to negotiation to offer the discounted price, and I am certain you are still making money on that.

Now, that may be my bias and my very elementary understanding of a very complex, industrial complex here. But nonetheless, I would like to move on there and very much appreciate your explanation of the discount and pointed that to the $26 and $16.52.

While the huge purchaser, like the Federal Government, likely received a discount for bulk, what you just described, smaller purchasers were still paying a higher price. Is that correct?

Mr. BANCEL. That is correct, sir.

Senator LUJÁN. They were paying $37 per dose or $32 to $37 per dose. Does that sound correct?

Mr. BANCEL. Which customer, Senator?

Senator LUJÁN. The volume purchasers.

Mr. BANCEL. Outside the U.S. you mean? Because in the U.S., we had only one customer, the U.S. Outside the U.S. It depends on volume, yes.

Senator LUJÁN. Yet Moderna announced that it plans to sell the vaccine in commercial market from $110 to $130, which is a 400 percent increase. Is that correct?

Mr. BANCEL. That is a price where we tend to sell it at.

Senator LUJÁN. There is still about 30 percent of Americans that Moderna estimates will still need a shot. That is a lot of people. And in 2002, yes or no, Mr. Bancel, Moderna matched the $3.3 billion it spent on research and development with $3.3 billion in stock buyback.

Mr. BANCEL. In 2022. Yes, it is correct, Senator.

Senator LUJÁN. Now, Jamie Dimon, who is the CEO of Chase, some of you may know who he is. He once described stock buybacks as one of the last uses of excess capital, particularly after investing in growth. I am trying to understand the statements that have been put forth by Moderna here.

According to your last call earning, you have $18 billion cash on hand and you plan to only spend $4.5 billion on additional R&D over the next year. For a company that has never had a commercial drug product before the COVID vaccine, that is a lot of profit.

Where I will conclude here, Mr. Chairman, is I support people doing well and profits in this regard. This was a national pandemic, and I am sorry, people are still getting sick and dying from COVID. That is real. Whether people want to admit that or not, that is a real. This just seems—it is hard for me to understand here.

The cash you are sitting on, your projections, looking at what the U.S. Government did, not just with investment, but accelerated treatment when it came to attention to approving a drug that was going to save people's lives. And I appreciate every one that was responsible for this. I am just having a hard time with this. Thank you, Mr. Chairman.

The CHAIR. Thank you, Senator Luján. I am going to ask some additional questions, then give the mic over to Senator Cassidy.

The issue we are really discussing today, and Senator Luján raised it, I think significantly, is some of us have a hard time understanding how a company that made $21 billion in profit, a company that enabled you and your associates to become multi-billionaires, a company that would not have developed this vaccine without the help of the taxpayers of this country, now comes before the public and says, oh, by the way, we want to quadruple prices, which will mean that the deficit goes up, the taxes go up because of the increased expense that Medicare and Medicaid and VA have to pay.

I concur with Senator Luján about that issue. I want to ask you, earlier, in response to Senator Smith, you talked about negotiating prices. Am I hearing from you that in fact you are prepared not to charge $130 for a vaccine to the U.S. Government, but less than that? Is that what I hear?

Mr. BANCEL. What I am saying, Mr. Chairman, is there is a list price. It depends if it is a single dose product or prefilled syringe product. There is a list price are on the $130. And then with the different customers, they are going to be discussions.

The CHAIR. But that is an issue that many have raised. We have no transparency in pricing. It is a totally insane situation. Everybody pays a different price. The U.S. Government helped you develop that vaccine. It is a huge consumer. Are you prepared to substantially charge less for the vaccine to the U.S. Government and our agencies?

Mr. BANCEL. Given the situation at hand, Mr. Chairman, we have no idea of a volume that will be needed this year. We have very increased complexity.

The CHAIR. You have complexity, but you have money for stock buybacks by the billions and you guys became billionaires. That doesn't seem too complex to me. Let me ask you this question at least. The United States pays, the people in our Country pay the highest prices in the world for prescription drugs in general, something this Committee will work on. Will you at least tell us today that the price you are charging for the vaccine will be lower than what other countries around the world are paying? Or once again, we are going to pay the highest prices?

Mr. BANCEL. Mr. Chairman, the price will depend on the value in each country. The cost of health care is different in each country.

The CHAIR. That is not the answer. That is a whole, all right—I am asking you a simple question. Your vaccine was developed with the help of the U.S. Government. I am asking you whether or not we are going to continue to pay the highest prices in the world for that vaccine.

I understand everything is complex, but I also understand you have money for stock buybacks and exorbitant compensation packages for yourself. Will you at least tell the taxpayers of this country that the price we pay for the vaccine will be less than other countries?

Mr. BANCEL. I cannot say that the price would be lower than in other countries.

The CHAIR. All right. Let me ask you this. When you talk about value, it is an interesting philosophical concept. In your judgment, what does value mean to a woman who lost her husband because the family cannot afford the price, the outrageous price of a prescription drug? Is that a value that we should consider or is it only—is that a value that we should consider?

Mr. BANCEL. We believe in access, Mr. Chairman. And as I said, our products, we are going to work really hard for the uninsured, that they are available for no cost.

The CHAIR. I understand. I may be asking you a broader question than just Moderna. Senator Markey mentioned Pfizer having a cancer drug for $175,000, I believe is what he said. All right, what do you——

Mr. BANCEL. That is another company.

The CHAIR. That is another company, of course, I know that. But I am asking you, your statement, is—you talk about value and the value is, well, we have helped the economy and we have done all these things. True enough. But what about the value of the human lives that are lost or the suffering while companies make billions

and people can't afford the price? Is that not a value to be considered?

Mr. BANCEL. Of course, Mr. Chairman. We need to work together, industry and the Governments, and all the players in the health care system to figure out how do we make sure the products are available. I completely agree with you. We work hard to make medicine and to do science to help people, so I agree with you.

The CHAIR. Well, you raise an interesting question. Okay, that is—and Senator Cassidy and Senator Romney kind of talked about it. Now, tell me this, and this is kind of a value issue that I think we should really get into as a nation. Jonas Salk—you are familiar with Jonas Salk.

Invented the polio vaccine. Did not make billions for his invention. In fact, he gave it away. And he said, I am so proud to have created this vaccine just to save lives. Alexander Fleming developed penicillin. A huge advance for medicine, saved millions of lives. Frederick Banting sold his intellectual property for $1 for insulin.

What do you think about those guys and those scientists who say what, our function in life is to create wonderful drugs that will ease human suffering and save lives, not to become excessively rich. Do you think they were crazy?

Mr. BANCEL. I think what they did was very noble. I think what we have to do is to invest in new technology. If we do not have a technology when the pandemic happened, there would have been no Moderna vaccine, Mr. Chairman.

The CHAIR. Look, we all agree that we need the technology. But what I am asking you and some of my friends here are saying, is that the only thing that motivates you is to become a billionaire.

Mr. BANCEL. That is not true.

The CHAIR. All right. But then can we have a science where people get paid well? I have no problem with Moderna making money. What you are hearing here, massive cash paybacks.

You are becoming a multi-billionaire. Do we—should we develop a counterculture, perhaps, which says your motive is not just making billions, but developing all of the drugs we need for the terrible diseases that this world faces?

Mr. BANCEL. That is what we are doing, Mr. Chairman. That is why Moderna is a different company. Our No. 1 investment this year in R&D. As I mentioned, the $4.5 billion.

The CHAIR. How much do you put in stock buybacks?

Mr. BANCEL. Sorry?

The CHAIR. How much do you provide in stock buybacks?

Mr. BANCEL. We have not decided yet as well. The number of a stock buyback that is still open is $2.8 billion, I think. Our No. 1 priority is R&D. If we could invest more in R&D, we would. The challenge we have is phase 3 studies takes time to happen, Mr. Chairman.

The CHAIR. Let me ask you this. And again, I am not—I am directing it to you, but it really applies to the whole industry. If we were to say to you, if the Government were to say to you, look, we

are interested in cures in cancer, obviously, diabetes, all the other—Alzheimer's, all the other terrible illnesses we face.

We are prepared to make sure that your company makes a good profit. Maybe you don't become a multi-billionaire, but you make a good profit. And if you develop a cure for that particular disease, you are going to make money on it, but we are going to take the intellectual property and make it available to the whole world so that people all over the world at a very reasonable price will be able to benefit from that discovery.

You make money, the world benefits. Everybody affords it. What do you think about that concept?

Mr. BANCEL. What is really hard in this industry, Mr. Chairman, is the very risk of failure. Most drugs fail. 90 percent of drugs in clinical trial fail, as you are aware. And that is what makes it really, really hard. What we want to do is to get access. Let me share a couple examples.

We are working on having a plant in Kenya to help a low-income country. There is an example of a rare disease called Crigler-Najjar. It is a very small, 100, 200 kids. We couldn't find a way to do it or it will be too expensive.

The CHAIR. But if we said to you, we are going to cover, you are not going to fail, you will be compensated. We are willing to pay you good money. You are going to get rich. Maybe not a multi-billionaire.

You will do very, very well. We will cover the risk. But if you succeed, that formulation is going to be available to people all over the world so that they can get that drug. We cover the risk. What do you think about that?

Mr. BANCEL. I will have to look into the details, Mr. Chairman, because, again, the risk is—I don't know how you manage the risk. I mean, are you suggesting in that thought process that the Government will pay all of R&D—?

The CHAIR. That is exactly what I am suggesting.

Mr. BANCEL. Okay.

The CHAIR. That is the deal. We are going to cover the R&D. You succeed, you are going to make profit, but the product goes all over to the world so that people can afford it.

Mr. BANCEL. I think we have to understand the details to have an opinion.

The CHAIR. Senator Markey made the point that I think millions of people appreciate, you can come up with all the great drugs in the world, we appreciate that, but if people can't access them, they go broke or they go bankrupt hoping to buy them, it doesn't mean anything to those people.

Certainly, by the way, we are talking about America, the wealthiest country on earth. What about Africa and poor people around the world? Should they die because they cannot afford that prescription drug?

Senator Cassidy.

Senator CASSIDY. I will be very short. One, I applaud those like Banting, and Best, and others like Maurice Hilleman, who devel-

oped vaccine and made them generally available. But I also want to quote in 1962 on a Senate hearing on drug development and the role of patents, Dr. Vannevar Bush, who is kind of famous for his role in the development of science in the United States.

At the time, he was the former head of the U.S. Office of Scientific Research and Development. He also led the first National Research and Development Council and contributed to the Manhattan Project. And he lamented that Fleming, when he discovered penicillin, didn't seek a patent, saying that if he had, we would have had penicillin 10 years earlier than we finally got it.

I say that because I learned, having emerged from a hospital for the uninsured, that there is an ecosystem of investors. And when you are a startup with really no assets, there are investors who invested in your company, as Senator Romney said, maybe taking a loss, but maybe winning big.

They could have invested in anything else, but they invested in you. And they did it because they anticipated a return. Some of them got it. Some of them did not. That they invested in a startup that failed, they lost their money. So, I say that because it isn't just so much the company that is established.

They may be a legitimate beast. But we are speaking about a company starting. I have learned that there is an ecosystem and they cannot get money unless that investor can see a return on that which he has put forward. No need to comment. With that, I yield.

The CHAIR. Thank you very much. And Mr. Bancel, thank you very much for being with us this morning. We appreciate it.

Mr. BANCEL. Thank you, Mr. Chairman.

The CHAIR. Now we are going to call our next panel. Our first witness will be Dr. Christopher Morten. Our next witness will be Dr. Ameet Sarpatwari. And our third witness will be Dr. Craig Garthwaite.

Let me thank all of our witnesses for being with us and for your patience. We appreciate your being here. Let's begin with Dr. Christopher Morten, who is an Associate Clinical Professor of Law at Columbia Law School.

Dr. Morten is trained as an Organic Chemist and Lawyer. He is a leading expert on equitable access to medicine. Dr. Morten, thanks for being here.

STATEMENT OF CHRISTOPHER J. MORTEN, PH.D., J.D., ASSOCIATE CLINICAL PROFESSOR OF LAW, COLUMBIA LAW SCHOOL, NEW YORK, NY

Dr. MORTEN. Chairman Sanders, Ranking Member Cassidy, and distinguished Members, thank you for this hearing and for inviting me to testify. mRNA based COVID vaccines are among the most important inventions of my lifetime.

They have saved millions of lives. For 2 years, we, the people of the United States, had free access to these vaccines because our Government purchased large quantities at affordable prices and distributed them for free. But that, sadly is changing. The U.S. Government will leave Americans on our own to foot the bill.

Moderna has proposed massive price increases, from $20 or $30 a dose to $110 or even $130, though each dose costs less than $3 to make. Moderna's proposed price increases will mean that people who need boosters won't get them. More people will get sick and die. Higher vaccine prices hurt us all. Higher prices mean higher insurance costs, including higher Medicare premiums.

Mr. Bancel claims the value of these vaccines justifies Moderna's proposed price increases. But his testimony ignored a key question, who created that value? It was the U.S. Government, the American taxpayer, that spent billions. It was Government scientists that toiled alongside Moderna's.

To quote Moncef Slaoui, former head of Operation Warp Speed and a Moderna board member, the U.S. Government, "held Moderna by the hand on a daily basis Moderna is not the primary inventor of any of the three key scientific features of the NIH Moderna vaccine that Moderna itself has identified as critical to its value.

We gave Moderna the specific mRNA sequence used in the vaccine. We designed and ran Moderna's early clinical trials. We gave Moderna money and resources to expand its manufacturing.

The National Institutes of Health was so integral that it aptly named the vaccine, the NIH-Moderna vaccine, built on over a decade of pioneering research into coronaviruses at NIH. Yet Moderna has repeatedly exaggerated its own contributions and downplayed or even erased essential Government support at almost every stage.

For example, Moderna's lawyers intentionally omitted NIH scientists as inventors of a key patent application, the same NIH scientists who sent Moderna the vaccine's precise mRNA sequence. To quote NIH, "omitting NIH inventors from the principal patent application deprives nature of a co-ownership interest."

Mr. Bancel just confirmed a moment ago that Moderna abandoned that patent application rather than share control with NIH. To be clear, Moderna's scientists and engineers made many contributions of their own, as did many academic scientists. These people and their work deserve credit and celebration, too.

But Moderna cannot claim the vaccine's value for itself. And the American people, the most important creators of the value of this vaccine, deserve a voice in the debate over the company's prices. To quote Senator Casey, "our partnership should not be extinguished just because we think the pandemic is over."

To justify price increases, Moderna also points to $4.5 billion in R&D commitments this year. But $4.5 billion is easily doable for this company. In 2021 and 2022, Moderna made over $20 billion in profits. The company has been so spectacularly successful that many of its executives and early investors became billionaires, including Mr. Bancel.

As I speak right now, Mr. Bancel's net worth is reportedly about $4.7 billion, meaning he might be rich enough to fund Moderna's entire 2023 R&D expenditure out of his own pocket. In 2022, Moderna spent $3.3 billion on stock buybacks to enrich Mr. Bancel and other shareholders.

That is as much as the company spent on R&D last year. Moderna's price increases are unjustifiable. If we let them happen, we set a terrible policy precedent. Other companies will double down on Moderna's playbook, extract billions in private profits from public science and public money, leave Americans with higher costs, inaccessible technologies, and poorer health.

I urge Moderna, do not raise your prices. Your vaccine is clearly profitable at $20 a dose. And if Moderna insists on higher prices, our leaders should act. I will make two recommendations now, and I present more in my written testimony.

First, Congress and the White House should work together to resume bulk purchases of COVID vaccines. Continue to use the buying power of the American people and provide vaccines free of charge to everyone.

Second, NIH and other scientific agencies must cut harder bargains with their industry partners so that we the people get access to the next generation of medical products that our money creates and that we need to survive and thrive. Thank you.

[The prepared statement of Dr. Morten follows:]

PREPARED STATEMENT OF CHRISTOPHER MORTEN

Written Statement of Christopher J. Morten, J.D., Ph.D., to the Senate HELP Committee
March 20, 2023

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Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for convening this important hearing and for inviting me to testify. I'm honored to.

I. Biography

My name is Christopher J. Morten. I'm an Associate Clinical Professor of Law at Columbia Law School in New York City.

I'm a lawyer, but before I went to law school, I studied science. I obtained a PhD in organic chemistry from the Massachusetts Institute of Technology. While at MIT, I received multiple awards and fellowships from pharmaceutical companies, on the basis of my research: fellowships from Merck and EMD Serono and awards from Roche and Wyeth (now part of Pfizer).[1]

After obtaining my PhD in 2011, I began working as a science advisor and patent agent at major law firms—Goodwin Procter and Baker Botts. At these firms, I represented numerous pharmaceutical companies, both generic and brand-name. I prosecuted patent applications, assisted with patent litigations, and performed other work for these companies. I worked closely with scientists and engineers in industry and academia to understand their inventions and prepare patent applications to protect them.

I graduated from NYU School of Law in 2015 and then clerked for Judge Timothy B. Dyk of the U.S. Court of Appeals for the Federal Circuit. After my clerkship, in 2016, I returned to Goodwin Procter as an associate in its Litigation Group, with a focus on Hatch-Waxman pharmaceutical patent litigation. I also worked on antitrust and FDA regulatory matters. As before, I represented both generic and brand-name drug companies.

In 2018, I began my law teaching career. I taught at Yale and NYU's law schools before beginning my current position at Columbia in 2021.

I'm a researcher and academic. I have published numerous peer-reviewed articles in the scientific, medical, and legal literatures. I would be glad to provide a complete list of publications or a full CV at the Committee's request. In the footnote at the end of this sentence, I

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[1] While preparing this testimony, I discovered that Roche's press release for its 2010 "Excellence in Chemistry Award" remains online: Roche, *Roche Symposium Showcases Accomplishments of Next Generation of Chemists* (Jun. 3, 2010), https://www.biospace.com/article/releases/roche-symposium-showcases-accomplishments-of-next-generation-of-chemists-330672/. Roche's press release includes a quote from Hans-Joachim Boehm, Ph.D., then-vice president and head, Medicinal Chemistry Nutley, global head, Chemistry at Roche, identifying me and ten other PhD students as "providing fundamental advances in the field of synthetic organic chemistry."

list some of my recently published papers that concern pharmaceuticals, vaccines, and Moderna specifically.[2]

At Columbia Law School, I direct and teach a student clinic, the Science, Health & Information Clinic.[3] Through the clinic, I continue to practice law. Clinic students and I provide legal services to activists and organizers, scientific and medical researchers, patient and consumer groups, nonprofit organizations, and other clients. Much of our work seeks to expand access to medicines, vaccines, diagnostics, and other medical technologies. Some of my past and current pro bono clients are Doctors for America, Doctors Without Borders, the Electronic Frontier Foundation, the Open Source Hardware Association, PrEP4All, the Public Interest Patent Law Institute, T1International, and Universities Allied for Essential Medicines. I have also assisted Public Citizen on certain investigations.

All the legal work my clinic and I do is pro bono. Other than my salary from Columbia, I do not make money from my legal work.

I have no direct personal stake in the outcome of this hearing. I'm not personally at risk of losing access to COVID-19 booster shots, at least in the near future, as I'm one of the lucky Americans with expensive health insurance that will cover the costs.

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[2] Ravi Gupta, Christopher J. Morten, Yaqian Zu, Reshma Ramachandran, Nilay D. Shah & Joseph S. Ross, *Approvals and Timing of New Formulations of Novel Drugs Approved by the US Food and Drug Administration Between 1995 and 2010 and Followed Through 2021*, 3(5) JAMA Health Forum e221096 (May 20, 2022); Reshma Ramachandran, Christopher J. Morten & Joseph S. Ross, *Strengthening the FDA's Enforcement of ClinicalTrials.gov Reporting Requirements*, 326(21) JAMA 2131-32 (November 12, 2021); Alexander C. Egilman, Amy Kapczynski, Margaret E. McCarthy, Anita T. Luxkaranayagam, Christopher J. Morten, Matthew Herder, Joshua D. Wallach & Joseph S. Ross, *Transparency of regulatory data across the European Medicines Agency, Health Canada, and US Food and Drug Administration*, 49 J.L. Med. & Ethics 456 (October 19, 2021); Christopher J. Morten, Zain Rizvi & Ameet Sarpatwari, *President Biden Already Has The COVID Vaccine Recipe. He Should Share It*, Health Affairs Blog (September 22, 2021); Christopher Morten & Matthew Herder, *We Can't Trust Big Pharma To Make Enough Vaccines*, The Nation (May 31, 2021); Christopher Morten, Laurel Boman (NYU JD '21), Joseph Rabinovitsj (NYU JD '21), and Celine Rohr (NYU JD '22), "U.S. 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent" (April 14, 2021) (white paper); Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 Calif. L. Rev. 493 (2021); Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 Yale J.L. & Tech. 1 (2020); Matthew Herder, Christopher J. Morten & Peter Doshi, *Integrated Drug Reviews at the US Food and Drug Administration—Legal Concerns and Knowledge Lost*, 180(5) JAMA Intern Med 629-30 (March 2, 2020), doi:10.1001/jamainternmed.2020.0074; Christopher J. Morten, Aaron S. Kesselheim & Joseph S. Ross, *The Supreme Court's Latest Ruling on Drug Liability and its Implications for Future Failure-to-Warn Litigation*, 47 Journal of Law, Medicine & Ethics 783 (January 19, 2020).

[3] Science, Health, and Information Clinic, https://www.law.columbia.edu/academics/experiential/clinics/science-health-and-information-clinic

However, I care deeply about the topic of this hearing because I care deeply about access to healthcare in this country. My clinic at Columbia Law School is a health justice clinic; we use the law to protect and expand people's access to healthcare.

I accepted the Committee's invitation to testify because I'm concerned that Moderna's proposed price increases would hurt people and their health. As I explain below, in detail, I believe these prices would lead to more sickness and death and will impose unreasonable new costs on American taxpayers. I'm disappointed and even angry at Moderna—at its proposed price increases, at its falsehoods, and at its exploitation of its once-close partnership with the U.S. government. I believe the distinguished Members of this Committee and the broader American public should be angry, too.

My testimony is based entirely on public sources. I have no inside knowledge of Moderna, NIH, or any of the other institutions mentioned here. I have done my best to piece together an extraordinary and extraordinarily complex story—scientific, legal, financial, and more.

I submit this testimony and speak in my individual capacity and not on behalf of Columbia Law School, Columbia University, or any of my clients. Nothing in my testimony should be construed to represent the institutional view of any of these organizations, if any.

II. A Few Key Background Facts

I understand that the hearing will cover Moderna's research, development, and commercialization of its COVID-19 vaccine, including its partnership with the U.S. federal government. I understand that the Committee would like to discuss the transition of the vaccine to the commercial market, including Moderna's planned pricing of the vaccine.

In short, I think Moderna's planned price increases are outrageous, unjustified, and harmful. I present my evidence and analysis below.

Before turning to that evidence and analysis, I would like to provide a brief overview of a few key facts.

Vaccines for COVID-19 are some of the important scientific inventions of my lifetime. They have saved millions of lives. One recent estimate concluded that COVID-19 vaccines averted over three million deaths and over 18 million hospitalizations in the U.S. alone between December 2020 and November 2022.[4] One consultancy has estimated that the mRNA-based

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[4] Meagan C. Fitzpatrick et al., *Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths*, THE COMMONWEALTH FUND (2022), https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations.

NIH-Moderna[5] vaccine alone saved more than 1.7 million lives in just one year, in the period between December 2020 and December 2021.[6]

But COVID-19 vaccines have not saved as many lives as they could have. One major factor has been the lack of access to COVID-19 vaccines in many parts of the Global South—especially a lack of access to mRNA-based vaccines such as the NIH-Moderna vaccine, which have proven most effective at preventing severe illness, hospitalization, and death. For example, a 2022 study by Sam Moore et al. estimated that broad global access to COVID-19 vaccines in 2021 could have prevented 1.3 million additional deaths through the end of 2021.[7]

Since December 2020, people in the United States have had free access to these vaccines, because our government purchased large quantities—so-called "bulk purchases"—at affordable prices and distributed them for free. Jennifer Kates, Cynthia Cox, and Josh Michaud at the Kaiser Family Foundation recently calculated that, through federally-funded bulk purchases, "[t]he federal government has so far purchased 1.2 billion doses of Pfizer and Moderna COVID-19 vaccines combined, at a cost of $25.3 billion, or a weighted average purchase price of $20.69 per dose."[8] In these bulk purchases, the U.S. government procured hundreds of millions of doses of the original version of the NIH-Moderna vaccine at prices that ranged between $15 and $18 per dose. More recently, the U.S. government has paid somewhat more for Moderna's new variant-targeted bivalent boosters: $26.36 per dose.[9]

In recent months, Moderna's executives have announced that Moderna intends to charge much more for bivalent boosters: $110 or even $130 per dose.[10] The math is simple; these prices would represent a quadrupling or even quintupling of the price Moderna had previously been charging for bivalent boosters in the United States.

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[5] I use the term "NIH-Moderna vaccine" to refer to Moderna's "SPIKEVAX™" product, which is also referred to as "mRNA-1273," the "Moderna COVID-19 Vaccine, mRNA," the "Moderna COVID-19 vaccine," "elasomeran," or simply the "Moderna vaccine." I use the term "NIH-Moderna vaccine" because I believe it most accurately reflects the scientific origins of the vaccine, which I detail below. *See* infra § III.B. The National Institutes of Health (NIH) itself has repeatedly and aptly referred to the vaccine as the "NIH-Moderna vaccine."

[6] AstraZeneca and Pfizer/BioNTech saved over 12 million lives in the first year of vaccination, AIRFINITY (2022), https://airfinity.com/articles/astrazeneca-and-pfizer-biontech-saved-over-12-million-lives-in-the-first (last visited Mar 7, 2023).

[7] Sam Moore et al., *Retrospectively modeling the effects of increased global vaccine sharing on the COVID-19 pandemic*, 28 NATURE MEDICINE 2416, 2417 (2022), https://www.nature.com/articles/s41591-022-02064-y

[8] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/

[9] *Id.*

[10] *See, e.g.*, Jared S. Hopkins, *Moderna CEO Defends Pricing Plans for COVID-19 Shot*, WALL ST. J. (Mar. 6, 2023), https://www.wsj.com/articles/moderna-ceo-defends-pricing-strategy-for-covid-shot-41582d36.

III. Evidence and Analysis of the Unreasonableness of Moderna's Proposed Price Increases

In my view, Moderna's proposed price increases are unreasonable and unjustifiable. Moderna's justifications for these increases—value and the need to sustain R&D—do not hold up to scrutiny. Moderna's proposed price increases represent simple profiteering. If they come to pass, they will cause harm to public health and to the public purse in the months and years to come. They will set a terrible policy precedent and encourage other companies to exploit public funding and public science, as Moderna has.

I divide this Part—my evidence and analysis—into three sections. The first section explains the harm that Moderna's proposed price increases would cause. The second section engages with Moderna's stated justifications for its price increases and concludes that they fail. The third section provides additional reasons to be skeptical of Moderna's stated justifications for its price increases and its commitment to safeguard access for patients: Moderna and its executives have broken numerous promises in the past and misrepresented important facts.

A. Moderna's proposed vaccine price increases would harm public health.

Moderna's proposed vaccine price increases would cause harm to public health and to many individual Americans in the months and years to come.

1. Harm to un- and underinsured Americans

About 8% of Americans—over 27 million people—had no health insurance at all in 2021.[11] Chairman Sanders and Ranking Member Cassidy, as you know, that total includes about 20,000 people in Vermont and about 337,000 people in Louisiana.[12] In addition, experts estimate that many tens of millions more Americans are "underinsured"—their insurance coverage does not guarantee them affordable access to the healthcare they need.[13]

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[11] Census Bureau, Report No. P60-278, Health Insurance Coverage in the United States: 2021 (2022), https://www.census.gov/library/publications/2022/demo/p60-278.html.

[12] Health Insurance Coverage of the Total Population, Kaiser Family Foundation, https://www.kff.org/other/state-indicator/total-population/.

[13] Sara R. Collins, Lauren A. Haynes,and Relebohile Masitha, *The State of U.S. Health Insurance in 2022*, The Commonwealth Fund (Sept. 29, 2022), https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey.

It is these people who would suffer most from increased COVID-19 vaccine prices—including Moderna's proposed price increases. As Jennifer Kates, Cynthia Cox, and Josh Michaud at the Kaiser Family Foundation wrote recently,

> For the uninsured and underinsured – who will not have guaranteed access to free COVID-19 vaccines – the commercial price could discourage vaccination. The suggested average price for COVID-19 vaccines after commercialization ($110 to $130 per dose) is significantly higher than the commercial price for the annual flu vaccine ($18 to 30 per dose), and could be a cost barrier for the uninsured and underinsured, who have no guaranteed mechanism for receiving COVID-19 (or any) vaccines once federal supplies are depleted.[14]

A growing body of research shows that out-of-pocket costs generally dissuade people from vaccination—especially (and understandably) low-income people.[15] Lower uptake of boosters could conceivably accelerate the evolution and spread of new variants.[16] People going unboosted—especially the elderly and immunocompromised—will lead to more illness and death from COVID-19.

In response to public criticism of its proposed price increases, Moderna has promised a patient assistance program. On February 15, 2023, Moderna issued a terse statement promising "to ensur[e] that people in the United States will have access to our COVID-19 vaccines regardless of ability to pay."[17] Moderna has stated that "Moderna's COVID-19 vaccines will continue to be available at no cost for insured people whether they receive them at their doctors'

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[14] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

[15] *See, e.g.*, Community Preventive Services Task Force, *Increasing Appropriate Vaccination: Reducing Client Out-of-Pocket Costs for Vaccinations* (Jan. 20, 2016), https://www.thecommunityguide.org/media/pdf/Vaccination-Reducing-Out-of-Pocket-Costs.pdf; Zhuliang Tao et al., *Impact of Out-of-Pocket Cost on Herpes Zoster Vaccine Uptake: An Observational Study in a Medicare Managed Care Population*, 6 Vaccines 78 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313857/; William F. Vásquez & Jennifer M. Trudeau, *Will Americans Get Vaccinated? Predicting COVID-19 Vaccine Uptake Rates Under Contingent Scenarios*, 24 Value in Health 1533 (2021), https://www.sciencedirect.com/science/article/pii/S1098301521015825.

[16] John LaMattina, *What's driving the COVID-19 vaccine price increases?* Forbes (Oct. 26, 2022), https://www.forbes.com/sites/johnlamattina/2022/10/26/whats-driving-the-covid-19-vaccine-price-increases/?sh=46eacefa4f69 ("One has to wonder if this will hurt efforts to combat new COVID-19 variants as those without insurance (roughly 10% of Americans) will likely not want to pay for the vaccine themselves thereby adding a new dimension to vaccine hesitancy.").

[17] Press Release, Moderna Inc., Moderna's Commitment to Patient Acess in the United States (Feb. 15, 2023), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx.

offices or local pharmacies."[18] Moderna has also promised that, "[f]or uninsured or underinsured people, Moderna's patient assistance program will provide COVID-19 vaccines at no cost," beginning on May 12, 2023.[19] To my knowledge, Moderna has not provided any further details of its planned patient assistance program.

There are many reasons to be skeptical about Moderna's patient assistance program. It may not reach all un- and underinsured Americans.

Drug-company-sponsored patient assistance programs tend to be complicated and confusing, and they tend to miss people—especially those already most marginalized by our broken healthcare system.[20] For example, Niteesh Choudry and co-authors have observed that "[t]he application processes [for patient assistance programs] are generally complex, with reading levels greater than those suggested for patients with low health literacy (a problem that is particularly relevant for patients with insufficient insurance coverage)."[21] These programs impose burdensome paperwork on patients who seek to use them. For example, a majority of drug companies' patient programs exclude uninsured people who make "too much" money, and enrollment typically requires patients to submit proof of income.[22]

Commentators have voiced these concerns vis-a-vis Moderna's proposed patient assistance program.[23] There is a real risk it will miss many Americans—including many of the most vulnerable.

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[18] *Id.*

[19] *Id.*

[20] *See, e.g.*, Katie Wedell, *Is prescription copay assistance contributing to rising drug prices? Why buyers should beware*, USA Today (Nov. 3, 2022),

https://www.usatoday.com/story/money/2022/11/01/prescription-copay-assistance-role-rising-drug-prices/10555488002/ (summarizing how drugmakers' patient assistance programs can be complicated, impose income restrictions, or limit access to people on certain types of insurance); Amy Killelea et al., *Financing and delivering pre-exposure prophylaxis (PrEP) to end the HIV epidemic* 50 J. L., Medicine & Ethics 8, https://doi.org/10.1017/jme.2022.30 (describing patient assistance programs for HIV medicines as "overly complex" and "difficult-to-navigate").

[21] Niteesh K. Choudhry et al., *Drug Company–Sponsored Patient Assistance Programs: A Viable Safety Net?*, 28 Health Affairs (Millwood) 827 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2873618/.

[22] *Id.*

[23] *See, e.g.*, Susanna Speier, *Moderna's patient assistance program promises to cover uninsured and underinsured Americans' vaccination and booster shot costs after May 11, 2023*, Immunocompromised Times (Feb. 20, 2023), https://immunocompromisedtimes.substack.com/p/will-modernas-patient-assistance; Sydney Lupkin, *Moderna announced a free COVID vaccine program. But will that be accessible enough?*, NPR (Mar. 2, 2023), https://www.npr.org/2023/03/02/1160714581/moderna-announced-a-free-covid-vaccine-program-but-will-that-be-accessible-enoug (quoting Larry Levitt, executive vice president for health policy at the Kaiser Family Foundation, as stating, "We are having trouble getting people vaccinated and boosted. And people who are uninsured are the

And, as I write this testimony, Moderna has shared nothing more substantive than a press release about its proposed patient assistance program.[24] It is unclear how exactly Moderna will implement this program; the company has never administered one before.

I hope that Moderna will fulfill the promises about a patient assistance program that it has made to the American public. I'm concerned, not just about the company's capacity but its sincerity. As I show below, Moderna is a company with an unfortunate track record of broken promises and false statements.[25] These broken promises and false statements are reason to demand from Moderna some concrete details of this still-hypothetical program.

2. Harm to all Americans

Even Americans who can expect their health insurance to fully cover the cost of a COVID-19 booster shot would be harmed by Moderna's proposed price increases. If Moderna charges higher prices to insurers, public and private, those prices will be "passed on" to all of us in the form of higher premiums. Kates, Cox & Michaud note that "[w]hile most people will still be able to get COVID-19 vaccines for free, these costs will be borne by both public and private vaccine payers."[26] They observe that "[f]or private insurers and their enrollees, these costs are expected to have an upward effect on premiums. Our recent analysis of 2023 premium filings from ACA Marketplace insurers found that some insurers say the end to federal purchasing could have a small upward effect on premiums next year. These costs could continue to push premiums upward in future years as well, particularly if private insurers under-estimated the cost of the vaccine dose before Pfizer and Moderna's price announcements."[27]

Indeed, even people with no need or wish for a COVID-19 booster shot in the near future should be concerned about the pressure Moderna's proposed price increases would place on Medicare premiums and the systemic costs of Medicare, borne by all Americans. As Kates, Cox & Michaud describe, "[t]hus far, about four in ten adults who have received an updated booster dose are over age 65 and likely covered by Medicare, while the remaining two thirds are likely primarily covered by either Medicaid or private insurance. As older adults are more likely to opt

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least likely to be vaccinated. So this is already a very hard to reach group and it's going to get harder even with this patient assistance program.").

[24] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

[25] Infra § III.C.

[26] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

[27] Id.

for booster shots, a disproportionate share of the total national spending [on COVID-19 boosters] may be borne by the Medicare program." Kates, Cox & Michaud also observe that Medicare pays close to full list price—such that if Moderna sets a price of $110 or $130 per dose, all American taxpayers would end up footing the bill for doses sold at over $100 apiece.[28]

Moderna and Pfizer each individually predict that about 100 million COVID-19 booster shots will be consumed in the United States in 2023.[29] If the companies end up charging an average net price of somewhere between $70 and $100 a dose, these 100 million doses would represent $7 to $10 billion of spending in the United States healthcare system. And, right now, it seems there is little to stop Moderna and Pfizer from increasing prices further in the future. It is clear COVID-19 boosters will remain "blockbuster" products for years to come—some of the most important and most costly medical products that our country consumes. We all have a stake in ensuring a fair price.

B. Moderna's proposed price increases are unjustifiable.

1. Moderna's claim of "value-based pricing" doesn't hold up to scrutiny.

Mr. Bancel and other representatives of Moderna claim that U.S. booster prices of $110, $130, or more are justified on the basis of the products' therapeutic and economic value.[30]

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[28] *Id.* ("For most preventive vaccines, Medicare pays 95% of the average wholesale price, which is often referred to as the 'list' price, but we do not account for this potential modest discount in our cost illustrations above.").

[29] Tyler van Buren, Tara Bancroft, Ph.D., and Brittany Woods, Ph.D., *Highlights from dinner with MRNA management at the 43rd Annual TD Cowen HC conference*, TD Cowen Equity Research (Mar. 6, 2023), https://tdcowen.bluematrix.com/docs/pdf/ab749e44-cf3c-443f-98f1-7ef0158b2002.pdf (" Moderna expects the 2023 US COVID-19 market volume to be ~100m doses based on 2022 vaccination rates (30% overall, including 16% BA. 4/5 bivalent booster uptake), which is consistent with Pfizer's 102m dose guidance").

[30] E.g., Beth Mole, *Moderna CEO: 400% price hike on COVID vaccine "consistent with the value"*, Ars Technica (Jan. 10, 2023, 2:21 PM), https://arstechnica.com/science/2023/01/moderna-may-match-pfizers-400-price-hike-on-covid-vaccines-report-says/ (Mr. Bancel: "I would think this type of pricing is consistent with the value."); Anjalee Khemlani, *'We agree that vaccines should be free': Moderna's Noubar Afeyan*, Yahoo Finance (Jan. 12, 2023), https://ca.finance.yahoo.com/news/we-agree-that-vaccines-should-be-free-modernas-noubar-afeyan-162811494.html (Noubar Afeyan: "[Noubar Afeyan, co-founder and board chair of Moderna] also noted that the economic value of a vaccine — preventing costly hospital visits — differs from the public health view of a vaccine's role. 'I think it's a hard argument to make in value-based pricing to say that vaccines ought to be priced at 10 cents ... That, I think, comes not form the economic argument, that comes from the public health argument,' Afeyan said."); Michael Hiltzik, *Column: Moderna and Pfizer are are jacking up the price of COVID vaccines. The government should stop them*, Los Angeles Times (Jan. 24, 2023, 11:41 PM), https://www.latimes.com/business/story/2023-01-24/column-moderna-and-pfizer-are-jacking-up-the-price-of-covid-vaccines-the-government-should-stop-them ("'Moderna is committed to pricing that reflects the value that COVID-19 vaccines bring to patients, healthcare systems, and society,' company spokesman Christopher Ridley said by email."); Yahoo Finance, *COVID-19: Moderna price hike to reflect 'the value of the vaccine,' company president*

I agree that the NIH-Moderna vaccine is valuable. However, in my view, value is not a credible basis on which Moderna could quadruple or quintuple the product's price.

In this subsection, I analyze Moderna's assertion of "value-based pricing," starting from one simple question: Can Moderna claim the value of the NIH-Moderna vaccine? The answer is no. The American public has at least as strong a claim as Moderna to the value of this vaccine. I will show as much from two distinct perspectives: scientific and financial. Let's start with the scientific perspective.

The scientific history shows the value created by the American taxpayer.

The scientific history of the NIH-Moderna vaccine suggests that the American taxpayer created at least as much scientific, therapeutic, and economic value as Moderna did.

I will trace here three key scientific features of the NIH-Moderna vaccine:

a. The immunogen—the chemically modified coronavirus spike protein the vaccine produces once inside the body, sparking a protective immune response;
b. The modified mRNA—the stabilized, chemically modified mRNA that "encodes" the immunogenic spike protein; and
c. The delivery system—the lipid nanoparticle that helps the mRNA stay stable and enter cells in the body to begin producing protein.

Moderna and its scientists have at different points identified these three features of the NIH-Moderna vaccine as particularly important.[31]

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says (Mar. 17, 2023) https://finance.yahoo.com/video/covid-19-moderna-price-hike-160246621.html (Moderna's President Stephen Hoge stating, "what we're trying to do, as one of the many manufacturers in this space, is pick a price that we think reflects the value of the vaccine, the value both to patients and health care systems and payers, and ultimately, in terms of lives and costs saved, but that also reflects the complexity of moving from this pandemic market to a commercial market.").

[31] A 2020 paper co-authored by Moderna scientists, NIH scientists, and other states that "[t]he rapid and robust immunogenicity profile of the [NIH-Moderna] vaccine most likely results from an innovative structure-based vaccine antigen design [i.e., the immunogen], coupled with a potent lipid-nanoparticle delivery system [i.e., the delivery system], and the use of modified nucleotides that avoid early intracellular activation of interferon-associated genes [i.e., the modified mRNA]." Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, 383 NEW ENGL. J. MED. 1920, 1929 (2020). Moderna also highlights these same three key features of mRNA-based COVID-19 vaccines in its complaint for patent infringement against Pfizer and BioNTech. Complaint at 6, *ModernaTX v. Pfizer*, No 1:22-cv-11378 (D. Mass., Aug. 26, 2022) (identifying the SARS-CoV-2 spike protein sequence encoded by the Pfizer-BioNTech and the Pfizer-BioNTech chemically-modified-mRNA platform as "critical features" of the Pfizer-BioNTech vaccine); *id.* at 17 (asserting that "packaging [] chemically-modified mRNA in a lipid nanoparticle formulation allow[s] for the efficient delivery of the mRNA to cells"). These

As I show below, Moderna did not invent any of these three features on its own. Indeed, how much contribution Moderna made to any of these three features is unclear.

In addition, Moderna received extensive help from the US government (via the National Institute of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DOD)) to combine these three features—and others—into one product. That is, the U.S. government helped Moderna coordinate its overall research and development effort and shepherded the NIH-Moderna vaccine into clinical trials. I describe this coordination help below.

The immunogen

Spike proteins are the primary weapon that coronaviruses—including SARS-CoV-2—use to invade human cells. They are proteins on the surface of virus particles that attach onto human host cells.[32] Once attached, the spike protein fuses with the human host cell, changing the structure of the spike protein—and permitting the virus to invade.[33] After fusion of the virus and host cell has occurred, the coronavirus's genes begin instructing the human host cell to make more copies of the virus. This replication is what produces the COVID-19 infection.

The NIH-Moderna vaccine works by prompting the cells of our bodies to create the SARS-CoV-2 spike protein, which in turn prompts production of antibodies and other immune responses. To quote the CDC, Moderna's vaccine encodes a "harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future."[34]

However, the NIH-Moderna vaccine does not encode and make, in the human body, the naturally occurring version of the SARS-CoV-2 spike protein. Instead, it encodes and makes a chemically modified version of the spike protein. Specifically, Moderna's vaccines use mRNA that encodes SARS-CoV-2 spike protein that is chemically modified with changes to its amino

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three key features of Moderna's vaccine have also been highlighted by other analysts, such as Kaiser Health News journalist Arthur Allen. Arthur Allen, *Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines*, Kaiser Health Network (Nov. 18, 2020), https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/.

[32] Ryan Cross, *The Tiny Tweak Behind COVID-19 Vaccines*, Chem. & Eng'g News (Sept. 29, 2020), https://cen.acs.org/pharmaceuticals/vaccines/tiny-tweak-behind-COVID-19/98/i38 ("Viruses multiply by dumping their genes into our cells and hijacking our cellular machinery to crank out new virus particles. But first, they need a doorway into our cells. Coronaviruses are studded with spikes, which grab hold of proteins decorating our own cells like doorknobs.").

[33] *Id.*

[34] *Overview of COVID-19 Vaccines: Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines*, Ctrs. for Disease Control & Prevention (Nov. 1, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html#mrna.

acid sequence, to stabilize the protein in its prefusion configuration, which increases immunogenicity and thus protection.[35] Moderna relies on this chemical modification in every dose of vaccine it makes and sells. In Moderna's own words, the original NIH-Moderna COVID-19 vaccine contained "nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2" virus.[36] Today, Moderna's bivalent booster shots rely on the same chemical modification.[37] Moderna agrees that this spike protein is the key active ingredient in its vaccines that confers immunity: "The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."[38] Moderna scientists also co-authored with NIH scientists a 2020 paper that stated, "[t]he rapid and robust immunogenicity profile of the [NIH-Moderna] vaccine most likely results from an innovative structure-based vaccine antigen design"[39]—i.e., the chemically modified spike protein stabilized in its prefusion configuration.

This key immunogen in the NIH-Moderna vaccine—the chemically modified coronavirus spike protein stabilized in its prefusion configuration—was not invented by Moderna. Instead, it was invented by NIH scientists working with NIH-funded academic collaborators at the Scripps Research Institute and Dartmouth College. This group of scientists included Kizzmekia Corbett (NIH), Barney Graham (NIH), Jason McClellan (Dartmouth), and Nianshuang Wang (Dartmouth). Their work was done in the 2010s, years before SARS-CoV-2 emerged and years before Moderna began any work on coronaviruses. In 2016, NIH and academic inventors filed a first patent application on their invention[40] and described the invention as a promising basis for coronavirus vaccines, "produc[ing] a superior immune response" when tested against a wide

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[35] Arthur Allen, *Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines*, KHN (Nov. 18, 2020), https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/.

[36] Fact Sheet for the Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna Covid-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19), Moderna U.S., Inc. at 34 (Revised: Dec. 8, 2022), https://eua.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf (emphasis added).

[37] Letter from Peter Marks, Director of Center for Biologics Evaluation and Research at FDA to Michelle Olsen, ModernaTX, Inc. at 20-22 (Dec. 8, 2022), https://www.fda.gov/media/144636/download (describing Moderna's bivalent booster shots sold in the U.S. as containing "mRNA encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Wuhan-Hu-1 strain (Original)" and "mRNA encoding the pre-fusion stabilized S-protein of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 (Omicron BA.4/BA.5)").

[38] Moderna U.S., Inc., *supra* n. 36 at 34.

[39] Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, 383 New Engl. J. Med. 1920, 1929 (2020), https://www.nejm.org/doi/full/10.1056/nejmoa2022483.

[40] U.S. Patent No. 10,960,070 (issued Mar. 30, 2021).

range of different coronaviruses.[41] Many of these inventors also published a high-profile 2017 scientific publication.[42] Even before SARS-CoV-2 emerged, others in the field described the NIH/Dartmouth/Scripps invention as "instrumental to design better immunogens" for coronavirus vaccines[43] and as providing "a basis for the design of structure-based CoV [coronavirus] vaccines."[44]

This research by NIH and its academic collaborators was critical and remarkably prescient. As NIH has observed, "Years before the COVID-19 pandemic began, experts at the NIH Vaccine Research Center (VRC) were studying coronaviruses to find out how to protect against them. The scientists chose to focus on one 'prototype' coronavirus and create a vaccine for it. That vaccine could then be customized to fight different coronaviruses. It was important that this vaccine be three things:" fast, reliable, and universal.[45]

Thus, when SARS-CoV-2 emerged, NIH's innovative coronavirus vaccine immunogen was on the shelf, ready to go. In NIH's words, "[h]aving this prototype approach, along with coronavirus research from labs around the world, made it possible for scientists to spring into action when the pandemic hit. Many vaccines take 10 to 15 years to reach the public. But the timeline for the COVID-19 vaccine was very different." NIH has also said, "[t]he COVID-19 outbreak in China was first reported publicly on December 31, 2019. By the second week of January 2020, researchers in China published the DNA sequence of SARS-CoV-2, the coronavirus that causes COVID-19. The [NIH Vaccine Research Center] worked with a company called Moderna to use this information to quickly customize their prototype approach to the SARS-CoV-2 spike protein. By early February, a COVID-19 vaccine candidate had been designed and manufactured. This vaccine is called mRNA-1273"[46]—the NIH-Moderna vaccine.

Independent accounts corroborate the fact that it was NIH, not Moderna, that invented the NIH-Moderna's vaccine specific immunogen (and the specific mRNA sequence encoding that

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[41] *Id.* at 2:7; 80:40-47; 83:7-12.

[42] Jesper Pallesen et al., *Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen*, PNAS (Aug. 29, 2017), https://www.pnas.org/content/114/35/E7348.long.

[43] Reham A. Al Kahlout et al., *Comparative Serological Study for the Prevalence of Anti-MERS Coronavirus Antibodies in High- and Low-Risk Groups in Qatar*, 2019 J. Immunology Rsch. (Feb. 18, 2019), https://www.hindawi.com/journals/jir/2019/1386740/.

[44] Yan-Hua Li et al., *Molecular Characteristics, Functions, and Related Pathogenicity of MERS-CoV Proteins*, 5 Eng'g 940, 945 (July 17, 2019), https://www.sciencedirect.com/science/article/pii/S2095809918307598#bb0025.

[45] *COVID-19 Vaccine Development: Behind the Scenes*, Nat'l Insts. of Health (Last visited Mar. 16, 2023), https://covid19.nih.gov/news-and-stories/vaccine-development. *See also* Anthony S. Fauci, *The story behind COVID-19 vaccines*, 372 Science at 109, https://www.science.org/doi/10.1126/science.abi839. (NIAID Director Dr. Tony Fauci describing NIH's prescient research).

[46] *Id.*

immunogen).[47] For example, Wall Street Journal reporter Peter Loftus describes this exchange between NIH's Barney Graham and Moderna's Stéphane Bancel in January 2020:

> Early in the process, when Bancel was still in Cannes with his family on vacation, he emailed Barney Graham, the veteran vaccine researcher at NIAID, to ask if he and his colleagues had learned the genetic sequence of the virus. This knowledge would allow the design of the right sequence of messenger RNA that could be used in a vaccine to trigger the right immune response.
>
> Graham said his team was on it. "If it's a SARS-like CoV we know what to do and have proven that mRNA is effective at a very low dose . . . this would be a great time to run the drill for how quickly can you have a scalable vaccine," Graham wrote back to Bancel.
>
> "Let us know in real time," Bancel wrote to Graham. "I will get the team aware of it and ready to run when you give us a sequence."[48]

Moderna had not previously worked on a coronavirus vaccine; it relied on NIH's long-standing expertise in this field.

Loftus also describes how Kizzmekia Corbett and other NIH researchers selected a precise sequence for the optimal, chemically modified, prefusion-stabilized SARS-CoV-2 spike protein and sent it to Moderna. Upon receipt of NIH's sequence, Moderna's scientists "agreed with [NIH's] assessment"[49] that NIH's sequence was optimal: "By Monday, January 13 [2020], three days after the [SARS-CoV-2 spike protein] sequence was posted, Corbett and the [NIH Vaccine Research Center] researchers had landed on what they felt was the best sequence of the spike protein to use in a vaccine, and the Moderna scientists agreed with their assessment."[50]

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[47] *See* David Heath & Gus Garcia-Roberts, *Luck, foresight and science: How an unheralded team developed a COVID-19 vaccine in record time*, USA Today (Jan. 31, 2021), https://www.usatoday.com/in-depth/news/investigations/2021/01/26/moderna-covid-vaccine-science-fast/6555783002/ (stating that NIH's Barney "Graham convened over the phone with scientists at Moderna two days later to sketch out the road map. Moderna would produce the vaccine, using the genetic code Graham provided. It would be the only vaccine for which the government would lead the first clinical trial, a trial Graham wanted to launch in a matter of weeks" and that "Graham's team [at NIH] designed a vaccine").

[48] Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 98.

[49] *Id.* at 101; *see also* COVID-19 Vaccine Development: Behind the Scenes, Nat'l Insts. of Health, *supra* n. 45; Harmeet Kaur, Fauci wants people to know that one of lead scientists who developed the Covid-19 vaccine is a Black woman, CNN (Dec. 10, 2020), https://www.cnn.com/2020/12/09/us/african-american-scientists-vaccine-development-trnd/index.html (NIAID Director Anthony Fauci stating that the NIH-Moderna vaccine "was actually developed in my institute's vaccine research center by a team of scientists led by Dr. Barney Graham and his close colleague, Dr. Kizzmekia Corbett, or Kizzy Corbett.").

[50] *Ibid.*

I mentioned above that NIH and its academic collaborators at Scripps and Dartmouth filed patent applications in the 2010s on their general-purpose coronavirus vaccine immunogen invention. These applications became a legally enforceable U.S. patent in early 2021—U.S. Patent No. 10,960,070.

PrEP4All, Public Citizen, four other civil society groups, and over a dozen prominent scientists sent a public letter to NIH and HHS, observing that Moderna likely relies on and infringes the patent, U.S. Patent No. 10,960,070.[51] In April 2021, my co-authors Laurel Boman, Joseph Rabinovitsj, Celine Rohr, and I published a report that confirmed that Moderna did indeed infringe the patent.[52] At the time, I observed that "Moderna infringes the National Institute of Health's patent with every dose of vaccine it makes or sells in the US."[53]

Moderna has never explicitly admitted—at least publicly—that it relies on NIH's patented immunogen technology. However, in February 2023, the company announced that it had finally paid NIH, Scripps, and Dartmouth for a license to the patent, thereby tacitly acknowledging its infringement and reliance on this publicly funded, publicly created technology.[54] Moderna agreed to pay NIH and its academic collaborators $400 million and an ongoing royalty on its vaccine sales[55]—further evidence of how central this public invention is to the NIH-Moderna vaccine.

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[51] Letter from PrEP4All et al. to Xavier Becerra et al. RE: Moderna and Its Use of an NIH-Owned Patent for COVID-19 Vaccines (Mar. 24, 2021), https://www.prep4all.org/news/nih-letter; Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. Times (Pub. Mar. 21, 2021, Rev. Nov. 10, 2021), https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html?smid=tw-share; Christopher Rowland, *Advocates want NIH to use its Moderna vaccine patent to push for global access*, Washington Post (Mar. 25, 2021), https://www.washingtonpost.com/business/2021/03/25/moderna-vaccine-patent-nih/. *See also Analysis: Pfizer Vaccine Relies on U.S. Government-Developed Spike Protein Technology*, Pub. Citizen (Nov. 10, 2020), https://www.citizen.org/news/analysis-pfizer-vaccine-relies-on-u-s-government-developed-spike-protein-technology/ (2020 Public Citizen report highlighting the NIH-owned patent application that would become the '070 patent).

[52] Christopher Morten et al., U.S. 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent, N.Y.U. Tech. L. & Pol'y Clinic (2021); Donato Paolo Mancini & Kiran Stacey, *Vaccine patent gives US 'leverage' over manufactures*, Fin. Times (Apr. 21 2021), https://www.ft.com/content/d0c70cc2-0ffa-42dd-b0d0-0f76eeb273f0.

[53] Mancini & Stacey, *supra* n. 52.

[54] Benjamin Mueller, *After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique*, N.Y. Times (Feb. 23, 2023), https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html; *Moderna-NIG Agreement on Publicly-Funded Discovery Will Be Dwarfed by Moderna's Unconscionable Price Spike*, Pub. Citizen (Feb. 24, 2023), https://www.citizen.org/news/moderna-nih-agreement-on-publicly-funded-discovery-will-be-dwarfed-by-modernas-unconscionable-price-spike/.

[55] Mueller, *supra* n. 54.

The modified mRNA

Naturally occurring mRNA is composed of four building blocks, or "nucleobases": guanine, uracil, adenine, and cytosine. When injected into a human body, mRNA composed of these natural building blocks can spark dangerous immune responses, such as allergic reactions and even anaphylactic shock.[56]

Thus, the mRNA in the NIH-Moderna vaccine is not composed of the four naturally occurring building blocks. Instead, the building blocks of the mRNA in the NIH-Moderna vaccine are modified; the result is called "nucleoside-modified mRNA." The NIH-Moderna vaccine specifically uses a nucleoside-modified mRNA in which all the uridine bases with a chemical variant known as N1-methylpseudouridine. This modified mRNA is less likely to cause a harmful immune response and more likely to prompt production of the desired protein.[57] As Moderna explains, "[o]ur mRNA is made with modified chemistry, replacing the uridine nucleoside found in mammalian mRNA with N1-methylpseudouridine (N1mψ), naturally found in transfer RNA (tRNA), to evade the host innate immune response mechanisms."[58]

Who invented the use of N1-methylpseudouridine in nucleoside-modified mRNA? It was not Moderna. It was instead researchers working at the University of Pennsylvania, including Katalin Karikó and Drew Weissman. As Karikó wrote in a 2021 retrospective,

> We set out to generate RNA with modified nucleosides by in vitro synthesis. Surprisingly, the replacement of uridine with pseudouridine rendered the RNAs non-immunogenic (Karikó, K. et al., 2005).
>
> In subsequent studies we demonstrated that mRNA containing pseudouridine was an ideal molecule for protein replacement therapy because it was efficiently translated and, unlike its unmodified counterpart, did not induce interferon in mice. Indeed, the injection of a small amount of mRNA was sufficient for the encoded

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[56] Kellie D. Nance & Jordan L. Meier, *Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines*,7 ACS Central Science 748, 751 (2021) ("[A] challenge to application of these agents as vaccines and protein replacement therapies was their immunogenicity. Cells contain a variety of pattern recognition receptors whose natural role is to identify and respond to viral RNAs by inducing downstream signaling. … While induction of an immune response is theoretically a positive attribute for a vaccine, uncontrolled immune activation can lead to allergic reactions and anaphylactic shock."); Katalin Karikó, *Modified uridines are the key to a successful message,* 21 Nature Reviews Immunology 619, 619 (2021) ("[W]e found that transfecting human dendritic cells (DCs) with mRNA, or even with non-coding ribonucleotide homopolymers, induced inflammatory cytokines (Ni, H. et al., 2002)."); Kellie D. Nance & Jordan L. Meier, *Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines,* 7 ACS Central Science 748, 750-751 (2021) ("When injected into mouse muscle, reporter mRNAs produced detectable proteins for weeks. However, a challenge to application of these agents as vaccines and protein replacement therapies was their immunogenicity.").

[57] Nance & Meier, *supra* n. 56 at 753.

[58] Moderna, *Our approach to mRNA Vaccines*, https://mrna-access.modernatx.com/technology (last visited Mar. 18, 2023).

> protein to exert its therapeutic effect (Karikó, K. et al., 2008; Karikó, K. et al., 2012).
>
> In parallel to these studies, we investigated mRNA as a platform for vaccine development. We predicted that uridine-containing (and thereby self-adjuvanted) mRNA encoding viral antigens would be optimal for vaccine development. Amazingly, non-immunogenic mRNA containing modified uridines also turned out to be a more suitable molecule for vaccine development (Pardi et al., 2017). Indeed, the first mRNA-based vaccines to receive regulatory authorization — developed by Moderna and by BioNTech/Pfizer for CovID-19 — are both based on 1-methylpseudouridine-containing mRNA.[59]

Others similarly recognize Karikó and Weissman as the main inventors of this key feature of the NIH-Moderna vaccine.[60]

To my knowledge, Moderna has not expressly acknowledged that the N1-methylpseudouridine-based modified mRNA used in the NIH-Moderna vaccine (and other Moderna product candidates) was initially invented by Karikó and Weissman. However, Moderna has licensed multiple patents filed by Karikó and Weissman on their N1-methylpseudouridine modification.[61] According to Peter Loftus, Moderna had paid over $600 million in royalties on these patents as of 2022.[62] Harold Brubaker of the Philadelphia Inquirer reported in June 2022 that Moderna may have paid over $800 million in royalties on these and related patents.[63]

Karikó and Weissman's work at the University of Pennsylvania to create modified mRNA was supported by NIH–i.e., the American taxpayer. Indeed, Luis Gil Abinader at Knowledge Ecology International has shown that many patents filed by Karikó, Weissman, and

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[59] Karikó, *supra* n. 56 at 619.

[60] E.g., Gina Kolata, *Kati Kariko Helped Shield the World From the Coronavirus*, N.Y. Times (Sept. 24, 2021) https://www.nytimes.com/2021/04/08/health/coronavirus-mrna-kariko.html (stating that Karikó's work, "with her close collaborator, Dr. Drew Weissman of the University of Pennsylvania, laid the foundation for the stunningly successful vaccines made by Pfizer-BioNTech and Moderna"); Damian Garde & Jonathan Saltzman, *The story of mRNA: How a once-dismissed idea became a leading technology in the Covid vaccine race,* STAT (Nov. 10, 2020) https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/ (Karikó and Weissman "creat[ed] a hybrid mRNA that could sneak its way into cells without alerting the body's defenses"); Anthony S. Fauci, Editorial, *The story behind COVID-19 vaccines*, Science (Apr. 9, 2021) https://www.science.org/doi/10.1126/science.abi8397 (Tony Fauci writes, "The RNA approach evolved over several years owing to the ingenuity of individual scientists, including Drew Weissman and Katalin Karikó, and the concentrated efforts of several biotech and pharmaceutical companies.").

[61] Garde & Saltzman, *supra* n. 60. *See also* Loftus, *supra* n. 48 at 83 (describing Moderna's decision to license and use Karikó and Weissman's patented technology rather than design around).

[62] Loftus, *supra* n. 48 at 266.

[63] Harold Brubaker, *Vaccine research pays big for Penn*, Philadelphia Inquirer (Jun. 12, 2022).

their collaborators (and later licensed and relied on by Moderna) acknowledge NIH grants as having supported their foundational research.[64]

The delivery system

The mRNA in the NIH-Moderna vaccine is encapsulated in a nanoparticle delivery system that keeps the mRNA sufficiently stable to make its way into cells and begin making the immunogenic spike protein. These nanoparticles are made of chemicals called lipids. To quote Moderna itself, "[t]he nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen [i.e., the spike protein]."[65]

These lipid nanoparticles are essential to the efficacy of the NIH-Moderna vaccine. As Moderna scientists co-wrote with NIH and other co-authors in 2020, "[t]he rapid and robust immunogenicity profile of the [NIH-Moderna] vaccine most likely results from an innovative structure-based vaccine antigen design, ***coupled with a potent lipid-nanoparticle delivery system***, and the use of modified nucleotides that avoid early intracellular activation of interferon-associated genes."[66] Independent analysts agree the nanoparticles are essential to the success of the NIH-Moderna vaccine and other mRNA-based vaccines.[67]

Who invented the lipid nanoparticles that stabilize the mRNA in the NIH-Moderna vaccine? Here the scientific history is complicated. As Matt Herder, E. Richard Gold, and Srinivas Murthy have written, "[t]he story behind the development of the LNP [lipid nanoparticle] delivery system is complex. According to patent filings, the LNP technology was originally invented in the mid-2000s by several scientists, including Ian MacLachlan, who were then employed at Protiva Biotherapeutics. Understanding who controls the LNP delivery system and what products it has been integrated into is, however, clouded by an array of corporate transactions, trade secrecy, regulatory rules and multiple rounds of litigation."[68] It seems, however, that the lipid nanoparticles used in mRNA vaccines have roots in publicly funded

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[64] Luis Gil Abinader, *Foundational mRNA patents are subject to the Bayh-Dole Act provisions*, Knowledge Ecology International (Nov. 30, 2020), https://www.keionline.org/34733.

[65] Moderna U.S., Inc., *supra* n. 36 at 34.

[66] Lisa A. Jackson et al., *supra* n. 39 at 1929 (emphasis added).

[67] See, e.g., Ryan Cross, *Without these lipid shells, there would be no mRNA vaccines for COVID-19*, Chem. & Eng'g News (Mar. 6, 2021), (https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8 ("To protect the fragile [mRNA] molecule as it sneaks into cells, [scientists] turned to a delivery technology with origins older than the idea of mRNA therapy itself: tiny balls of fat called lipid nanoparticles, or LNPs.").

[68] Matthew Herder et al., *University Technology Transfer Has Failed to Improve Access to Global Health Products during the COVID-19 Pandemic*, 17(4) Healthcare Policy 15, 17 (May 2022).

research in Canada, at the University of British Columbia. As Reshma Ramachandran has written—in summarizing the investigation of Herder et al.—these lipid nanoparticles have origins "at the University of British Columbia (UBC). Through significant financial support from the [Canadian] federal government, researchers at UBC developed the LNP delivery system, filing patents and licensing this technology to various entities including spin-off companies founded by these researchers, as well as COVID-19 mRNA vaccine manufacturers."[69]

Moderna seems to rely on lipid nanoparticle technology very similar to the above. As Nathan Vardi reported in Forbes in 2021, "scientific papers and regulatory documents filed with the FDA show that both Moderna and Pfizer-BioNTech's vaccines use a delivery system strikingly similar to what [Ian] MacLachlan and his team created—a carefully formulated four-lipid component that encapsulates mRNA in a dense particle through a mixing process involving ethanol and a T-connector apparatus."[70] Vardi concludes that "when humanity needed a way to deliver mRNA to human cells to arrest the pandemic, there was only one reliable method available—and it wasn't one originated in-house by Pfizer, Moderna, BioNTech or any of the other major vaccine companies."[71] A 2021 paper co-authored by mRNA pioneer Drew Weissman similarly concluded that Moderna's lipid nanoparticles are similar to those that MacLachlan had developed, with some small changes made by Moderna's own scientists.[72]

Vardi notes that Moderna "vigorously disputes the idea that its mRNA vaccine uses MacLachlan's delivery system.... Legal proceedings are pending, and big money is at stake."[73] Because of Moderna's secrecy, it is hard to tell exactly how much Moderna relies on others' lipid nanoparticle technology and how much the company has itself contributed. Herder and co-authors noted that "outsiders cannot discern what precise LNP formulation is in use or whether

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[69] Reshma Ramachandran, *Commentary: Fulfilling the Promise of Global Access Licensing Principles to Enable Equitable Access*, 17(4) Healthcare Policy, 37, 38 (May 2022). See also, Elie Dolgin, *The tangled history of mRNA vaccines*, 597 Nature 318, 322 (Sept. 16, 2021) ("As for linchpin technologies, many experts highlight another innovation that was crucial for mRNA vaccines — one that has nothing to do with the mRNA. It is the tiny fat bubbles known as lipid nanoparticles, or LNPs, that protect the mRNA and shuttle it into cells. This technology comes from the laboratory of Pieter Cullis, a biochemist at the University of British Columbia in Vancouver, Canada, and several companies that he founded or led.").

[70] Nathan Vardi, *Covid's Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made the Vaccines Possible*, Forbes (Apr. 17, 2021), https://www.forbes.com/sites/nathanvardi/2021/08/17/covids-forgotten-hero-the-untold-story-of-the-scientist-whose-breakthrough-made-the-vaccines-possible/?sh=53d73f4e354f.

[71] *Id.*

[72] Michael D. Buschmann et al., *Nanomaterial Delivery Systems for mRNA Vaccines*, 2021 Vaccines, 3 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7836001/pdf/vaccines-09-00065.pdf. *See also* Vardi, *supra* n. 70 ("After the Moderna and Pfizer-BioNTech vaccines were authorized, Drew Weissman, a prominent mRNA researcher at the University of Pennsylvania, concluded in a peer-reviewed journal that both use delivery systems that are 'similar to the Alnylam Onpattro product' but with a proprietary version of one of the lipids.").

[73] *Id.*

the LNP technology within the Pfizer/BioNTech and NIH/Moderna vaccines is one and the same."[74] Science journalist Ryan Cross similarly noted in 2021 that "details on how Moderna arrived at its optimal [vaccine] formulation in the first place are scant. The company did not grant an interview to talk about its nanoparticle development…."[75]

Based on the factual record we have, it seems clear that Moderna's critical lipid nanoparticle delivery system relies at least to some extent on technology developed by other companies. The company cannot claim to have invented this key feature of the NIH-Moderna on its own. Moderna has been sued for patent infringement by Genevant, Alnylam, and Arbutus (a UBC spin-off company) for allegedly relying on those companies' patented lipid nanoparticle technology without their permission.[76] Those cases remain pending as I write; to my knowledge, Moderna has not conceded infringement or paid for a license to any of Genevant, Alnylam, and Arbutus's patents.

Coordination of the overall effort

Now let's see how Moderna and NIH put these three features, and others, together to create the NIH-Moderna vaccine. As part of Operation Warp Speed, Moderna received enormous—unprecedented—help from NIH and other federal agencies to orchestrate the creation of a new vaccine on a remarkably short deadline.[77] Numerous publications describe how Barney Graham, Kizzmekia Corbett, and other NIH scientists worked hand-in-hand with Moderna to develop the NIH-Moderna vaccine in record time.[78] News coverage from 2020 and 2021 often (correctly) described the NIH-Moderna as co-created, co-designed, or co-developed

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[74] Herder et al., *supra* n. 68 at 21.

[75] Ryan Cross, *Without these lipid shells, there would be no mRNA vaccines for COVID-19*, Chem. & Eng'g News (Mar. 6, 2021), https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8

[76] Dan Shores, *mRNA IP 2022 Year in Review: Pioneers Clash in Major Patent Litigations*, IP Watchdog (Jan. 1, 2023), https://ipwatchdog.com/2023/01/01/mrna-ip-2022-year-in-review-pioneers-clash-in-major-patent-litigations/id=154489/.

[77] Operation Warp Speed:

Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges

GAO-21-319, Government Accountability Office (Feb. 11, 2021), https://www.gao.gov/products/gao-21-319

[78] See, e.g., Melissa Glim,*That Record-breaking Sprint to Create a COVID-19 Vaccine*, 29 The NIH Catalyst 1 (2021), https://irp.nih.gov/catalyst/29/5/that-record-breaking-sprint-to-create-a-covid-19-vaccine ("Dr. Corbett was directing a team doing coronavirus work, and we had relationships with three or four really good academic collaborators and had been having monthly conference calls for years," Graham said. "We also had our industry collaborators [at Moderna], and we had a strategy and all the technology, so we were ready to go."); Arthur Allen, *Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines*, KHN (Nov. 18, 2020), https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/ ("The Moderna vaccine, whose remarkable effectiveness in a late-stage trial was announced Monday morning, emerged directly out of a partnership between Moderna and Graham's NIH laboratory.").

with NIH.[79] Moderna itself used to recognize and even celebrate that fact; its early press releases acknowledged the vaccine as "co-developed."[80] And, in the early days of the pandemic, NIH often—justly—referred to the vaccine as the "NIH-Moderna vaccine" rather than the "Moderna vaccine."[81] I do the same.

In many ways, the U.S. government acted as Moderna's senior partner in this joint enterprise. Then-head of Operation Warp Speed Moncef Slaoui (himself a former member of Moderna's board of directors) summed it up in late 2020, shortly before the NIH-Moderna vaccine received its first emergency use authorization from the FDA: "We held Moderna by the hand on a daily basis."[82]

I will recount here just three examples of how U.S. government scientists and engineers worked hand-in-hand with Moderna's in 2020 and 2021 to develop, validate, manufacture, and distribute the NIH-Moderna vaccine: (1) clinical trials to validate the original NIH-Moderna vaccine, (2) manufacturing, and (3) development of variant-specific booster shots. Again, all this help was on top of the fundamental science, outlined above, that Moderna gathered from other sources, including the U.S. government.

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[79] See, e.g.,Peter Loftus, *Drugmaker Moderna Delivers First Experimental Coronavirus Vaccine for Human Testing*, Wall St. J. (Feb. 24, 2020), https://www.wsj.com/articles/drugmaker-moderna-delivers-first-coronavirus-vaccine-for-human-testing-11582579099 ("Moderna's turnaround time in producing the first batch of the vaccine—co-designed with NIAID, after learning the new virus's genetic sequence in January—is a stunningly fast response to an emerging outbreak."); Gregory Zuckerman, *How Moderna almost lost the race to develop a COVID-19 vaccine*, STAT News (Oct. 26, 2021), https://www.statnews.com/2021/10/26/how-moderna-nearly-lost-the-race-to-develop-a-covid-19-vaccine/ ("Working with scientists from the National Institutes of Health, Moderna produced a promising Covid-19 vaccine in January 2020, just weeks after the virus's sequence had been shared by Chinese scientists.").

[80] See, e.g., Moderna Provides Updates on the Clinical Development and Production of Its COVID-19 Vaccine Candidate, BusinessWire (Dec. 03, 2020),

https://www.businesswire.com/news/home/20201203006097/en/Moderna-Provides-Updates-on-the-Clinical-Development-and-Production-of-Its-COVID-19-Vaccine-Candidate ("mRNA-1273 is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein, which was co-developed by Moderna and investigators from NIAID's Vaccine Research Center.").

[81] See, e.g, Press Release, NIH, Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine (Nov. 16, 2020), https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine; Press Release, NIH, NIH clinical trial evaluating Moderna COVID-19 variant vaccine begins (Mar. 31, 2021), https://www.nih.gov/news-events/news-releases/nih-clinical-trial-evaluating-moderna-covid-19-variant-vaccine-begins ("Investigators from NIAID and Moderna co-developed the mRNA-1273 vaccine").

[82] Karen Weintraub, *Deliver a safe, effective COVID-19 vaccine in less than a year? Impossible, Meet Moncef Slaoui*, USA Today (Dec. 1, 2020), https://www.usatoday.com/in-depth/news/health/2020/12/01/operation-warp-speeds-moncef-slaoui-guided-covid-19-vaccine-creation/6375043002/.

Clinical trials to validate the original NIH-Moderna vaccine

NIH designed, conducted, and interpreted the first-ever clinical trial of the NIH-Moderna vaccine.[83] Operation Warp Speed head Slaoui and NIH officials also helped Moderna recruit patients to a later, larger clinical trial of the original NIH-Moderna vaccine, helping Moderna make the population of people enrolled in the trial more diverse and representative of the American public.[84] (These trials, and other trials of the NIH-Moderna vaccine, were also entirely funded by American taxpayers, as I describe below.) Moderna relied on this trial for initial FDA authorization to sell the NIH-Moderna vaccine.

Manufacturing

In 2018, Moderna spent about $100 million to open its first-ever dedicated manufacturing facility in Norwood, Massachusetts.[85] The space was formerly a Polaroid factory. Moderna made only small quantities of products there; prior to the NIH-Moderna vaccine, it had never manufactured a product on commercial scale.

In April 2020, the Biomedical Advanced Research and Development Authority (BARDA) agreed to provide Moderna with over $50 million specifically earmarked to expand the company's manufacturing capacity.[86] With money provided by BARDA under that contract

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[83] See, e.g., Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 119-21; Melissa Glim,*That Record-breaking Sprint to Create a COVID-19 Vaccine*, 29 The NIH Catalyst 1, 18 (2021) https://irp.nih.gov/catalyst/29/5/that-record-breaking-sprint-to-create-a-covid-19-vaccine ("Less than 48 hours after the release of the novel coronavirus's genome, the team had designed the protein that their candidate COVID-19 vaccine would use to teach the immune system to fend off the virus. Sixty-five days later, the VRC began clinical trials in collaboration with Moderna and clinical investigators from NIH's Division of Microbiology and Infectious Diseases.").

[84] Karen Weintraub, *Deliver a safe, effective COVID-19 vaccine in less than a year? Impossible, Meet Moncef Slaoui*, USA Today (Dec. 1, 2020) https://www.usatoday.com/in-depth/news/health/2020/12/01/operation-warp-speeds-moncef-slaoui-guided-covid-19-vaccine-creation/6375043002/ ("Moderna's trial was recruiting well, but not many participants were people of color, who have been hit particularly hard by the pandemic. Slaoui understood that if the trials were not diverse enough, people of color wouldn't trust that the results were relevant and wouldn't feel safe getting vaccinated. Slaoui knew the team at Moderna from his time on its board. He got annoyed when researchers wouldn't listen about the importance of trial diversity. 'We ended up shouting at each other,' Slaoui said. 'In a respectful but very stressed way.' He convinced the company to slow down its recruitment of white participants and brought in the head of the National Institutes of Health, Dr. Francis Collins, and the head of the National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci, to rapidly bring more Blacks and Hispanics into the trial.").

[85] Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 103; Allison DeAngelis, *Moderna's $110M Norwood site with expansion hopes*, Boston Bussiness J. (Jul. 17, 2018), https://www.bizjournals.com/boston/news/2018/07/17/modernas-110m-norwood-site-built-with-expansion.html.

[86] Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 137. See also Zain Rizvi, *Sharing the NIH-Moderna Vaccine Recipe*, Public Citizen, Aug. 10, 2021, at fn. 14, https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/#_ftn14 (indicating that BARDA disbursed over $50 million to Moderna in early 2020 to expand manufacturing); Gregory Zuckerman, *How Moderna almost*

and material assistance from U.S. government scientists, engineers, officials and other public employees, Moderna dramatically expanded its manufacturing. As Peter Loftus describes, "Effectively, BARDA took the risk other governments wouldn't when Bancel asked for up-front funding from them. For Moderna, the [April 2020 BARDA] contract meant speed. It planned a move to round-the-clock production [at its Norwood plant], upping production from ten weekly shifts (two a day five days a week) to twenty-one shifts (three a day, seven days a week). The company also hired 150 new employees to accelerate development and testing, and to prepare for the manufacturing scale-up."[87] Karen Weintraub describes a vivid example of how U.S. government employees provided material support to Moderna's manufacturing in unprecedented ways: In 2020, "[w]hen a train carrying a crucial pump needed to make vaccine for Moderna's latest trial became stalled on its tracks, the military put the pump on an airplane."[88]

Development of variant-specific booster shots

In 2021, NIH researchers—including Kizzmekia Corbett and Barney Graham—helped Moderna develop its first variant-specific COVID-19 booster shots.[89] According to Peter Loftus, NIH researchers "analyzed blood samples taken from eight people who were vaccinated with Moderna's shot in the Phase 1 trial back in early 2020. They essentially mixed these blood samples with the coronavirus variants, engineered so they copied the mutations of the variants but couldn't replicate and pose a threat to lab researchers. Researchers then analyzed whether the vaccine-induced antibodies present in the human blood samples could effectively neutralize the virus variants."[90] Later that year, NIH ran for Moderna the first clinical trial of a variant-specific booster.[91]

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lost the race to develop a COVID-19 vaccine, STAT News (Oct. 26, 2021), https://www.statnews.com/2021/10/26/how-moderna-nearly-lost-the-race-to-develop-a-covid-19-vaccine/ ("Moderna managed to get some money from the Biomedical Advanced Research and Development Authority (BARDA), an arm of the U.S. government, but it wasn't enough to manufacture many doses." Moderna later raised much more money from private investors in a May 2020 stock sale.). A redacted version of the April 2020 contract is available here: https://drive.google.com/file/d/1fS3LhRnVpEb8MokpWFmsDIrD2qjvvPTd/view.

[87] Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 138.

[88] Karen Weintraub, *Deliver a safe, effective COVID-19 vaccine in less than a year? Impossible, Meet Moncef Slaoui*, USA Today (Dec. 1, 2020) https://www.usatoday.com/in-depth/news/health/2020/12/01/operation-warp-speeds-moncef-slaoui-guided-covid-19-vaccine-creation/6375043002/

[89] Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 234.

[90] *Id.* at 234.

[91] *Id.* at 235.

Allow me to summarize the preceding 14 pages. I have pointed out that Moderna cannot take credit for having invented any of the three features of the NIH-Moderna vaccine that Moderna itself has pointed to as key: (1) the immunogen, (2) the modified mRNA, and (3) the delivery system. Instead, the historical record suggests that NIH and its academic collaborators at Dartmouth and Scripps deserve primary credit for the immunogen; Karikó, Weissman, and other (NIH-funded) collaborators at the University of Pennsylvania deserve primary credit for the modified mRNA; and researchers associated with the University of British Columbia and spinoff companies deserve primary credit for the delivery system. The U.S. government funded and drove the invention of the immunogen and largely funded invention of the modified mRNA. In addition, the U.S. government "held Moderna by the hand" throughout 2020 and into 2021, to bring these and other features together in the NIH-Moderna vaccine, and then help the company validate, manufacture, and distribute that vaccine.

I do not mean to suggest that I have told the comprehensive scientific story of the NIH-Moderna vaccine. Far from it. I have highlighted only a few key features, and there are many details of the science that I don't have time or space to include. The process of generating and validating scientific knowledge is complex, collective, and iterative.[92] Moderna and its scientists made many significant contributions, such as to the "stop codon" used in the NIH-Moderna vaccine and in Moderna's manufacturing process.[93] Moderna's scientists and engineers deserve celebration for their hard work, creativity, and dedication, just as scientists and engineers in government, academia, and other companies do.

However, Moderna cannot use science to claim the value of the NIH-Moderna vaccine for itself. The NIH and the broad American public have at least as strong a claim as Moderna's to having done the science to create this value.

The financial history likewise shows the value created by the American taxpayer

The scientific story above emphasized how much scientific value the American public created, through its scientific agencies and academic research funded by taxpayers. That story

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[92] Erie Dolgin, *The tangled history of mRNA vaccines*, Nature (Oct. 22, 2021), https://www.nature.com/articles/d41586-021-02483-w; Carolyn Y. Johnson, *A gamble pays off in 'spectacular success': How the leading coronavirus vaccines made it to the finish line*, Wash. Post (Dec. 6, 2020), https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/ ("the recent success of messenger RNA vaccines is a story of countless improvements that turned an alluring biological idea into a beneficial technology.").

[93] Our Approach to mRNA Vaccines, Moderna, https://mrna-access.modernatx.com/technology

suggests that, through the U.S. government, the American public contributed at least as much value to the NIH-Moderna vaccine as Moderna did.

Now I want to tell a related but distinct story—the financial story. Here, too, the American public can claim to be a main driver of and investor in the value of the NIH-Moderna vaccine, and almost certainly the largest.

Some key numbers: Moderna received about $2 billion in grants and other direct support for its R&D (including clinical trials) and its manufacturing.[94] (Moderna itself acknowledges taking $1.7 billion in direct support from BARDA alone.[95]) All the clinical trials of the NIH-Moderna vaccine that supported the product's initial FDA authorization were funded by noncommercial funders—not Moderna.[96] The U.S. government was far and away the largest of these funders, and NIH played an additional, central role in the design and conduct of these trials.[97]

Moderna has also so far received about $10 billion from the U.S. government in the form of purchase contracts.[98] The first of these contracts "derisked" Moderna's development in a major way[99]: Executed while clinical trials were still underway and uncertain, the contract guaranteed that the U.S. government would purchase 100 million doses from Moderna at a price

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[94] *See* Hussain S. Lalani et al., *US public investment in development of mRNA covid-19 vaccines: retrospective cohort study*, BMJ (Feb. 2, 2023), at 4, https://www.bmj.com/content/380/bmj-2022-073747 ("Moderna received $10.8bn, of which $8.8bn (81%) was for vaccine supply." (implying $2.0 bn in direct support)); *Key Facts Senators Need to Know Before the Moderna Hearing*, Public Citizen (Mar. 10, 2023), https://www.citizen.org/article/key-facts-senators-need-to-know-before-the-moderna-hearing/ ("From 2020 through 2022, BARDA provided Moderna with $1.7 billion to support clinical trials. The NIH provided Moderna with more than $400 million to support preclinical work and clinical trials, bringing the total U.S. Government R&D contribution to $2.1 billion.")

[95] Moderna, *2023 Proxy Statement* at 77, (Mar. 15, 2023) https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/a3589eb3-e49a-4135-a05c-746fe30f466a.pdf("Moderna paid the U.S. government $2.9 billion--the full amount that was received through BARDA funding plus $1.2 billion more.")

[96] Allie Clouse, *Fact check: Moderna vaccine funded by government spending, with notable private donation*, USA Today (Nov. 24, 2020), https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/.

[97] *Id.*

[98] Moderna, Fourth Quarter & Full Year 2021 Financial Results Presentation at 29(Feb. 24, 2022), https://s29.q4cdn.com/435878511/files/doc_presentations/2022/02/24/Master-Final-4Q21-Earnings-Call-(02.24).pdf ($5.4B in product sales in the US in 2021); Moderna, Fourth Quarter & Full Year 2022 Financial Results Presentation at 20 (Feb. 23, 2023), https://s29.q4cdn.com/435878511/files/doc_financials/2022/q4/Moderna-4Q22-Earnings-Presentation.pdf ($4.4 billion in product sales in the US in 2022). In 2021 and 2022, all Moderna's sales in the United States were to the U.S. government; there was no "commercial market" for the NIH-Moderna vaccine. Lalani et al., *supra* n. 94 at 4, calculate that Moderna received $8.8 billion in U.S. government money for vaccine purchases, rather than ~$10 billion.

[99] See Lalani at al., *supra* n. 94 at 7 ("By committing to purchase hundreds of millions of mRNA vaccine doses in advance and directly funding clinical trials and manufacturing capacity for the Moderna vaccine, the US government substantially de-risked the vaccine development process.").

of $15.25 per dose—a $1.5 billion order—even if the NIH-Moderna vaccine failed its clinical trials and never received FDA authorization.[100] This $1.5 billion order should be viewed as an additional subsidy to the company at a time when the value of the NIH-Moderna vaccine was still uncertain.

Lalani et al. also identify $337 million that the U.S. government invested pre-pandemic (prior to 2020) in mRNA and coronavirus vaccine research.[101]

I would like to point out one further subsidy that the U.S. government has given Moderna. This subsidy has attracted comparatively little attention outside of patent law circles, but it is nonetheless significant. The subsidy is this: Vis-a-vis some (not all) of Moderna's sales of the NIH-Moderna vaccine to the U.S. government, the U.S. government has attempted to assume Moderna's liability for infringing any and all U.S. patents owned by other companies.[102] This assumption of liability is a financial gift to Moderna—one that might substantially decrease Moderna's costs of doing business as it defends multiple patent infringement lawsuits that could conceivably cost the company hundreds of millions of dollars—even billions. (These lawsuits include the above-described suits brought by Genevant, Alnylam, and Arbutus, which allege that Moderna relies on these companies' patent lipid nanoparticle technology.)

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[100] See, e.g., Jennifer Kates et al., *How Much Could COVID-19 Vaccines Cost the U.S. After Commercialization?*, Kaiser Family Foundation (Mar. 10, 2023) https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/ (showing a U.S. government contractual commitment to purchase 100 million doses of the NIH-Moderna made in August 2020); Noah Higgins-Dunn, *Trump says U.S. has reached deal with Moderna for 100 million doses of coronavirus vaccine*, CNBC (Updated: Aug. 12, 2020) https://www.cnbc.com/2020/08/11/trump-says-us-has-reached-deal-with-moderna-for-100-million-doses-of-coronavirus-vaccine.html ("President Donald Trump on Tuesday announced the U.S. government will purchase 100 million doses of Moderna's experimental coronavirus vaccine, which is currently in late-stage human trials."); Trump Administration Collaborates With Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine, Department of Defense (Aug. 11, 2020), https://www.defense.gov/News/Releases/Release/Article/2309561/trump-administration-collaborates-with-moderna-to-produce-100-million-doses-of/ ("The federal government will own these vaccine doses. . . . If the U.S. Food and Drug Administration (FDA) authorizes use as outlined in agency guidance, the vaccine doses would be distributed and used as part of a COVID-19 vaccination campaign.").

[101] Lalani at al., *supra* n. 94 at 3 ("Additional investments by the Department of Defense and BARDA brought the total US public investment in pre-pandemic research and development to $337m, and a total contribution of $31.9bn from 1985 through March 2022, including research, development, and vaccine supply expenditures (table 1). … Of the $337m in pre-pandemic investments in research and development, $116m (35%) was from the NIH, $148m (44%) from BARDA, and $72m (21%) from the Department of Defense (table 1).").

[102] Lauren Berg, *Moderna Is Wrong Target Of COVID Vax IP Claims, Feds Say*, Law360 (Feb. 14, 2023, 10:42 PM) https://www.law360.com/articles/1576477/moderna-is-wrong-target-of-covid-vax-ip-claims-feds-say; Statement of Interest of the United States, Arbutus Biopharma v. Moderna, No 1:22-cv-00252-MSG (D. Del., Feb. 14, 2023) (stating that the U.S. government accepts and assumes, in Moderna's stead, any liability that Moderna would otherwise incur for infringing U.S. patents in the course of manufacturing and distributing doses of the NIH-Moderna vaccine delivered to the U.S. government pursuant to Contract No. W911QY-20-C-0100).

Finally, I remind the Committee that Moderna also benefited enormously from nonmonetary "hand-in-hand" help with the science of the NIH-Moderna vaccine. (This is the sort of help highlighted in the scientific story presented in the section above.[103]) Valuing this sort of contribution is difficult—how, for example, to value Moderna's access to the time and expertise of some of NIH's preeminent immunologists? How to value the Department of Defense putting a pump on a military plane and flying it to Moderna when Moderna needed a pump quickly? I raise this point simply to reiterate that, on top of financial support, the American public also contributed invaluable scientific and other help to Moderna and its shareholders.

In short, the U.S. government has been both Moderna's largest single investor and single largest customer. It seems to me that the American public's financial contributions to Moderna are at least comparable to the company's private investors'. One recent publication from an industry author[104] estimates, without citation, that "Moderna secured $3.8 bn at risk to develop its mRNA platform" from 2010 to the present.[105] Between pre-pandemic investments of >$300 million, the $2 billion in grants and other direct support given Moderna during the pandemic, the $1.5 billion advance purchase commitment in August 2020 that guaranteed Moderna payment even if the vaccine failed, assumption of some of Moderna's liability for infringing other company's patents, and hard-to-quantify and essential scientific help, it seems to me that the American public has invested an amount comparable to private investors, and perhaps even more.

Indeed, even if the NIH-Moderna vaccine had failed its clinical trials, failed at the FDA, and never made it to market at all, Moderna would still have benefited substantially from this influx of public money and scientific support. At the beginning of 2020, Moderna had no commercial products, minimal manufacturing capacity, and an uncertain future. Peter Loftus has reported that, at the beginning of 2020, no more than about 1,500 people had ever received a Moderna drug or vaccine candidate, in small clinical trials.[106] At the beginning of 2020, the company had not yet gathered "any evidence that mRNA vaccines protect[] people from disease."[107] The company's partnership with the U.S. government changed that. Even without selling a single dose of vaccine, that partnership left Moderna with expanded manufacturing

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[103] *Supra* § III.B.

[104] Thomas Cueni, Director General of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the pharmaceutical industry's largest international trade organization.

[105] Thomas Cueni, *Re: US public investment in development of mRNA covid-19 vaccines: retrospective cohort study*, BMJ (Mar. 8, 2023) https://www.bmj.com/content/380/bmj-2022-073747/rr-0.

[106] Loftus, *supra* n. 48 at 115.

[107] *Id.*

expertise and capacity;[108] dramatically expanded knowledge of the safety, stability, and other properties of mRNA products; and more. By undertaking collaboration with NIH and accepting billions in public money, Moderna was learning more about its mRNA platform—a major benefit unto itself.

In short, the financial history of the NIH-Moderna shows the value created by the American taxpayer and the unreasonableness of Moderna unilaterally claiming this value for itself.

2. Moderna's proposed price increases are not needed to fund R&D.

In defending its proposed price increases, Moderna has mostly emphasized the vaccine's value. I have argued above that that justification does not hold up to scrutiny.

Moderna has also claimed a second justification for increased vaccine prices: that high vaccine prices are necessary to produce the high revenues needed to sustain its R&D efforts. For example, in the past year, Moderna's executives have told news media that the company's "top priority is to reinvest the money it's made from the Covid-19 vaccine into new drugs, with the goal of expanding into other disease areas"[109] and that "[w]ith its capital, Moderna chiefly plans to reinvest in its 46 research and development programs which include its pipeline vaccine programs for COVID-19 and respiratory syncytial virus (RSV) and development-stage vaccine programs which include trials in Zika virus and Epstein-Barr virus (EBV)."[110]

However, this second justification also fails scrutiny. Moderna does not need to increase prices of booster shots to sustain its planned R&D.

I'll show in two ways that Moderna's claim that massive price increases are needed to fund R&D doesn't hold up to scrutiny. First, Moderna has more than ample financial resources to fund its R&D in 2023 and beyond. Second, Moderna's actions belie its purported commitment to make R&D its top priority. Instead, Moderna's top priority seems to be to enrich its shareholders—including its executives.

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[108] As Peter Loftus describes, "For Moderna, the [April 2020 BARDA] contract meant speed. It planned a move to round-the-clock production [at its Norwood plant], upping production from ten weekly shifts (two a day five days a week) to twenty-one shifts (three a day, seven days a week). The company also hired 150 new employees to accelerate development and testing, and to prepare for the manufacturing scale-up." Loftus, *supra* n. 48 at 138.

[109] Rowan Walrath, *Moderna aiming to deliver updated Covid-19 vaccine boosters next month*, Boston Bus. J. (Aug. 3, 2022), https://www.bizjournals.com/boston/news/2022/08/03/moderna-covid-19-omicron-booster-ba4-ba5-earnings.html

[110] Hayley Shasteen, *Moderna Highlights More than $6B in Revenue, Talks Boosters*, BioSpace (May 4, 2022), https://www.biospace.com/article/moderna-s-revenues-boosted-6-1b-ahead-of-covid-19-vaccine-plans/

Moderna has more than ample resources to fund its R&D in 2023 and beyond

Moderna has committed to spend an impressive amount on R&D in 2023—approximately $4.5 billion. (However, it has shared fewer than all relevant details of how it will allocate that planned spending.[111])

In 2021 and 2022, Moderna made about $21 billion in profits on about $38 billion in revenues,[112] including about $10 billion in U.S. revenues alone.[113] After that bonanza, the company reported that it held over $18 billion in cash and investments at the end of 2022.[114] This is one of the richest companies in the world, with more than enough money already saved to cover its planned R&D this year and beyond.

And, of course, Moderna will continue earning more money from sales of the NIH-Moderna vaccine. Earlier this year, Moderna predicted minimum revenues of $5 billion on new COVID-19 vaccine sales in 2023.[115] In addition, the company told investors to "continue to expect additional contracts for 2023"[116]—meaning more revenues are likely. Many observers characterized that estimate as conservative[117]—meaning that they think Moderna is likely to

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[111] *See*, *e.g.*, Motley Fool Transcribing, *Moderna (MRNA) Q4 2022 Earnings Call Transcript*, (Feb. 23, 2023), https://www.fool.com/earnings/call-transcripts/2023/02/23/moderna-mrna-q4-2022-earnings-call-transcript/ (comments of Jamie Mock, Chief Financial Officer of Moderna, stating only that "[t]he increase in R&D spend continues to be driven by our clinical trial expenses, particularly with our phase 3 studies for RSV, seasonal flu, and CMV. The increase in R&D was also driven by the acquisition of a priority review voucher and an increase in personnel-related costs due to increased headcount.").

[112] Moderna, Fourth Quarter & Full Year 2021 Financial Results Presentation at 4 (Feb. 24, 2022), https://s29.q4cdn.com/435878511/files/doc_presentations/2022/02/24/Master-Final-4Q21-Earnings-Call-(02.24).pdf ($18.5 billion in total revenues and $12.2 billion in net income in 2021); Moderna, Fourth Quarter & Full Year 2022 Financial Results Presentation at 20 (Feb. 23, 2023), https://s29.q4cdn.com/435878511/files/doc_financials/2022/q4/Moderna-4Q22-Earnings-Presentation.pdf ($19.3 billion in total revenues and $8.4 billion in net income in 2022).

[113] Moderna, Fourth Quarter & Full Year 2021 Financial Results Presentation at 29 (Feb. 24, 2022), https://s29.q4cdn.com/435878511/files/doc_presentations/2022/02/24/Master-Final-4Q21-Earnings-Call-(02.24).pdf ($5.4B in product sales in the US in 2021); Moderna, Fourth Quarter & Full Year 2022 Financial Results Presentation at 20 (Feb. 23, 2023),https://s29.q4cdn.com/435878511/files/doc_financials/2022/q4/Moderna-4Q22-Earnings-Presentation.pdf ($4.4 billion in product sales in the US in 2022).

[114] Moderna, Fourth Quarter & Full Year 2022 Financial Results Presentation at 4 (Feb. 23, 2023).

[115] Press Release, *Moderna Announces Advances Across mRNA Pipeline and Provides Business Update*, Moderna (Jan. 9, 2023), https://investors.modernatx.com/news/news-details/2023/Moderna-Announces-Advances-Across-mRNA-Pipeline-and-Provides-Business-Update/default.aspx

[116] *Id.*

[117] *See*, *e.g.*, David Wainer, *Moderna Peers Over a Scary Profit Cliff*, Wall St. J. (Feb. 23, 2023), https://www.wsj.com/articles/moderna-peers-over-a-scary-profit-cliff-5374e4d4 ("[T]he company's forecast of at least $5 billion in sales is conservative. Moderna isn't including potential new sales in places like the U.S., Europe and Japan).

bring in significantly more than $5 billion.[118] Of course, some fraction of Moderna's revenue projections is likely based on Moderna's expectation that it will be able to increase the prices paid for each booster shot, at least in the United States. To my knowledge, Moderna has not revealed what it expects the average "net" price of boosters sold in the U.S. to be in 2023 or beyond.

One more point to make here: While Moderna is investing billions to investigate new mRNA-based vaccine and therapeutic products, the American taxpayer is also making new investments in the company and many of these investigational products. Through NIH, the American public continues to invest in and subsidize some of Moderna's new research into other vaccines. Thus, I think we should think of the public as an early investor in these investigational products—though the investment is not on the same scale as it was in the NIH-Moderna COVID-19 vaccine. Moderna's 2022 annual report acknowledges "reliance on government funding and collaboration from governmental and quasi-governmental entities for certain of our programs[, which] adds uncertainty to our research and development efforts with respect to those programs and may impose requirements related to intellectual property rights and requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs."[119] The same report indicates that Moderna vaccine candidates in HIV, Nipah, and Zika viruses are receiving taxpayer support, through NIH and BARDA.[120] NIH and Moderna are collaborating closely on development of a potential HIV vaccine, and NIH is paying for an important clinical trial.[121]

Moderna's actions belie its purported commitment to make R&D its top priority.

Moderna's actions show that reinvestment in new R&D has not been the company's primary concern. Instead, Moderna's actions suggest that its primary concern is enriching its shareholders—including its executives.

Through the pandemic, Moderna has spent at least as much on stock buybacks (to boost share price) as it has on R&D. According to Victor Roy, Moderna announced or executed $7 billion in share buybacks between 2021 and 2022, $3 billion more than the company spent on

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[119] Moderna, Annual Report (Form 10-K) (Feb.24, 2023).

[120] *Id.*

[121] Press Release, *NIH Launches Clinical Trial of Three mRNA HIV Vaccines*, Nat'l Insts. Of Health (Mar. 14, 2022), https://www.niaid.nih.gov/news-events/nih-launches-clinical-trial-three-mrna-hiv-vaccines; *see also* Study Record Detail, *A Clinical Trial to Evaluate the Safety and Immunogenicity of BG505 MD39.3, BG505 MD39.3 gp151, and BG505 MD39.3 gp151 CD4KO HIV Trimer mRNA Vaccines in Healthy, HIV-uninfected Adult Participants*, ClinicalTrials.gov (Feb. 1, 2022), https://clinicaltrials.gov/ct2/show/NCT05217641.

research and development in that time.[122] Moderna's recent financial disclosure for Fiscal Year 2022 disclosed that the company "[r]eturn[ed] capital to shareholders" through "repurchase[]" (i.e., buyback) of "$3.3 billion in 2022, with $2.8 billion remaining for future repurchases from the $3.0 billion August authorization."[123] The same disclosure estimates that Moderna spent $3.3 billion on R&D in 2022.[124] As such, Moderna's latest disclosures seem to confirm that the company spent at least as much on buybacks as on R&D in 2022.

Moderna's stock buybacks have benefited a small handful of Moderna executives and early investors who own a large fraction of the company's shares.[125] Mr. Bancel himself reportedly owns about 8% of Moderna's stock.[126] He reportedly began 2020 with a net worth of about $500 million;[127] he is now reportedly worth about $4.7 billion.[128] Indeed, he has become a billionaire on the basis of Moderna's extraordinary financial success—and its focus on redistributing its enormous profits to its shareholders. As I write, on the morning of March 20, 2023, Forbes estimates that Mr. Bancel is the 566th richest person in the world.[129] If indeed Mr. Bancel is worth $4.7 billion, he could theoretically fund all Moderna's expected R&D expenses in 2023 out of his own pocket—and still have $200 million left over.

C. Moderna has given us reasons for skepticism about its claims on pricing.

In the sections above, I've expressed my view that Moderna's proposed justifications for its proposed price increases—the vaccine's value and the cost of future R&D—don't hold up to scrutiny. Indeed, I think Moderna's proposed price increases are simply unjustifiable.

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[122] Moderna, Fourth Quarter & Full Year 2022 Financial Results Presentation (Feb. 23, 2023.)

[123] *Id.* at 5.

[124] *Id.* at 4.

[125] Press Release, *COVID vaccines create 9 new billionaires with combined wealth greater than cost of vaccinating world's poorest countries*, Oxfam Int'l (May 20, 2021), https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating

[126] *Profile: Stéphane Bancel*, Forbes (last visited Mar. 23 2023), https://www.forbes.com/profile/stephane-bancel/?sh=1c6e05c33742

[127] Robert Frank, *New vaccine billionaires gain wealth as Moderna and BioNTech shares soar*, CNBC (Dec. 9, 2020), https://www.cnbc.com/2020/12/09/new-vaccine-billionaires-gain-wealth-as-moderna-pfizer-shares-soar-.html ("CEO Stephane Bancel has gained $4.8 billion in wealth this year, giving him a net worth of $5.3 billion.").

[128] Forbes, *supra* n. 126.

[129] *Id.*

In this section, I want to say a few additional words about why I think there are good reasons to be skeptical of Moderna's claims. I'll show here that Moderna has proved itself to be an unusually bad corporate citizen in important ways.

1. Moderna has broken some of its past promises

Moderna has broken promises it has made in the past—promises to patients, to competitors, to non-governmental organizations, and to the world. In my view, this is reason to be skeptical when Moderna promises that it "remains committed to ensuring that people in the United States will have access to our COVID-19 vaccines regardless of ability to pay" and that, "[f]or uninsured or underinsured people, Moderna's patient assistance program[] will provide COVID-19 vaccines at no cost."[130]

In October 2020, Moderna pledged that it would not enforce any of its patents on mRNA vaccines "while the pandemic continues."[131] At the time, Peter Loftus of the Wall Street Journal quoted Moderna President Stephen Hoge as saying the following: "We're quite studiously not asserting infringement. We're doing the opposite of creating that kind of anxiety for folks. We're not interested in using that IP to decrease the number of vaccines available in a pandemic."[132] Moderna's patent pledge generated a wave of favorable news coverage for the company.

Then, in March 2022, Moderna reneged on its patent pledge. It issued a new, "updated" patent "pledge" that was significantly different.[133] (At some point, Moderna deleted its original 2020 pledge from its website. The URL now gives a "Page Not Found" error.[134]) In its "updated" "pledge," Moderna indicated that it might actually sue competitors in over 100 countries.[135]

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[130] Press Release, Moderna Inc., Moderna's Commitment to Patient Access in the United States (Feb. 15, 2023) (https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx).

[131] Peter Loftus, *Moderna Vows to Not Enforce Covid-19 Vaccine Patents During Pandemic*, Wall St. J. (Oct. 8, 2020), https://www.wsj.com/articles/moderna-vows-to-not-enforce-covid-19-vaccine-patents-during-pandemic-11602154805.

[132] *Id.*

[133] Press Release, Moderna, Inc., Moderna's Updated Patent Pledge (March 07, 2022) (https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx).

[134] Page Not Found, Moderna, Inc., https://investors.modernatx.com/node/10066/pdf/.

[135] Rebecca Robbins, *Moderna opens the door to enforcing its vaccine patents in some Countries*, N.Y. Times (March 7, 2022), https://www.nytimes.com/2022/03/07/world/africa/moderna-opens-the-door-to-enforcing-its-vaccine-patents-in-some-countries.html.

Then, in August 2022, Moderna sued its most important competitors, Pfizer and BioNTech.[136] That litigation is ongoing. Experts including Health Justice Initiative's Fatima Hassan have expressed concern that Moderna could further backtrack on its promises and sue the World Health Organization's mRNA vaccine hubs in South Africa and other countries.[137] Professor Jorge Contreras has observed that Moderna's broken patent pledge is unusual; companies don't usually break these pledges: "The reason that Moderna's attempt to renege on its 2020 patent pledge is so important is its potentially damaging effect on the integrity of the much larger patent pledging ecosystem."[138]

Moderna has broken other promises, including promises it made to distribute the NIH-Moderna vaccine to countries in the Global South. For example, in February 2021, Emily Rauhala of the Washington Post reported that Moderna had promised to uphold the equitable access principles of the Coalition for Epidemic Preparedness Innovations (CEPI) and distribute doses of the NIH-Moderna vaccine to people in the Global South; instead, those countries were "almost entirely shut out" as Moderna chose to focus on profitable sales to rich countries in the Global North.[139]

2. Moderna has exaggerated and misstated its role in the NIH-Moderna vaccine

Moderna and NIH began in 2020 as close collaborators. Together, they invented the NIH-Moderna vaccine.

However, over time, Moderna exaggerated its role and downplayed the role of NIH and the U.S. government—even sought to erase NIH completely from key parts of the story. Moderna has misled the public about the many ways that NIH and the U.S. government contributed to this vaccine, both scientifically and financially.

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[136] Carmel Wroth and Joe Palca, *Moderna sues Pfizer over COVID-19 Vaccine patents*, NPR (Aug. 26, 2022), https://www.npr.org/sections/health-shots/2022/08/26/1119608060/moderna-sues-pfizer-over-covid-19-vaccine-patents.

[137] Laura Angela Bagnetto, *Africa: How Western Countries Could Stop Africa Making Vaccines of the Future*, All Africa (Oct. 14, 2022), https://allafrica.com/stories/202210140388.html; Fatima Hassan, *Vaccine Apartheid is Racist and Wrong*, Speaking of Medicine and Health (May 23, 2022), https://speakingofmedicine.plos.org/2022/05/23/vaccine-apartheid-is-racist-and-wrong/.

[138] Jorge Contreras, *No Take-Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge*, Bill Of Health (Aug, 29, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/.

[139] Emily Rauhala, *Moderna agreed to 'equitable access' for its coronavirus vaccine, but most of its doses are going to wealthy countries*, Wash. Post (Feb. 13, 2021), https://www.washingtonpost.com/world/coronavirus-vaccine-access-poor-countries-moderna/2021/02/12/0586e532-6712-11eb-bf81-c618c88ed605_story.html.

One of the most notable efforts by Moderna to erase the role of NIH was Moderna's decision to omit NIH scientists, including Barney Graham and Kizzmekia Corbett, from a patent application filed by Moderna on the sequence of the NIH-Moderna vaccine immunogen described above. This move by Moderna and its lawyers is particularly galling, as the factual record shows that it was the NIH team led by Graham that gave Moderna this extraordinarily valuable sequence, as I showed above.[140] NIH has been consistent and clear that it disagrees with Moderna's attempt to omit its inventors from this story and this patent application: "[T]hree scientists at [NIH's] Vaccine Research Center — Dr. John R. Mascola, the center's director; Dr. Barney S. Graham, who recently retired; and Dr. Kizzmekia S. Corbett, who is now at Harvard — worked with Moderna scientists to design the genetic sequence that prompts the vaccine to produce an immune response, and should be named on the 'principal patent application.'"[141]

The story of Moderna omitting NIH inventors from its patent application was first broken by Zain Rizvi, Peter Maybarduk, and other researchers at Public Citizen[142] and was widely reported in November 2021.[143]

Moderna's omission of NIH inventors from its patent application operated on two levels. On one level, the omission deprived NIH and its scientists of their share of scientific credit for developing the NIH-Moderna vaccine. John P. Moore, a professor of microbiology and immunology at Cornell University, called it a matter of "fairness and morality at the scientific level," adding, "[t]hese two institutions have been working together for four or five years."[144] On another, legal and financial level, Moderna's omission deprived NIH of ownership rights in the patent—and thus shared control. To quote an NIH spokesperson, "[o]mitting N.I.H. inventors from the principal patent application deprives N.I.H. of a co-ownership interest in that

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[140] *Supra* § III.B.

[141] Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at odds over vaccine patent rights*, N.Y. Times (Nov. 11, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

[142] Letter from Peter Maybarduk, Director, Access to Medicines Program, Public Citizen, to Dr. Francis Collins, Director, NIH (Nov. 2, 2021), https://int.nyt.com/data/documenttools/public-citizen-nih-moderna-vaccine/6eed9709767cc988/full.pdf.

[143] See, e.g., Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at odds over vaccine patent rights*, N.Y. Times (Nov. 11, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html; Rebecca Robbins and Sheryl Gay Stolberg, *Moderna backs down in its vaccine patent fight with the N.I.H.*, N.Y. Times (Dec. 17, 2021), https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html; Julie Steenhuysen, *Moderna COVID-19 vaccine patent dispute headed to court, U.S. N.I.H. head says* (Nov. 11, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-covid-19-vaccine-patent-dispute-headed-court-us-nih-head-says-2021-11-10/; Alexander Tin, *Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government*, CBS News (Nov. 15, 2021), https://www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/.

[144] Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at odds over vaccine patent rights*, N.Y. Times (Nov. 11, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

application and the patent that will eventually issue from it."[145] Then-NIH Director Francis Collins told the Los Angeles Times, "I think Moderna has made a serious mistake here in not providing the kind of co-inventorship credit to people who played a major role in the development of the vaccine that they're now making a fair amount of money off of."[146] Implicit in NIH's statements is an agreement or understanding by NIH leadership that Moderna would share control in this way—an agreement that Moderna seems to have breached.

Earlier this year, Moderna ultimately abandoned the disputed patent application rather than name the NIH scientists as co-inventors.[147] NIH has continued to insist, into March 2023, that its scientists deserve credit as co-inventors of the mRNA sequence used in the NIH-Moderna vaccine.[148]

There are other ways that Moderna has omitted—even falsified—information about the sweeping extent to which it has benefited from federal funding. For example, in 2020, research from Knowledge Ecology International and Public Citizen showed that Moderna had not disclosed U.S. government funding in its press releases—a violation of its contracts with those government funders.[149]

Separate research from Luis Gil Abinader and Jamie Love of Knowledge Ecology International showed that Moderna had additionally omitted—accidentally or not—statutorily mandated notices of federal funding from over 100 patents and patent applications.[150] Omission of these notices of federal funding in Moderna's patents further deprived NIH and other funding agencies of public acknowledgement of their vital support. Omission of these notices may also

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[145] Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at odds over vaccine patent rights*, N.Y. Times (Nov. 11, 2021),

https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

[146] Michael Hiltzik, *Column: raking in profits, Moderna denies government scientists credit for the COVID vaccine*, L.A. Times (Nov. 30, 2021), https://www.latimes.com/business/story/2021-11-30/moderna-denies-government-scientists-credit-for-inventing-covid-vaccine.

[147] Katherine Ellen Foley and David Lim, *Lilly's perfect timing for insulin cost cuts*, Politico (Mar. 7, 2023), https://www.politico.com/newsletters/prescription-pulse/2023/03/07/eli-lilly-insulin-cost-cuts-00085724 (

[148] *Id.* ("'For years, we tried to reach a resolution, but while the NIH asserts its scientists should be listed as co-inventors on the relevant patent applications, we disagree and believe that our scientists invented the specific mRNA sequence at issue,' Christopher Ridley, a spokesperson for the company, said to POLITICO in a statement.").

[149] Bob Herman, *Moderna skirts disclosures of coronavirus vaccine costs*, Axios (Aug. 5, 2020), https://www.axios.com/2020/08/05/moderna-barda-coronavirus-funding-disclosure.

[150] James Love, *KEI asks DOD to investigate failure to disclose DARPA funding in Moderna patents*, Knowledge Ecology Int'l (Aug. 28, 2020), https://www.keionline.org/33763.

have made it more difficult for NIH and other federal funders to assert the legal rights—so-called Bayh-Dole rights—in Moderna-owned patents that were created with federal dollars.[151]

And just this month, on March 6, Moderna CEO Stéphane Bancel provided false information to the Wall Street Journal about the funding Moderna received in 2020. On March 6, Bancel stated that Moderna's "platform was funded by private investors" and that Moderna "asked governments around the world in the first half of 2020 to help [Moderna] with manufacturing" but that "[Moderna] didn't get any help."[152] "We didn't get a penny," claimed Mr. Bancel.[153] That claim is clearly false. In fact Moderna received a contract from BARDA worth almost $500 million in April 2020.[154] Part of that award was specifically directed at expanding Moderna's manufacturing of the NIH-Moderna vaccine. A press release from Moderna itself, dated April 16, 2020, states that the BARDA "[a]ward will fund manufacturing process scale-up to enable large-scale production in 2020 for pandemic response."[155] Indeed, weeks after the contract was executed, Moderna used approximately $50 million provided by BARDA under the contract to expand its manufacturing, as I described above.[156] I will quote Moderna's April 2020 press release at length, because the disconnect between what Mr. Bancel said then and what Mr. Bancel says now is remarkable:

> BARDA funding will support these late-stage clinical development programs, as well as the scale-up of mRNA-1273 manufacture in 2020 to enable potential pandemic response.

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[151] Christopher Rowland, *Moderna failed to disclose federal support in vaccine patents, researchers say* (Aug. 28, 2020), https://www.washingtonpost.com/business/2020/08/28/moderna-vaccine-patents-darpa-funding/.

[152] Jared S. Hopkins, *Moderna CEO defends pricing plans for COVID-19 shot*, Wall St. J. (Mar. 6, 2023), https://www.wsj.com/amp/articles/moderna-ceo-defends-pricing-strategy-for-covid-shot-41582d36.

[153] *Id.*

[154] Press Release, Medical Countermeasures Department of Health & Human Services, BARDA engages Moderna to expand domestic manufacturing of the Moderna SARS-CoV-2 vaccine (mRNA-1273) to protect against COVID-19 (Jun. 5, 2020), https://medicalcountermeasures.gov/newsroom/2020/moderna-vaccine/; Press Release, Moderna, Inc., Moderna announces award from U.S. Government agency BARDA for up to $483 million to accelerate development of mRNA vaccine (mRNA-1273) against novel coronavirus (Apr. 16, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Award-from-U.S.-Government-Agency-BARDA-for-up-to-483-Million-to-Accelerate-Development-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx.

[155] Press Release, Moderna, Inc., Moderna announces award from U.S. Government agency BARDA for up to $483 million to accelerate development of mRNA vaccine (mRNA-1273) against novel coronavirus (Apr. 16, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Award-from-U.S.-Government-Agency-BARDA-for-up-to-483-Million-to-Accelerate-Development-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx.

[156] *Supra* § III.B; *see also* Peter Loftus, The Messenger: Moderna, the Vaccine, and the Business Gamble That Changed the World (2022) at 119-21 at 137-39 (explaining how April 2020 BARDA contract permitted Moderna to expand manufacturing).

> To support the scale-up, Moderna plans to hire up to 150 new team members in the U.S. this year. This includes a significant increase in its skilled manufacturing staff to expand manufacturing capacity from two shifts per day, 5 days per week to three shifts per day, 7 days per week, engineers to manage process scale-up, and clinical and regulatory staff to support clinical development.
>
> "We are thankful for BARDA's support to fund the accelerated development of mRNA-1273, our vaccine candidate against SARS-CoV-2," said Stéphane Bancel, Moderna's Chief Executive Officer. "Time is of the essence to provide a vaccine against this pandemic virus. By investing now in our manufacturing process scale-up to enable large scale production for pandemic response, we believe that we would be able to supply millions of doses per month in 2020 and with further investments, tens of millions per month in 2021, if the vaccine candidate is successful in the clinic."
>
> "Vaccines are a critical tool for saving lives and stopping the spread of the SARS-CoV-2 virus," said BARDA Director Rick Bright, Ph.D. "Delivering a safe and effective vaccine for a rapidly spreading virus requires accelerated action. BARDA's goal is to have vaccine available as quickly as possible and preparing now for advanced stage clinical trials and production scale-up while the Phase 1 is underway could shave months off development of COVID-19 vaccines."[157]

Further evidence of how Mr. Bancel's story has shifted: In April 2020, Mr. Bancel spoke to the Wall Street Journal about the BARDA contract and was explicit then that BARDA was giving Moderna millions to expand its manufacturing capacity: "'This [BARDA] grant is enabling us to aggressively fund the best and largest clinical studies that we can do,' Moderna Chief Executive Stephane Bancel said in an interview. 'We can fund the manufacturing process so we can make as much product as we can.'"[158]

* * *

Moderna's broken promises and its falsehoods about the creation of the NIH-Moderna vaccine are breaches of the public's trust. They are reason to be skeptical of its new claims about its need to raise prices and the reach of its patient assistance program. We should demand clear answers and binding commitments from the company about the patient assistance program it

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[157] Press Release, Moderna, Inc., Moderna announces award from U.S. Government agency BARDA for up to $483 million to accelerate development of mRNA vaccine (mRNA-1273) against novel coronavirus (Apr. 16, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Award-from-U.S.-Government-Agency-BARDA-for-up-to-483-Million-to-Accelerate-Development-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx.

[158] Peter Loftus, *Moderna Gets U.S. Funding for Development, Manufacturing of Experimental Coronavirus Vaccine*, Wall Street Journal (Apr. 16, 2020), https://www.wsj.com/articles/u-s-awards-up-to-483-million-to-moderna-to-accelerate-coronavirus-vaccine-development-and-production-11587075412.

promises. And we should similarly demand clear answers and binding commitments about the R&D it promises.

We should also ask ourselves whether per-dose list prices of $110 or 130 might be just the beginning. The NIH-Moderna vaccine is only three years old. Historically, drug companies have raised prices of brand-name products twice a year, year after year. Moderna says it wants to quadruple the price. Will it go even higher? Will we see COVID-19 vaccines sold for $200 a dose? $500? Is there an upper limit to what Moderna would charge for a booster shot? As prices for COVID-19 vaccines go up, will we see ever-greater disparities in access and ever-greater burdens on healthcare systems? Will COVID-19 boosters become luxury products, available only to the wealthy?

We should also think about what will happen with any future breakthrough products the company creates (or co-creates). Imagine Moderna develops an effective vaccine for RSV, HIV, or Zika, or a powerful treatment for cancer. (This is no mere speculation; all these products are currently in various stages of development. For example, NIH is currently conducting clinical trials of HIV vaccine candidates jointly developed by Moderna, the Scripps Consortium for HIV/AIDS Development (CHAVD) at the Scripps Research Institute, and the IAVI Neutralizing Antibody Center at Scripps.[159]) That would be wonderful—new hope for patients and further proof of the value of mRNA. But who would get those products? Will all the American taxpayers who helped create the products get access to them? What about people in other countries? Do we trust this company to price new products reasonably, and ensure that everyone who needs them gets them?

What happens next with Moderna's proposed price increases on its COVID-19 vaccines will set an important policy precedent. The ripple effects are much bigger than just one company.

All this is why I recommend that Moderna cut its prices on its COVID-19 vaccines. If Moderna does not, I recommend that our leaders act to bring prices down. I will explain my recommendations in detail in the next part.

IV. Recommendations

In the preceding part, I shared my analysis of Moderna's plan to quadruple its vaccine prices. I concluded that Moderna's proposed price increases would harm public health and that the company's stated justifications for its proposed price increases don't hold up to scrutiny. I

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[159] Rachel Arthur, *Moderna takes HIV trimer mRNA vaccine into clinical trials*, BioPharma Reporter (Mar. 14, 2022), https://www.biopharma-reporter.com/Article/2022/03/14/moderna-takes-mrna-hiv-candidate-into-clinical-trials; Press Release, NIH, NIH launches clinical trial of three mRNA HIV vaccines (Mar. 14, 2022), https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-three-mrna-hiv-vaccines.

also showed that Moderna has given the American public—and this Committee—reason for skepticism and caution about some of its assertions.

In this part, I will present recommendations as to what should come next. I break those recommendations in two: first, what I urge Moderna to do, and, second, what I urge our leaders in Washington to do if the company does not act.

A. What Moderna should do

First and foremost, Moderna should reverse its decision to quadruple its U.S. prices for booster shots. In my view, Moderna could and should, at minimum, keep prices in line with what they have been since 2020: approximately $20 to $30 per dose.

As I noted above, Moderna's manufacturing costs are less than $3/dose. I recognize that producing variant-specific boosters requires more than just manufacturing, as Moderna is incurring some new R&D expenses, and will continue to, as it adapts the NIH-Moderna vaccine to new variants of concern. However, these R&D costs are much lower than the costs associated with developing the initial NIH-Moderna vaccine. In 2021, Mr. Bancel explained on CNBC that Moderna's booster shots use the same technology, chemistry and manufacturing process as the initial NIH-Moderna vaccine: "the products are very similar with just a few mutation changes" to the immunogenic mRNA sequence.[160] Moderna's President, Stephen Hoge, similarly told Time Magazine that the process of creating new variant-specific boosters is quick and can be completed in a matter of weeks: "One advantage of Moderna's mRNA technology is its flexibility—because it is based on the virus's genetic sequence, developing a new vaccine against a new variant would be a matter of 'copying and pasting—we could paste the South African strain mutations into our vaccine very quickly,' says Hoge, and have shots ready to test 'in a matter of six to nine weeks.'"[161]

New variant-specific boosters still require new clinical trials and other testing, of course. But still it seems clear that Moderna's costs associated with developing new variant-specific boosters will remain low—much lower than the costs of developing the original NIH-Moderna vaccine, which were borne mostly by U.S. taxpayers.

It's not too late for Mr. Bancel and other Moderna leadership to do the right thing: reverse course on their proposed price increases.

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[160] Cory Stieg, *How scientists can 'copy and paste' COVID vaccines to work on the strain from South Africa*, CNBC (Jan. 28, 2021), https://www.cnbc.com/2021/01/28/why-mrna-vaccines-like-covid-vaccines-are-more-flexible-to-variants.html.

[161] Alice Park, *Moderna's COVID-19 vaccine works against the new mutant strains. Is that enough?* TIME (Jan. 26 2021), https://time.com/5933340/moderna-covid-19-vaccine-new-strains/.

Moderna must also follow through on its recent commitment "to ensur[e] that people in the United States will have access to our COVID-19 vaccines regardless of ability to pay."[162] Moderna has stated that "Moderna's COVID-19 vaccines will continue to be available at no cost for insured people whether they receive them at their doctors' offices or local pharmacies."[163] Moderna has also promised that, "[f]or uninsured or underinsured people, Moderna's patient assistance program will provide COVID-19 vaccines at no cost," beginning on May 12, 2023.[164]

I urge Mr. Bancel and other leaders of Moderna to provide details of Moderna's planned patient assistance program. For example, will Moderna commit to extending the program for as long it continues selling COVID-19 booster shots? Will Moderna impose an income cap on uninsured people who seek to use the program? If so, how does it justify such a cap? How will Moderna ensure that people learn of the program and are able to use it? Will Moderna commit to financial transparency of its patient assistance program, including the potential tax benefits it may confer on the company?

B. What our leaders should do

We cannot sit back and trust Moderna to do the right thing—to reverse its plans to increase its prices or to ensure that all Americans get access to its booster shots. As shown above, Moderna has broken past commitments to the American public. Leaders in Washington must act on our behalf.

Our leaders must pay attention to Moderna's proposed price increases. I applaud the Committee and its leadership for convening this hearing now, and I encourage other Members of Congress and other leaders to work together on a path forward.

Moderna's proposed price increases are important in their own right for all the reasons I presented above.[165] More people will get sick and die from COVID-19 and premiums will rise for everyone.

But Moderna's proposed price increases are also important because of what happens next. If our leaders decline to act and simply let Moderna quadruple its prices, other powerful companies will double down on Moderna's playbook: Partner with the U.S. government to create valuable new technology, then seize exclusive control of that technology and deny that public

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[162] Press Release, Moderna, Inc., Moderna's commitment to patient access in the United States (Feb. 15, 2023), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx.

[163] *Id.*

[164] *Id.*

[165] *Supra* § III.A.

science and taxpayer money played a central role in its creation. More companies will capture and privatize the fruits of public-private partnerships. More companies will extract billions in private profits from public science and public money and leave the American public with higher costs, inaccessible technologies, poorer health.

Our leaders can act. Congress and the White House can reassert the U.S. government's contributions to the NIH-Moderna vaccine, reassert their own power, and negotiate better deals for the American public. Here I will present four distinct steps our leaders could take: (1) resume bulk purchases, (2) explore use of the Defense Production Act to bring prices down, (3) cut harder bargains with future industry partners, to better protect the American public next time around, and (4) explore legislation for deeper reform. The first and second steps address Moderna and the NIH-Moderna vaccine specifically. The third and fourth steps are directed to pharma and biotech more broadly, and future innovation.

1. Resume bulk purchases of COVID-19 vaccines

I recommend that Congress and the White House work together to resume bulk purchases of COVID-19 vaccines. Doing so would continue to leverage the buying power of the American people to negotiate better prices from Moderna (and Pfizer and other manufacturers of anti-COVID-19 products). Government distribution of vaccines purchased this way, free of charge to clinics and patients, would also ensure that everyone in the United States can get boosted without any out-of-pocket costs or complex paperwork.

As I noted above, Jennifer Kates, Cynthia Cox, and Josh Michaud at the Kaiser Family Foundation recently calculated that, through federally-funded bulk purchases, "[t]he federal government has so far purchased 1.2 billion doses of Pfizer and Moderna COVID-19 vaccines combined, at a cost of $25.3 billion, or a weighted average purchase price of $20.69 per dose."[166] More recently, the U.S. government has paid a bit more for Moderna's new variant-targeted bivalent boosters: $26.36 per dose.[167]

The U.S. government was able to negotiate these prices because it actively negotiated with both Moderna and Pfizer, whose similar vaccines can and should have to compete on price. For example, in July 2022, Josh Nathan-Kazis reported in Barrons that Moderna had sought to sell tens of millions of doses of booster shots to the U.S. government at $35 per dose, but the

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[166] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

[167] *Id.*

U.S. government negotiated Moderna's price down to $26.36.[168] (A price of $26.36 per dose is, of course, many times Moderna's manufacturing costs, which are less than $3 per dose.) At that time, a Moderna spokesperson stated, "[t]he government sets the price" in these negotiations—not Moderna.[169]

That is the key—when the U.S. government wields its power as the world's largest payer for vaccines, prescription drugs, and other medical products, it can negotiate better deals for the American public.

Now, Congress has ceased funding for these bulk vaccine purchases,[170] and the White House has announced that it will stop negotiating them.[171] The result, as I've described above, will be Americans left to navigate the market on their own and drug companies—including Moderna—free to set arbitrarily high prices. Kates, Cox, and Michaud observe that "insurers and public programs will not have much leverage [on price] since they are generally required to cover all ACIP recommended COVID vaccines with no patient out-of-pocket cost."[172] The result may be much higher overall spending along with reduced access.

To its credit, the Biden administration has proposed creating a new "Vaccines for Adults" (VFA) program that would provide uninsured adults with free access to all ACIP-recommended vaccines, including COVID-19 vaccines.[173] To protect the public purse and public health,

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[168] Nathan-Kazis, J., *Moderna lands $1.7 billion deal with government. Pfizer is getting more per dose*, Barron's (Online) (Jul. 29, 2022), https://www.barrons.com/articles/moderna-pfizer-covid-vaccine-sale-51659110407. ("Last week, *Barron*'s wrote that the price that Moderna extracted from the U.S. government for the fall boosters would be an important signpost as to how competition in the COVID-19 vaccine market will shake out. At the time, Oppenheimer analyst Hartaj Singh told Barron's that he thought that Moderna was holding out for $35 per dose or more.").

[169] Id.

[170] Press Release, The White House, FACT SHEET: Consequences of lack of funding for efforts to combat COVID-19 if Congress does not act, Mar. 15, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/15/fact-sheet-consequences-of-lack-of-funding-for-efforts-to-combat-covid-19-if-congress-does-not-act/; Adam Cancryn and Erin Banco, *Biden's Operation Warp Speed revival stumbles out of the gate*, POLITICO (Oct. 5, 2022), https://www.politico.com/news/2022/10/05/white-house-warp-speed-covid-vaccine-research-funding-00060448.

[171] Brenda Goodman, *Biden administration will stop buying COVD-19 vaccines, treatments and tests as early as this fall, Jha says*, CNN (Aug. 16, 2022), https://www.cnn.com/2022/08/16/health/biden-administration-covid-19-vaccines-tests-treatments/index.html.

[172] Jennifer Kates, Cynthia Cox, and Josh Michaud, *How much could COVID-19 vaccines cost the U.S. after commercialization?* KAISER FAMILY FOUNDATION (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

[173] White House Budget of the U.S. Government Fiscal Year 2024, Office of Management and Budget, https://www.whitehouse.gov/wp-content/uploads/2023/03/budget_fy2024.pdf

Congress should fund this program and resume funding for bulk purchases of COVID-19 vaccines for everyone (not just the uninsured).

2. Explore use of the Defense Production Act to bring prices down

The Defense Production Act (DPA) is a 1950 federal statute that provides the U.S. President with broad authority to protect the national defense. The statute defines "national defense" as encompassing "critical infrastructure," which in turn encompasses "public health."[174]

In 2020, the Trump administration reportedly used the Defense Production Act to Moderna's benefit, to accelerate the company's R&D and manufacturing.[175] And when President Biden came into office in January 2021, he vowed to "fully use the Defense Production Act and to safeguard the country by producing more pandemic supplies in the U.S."[176]

The Defense Production Act could conceivably be used assertively by the White House, to compel Moderna to make certain concessions in the name of public health and national safety. In 2021, legal experts Amy Kapczynski, Zain Rizvi, and Jishian Ravinthiran analyzed the DPA and concluded that it could be used to compel Moderna, Pfizer, and other vaccine manufacturers to share valuable information on mRNA vaccine manufacturing with the World Health Organization.[177] That same year, David Kessler—Chief Science Officer of COVID-19 Response on the White House COVID-19 Response Team, former head of Operation Warp Speed, and former Commissioner of the FDA—suggested some agreement with these legal experts; he

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[174] 50 U.S.C. § 4552. More specifically, the DPA defines "critical infrastructure" as "any systems and assets, whether physical or cyber-based, so vital to the United States that the degradation or destruction of such systems and assets would have a debilitating impact on national security, including, but not limited to, national economic security and national public health or safety."

[175] Lisa Simunaci, *Defense Production Act is shot in the arm for Warp Speed's mission*, Defense Visual Information Distribution Service (Dec. 31, 2020), https://www.dvidshub.net/news/386211/defense-production-act-shot-arm-warp-speeds-mission ("To date, all six vaccine candidates in the Operation Warp Speed portfolio – Moderna, AstraZeneca, Novavax, Jannsen, Sanofi and Pfizer – and companies manufacturing therapeutics, such as AstraZeneca, Eli Lilly, Regeneron and SAb BioTherapeutics, have priority ratings under the Defense Production Act and have all received extensive assistance from Operation Warp Speed to acquire access to scarce supplies, materials, and equipment, Gillette said.").

[176] *President Biden Announces American Rescue Plan*, The White House (Jan. 20, 2021). https://www.whitehouse.gov/briefing-room/legislation/2021/01/20/president-biden-announces-american-rescue-plan/.

[177] Amy Kapczynski and Jishian Ravinthiran, *How to Vaccinate the World, Part 2* Post to *LPE Blog* , The Law and Political Economy (LPE) Project (May 4, 2021), https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/; Zain Rizvi, Jishian Ravinthiran, and Amy Kapczynski, *Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide* Health Affairs Forefront, (Aug. 6, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210804.101816/full/.

stated that the Defense Production Act "is probably the strongest authority [the President has over vaccine manufacturers], and that does give the president the authority to allocate doses" of vaccine.[178]

Now that Moderna has threatened to quadruple prices of its booster shots (and Pfizer too), I encourage the White House to revisit potential uses of the Defense Production Act to negotiate lower prices. For example, the Defense Production Act permits the President to demand that suppliers of HHS accept certain purchase orders and place those orders at the front of their manufacturing "queue."[179] The Biden administration could consider using this authority to negotiate lower prices, and thereby expand access to booster shots and better protect the American public from COVID-19.

3. Cut harder bargains with future pharma industry partners

The entire "Moderna affair"—a close public-private partnership that has soured into a private company's attempted profiteering—should teach us lessons about the next generation of public-private partnership, in pharmaceuticals and beyond. In my view, one of the most important lessons is that the U.S. government should cut harder bargains with its industry partners, to better protect the American public.

To quote a recent piece from physician and sociologist Victor Roy,

> [T]o achieve public goals, the US government can use its position as a pivotal investor and buyer to set conditions in contracts. These conditions would relate to pricing and access, technology transfer, and reinvestment in innovation. The UK government, for example, negotiated pricing and access provisions with Astra-Zeneca during development of its covid-19 vaccine. The Bush administration created a program to transfer technology and scale-up for influenza vaccine manufacturing around the world in the mid-2000s. And for companies receiving government pandemic aid, US officials prohibited share buybacks and considered taking equity stakes to encourage reinvestment and a fairer return on public investment.[180]

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[178] Bob Herman, *Biden admin warns Moderna to "step up" global vaccine supply*, Axios (Oct. 13, 2021) https://www.axios.com/2021/10/13/covid-vaccine-moderna-biden-global-supply-covax.

[179] Amy Kapczynski and Jishian Ravinthiran, *supra* n. 177, https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/; 45 CFR § 101.33.

[180] Victor Roy, Financing COVID-19 mRNA vaccines, 380 BMJ 413 (2023), https://www.bmj.com/content/380/bmj.p413.short. See also Mariana Mazzucato, *A collective response to global challenges: a common good and 'market-shaping' approach* 1 (UCL Inst' for Innovation and Public Purpose, Working Paper No. 2023—01), https://www.ucl.ac.uk/bartlett/public-purpose/publications/2023/jan/collective-response-our-global-challenges-common-good-and-market-shaping ("To effectively address the grand challenges of our time, we cannot simply tinker around the edges by fixing market failures. We must actively shape markets to deliver on the objective of generating more sustainable and inclusive growth. This paper argues that an objective-

There are concrete steps that NIH and other scientific agencies can take in this direction, with the next generation of public-private partnerships they enter into. For example, NIH and other funders should curtail the worrisome practice of using "Other Transaction Agreements," which dispense with standard protections for the American public on pricing, access, and competition.[181]

In addition, NIH and other agencies could revise some of their standard contracts. As Ameet Sarpatwari, Alison LaPidus, and Aaron Kesselheim have explained, these agencies could reintroduce fair pricing and other pro-access conditions into its model cooperative research and development agreement (CRADA).[182] This standard agreement allows private institutions to work with government agencies and negotiate exclusive licenses for inventions stemming from such work. Sarpatwari, LaPidus, and Kesselheim argue that fair pricing conditions will not dissuade industry from ever partnering with government, "given that private industry reliance on government-sponsored research has increased as more large manufacturers have reduced investment in their own laboratories. A new fair pricing condition that is well designed and well enforced could better ensure that Americans can affordably access drugs created with NIH support."[183] Operation Warp Speed's success, and the incredible scientific success of NIH's collaboration with Moderna, further underscore the value and common reliance of industry on government and government-funded research. To the extent that revision of CRADAs and other standard agreements requires new legislation, I encourage the distinguished Members of this Committee to explore such legislation.

4. Explore legislation for deeper reform

Finally, I urge both President Biden and Congress—including Members of this distinguished Committee—to explore legislation that would fundamentally reshape the broken ecosystem of pharma and biotech in various ways. I think the status quo—one in which

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oriented economy requires a market-shaping approach; one that accompanies the concept of the public good with the common good framing that is needed to design the interface for this collaboration. This is about structuring the conditions and governance mechanisms that shape the capabilities, tools, institutions and partnerships needed to take concrete action.").

[181] Katherine Ardizzone and James Love, *Other transactions agreements: Government contracts that eliminate protections for the public on pricing, access and competition, including in connection with COVID-19 vaccines and treatments*, Knowledge Ecology International (June 29, 2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf.

[182] Ameet Sarpatwari, Alison LaPidus, and Aaron Kesselheim, *Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support*, Annals of Internal Medicine (Mar. 3, 2020), https://www.acpjournals.org/doi/full/10.7326/M19-2576.

[183] *Id.*

Americans pay twice for medicines, first by acting as the world's most important early-stage investors in new technology and then by paying the world's highest prices at the pharmacy—is increasingly untenable.

I have written about such potential legislation in other contexts.[184] Here I will focus on just one important idea: a "public option" in pharmaceuticals.

We could build on the extraordinary success of scientific research at U.S. government agencies—embodied in the NIH-Moderna vaccine—and expand the role that NIH and other public agencies play, not just in early-stage research but in late-stage R&D and even in manufacturing. As Dana Brown, Ameet Sarpatwari, and Aaron Kesselheim have argued, a national public pharmaceutical R&D institute for full-cycle drug development could focus on the most important areas of unmet medical need or public health importance and be statutorily committed to contributing to safe, adequate, and accessible supply of essential medicines in the US; to maximum transparency; and to management in the public interest.[185] Dana Brown and Thomas Latkowski argue, convincingly, that "public pharma" initiatives could have a range of benefits beyond affordable access to patients and payers, including stable, well-paying, unionized jobs in public-sector manufacturing and R&D.[186] To again quote Victor Roy,

> [G]overnments should explore building public options to manufacture critical health technologies. In addition to securing supply in public health emergencies, public production has two other benefits. Revenues can be reinvested into domestic innovation and manufacturing; and a public option serves as negotiating leverage for fairer deals with private manufacturers. Old and fresh experiments in public production of pharmaceuticals can provide a basis for scaling up public options.[187]

Public development and manufacturing of vaccines is no pipe dream. It is already happening. Matthew Herder, Janice Graham & Richard Gold have shown how Canada's public National Microbiology Laboratory and other public institutions developed "Merck's" Ebola vaccine essentially on their own, with negligible help from Merck.[188] In addition, the

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[184] *See, e.g.*, Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 Calif. L. Rev. 493 (2021); Dana Brown, Alex Lawson, Christopher Morten & Fran Quigley, *Reclaim Public Medicine for Public Health*, Common Dreams (Aug. 20, 2020).

[185] Dana Brown, Ameet Sarpatwari, and Aaron Kesselheim, *Development of a National Public Pharmaceutical Research and Development Institute*, 48 J. L. Med. Ethics 225 (2020), https://pubmed.ncbi.nlm.nih.gov/32342778/.

[186] Dana Brown and Thomas Latkowski, *Public Pharmaceuticals*, Democracy Policy Network, https://democracypolicy.network/agenda/strong-people/strong-bodies/public-pharmaceuticals.

[187] Victor Roy, Financing COVID-19 mRNA vaccines, 380 BMJ 413 (2023), https://www.bmj.com/content/380/bmj.p413.short. https://www.bmj.com/content/380/bmj.p413.short

[188] Matthew Herder, Janice E. Graham, and Richard Gold, *From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine*, 7 J. L. Bioscience 1 (2020),

Commonwealth of Massachusetts owns a long-running, public, not-for-profit vaccine developer and manufacturer called MassBiologics.[189] MassBiologics currently manufactures the Tetanus and Diphtheria Toxoids, Adsorbed (Td) vaccine and distributes products nationwide.[190] And the State of California has made headlines with large recent investments toward public sector manufacturing of insulin and other medicines.[191]

NIH's recently created Advanced Research Projects Agency for Health (ARPA-H) unit is arguably a promising step in this direction.[192] I urge the Committee to consider further investments in a "public option" in pharmaceuticals, to better protect taxpayers and patients.

V. Acknowledgments

I gratefully acknowledge Columbia Law students Matt Tracy, Rubí Rodriguez, Davis Gonsalves-DeDobbelaere, Stijn Talloen, Hiba Ismail, Emily Davidson, Stephanie Lim, Wisdom Onwuchekwa-Banogu, David Ratnoff, Keerthi Manimaran, and Nancy Lu for research assistance. All views expressed herein are my own, as are all errors.

* * *

I again thank the Committee for inviting me to testify. I look forward to your questions.

Respectfully submitted,

/s/ Christopher J. Morten
Christopher J. Morten
March 20, 2023

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249092/; *see also* Matthew Herder, Janice E. Graham, and Richard Gold, *The public science behind the 'Merck' Ebola vaccine*, STAT News (Jan. 16, 2020), https://www.statnews.com/2020/01/16/public-science-behind-merck-ebola-vaccine/; Kelly Crowe, *Canada's Ebola vaccine almost didn't happen, new study reveals*, CBC (Jan. 17, 2020), https://www.cbc.ca/news/health/ebola-vaccine-national-microbiology-laboratory-pharmaceutical-industry-scientists-1.5429060.

[189] Dana Brown and Thomas Latkowski, *Public Pharmaceutical State Policy Kit*, Democracy Policy Network (Dec. 2020), https://api.democracypolicy.network/wp-content/uploads/2022/12/Public-Pharmaceuticals-State-Policy-Kit.pdf.

[190] *Id.*

[191] Aya Elamroussi, *California to make its own low-cost insulin, governor says*, CNN (July 8, 2022), https://www.cnn.com/2022/07/08/us/california-makes-own-insulin/index.html. *See also Legislative Guide for Insulin for All, Public Citizen and T1International (May 2020),* https://www.t1international.com/media/assets/file/Public_Citizen__T1International_Insulin_for_All_Legislative_Guide_-_May_2020.pdf (discussing state and federal proposals to manufacture insulin in the public sector).

[192] Advanced Research Projects Agency for Health (ARPA-H), NIH, https://www.nih.gov/arpa-h.

[SUMMARY STATEMENT OF CHRISTOPHER MORTEN]

The NIH-Moderna vaccine is in many ways an incredible success story: A public-private partnership developed and deployed an innovative new vaccine in record time. Millions of deaths and hospitalizations were averted. Moderna and its investors made tens of billions of dollars.

For 2 years, we, the people of the United States, had free access to this vaccine, because our government purchased large quantities at affordable prices and distributed them for free. That, sadly, is changing—and the story of the NIH-Moderna vaccine may turn to failure.

The U.S. Government plans to leave Americans on their own to figure out how to pay for booster shots. Moderna proposes massive price increases, from $20-$30 per dose to $110 or even $130, though each costs less than $3 to make. Moderna's proposed increases would likely cause some people who need boosters to forego them. More Americans would get sick and die.

Moderna pledges a patient assistance program, but these programs are complicated and inevitably miss people—especially those most likely to need assistance. Even with a patient assistance program, higher vaccine prices would hurt us all through higher systemic costs.

Moderna has given us reason to take its pledges skeptically. As I show in my testimony, Moderna broke its past pledge not to enforce patents while the pandemic continues, and, just this month, Mr. Bancel made false statements when defending Moderna's proposed price increases.

Moderna's proposed price increases are indefensible. Moderna cannot reasonably claim the value of the NIH-Moderna vaccine for itself. Much, and arguably most, of the vaccine's value is traceable to the American public and our tax dollars. Americans should be deeply proud of our collective contributions, which included not just enormous and unprecedented direct financial support of Moderna but also innovative, prescient scientific research conducted by NIH and NIH-funded university researchers years before COVID–19 emerged.

My testimony summarizes the scientific history of three key features of the NIH-Moderna vaccine—three features that Moderna's own scientists have identified as essential to the vaccine's success. U.S. Government and government-funded academic researchers can proudly claim to have invented two of these three features. Moderna lacks a strong claim to have invented any of these three features—though that has not stopped Moderna from exaggerating its own role or omitting NIH scientists from an important patent application.

To be sure, Moderna's scientists and engineers have made many other meaningful contributions to other features of the vaccine. They deserve celebration, even as the company's executives deserve criticism.

The U.S. Government and Moderna were once close partners. Moncef Slaoui, former head of Operation Warp Speed, said the government "held Moderna by the hand on a daily basis." We had a bargain—perhaps unwritten, but a bargain nonetheless. In my view, Moderna's new plan to quadruple prices for the American public breaks that partnership and that bargain. It sets a troubling precedent. Other powerful companies will double down on Moderna's playbook: Exploit public science and public money to extract billions in private profit; leave us all with higher costs, inaccessible technologies, poorer health.

If Moderna insists on higher prices, I urge our leaders to act, including the Members of this Committee. I'll make two recommendations here. (I present more in my written testimony.)

1. Congress and the White House should work together to resume bulk purchases of COVID vaccines. Leverage the buying power of the American people. Provide affordable vaccines to all.

2. NIH and other scientific agencies must cut harder bargains with pharma industry partners—with explicit, legally binding commitments to shared control—so that the public gets access to the next generation of medical products that our money creates and that we need to survive and thrive.

The CHAIR. Thank you very much. Our next witness is Dr. Ameet Sarpatwari, who is an Assistant Professor of Medicine at Harvard Medical School. He is an Epidemiologist and a Lawyer. He is an

expert on the role of public investment in driving new medical breakthroughs. Doctor, thanks very much for being with us.

STATEMENT OF AMEET SARPATWARI, PH.D., J.D., ASSISTANT PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. SARPATWARI. Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Senate HELP Committee, thank you for the opportunity to testify. I urge you today to strongly condemn and swiftly act to prevent Moderna's attempt to quadruple the price of the NIH Moderna vaccine, which would fill the company's coffers with unmerited public funds and severely threaten public health.

The reasons why, centered on the extraordinary role the Federal Government played in Moderna's success, and the substantial barrier to access that this price increase would have. Building on $337 million in pre-pandemic funding of research directly contributing to key investments in mRNA vaccines, the Federal Government made a series of unprecedented investments in multiple pharmaceutical companies to develop a vaccine under Operation Warp Speed.

Moderna was one of the largest beneficiaries, receiving over $2 billion to support clinical trials of the NIH Moderna vaccine, $1.5 billion in an advanced market purchase for a then unapproved product, and over $50 million to scale up manufacturing. In this respect, the Federal Government turned traditional therapeutic development on its head.

The brunt of the risk, for which we reward pharmaceutical companies the ability to charge monopoly like pricing, was borne by taxpayers. Moderna's benefits from the Federal Government didn't end there.

NIH scientists co-developed the mRNA sequence encoding the vaccines immunogen and independently developed the vaccine spike protein. Moderna was also granted broad immunity against patent infringement for use of other patented technologies, which the company has cited as a defense in ongoing litigation.

Through these Federal Government contributions, Moderna, a company that had never brought a product to market, was able to secure emergency use authorization of the NIH Moderna vaccine, benefiting handsomely from its use.

Moderna earned $37 billion in revenue in 2021 and 2022, $20 billion of which was profit. Despite these riches, Moderna has at every turn sought to enrich itself further at the expense of Americans and the global South.

In the U.S., Moderna has already denied the pivotal contributions of the Federal Government in the development of the NIH Moderna vaccine and broken its pledge not to enforce its patents during the pandemic.

In October 2021, as the pandemic raged globally, Moderna was supplying its doses almost exclusively to wealthy nations, more so than any other manufacturer. Moderna's price increase is an escalation in this troubling pattern of behavior and a step too far.

It cannot be justified based on the value of the vaccine which was created on the backs of taxpayers and with the central contributions of NIH scientists. It also cannot be justified on the need for research and development.

Moderna had ample funds for this. Flush with money, it maximized short term profit. In 2022, Moderna spent more on stock buybacks than it did on research and development. Moderna's offer of a patient assistance program is no solution.

These programs are often complicated with applications that take considerable time to complete and frequent changes in eligibility, as well as onerous income documentation requirements.

We have received no details of this patient assistance program to date. Given these barriers, it is likely that many Americans will miss booster shots and this will result in more infections and more deaths, particularly among vulnerable populations. The public will also still bear the full cost of an unconscionable price increase.

Now is the time to say enough. The Federal Government should resume purchasing doses for all Americans, leveraging its purchasing power to obtain a fair price. Such an act would not threaten innovation or the willingness of companies to race for a cure in a subsequent pandemic.

Instead, it would demonstrate a dual commitment to allow pharmaceutical companies to profit handsomely for their efforts under reduced risk, and to ensure reasonable access to Americans in a time of crisis. Thank you.

[The prepared statement of Dr. Sarpatwari follows:]

RECENT EVENTS

In January 2023, Moderna announced that it was considering increasing the price of its vaccine about 400% in the United States, from $26 to $110-130 per dose.[4] This news prompted criticism, most notably from Sen. Sanders (D-VT), who pointed out Moderna's "corporate greed" during the "worse public health crisis in America in 100 years."[5]

In response to public pressure, Moderna published an eleven-line press release on February 15 stating that the manufacturer would launch a patient assistance program for under- and non-insured Americans while ensuring that the NIH-Moderna vaccine would also be available "at no cost for insured people," without additional specifics.[6] One month later, Moderna has still offered no details on this plan.

EXTENSIVE FEDERAL GOVERNMENT CONTRIBUTION TO DEVELOPMENT

Moderna's justification for its proposed price increase—the value of the NIH-Moderna vaccine[7]—does not withstand scrutiny. Although the vaccine has saved countless lives,[8] Moderna is not entitled to extract its full value, which was created with essential, unprecedented contributions from the federal government via the US taxpayer.

The development of the NIH-Moderna vaccine is an incredible public funding success story. Prior to the pandemic, the federal government invested at least $337 million into research and development leading to three inventions integral to mRNA vaccines.[9] With NIH funding at the University of Pennsylvania, Katalin Karikó and Drew Weissman successfully synthesized modified mRNA able to avoid a vigorous immune response.[10] NIH funding also supported the discovery of the structure and effectiveness of targeting

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[4] Peter Loftus, *Moderna Considers Price of $110-$130 for Covid-19 Vaccine*, WALL ST. J. (Jan. 9, 2023), https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609.

[5] *Letter from U.S. Senator Bernie Sanders to Moderna Chief Executive Stéphane Bancel*, SENATOR BERNIE SANDERS (Jan. 10, 2023), https://www.sanders.senate.gov/wp-content/uploads/Moderna-Letter-01.09.20231.pdf.

[6] *Moderna's Commitment to Patient Access in the United States*, MODERNA (Feb. 15, 2023), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx.

[7] *See* Beth Mole, *Moderna CEO: 400% price hike on COVID vaccine "consistent with the value"*, ARS TECHNICA (Jan. 10, 2023), https://arstechnica.com/science/2023/01/moderna-may-match-pfizers-400-price-hike-on-covid-vaccines-report-says/ ("The Journal spoke with Moderna CEO Stephane Bancel at the JP Morgan Healthcare Conference in San Francisco Monday, who said of the 400 percent price hike: 'I would think this type of pricing is consistent with the value.'").

[8] Meagan C. Fitzpatrick et al., *Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths*, THE COMMONWEALTH FUND (Dec. 13, 2022), https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations.

[9] Hussain S. Lalani et al., *US Public Investment in Development of mRNA Covid-19 Vaccines: Retrospective Cohort Study*, 380 BMJ e073747 (2023), https://pubmed.ncbi.nlm.nih.gov/36858453/.

[10] *Id.*

prefusion coronavirus proteins.[11] Department of Defense funding was critical to the development of mRNA vaccine technology, supporting the first human trial of an mRNA vaccine (for rabies) and the development of other mRNA vaccines for Chikungunya, Zika, and HIV.[12]

At the start of the pandemic, NIH scientists Barney Graham, Kizzmekia Corbet, and Olubukola Abiona—together with university researchers Jason McLellan, Nianshuang Wang, and Daniel Wrapp—raced to engineer the prefusion-stabilized SARS-CoV-2 spike protein used in multiple COVID-19 vaccines.[13] NIH scientists even co-invented the mRNA sequence at the heart of the vaccine.[14]

Critical federal government support extended into clinical trial testing and manufacturing. In May 2020, the Trump Administration launched Operation Warp Speed, an interagency partnership between the Department of Health and Human Services and the Department of Defense to support the development of COVID-19 medical countermeasures, including vaccines, therapeutics, and diagnostics.[15] By November 2020, the Biomedical Advanced Research and Development Authority (BARDA) had provided 7 manufacturers with $10.8 billion to support the development of COVID-19 vaccines.[16]

Moderna—a manufacturer that had yet to commercialize a product—received $902 million for late-stage clinical trials and $57 million to boost manufacturing capacity.[17] The National Institute of Allergy and Infectious Diseases, within NIH, spent an additional $410 million "on Moderna studies from preclinical work all the way to the phase three clinical trial that started on July 27 [2020]."[18]

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[11] *Id.* Even the lipoprotein nanoparticle technology used in the COVID-19 mRNA technology has roots in Canadian funding. *See id.* ("The US government was not alone in publicly funding basic and translational science underlying mRNA covid-19 vaccines before the pandemic. Canada made significant investments in the lipid nanoparticle invention . . . .") (citing Elie Dolgin, *The Tangled History of mRNA Vaccines*, 597(7876) NATURE 318 (2021), https://pubmed.ncbi.nlm.nih.gov/34522017/).

[12] *Id.*

[13] Carolyn Y. Johnson, *Serendipity and Foresight Prepared the World to Fight the Coronavirus*, WASH. POST (Oct. 1, 2021), https://www.washingtonpost.com/health/2021/10/01/barney-graham-covid-vaccines/.

[14] Julie Steenhuysen, *Moderna COVID-19 Vaccine Patent Dispute Headed to Court, U.S. NIH Head Says*, REUTERS (Nov. 11, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-covid-19-vaccine-patent-dispute-headed-court-us-nih-head-says-2021-11-10/.

[15] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGE (2021), https://www.gao.gov/products/gao-21-319#:~:text=What%20GAO%20Found,vaccine%20development%20and%20mitigate%20risk.

[16] Zain Rizvi, *BARDA Funding Tracker: Tracker Details Billions in Taxpayer Funds Supporting COVID-19 R&D Efforts*, PUBLIC CITIZEN (last updated Nov. 2, 2020), https://www.citizen.org/article/barda-funding-tracker/.

[17] Lalani et al., *supra* note 9. By March 2022, BARDA and NIH had provided Moderna with $1.7 billion and $490 million, respectively, for clinical trials. *Id.*

[18] Sydney Lupkin, *Moderna Announced a Free COVID Vaccine Program. But Will That be Accessible Enough?*, NPR (Mar. 2, 2023), https://www.npr.org/2023/03/02/1160714581/moderna-announced-a-free-covid-vaccine-program-but-will-that-be-accessible-enoug.

Federal support for Moderna did not end there. In August 2021, BARDA gave Moderna a $1.5 billion "at-risk" advanced market commitment to purchase 100 million doses of the then-unapproved NIH-Moderna vaccine.[19] Under the terms of the contract, Moderna claims that it was also provided protection from possible patent infringement for use of lipid nanoparticle technology via the government's patent use rights, which it has asserted in ongoing lawsuits with the companies Arbutus and Alnylam.[20]

Comments from key US officials highlights the extent of the federal government's role. Upon making the at-risk market commitment, then-HHS Secretary Azar noted,

> Today's investment represents the next step in supporting this vaccine candidate all the way from early development by Moderna and the National Institutes of Health, through clinical trials, and now large-scale manufacturing, with the potential to bring hundreds of millions of safe and effective doses to the American people.[21]

Moncef Slaoui, then-head of Operation Warp Speed and a former member of the Moderna Board of Directors, was more colorful, stating, "We held Moderna by the hand on a daily basis."[22]

Combined, the above taxpayer-funded contributions by the federal government turned the traditional model of therapeutic development on its head. The therapeutic development enterprise is long, risky, and capital-intensive. For example, for every 10 drugs that enter Phase I testing, approximately 1-2 make it to market.[23] The costs of vaccine development to the end of early clinical safety and efficacy testing, including the possibility of failure, has been estimated to be between $84 and $112 million.[24] Late-stage

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[19] *Trump Administration Collaborates With Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine*, U.S. DEP'T OF DEFENSE (Aug. 11, 2020), https://www.defense.gov/News/Releases/Release/Article/2309561/trump-administration-collaborates-with-moderna-to-produce-100-million-doses-of/.

[20] Blake Brittain, *Moderna Again Points at U.S. Gov't in COVID-19 Vaccine Patent Lawsuit*, REUTERS (May 24, 2022), https://www.reuters.com/legal/litigation/moderna-again-points-us-govt-covid-19-vaccine-patent-lawsuit-2022-05-24/.

[21] *Trump Administration collaborates with Moderna to produce 100 million doses of COVID-19 investigational vaccine*, MEDICAL COUNTERMEASURES | USA PUBLIC HEALTH SECURITY (last updated Aug. 11, 2020), https://www.medicalcountermeasures.gov/newsroom/2020/modernamanufacturing/.

[22] Karen Weintraub, *Deliver a Safe, Effective COVID-19 Vaccine in Less Than a Year? Impossible. Meet Moncef Slaoui.*, USA TODAY (Dec. 1, 2020), https://www.usatoday.com/in-depth/news/health/2020/12/01/operation-warp-speeds-moncef-slaoui-guided-covid-19-vaccine-creation/6375043002/.

[23] *See* CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (April 2021), https://www.cbo.gov/publication/57126.

[24] Dimitrios Gouglas et al., *Estimating the Cost of Vaccine Development against epidemic infectious diseases: a cost minimisation study*, 6(12) LANCET GLOBAL HEALTH E1386 (2018), https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext.

clinical trials are often more expensive, with one study reporting a mean cost of $240 million.[25]

We reward companies for shouldering these at-risk costs with market exclusivity for approved therapeutics and, thus, the ability to charge monopoly-like prices for a fixed time. As Marcia Angell and Arnold Relman commented, "the theory behind patents and other forms of exclusivity is that they will provide an appropriate but limited incentive for companies to develop important and innovative new drugs."[26] If the incentives are too low, private companies may not invest in researching these therapeutics, as has been seen in the antibiotics space.[27] However, if the incentives are too great, reducing the likelihood of important treatments for ongoing unmet medical need.[28] Thus, a balance must be struck between risks and rewards.

In the case of the NIH-Moderna vaccine, much of the cost and risk was borne by US taxpayers. The return for this extensive de-risking, which lowered the incentive necessary to spur companies to act, was and remains affordable access to the NIH-Moderna vaccine.

RECORD PROFITS AND RESEARCH AND DEVELOPMENT COSTS

Another argument that has been made to support the massive, proposed price increase of the NIH-Moderna vaccine is that additional revenue is needed to support investment in research and development, which for Moderna totaled just under $3.3 billion in 2022.[29] This argument is also weak.

Moderna has already secured ample revenue for research and development. With the essential contributions of the federal government, Moderna received emergency use authorization of the NIH-Moderna vaccine in January 2021. Over the course of the next two years. Moderna earned $37 billion in revenue, $20 billion of which was profit.[30] In 2021,

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[25] *See* Christopher M. Snyder, Kendall Hoyt, & Dimitrios Gouglas, *An Optimal Mechanism To Fund The Development Of Vaccines Against Emerging Epidemics* (National Bureau of Economic Research Working Paper 30619 November 2022), https://www.nber.org/system/files/working_papers/w30619/w30619.pdf.

[26] Marcia Angell & Arnold Seymour Relman, *Patents, profits & American medicine: conflicts of interest in the testing & marketing of new drugs*, DÆDALUS (2002), https://www.amacad.org/publication/patents-profits-american-medicine-conflicts-interest-testing-marketing-new-drugs.

[27] *See* Benjamin Plackett, *Why big pharma has abandoned antibiotics*, 586 NATURE S50 (2020), https://www.nature.com/articles/d41586-020-02884-3.

[28] *See, e.g.*, Brigitte Tenni et al., *What is the impact of intellectual property rules on access to medicines? A systematic review*, 18 GLOBAL HEALTH 40 (2022), https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4#citeas (finding exclusivities are associated with delayed availability).

[29] *See* Moderna, Inc., Annual Report Form 10-K (2022), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285223000011/mrna-20221231.htm; Moderna Inc., Annual Report Form 10-K (2021), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285222000012/mrna-20211231.htm.

[30] David Wainer, *Moderna Peers Over a Scary Profit Cliff*, WALL ST. J. (Feb. 23, 2023), https://www.wsj.com/articles/moderna-peers-over-a-scary-profit-cliff-5374e4d4.

the NIH-Moderna vaccine—the sole company product—made Moderna the sixth most profitable pharmaceutical company in the world.[31]

This success translated to rising share prices. Between January 31, 2020 (WHO declaration of the pandemic) and September 10, 2021 (peak price), Moderna's share price increased 2038%, from $21 to $449.[32] Such growth would be the envy of any biotechnology investor and helped increase Mr. Bancel's personal wealth to $4.7 billion.[33] Moderna co-founders Robert Langer and Noubar Afeyan have seen their net worth rise to $1.7 billion and $1.8 billion, respectively.[34]

Flush with cash, Moderna and its executives maximized short-term profit. In 2022, the company spent $3.3 billion on share buybacks to further enrich its investors, more than it spent on research and development.[35] The same year, Moderna structured a $926 million "golden parachute" for Mr. Bancel in the event of his dismissal.[36] Between June and September 2020, numerous Moderns executives sold approximately $90 million in Moderna shares despite widespread anger.[37] In 2022, Mr. Bancel made $398 million on actual realized gains of stock exercised and sold, a pay package STAT News reported "is likely to be one of the largest in health care for 2022."[38]

UNBRIDLED OPPORTUNISM

Despite its record profits, Moderna has repeatedly sought further enrichment at the expense of not only Americans but also the global south, downplaying the critical contributions of the federal government in the process. In the US, Moderna has already implemented price increases. Over the course of 5 orders with the federal government

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[31] Angus Liu et al., *The Top 10 Most Profitable Pharma Companies in 2021*, FIERCE PHARMA (June 14, 2022), https://www.fiercepharma.com/special-reports/top-10-most-profitable-pharma-companies-2021.

[32] *Moderna, Inc. Common Stock (MRNA) Historical Data*, NASDAQ, https://www.nasdaq.com/market-activity/stocks/mrna/historical (accessed Mar. 19, 2023).

[33] *Stéphane Bancel*, FORBES, https://www.forbes.com/profile/stephane-bancel/?sh=97d89463742f (accessed Mar. 19, 2023).

[34] *Robert Langer*, FORBES, https://www.forbes.com/profile/robert-langer/?sh=7a1e7ebd4537 (accessed Mar. 19, 2023); *Noubar Afeyan*, FORBES, https://www.forbes.com/profile/noubar-afeyan/?sh=798ef8c41d14 (accessed Mar. 19, 2023).

[35] *Moderna Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Updates*, MODERNA (Feb. 23, 2023), https://investors.modernatx.com/news/news-details/2023/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2022-Financial-Results-and-Provides-Business-Updates/default.aspx.

[36] Spencer Kimball, *Moderna CEO Bancel's Golden Parachute Soared by Hundreds of Millions over the Pandemic*, CNBC (Mar. 10, 2022), https://www.cnbc.com/2022/03/10/moderna-ceos-golden-parachute-soared-by-hundreds-of-millions-over-the-pandemic.html.

[37] Tom Dreisbach, *'Bad Optics' Or Something More? Moderna Executives' Stock Sales Raise Concerns*, NPR (Sept. 4, 2020), https://www.npr.org/2020/09/04/908305074/bad-optics-or-something-more-moderna-executives-stock-sales-raise-concerns.

[38] Bob Herman & Damian Garde, *Moderna CEO Made $398 Million in 2022, but Still Pledges to Give Most to Charity*, STAT NEWS (Mar. 17, 2023), https://www.statnews.com/2023/03/17/moderna-stephane-bancel-compensation/.

between August 2020 and July 2022, the company raised the price of the NIH-Moderna vaccine from $15 (monovalent) to $26 (bivalent).[39]

Moderna has also engaged in extensive patent gamesmanship. Unlike other manufacturers, Moderna resisted paying NIH and partnering universities for use of the patented technique to develop the prefusion-stabilized SARS-CoV-2 spike protein. Only last month did the company agree to pay NIH a $400 million "catch-up" payment.[40]

In a July 2021 patent filing for the modified mRNA sequence of the immunogen used in the NIH-Moderna vaccine, Moderna omitted three NIH scientists who played a major role in its creation: John Mascola, Barney Graham, and Kizzmekia Corbett.[41] NIH threatened legal action, with Francis Collins remarking: "I think Moderna has made a serious mistake here in not providing the kind of co-inventorship credit to people who played a major role in the development of the vaccine that they're now making a fair amount of money off of."[42] A month after the dispute spilled out into the public, Moderna partially backed down by not paying for the patent to be issued.[43]

Moderna also abandoned its pledge not to enforce its patents during the pandemic. Citing "a special obligation…to bring [the] pandemic to an end as quickly as possible," the company vowed in October 2020 that "while the pandemic continues," it would not enforce its COVID-19-related patents "against those making vaccines intended to combat the pandemic."[44] However, in August 2022, Moderna broke that promise, suing Pfizer and BioNTech for alleged patent infringement.[45]

As the pandemic raged globally, Moderna failed its obligations to low-income countries. In October 2021, Moderna supplied its doses almost exclusively to wealthy nations, more so than any other vaccine manufacturer.[46] Chastising the company and its executives, former Centers for Disease Control and Prevention Director Tom Frieden

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[39] *See* Jennifer Kates, Cynthia Cox, & Josh Michaud, *How Much Could COVID-19 Vaccines Cost the U.S. After Commercialization*, KAISER FAMILY FOUND. (Mar. 10, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization.

[40] Benjamin Mueller, *After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique*, N.Y. TIMES (Feb. 23, 2023), https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html.

[41] *See* Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 9, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

[42] Steenhuysen, *supra* note 14.

[43] *See* Rebecca Robbins & Sheryl Gay Stolberg, *Moderna Backs Down in its Vaccine Patent Fight with the N.I.H.*, N.Y. TIMES (Dec. 17, 2021), https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html.

[44] Jorge L. Contreras, *No Take-Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge*, HARV. L. SCHOOL BILL OF HEALTH (Aug. 29, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/.

[45] Carmel Wroth & Joe Palca, *Moderna Sues Pfizer Over COVID-19 Vaccine Patents*, NPR (Aug. 26, 2022), https://www.npr.org/sections/health-shots/2022/08/26/1119608060/moderna-sues-pfizer-over-covid-19-vaccine-patents.

[46] Rebecca Robbins, *Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor*, N.Y. TIMES (Oct. 9, 2021), https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html.

said, "They are behaving as if they have absolutely no responsibility beyond maximizing the return on investment."[47]

Moderna further refused to cooperate with manufacturers in low-income countries. It rejected multiple entreaties to share its vaccine technology, while simultaneously disparaging an independent effort by the South African manufacturer Afrigen to replicate the NIH-Moderna vaccine.[48] As Carrie Teicher at Doctors Without Borders commented, "Instead, Moderna…offered hollow declarations, saying it will boost its supply by creating a new vaccine production facility in Africa—fully controlled by the company—within the next four years," beyond the pressing need arising from the pandemic.[49] Moderna's proposed fourfold price increase of the NIH-Moderna vaccine represents an escalation of this troubling pattern of behavior.

PUBLIC HEALTH IMPLICATIONS

If implemented, the proposed price increase would severely harm public health and place considerable strain on payers, including Medicare and Medicaid. Upon the expected end of the public health emergency on May 11, 2023, the cost of vaccines will shift to insurers and individuals. For the insured, this shift raises concerns over possible co-pays and their effects. As the Kaiser Family Foundation noted: "A wide range of studies find that even relatively small levels of cost sharing," including vaccination.[50] Under the status quo, 27 million uninsured Americans[51] would shoulder the full cost of the NIH-Moderna vaccine.

Some potential harms of this shift in coverage will be mitigated. Medicare will cover the full cost of the vaccine under Part B.[52] Medicaid will cover the vaccine without cost sharing until September 30, 2024 (if the public health emergency ends on May 11, 2023).[53] It is also likely that the CDC's Advisory Committee on Immunization Practices will recommend COVID-19 vaccines, which would require individual and employer-sponsored private health plans subject to the Affordable Care Act's preventive services coverage

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[47] *Id.*

[48] Lauren Paremoer & Anne Pollock, *"A Passion to Change the Landscape and Drive a Renaissance": The mRNA Hub at Afrigen as Decolonial Aspiration*, 10 FRONTIERS IN PUBLIC HEALTH 1065993 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9742483/.

[49] Carrie Teicher, *What Moderna Owes the World*, STAT NEWS (Nov. 4, 2021), https://www.statnews.com/2021/11/04/what-moderna-owes-the-world/.

[50] Samantha Artiga, Petry Ubri, & Julia Zur, *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings*, KAISER FAMILY FOUND. (June 2017), https://files.kff.org/attachment/Issue-Brief-The-Effects-of-Premiums-and-Cost-Sharing-on-Low-Income-Populations.

[51] *See* Jennifer Tolbert, Patrick Drake, & Anthony Damico, *Key Facts about the Uninsured Population*, KAISER FAMILY FOUND. (Dec. 19, 2022), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.

[52] *CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

[53] *Id.*

standards to cover the vaccine without cost sharing. However, the requirement would not extend to short-term plans, in which an estimated 3 million Americans are enrolled.[54]

Moderna's proposed patient assistance plan for underinsured and uninsured Americans—the former presumably including enrollees in short-term plans—is not an effective solution. Patient assistance plans can be complicated to navigate, with applications that take considerable time to complete, frequent changes in eligibility, and "unrealistic" income document requirements.[55] At the time of completion of this testimony, no details about the program were available, prompting worries over its scope and design.

Given the barriers associated with patient assistance plans, it is likely that many of Americans will miss booster shots who would have otherwise gotten them. The consequences of this underuse will be more infections and deaths, particularly among vulnerable populations, and more opportunities for the virus to mutate.

Payers and the public will also still bear the full cost of an unconscionable price increase. Under a scenario in which 50% of American adults received one dose of a booster, US payers would spend just shy of $35 billion on COVID-19 vaccine doses [in 2023], more than "the total cost to purchase COVID vaccines for everyone at the federal bivalent booster price."[56]

RECOMMENDED ACTIONS AND IMPLICATIONS

Moderna cannot be permitted to price gouge Americans and the US government for the NIH-Moderna vaccine. To prevent this outcome, Congress can continue to place pressure on the company to cancel its proposed price increase. Such public spotlighting has caused Moderna to change course before. Congress can reverse the soon-to-be implemented shift of COVID-19 vaccine coverage to insurers and patients and continue to have the federal government purchasing doses for all Americans—or at a minimum all public payers—leveraging its purchasing power to obtain a fair price. Finally, Congress can authorize the Centers for Medicaid and Medicare (CMS) to impose a price for the NIH-Moderna vaccine based on the same factors CMS will have to consider when negotiating drug prices under the Inflation Reduction Act. These include the comparative effectiveness

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[54] *See E&C Investigation Finds Millions of Americans Enrolled in Junk Health Insurance Plans That Are Bad for Consumers & Fly Under the Radar of State Regulators*, HOUSE COMMITTEE ON ENERGY & COMMERCE (June 25, 2020), https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health.

[55] *See* Yelba M. Castellon & Shahrzad Bazargan-Hejazi, *The Impact of Patient Assistance Programs and the 340B Drug Pricing Program on Medication Cost*, 20(2) AM. J. MANAGED CARE 146 (2014), https://www.ajmc.com/view/the-impact-of-patient-assistance-programs-and-the-340b-drug-pricing-program-on-medication-cost. *See also* Niteesh K. Choudhry, *Drug company-sponsored patient assistance programs: a viable safety net?*, 28(3) HEALTH AFF. 827 (2009), https://pubmed.ncbi.nlm.nih.gov/19414893.

[56] Kates, Cox, & Michaud, *supra* note 39.

of the drug, federal financial support for its development and testing, and unit costs of production and distribution.[57]

To prepare for future public health emergencies, Congress can expand this framework to cover all emergency-related therapeutics, while ensuring adequate funding for BARDA and NIH to support late-stage research and development. BARDA and NIH, in turn, can more explicitly incorporate affordable access in their contracting.

These actions will not chill innovation, a tired and often baseless industry refrain to any reform, nor will it deter companies from responding in subsequent pandemics. The facts are that Moderna was permitted to and has profited immensely from its extraordinarily de-risked research and development. If asked to join an Operation Warp Speed 2.0 with the same extent of federal government support and the opportunity to profit only a quarter of what it did under the present pandemic, Moderna would inevitably sign up again. Tellingly, Francis Collins noted of the initiative in May 2020,

> Talking to the companies, I don't hear any of them say they think this is a money maker. I think they want to recoup their costs and maybe make a tiny percentage of increase of profit over that, like single digits percentagewise, but that's it. Nobody sees this as a way to make billions of dollars.[58]

Others with far greater capital might choose a more independent path, as happened in Operation Warp Speed. Regardless, the pursuit of a cure would continue at full speed.

CONCLUSION

Moderna benefited immensely from the federal government in the development of the NIH-Moderna vaccine. This investment and its associated risk associated were borne by US taxpayers. Their return on their investment should be affordable access. Moderna's attempt to increase the price of the vaccine four-fold shatters this social compact and should be fought. Now is the time to say enough.[59]

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[57] Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAMILY FOUND. (Jan. 24 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

[58] *Virtual Signature Event | Dr. Francis Collins, Chris Nassetta, and Mary Brady*, THE ECONOMIC CLUB (May 29, 2020), https://www.economicclub.org/sites/default/files/transcripts/Interview%20with%20Collins%20Nassetta%20Brady%20Edited%20Transcript.pdf.

[59] I am indebted to Aaron S. Kesselheim and Ryan P. Knox for their insightful comments on an earlier draft of this testimony. I would also like to thank Alex C. Egilman and Ryan P. Knox for their excellent research assistance.

[SUMMARY STATEMENT OF AMEET SARPATWARI]

Moderna's proposed 400 percent price increase of the NIH-Moderna vaccine, from $26 to $110–130 per dose, is unjustified. Although the vaccine has saved countless lives, Moderna is not entitled to extract its full value, which was created on the backs of taxpayers. Public funding, research and development, and knowledge played a large role in the vaccine's commercialization. In addition to $337 million in pre-pandemic funding of research development that directly contributed to key inventions in mRNA vaccines, the Federal Government provided Moderna with over $2 billion to support clinical trials, $1.5 billion in an advanced market commitment to purchase a still unapproved vaccine, and protection to use others' patents critical for vaccine development. For this unprecedented "de-risking," Moderna owes Americans affordable access to the NIH-Moderna vaccine.

The argument that the revenue derived from the proposed price increase is needed to support research and development is also weak. Moderna had ample funds for this purpose. Over the last 2 years, Moderna reported $37 billion in revenue, a staggering $20 billion of which was profit. Yet, in 2022, Moderna spent more on stock buy backs than on research and development.

Despite record profits, Moderna has repeatedly sought further enrichment at the expense of not only Americans but also low-income countries. In the U.S., Moderna has already implemented price increases, denied critical contributions of the Federal Government in the development of the NIH-Moderna vaccine, and broke its pledge not to enforce its patents during the pandemic. Globally, as the pandemic raged in the global south, Moderna was supplying its doses almost exclusively to wealthy nations, more so than any other vaccine manufacturer. Moderna's proposed price increase is an escalation in this troubling pattern of behavior.

Were it to be implemented, the four fold price increase of the NIH-Moderna vaccine would severely harm public health and financially strain payers. Even with Moderna's still non-detailed patient assistance plan for under-and uninsured people, there would be far fewer vaccinations. This would increase the number of infections and deaths from SARScoV–2 and provide more opportunities for the virus to mutate. Additionally, if just 50 percent of American adults receive done dose of a booster under the new price, payers would spend more than the total cost of the U.S. purchasing vaccines for everyone at its current price.

Now is the time to say enough. The Federal government should continue placing public pressure on Moderna and resume purchasing doses for all Americans, leveraging its purchasing power to obtain a fair price. Such an act would not threaten innovation or the willingness of companies to race for a cure in a subsequent pandemic. Instead, it would demonstrate a dual commitment to allow pharmaceutical companies to profit handsomely from their efforts under reduced risk and to ensure reasonable access to Americans in times of crisis.

The CHAIR. Thank you very much. Our next panelist was invited by Senator Cassidy, who is now voting, but I am happy to introduce him.

Dr. Craig Garthwaite is the Herman Smith Research Professor in Hospital and Health Services at Northwestern University. Is an applied Economist whose research examines the business of health care? Dr. Garthwaite, thanks a lot for being with us.

STATEMENT OF CRAIG GARTHWAITE, PH.D., M.P.P., HERMAN SMITH RESEARCH PROFESSOR IN HOSPITAL AND HEALTH SERVICES MANAGEMENT, KELLOGG SCHOOL OF MANAGEMENT, NORTHWESTERN UNIVERSITY, EVANSTON, IL

Dr. GARTHWAITE. Thank you, Chairman Sanders, Ranking Member Cassidy, and Members of the Committee for inviting me to testify today. Today's hearing is about Moderna's decision to raise prices for its COVID vaccine and some Members of the Committee's desire to push back on that increase.

While potentially well-intentioned, the Government's attempts to stop this price increase could impact drug development well beyond

both Moderna and the COVID–19 pandemic. When the Government provided what is undisputedly a large amount of funding to member Moderna, it did so without regulatory conditions on future pricing.

It is inappropriate to now attempt to relitigate that question after refusing to accept the funding. To put it quite simply, the correct time for Government officials to discuss price restrictions with Moderna was before they finalized the funding agreement.

Facing such potential restrictions on future profits, Moderna could have weighed its options and made the optimal choice for its investors, who we will note, already provided $3 billion in private capital at that point.

We chose not to walk down that road, likely because we knew it would delay the process of getting the lifesaving vaccine, we so desired. That was a policy choice and one we should abide by.

Moderna, perhaps ultimately naively, trusted the Government would honor its commitments and not try to enact ex-post modifications to the funding agreements. Notably, Pfizer had a different view, and Pfizer CEO, I would also note, was not in attendance today.

Trust of that nature, trust in the Government is critical to our overall system for drug development. And for that reason, why we gather today to ostensibly discuss vaccine pricing, we are actually having a far broader conversation about how economic markets can continue to provide new innovations for patients.

Such markets are essential to discovering novel pharmaceutical products. In those markets, we provide firms making large investments in drug development with a time limited period where they can profit from these successful innovations. In this way, we tradeoff some reduction in access today from higher prices for the incentives for firms to invest in future products.

These incentives are critical drivers of innovation that provide access to patients who might otherwise be left without any treatments for horrendous medical conditions. Over the past several decades, the world has enjoyed tremendous benefits from this free market system of drug development.

Patients with diagnoses that previously amounted to death sentences have been completely cured or now have entirely manageable chronic conditions. Despite this progress, many other patients struggle with serious unmet medical conditions, and many others die every year because treatments simply do not exist for their condition yet.

In debates about pharmaceutical pricing, access to medications for these individuals is all too often left unmentioned when we discuss the morality of drug pricing and access. These patients depend on firms being willing to continue to invest in future innovations.

After all, few of our existing treatments came to market without meaningful private investment. Firms make such investments when they believe there are clear and identifiable rules that govern how they will earn potential returns with successful innovations and a trustworthy regulatory state to enforce those rules.

Historically, the U.S. Government has admirably served in this trustworthy role, but I fear private firms watching these hearings, along with other recent policy actions and statements regarding Government price regulations and margin rates, are beginning to doubt the future wisdom of this trust.

Understanding the potentially broader ramifications of a loss in trust in Government does require acknowledging the incontrovertible fact that new pharmaceutical products are developed in an expensive ecosystem where private firms invest large amounts of fixed and sunk capital with little certainty of a profitable return.

While there may be some limited anecdotal evidence of altruistic individuals giving up profits solely to benefit society, these examples are unfortunately exceedingly rare. Hoping such altruistic funding will emerge from the ether is simply not a strategy for drug development.

Instead, we must accept the reality that the private firms crucial to drug development can only attract the capital they need if they can generate a risk adjusted return for their investors that is sufficiently attractive compared to other non-pharmaceutical investments. And most of these investments ultimately fail.

Firms can withstand these failures because a small number of large successful investments support a larger number of failed projects. If firms believe that policymakers will ultimately expropriate the gains from investments that are deemed too successful, they will not invest in the first place and we will get fewer products.

As much as we may not like it, this is true even when it means allowing firms to capture large windfalls from products that generate massive amounts of value for society. And if we choose to ignore this fact in favor of specious arguments and grandstanding about pharmaceutical greed, we will clearly forfeit access to future medical innovations.

That said, our goal is not to provide firms with unlimited returns on their investment. We must aim to balance the incentives necessary to attract private capital with the ability of patients to access the resulting medical innovations, and I provide numerous suggestions to that end in my written testimony.

Regardless of the choices that we make, it is critical that we understand that if we decrease spending on health care—on pharmaceuticals, we will get fewer products. That might be acceptable. We might want less innovation and lower prices. But that is the debate we should have.

We should be debating how much innovation are we willing to give up, not falling for promises that we will have lower spending and the same level or more prices. Thank you, Senator Sanders and Senator Cassidy.

[The prepared statement of Dr. Garthwaite follows:]

PREPARED STATEMENT OF CRAIG GARTHWAITE

In contrast to all other developed countries, the United States relies more heavily on private markets to finance and provide healthcare goods and services. While this is a source of consternation for some, using economic markets for healthcare is not a policy accident and instead represents the many advantages provided by market-

based healthcare. A large and diverse country such as the United States reflects a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize health and welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the wide variety of economic actors that take part in the development of innovative new healthcare products and services. It is hard to imagine that the Federal Government, or frankly any other plausible actor, would have enough omniscience to balance these forces more efficiently than a market. Therefore, despite many contentions to the contrary, a market-based system remains the best available mechanism for providing the appropriate incentives for long term welfare maximization.

Nowhere is the benefit of economic markets for healthcare clearer than in the development of novel pharmaceutical products. Over the past several decades, the world has benefited from remarkable progress in the ability to address a wide range of medical conditions using pharmaceutical innovations. Patients with medical conditions that previously amounted to death sentences have either been completely cured or now live with manageable chronic conditions, those suffering from a multitude of cancers have seen their lives meaningfully extended, and cardiovascular mortality has remarkable declined.

Few, if any, of these advancements came to market without the involvement of private firms investing capital in a market-based setting. This demonstrates the centrality of private markets and capital to our system of drug development. Given this fact, our policies should focus on how best to support and organize efficient markets for drug development and commercialization. Such markets require, among other features, a clear and identifiable set of rules governing how firms will earn potential returns from successful innovations and a trustworthy regulatory state to enforce those rules.

Today's hearing focuses on the question of whether Moderna, a private firm that received unconditional government funding, should be able to charge a market price for its product. While this topic is important, it is imperative we also understand that such discussions have the potential to impact more meaningful questions about optimal drug development. In particular, we must be aware that private firms and their investors are watching hearings such as these to better understand the degree to which they can continue to place their trust in the explicit and implicit contracts that have historically served as the foundation of their investments in drug development. Therefore, attempts by the government to change the rules of the game *midstream* for Moderna (or other firms) will likely have far reaching consequences that impact health and welfare long into the future.

Understanding the potentially broader ramifications of today's hearing requires acknowledging the basic and incontrovertible fact that new pharmaceutical products are developed in an expensive and risky ecosystem that involves a variety of institutions and firms. Each type of firm plays a different role along the complex path from early stage research to proof of concept to clinical trials and ultimately, if successful, to commercialization. The variety of organizations at each step of this process are motivated by different goals and each provides their own unique contribution to this development process. Therefore, optimal policies must carefully understand and respect the incentives of these firms.

While early-stage research is more often funded by public actors (i.e. governments or nonprofit organizations), this is only the first step in the long path from bench to bedside. Navigating the rest of this path requires private firms to invest large amounts of fixed and sunk capital with little certainty of a profitable return. Firms are willing to make these investments based on risk adjusted models of the profitability of their investments—models that require making strong predictions and assumptions about market conditions many years in the future.

These private firms can only attract the capital required for drug development if they can generate a return for their investors that is sufficiently attractive compared to other non-pharmaceutical investment options. This is the fundamental economic reality at the center of the drug development process. If we choose to ignore this fact in favor specious arguments and grandstanding about pharmaceutical greed, it is incontrovertible that we will forfeit access to some future medical innovations—which will likely decrease health and welfare.

While uncertainty around the scientific and commercial prospects of potential products makes all pharmaceutical investments inherently risky, we should strive to reduce additional uncertainty stemming from the policy environment. This is particularly true for policies that alter the rules of the game only after firms make their large, fixed, and sunk investments to develop new products. Sunk investments are

expenditures that cannot be recouped by firms after they are made. For example, once a firm spends money to run a clinical trial it is unable to get that money back if the trial fails or the product is not commercially successful. To avoid being stuck in unprofitable situations, before making such an investment firms must be careful and diligent in attempting to predict how the market might subsequently evolve.

If firms believe policymakers will expropriate the gains from investments that are deemed "too successful," they will almost certainly be less willing to make the same portfolio of investments as they make today. We must always remember that it is this portfolio approach, where a small number of large successful investments support a larger number of failed projects, that serves as the foundation of drug development. If we desire to have firms to continue to willingly make the large capital investments necessary to promote health and economic welfare, we must sustain a system where firms trust that the government will be a reliable counter party that establishes the rules of the game and then abides by those rules. This is true even when it means allowing firms to capture large windfalls from products that generate massive amounts of value and health for society.

The potential for sowing distrust in the process exists across a wide variety of dimensions. Consider the question of whether or not Moderna should be constrained from raising the price of SPIKEVAX (i.e. its vaccine for Covid–19). It is clear and undisputed that Moderna benefited from extensive government financial support in the development of this vaccine through Operation Warp Speed (OWS). It is also clear that this was part of an agreement our government made with this private firm where we provided zero cost of capital funds. In return, Moderna was expected to work as quickly as possible to develop a vaccine that would address the negative health and economic effects from the pandemic. It was a proverbial win-win situation. Moderna would only earn large profits for its investors if they could develop a workable vaccine. Society would get such a vaccine more quickly than if we relied solely on the provision of private capital in remarkably uncertain times.

We provided these public funds to decrease a private firm's risk of product development and increase the speed of these products to patients. Absent government support, it is unclear whether private capital markets would have provided a similar amount of investment on a similarly short timeframe. When these transfers occurred in early 2020, private firms faced risks from developing vaccines along two dimensions. First, they faced *commercial risk*, i.e. the possibility that by the time a vaccine was developed and manufactured in sufficient quantities the pandemic would be "over" and demand for the product would be quite low (or at least lower than would have been necessary to justify investing in the vaccine in the first place). This is a common concern of firms reacting to a novel pandemic with an uncertain duration. To address this first type of risk, the U.S. Government (and other governments around the world) offered firms funding in the form of advanced market commitments (AMCs). These commitments guaranteed purchases of specific amounts of vaccine if the product was proven to be successful—purchases that would occur even if the pandemic "burned itself out" and demand for the vaccines was low.

The second form of funding was for clinical trials. This type of funding was intended to shield firms such as Moderna from *scientific* risk about whether its product would actually succeed in clinical trials. In this case there was meaningful scientific risk because mRNA vaccines had never been developed. As a result, Moderna faced risk related to both this entire scientific approach to vaccine development as well as to their specific approach to this vaccine. In this particular case, this scientific risk was compounded by additional manufacturing risk related to a desire to have large amounts of product available as soon as possible—which required expending resources on manufacturing assets before it was even known whether mRNA would prove successful as a means of developing a vaccine of this nature.

Moderna accepted such funds to quickly move forward and develop a vaccine.[1] Absent such funding it is unlikely Moderna would have been willing to move as quickly as they ultimately did. For example, it likely would have followed the more traditional and deliberate development path of waiting until each trial was over before initiating the next stage of development. It is certainly unlikely it would have built the manufacturing scale necessary to quickly serve the entire market before it knew whether its product actually worked.

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[1] Notably, Pfizer (the other firm successful at developing an mRNA based Covid–19 vaccine) did not accept funding to shield it from scientific risk. Perhaps they feared that there were unstated strings attached to such funding—a belief that might seem prescient given their CEO is not testifying today despite announcing a similarly large price increase.

This swift approach was exactly our goal as a nation. It is my understanding from publicly available documents and news coverage that there were no constraints placed on Moderna about the future pricing of its product if it accepted these funds.[2] If the government did not desire for this to be the case, then they had the opportunity to address this issue at the time. Of course, that likely would have slowed down the process of vaccine development, which was our priority and appears to have been deemed an unacceptable cost in 2020.

Therefore, Moderna entered into an agreement with the U.S. Government to accept the funds and develop the project with the reasonable expectation that at some point they would be able to charge a higher market price for the product than what they would initially charge the government. In understanding the decision facing Moderna's leadership at this time, it is important to consider that while the government paid for much of the scientific activity related to SPIKEVAX, this product would never have been possible without the meaningful private capital used to develop all of Moderna's existing infrastructure, including, but not limited to, its platform for developing mRNA vaccines. Moderna had previously raised over $2 billion dollars in private capital from investors who were, in 2020, still seeking a profitable return on these investments.[3],[4] Moderna was also a publicly traded firm with a responsibility to maximize long term shareholder value. If faced with a future constraint on pricing as a condition for receiving government funds, Moderna's leadership would have evaluated that option against raising additional private capital that would have initially been costlier but would not have included such restrictions on future prices (and the resulting profits). Moderna's leadership accepted the government funding with the belief they could trust the government to be a reliable counter party that would not try and impose *ex post* conditions that were not present in the original funding agreement.[5]

Moderna lived up to its end of the deal by providing a vaccine in a timeline that beat most expectations.[6] As a result, we were able to limit the negative health effects for individuals who became infected with SARS-COV–2 and governments felt comfortable reopening the economy. The question is whether the government will now live up to its end of the bargain or will instead attempt to change the terms of the deal they offered by instituting *ex post* controls on the pricing of SPIKEVAX. This includes attempts to shame Moderna for undertaking the actions that we should have rationally expected from a for-profit publicly traded firm. It would be unfortunate if Moderna's trust in the government ultimately proved to be niave. However, this hearing and the broader commentary around Moderna's actions since developing a world-saving vaccine casts reasonable doubt on the U.S. Government as a reliable counter party for drug development—a reliability that has always served as a fundamental building block of innovation. This could have direct impacts on the willingness of firms to engage with the government in the case of another pandemic and broader indirect effects if firms lose more general trust in the government.

The potential broader loss of trust is only exacerbated by recent commentary and policy proposals regarding expansions to price setting power for pharmaceuticals granted to the Center for Medicare and Medicaid Services (CMS) as part of the Inflation Reduction Act (IRA). The already passed legislation will decrease investments in particular types of products likely to be affected by government mandated prices in the future. Perhaps more concerning, President Biden and other policymakers are already attempting to expand the scope of the IRA before it has been implemented or its impacts have been evaluated. Suggesting a desire to shrink the time period before negotiation to only 5 years would further chill investments.[7] Even the suggestion of meaningful uncertainty of this nature around the value of potential investments will likely cause firms to pull back capital they might otherwise have invested.

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[2] It is possible that such constraints exist in parts of the contract that have not been disclosed, but I have not seen any evidence of this fact.

[3] *https://news.crunchbase.com/startups/with-flagship-behind-it-moderna-quickly-scaled-from-startup-to-world-changing-biotech/*.

[4] *https://www.science.org/content/article/mysterious-2-billion-biotech-revealing-secrets-behind-its-new-drugs-and-vaccines.*

[5] It is my understanding that this initial funding agreement did contain a large number of restrictions on how funds could be used, so it seems even more reasonable that firm believed it would represent a complete set of future constraints.

[6] *https://www.wsj.com/articles/moderna-says-its-covid-19-vaccine-was-94-5-effective-in-latest-trial-11605528008.*

[7] *https://www.biopharmadive.com/news/biden-2024-budget-proposal-drug-prices/644674/*.

A degradation of trust in government institutions is not an abstract concern. A fundamental tenet of investments in new pharmaceutical products is that a robust, fair, and trustworthy regulatory state will enforce existing market rules and regulations. Beyond the methods of determining market prices, these regulations include those surrounding valuable institutions such as patents and other forms of intellectual property protection. Firms require these government provided protections because the very heart of the innovative process for new drugs represents a market failure that must be addressed. The failure results from the fact that the scientific advancements generated by firms in the development of innovative pharmaceutical products are essentially a public good, i.e. the knowledge generated by these investments is effectively non-rival and non-excludable protection. Firms require these government provided protections because the very heart of the innovative process for new drugs represents a market failure that must be addressed. The failure results from the fact that the scientific advancements generated by firms in the development of innovative pharmaceutical products are essentially a public good, i.e. the knowledge generated by these investments is effectively non-rival and non-excludable. [8] Rational firms realize that, absent some form of government intervention, they will be unlikely to capture the value generated by the large investments necessary to bring a product to market. This results in an economic phenomenon known as "hold up" whereby firms, absent some form of intellectual property protection to protect their eventual returns are unwilling to make value-creating investments in the first place.

To address this initial market failure, governments offer various forms of intellectual property protection. Through patents or other forms of market exclusivity, governments arm firms with *time-limited periods* of enhanced market power that allow them to capture the value created by their innovative products. During this time period, the high prices curtail some access to valuable medicines. [9] However, this reduced access today is deliberately traded off against the development of new products in the future. These new products provide access to patients for whom there would otherwise be no treatment—a situation could be seen as a more severe access problem than patient access restrictions due to higher prices. After all, prices can always be negotiated downward while there is no amount of negotiation that will grant access to treatments that don't currently exist. Such treatments will only come from new investments in technologies that will improve patient health.

In this way, policies governing drug development exemplify the old adage that there is no proverbial "free lunch." Instead, policies governing the development of pharmaceutical products involve trading off the static inefficiency of reduced access to products today in order to create the dynamic efficiency of the increased development of new products in the future. The goal is in balancing the magnitudes of these two effects. To the extent the value created by the new products exceeds the welfare losses created by the high prices (and resulting decreased quantity sold), the periods of market exclusivity are welfare-enhancing. Importantly, this could be true even if the prices today are quite high. [10] In fact, for some products treating small patient populations the only thing that will induce an optimal level of private investment may in fact be very high prices per patient.

This tradeoff is a root cause of much of the controversy for prescription drugs because the reduced access today involves some number of readily identifiable individuals who are unable to access existing and potentially life-saving medications because of price. [11] Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is always critical to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all. For these individuals, there is no price at which a treatment is available. These patients will gain access in the future only

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[8] The degree to which this is fully a public good depends on how much information can be gleaned from the actual product, the regulatory filings, and the published research. For example, small molecule products can be more easily reverse-engineered and therefore absent intellectual property protections are relatively easier to copy. Biologic products, however, have a more complex production process and therefore copying the technology is easier than making the product *de novo* but harder than for a small molecule product.

[9] The amount of reduced access is complicated by the presence of health insurance which mitigates the output restrictions by lower prices (Lakdawalla and Sood, 2013).

[10] This is particularly true because the impact of high prices on quantity is far more complicated in a world of widely available health insurance. Those who are insured may not suffer as much decreased access as they would in a market without third party payment. However, those for whom drugs do not exist certainly will not access a treatment at any price.

[11] Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

as a result of the dynamic incentives created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, we must balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

To be clear, it is perfectly acceptable to make reasoned and considered alterations to our existing regulatory frameworks. However, we should do so with careful deliberation and respect for the underlying economic facts. We must be honest and recognize that such changes will result in a lower level of investment in innovation, however, we may be willing to forgo such innovation in return for lower prices. That is the a debate that we should be having.

Regardless of the policy we pick, it is critical that we make large changes before firms sink capital at risk into drug development. If instead, we attempt to expropriate the value of successful products from the firms that invested to create them we will ultimately chill some amount of future investment.

Making changes to the explicit and implicit contracts that currently govern the drug development process will have long run impacts on future innovations. For example, some activists and policymakers have put forward theories that the government, by virtue of its investments in basic scientific research, have broad abilities to seize intellectual property. Putting aside whether such "march-in" rights actually exist in response to high prices (which is a legal question beyond my expertise) it is clear that such rights have never been exercised in that way in the modern biopharmaceutical market. Therefore, this would represent a fundamental shift in the beliefs of firms about the value of intellectual property—beliefs that serve as the foundation of modern drug development. This would have widespread ramifications on how people and firms engage with government-funded science and the ability of such public investments in basic science to improve the availability of treatments in the market. It is hard to imagine that firms making decisions about commercializing products using NIH-funded basic science will not look at commentary by policymakers about Moderna's pricing as further increasing the potential risk to their future profits from tools such as march-in rights.

That said, the time period where firms are granted market power over their innovations must be time-limited. Our goal is not to provide firms with unending returns on their investments but to balance the incentives necessary to attract private capital to these markets with access to medical innovations. Striking this balance requires the government to establish clear and firm rules about how long such a time period will last and then ensure we have strong and robust competition when periods of market exclusivity expire.

In my testimony below I provide details on policy solutions that will facilitate competition for products as their intellectual property expires—an area that is a critical component of our system. When considering optimal policies to promote competition and generic (or biosimilar) entry, it is important to remember that our goal is to decide on the preferred degree of intellectual property protection required to encourage the desired level and type of future innovation. After setting these parameters, it is incumbent on regulators to monitor and enforce these systems. This includes providing the necessary structures for strong competition between therapeutic substitutes during periods of exclusivity and the development of robust generic competition beginning immediately at the end of the exclusivity period.

Ultimately, firms will attempt to optimally respond to any incentives governments create—and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome. In particular, we must ensure that our policy infrastructure matches the existing economic conditions created by the more complex and expensive medications we are currently developing. Much of the successful infrastructure that we have built over time for post-exclusivity competition was designed for the small molecule generic market. Small molecule generic products are exact bioequivalent copies of approved innovative medicines. As a result, we as a society are often more comfortable with competition promoting regulations such as automatic substitution that swiftly and effectively move almost the entire market to generic products after patent expiration. Large molecule (or biologic) products, however, are too complicated to create exact copies and therefore "generic" competitors come to market as "biosimilars"—a designation that means they are not automatically substituted.[12] This introduces important nuance for how we think about competition and entry after patent expira-

[12] While there is a pathway for biosimilars to be labeled as interchangeable, this greatly increases the costs of development and to date has been rarely used by new entrants.

tion. It also leads to an inherently more complex patenting environment that makes questions about entry timing more difficult.

For example, biologic products are more often used to treat a wider variety of conditions and indications than many historical small molecule products. These broader uses for a product are socially valuable and are developed based on meaningful investments by firms in clinical trial evidence. As a society we must support the use of existing products for as many conditions as is appropriate. However, we must also develop and enforce policies that promote competition at the *indication level* which balances incentives for developing new uses for existing drugs with the need for time limitations for market power over a firm's initial innovations.

Firms should be rewarded for making the investments necessary to prove their products would be clinically effective against additional indications. However, as a society we must balance these additional financial rewards for firms with our desire to support competition in the market. Specifically, we must be wary that new indications could be exploited to thwart potential entry into the market by new firms attempting to market a generic version to treat only the original indications. If this were to occur, an innovative firm could capture an inappropriately large amount of the economic surplus created by the ability of their product to treat the original medical condition (as opposed to value created by the new indication).

To address this concern, one area where we require greater clarity, guidance, and potentially legislation is around the ability of new entrants to implement a so-called "skinny label" strategy. Under such a strategy, firms could introduce generic or biosimilar competitors to the market for single indications that are not protected by patents or FDA exclusivity. However, the new entrant would be prohibited from *marketing* this product for any indications that were still protected by a patent. As I discuss below, it is imperative we create a clear and appropriate pathway for competitors to enter at the indication level even if patents exist for other indications.

Emerging questions around skinny labels and market entry are examples of the inherent complexities created by the more sophisticated products and processes involved in modern drug development. These complexities also result in a wide array of patents for the same product. While many cite the existence of such a large number of patents as *prima facie* evidence of "gaming" and anti-competitive behavior by firms, the story is actually more complicated. Increasingly complex pharmaceutical products likely give rise to a far more complicated patenting environment. Given the sophistication of production methods and the increasing ability of products to be used for a variety of indications, successful products are now surrounded by meaningfully large patent estates. There is no question that this makes it harder for potential competitors to enter. There is, however, an open question as to whether large numbers of patents represent the large amount of intellectual property required to develop these types of products or a deliberate strategy by firms to deter entry. Of course, there is no single broad answer to this question and any policy solutions must respect the nuance of intellectual property protection and the resulting incentives in this area. That said, I outline several policy solutions below intended to both increase the rigor of patent review (and therefore the strength of the resulting patents) and better regulate the process of generic and biosimilar entry.

Beyond questions around patents and labeling strategies, it is also clear that the lack of bioequivalent "generic" products for biologics creates difficulties for market entry. In particular, the lack of an exact, substitutable copy (an interchangeable biologic) creates some hesitancy for physicians to move patients off of existing reference products on which the patient is medically stable. This hesitancy likely results from the fact that achieving medical stability is often a process that can take many months or years of identifying the correct medication and dose for the patient. As a result, biosimilar entrants are often competing for only a portion of the existing market (either patients who are not medically stable or newly diagnosed patients who have not yet started a treatment regime). As I discuss below, this inability to rapidly access the entire market, combined with features of our existing pricing and rebate system can make it difficult (or impossible) for biosimilar firms to enter and gain meaningful market share. In particular, an existing system where firms often make rebates contingent (all or in part) on competitors not being "on formulary" can meaningfully benefit incumbents at the expense of new market entrants.[13] Such formulary contracts that "reference a rival product" could dissuade entry and artificially extend the incumbent's market position for particular types of biologic prod-

[13] It is important to note that the source of such exclusionary contracts is unclear. It is quite possible, and even likely, that firms are encouraged by PBMs to make an offer that would grant them the entire market. This could be optimal for each PBM even if it is not optimal for the entire market.

ucts. In the same way that rules around generic entry differ for small and large molecule products, it may be necessary to create different regulations for how formularies are constructed for biologic products.

In addition to concerns about formulary placement, our existing system of physician reimbursement for many biologic products creates incentives for physicians to continue to use more expensive products. This is particularly true under Medicare Part B but also pervades portions of the commercial market—where reimbursements often follow the structure (but not the absolute level) of Medicare payments. Reforms to Medicare Part B reimbursements could both promote entry and decrease artificial incentives to increase prices in the private market—both of which should be policy goals.

Finally, the difficulties for competitive markets created by more complex products are not limited to biologics. While we traditionally believe the small molecule generic market works well, this is primarily true with the more common large markets with numerous patients available to multiple firms. The success of the system supporting generic entry is far less clear when the size of the market is small and therefore struggles to support multiple competitors. In such cases, single firms can acquire all existing rights to market a drug, raise prices, and still face little entry because there are insufficient incentives for new firms to enter. In this way, the generic market would function as if a firm continued to enjoy some form of intellectual property protection. While this problem is limited to a relatively small number of products today, an increase in "precision medicine" where even small molecule products can be targeted at very small populations means this concern will only grow in prominence over time. Therefore, it is important to address these questions today before they become a dominant market feature with powerful political supporters.

As you can see, my testimony today focuses on promoting competition in pharmaceutical markets—with a particular focus on competition after regulatory exclusivity. That said, it is always important to remember that the goal of government policy in this area is to balance the incentives for innovation with a patient's access to value-creating products. Others have proposed more drastic exercises of government power in order to simply reduce prices today. This is often driven by inappropriate promises that these price decreases will come without cost. However, that is not the case. When considering the potential patient access benefits of such proposals to artificially reduce prices, we must be comprehensive in our analysis and consider both the degree of improved access today and the ability of the market to continue to provide access in the future to patients who currently lack existing treatments.

I understand it is tempting to cave to the crass political calculus that purports to increase access in a visible way today and obscures the potential long-term costs of such decisions. After all, once we observe the magnitude of those costs most elected officials making these decisions will have moved on to other careers. But the goal of policy is to carefully weigh those future costs and not believe snake oil promises that expropriating value from firms today can cure all of our ills with no side effects. In the testimony below I provide more details about policies that will balance these various forces to ideally enhance health and economic welfare.

I. The Tradeoff Between Access and Innovation in the Modern Pharmaceutical Market

It is not surprising that attention to high healthcare prices has focused so heavily on the pharmaceutical sector.[14] Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms *appear* to simply be profiteering at the expense of patients. Complaints that high prices are primarily about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the continued development of innovative products. By granting intellectual property protection, governments allow innovative firms to earn positive economic profits for a period of time without facing the threat of competition that would result from the immediate entry of a firm making an identical product. Economic research suggests this profit incentive matters and consistently documents that pharmaceutical R&D responds to expected market size. Pretending this is not the case ignores reality and will only lead to inefficient, value-destroying policies.

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[14] In thinking about this attention, we should note that pharmaceuticals make up at most 20 percent of healthcare spending.

While the logic of trading off some amount of access today in order to gain access tomorrow is clear, the parameters of the length and breadth of this tradeoff are policy decisions for which there is no definitive economic answer. These policy parameters reflect the relative value society places on lost access today and potential welfare gains from future innovation. They also reflect the degree to which high prices today may not lead to a correspondingly large reduction in access because of the market-expanding features of health insurance. [15]

Understanding the nature of the tradeoff and determining the appropriate policy parameters in the contemporary market requires understanding a bit more about the modern pharmaceutical development process. New products come to market through the partnership of a variety of actors in the value chain. This includes basic science done for understanding the nature of disease, early stage pre-clinical research to develop a proof of concept, and then an arduous process of navigating the regulatory process to prove that a product is ultimately safe and efficacious. Each stage of this process represents meaningful risk and firms will only undertake each successive step in the development process if the expected net returns are sufficiently attractive compared to the next best use of the invested funds.

I.A. Basic Science Research and the National Institutes of Health

Certainly, the development process begins with basic science research—a meaningful portion of which is financed by government entities such as the National Institutes of Health (NIH) as well a variety of other non-profit organizations. This means many expensive products on the market rely to some degree on knowledge generated as a result of government funding. For example, one study found that all of the 210 products approved from 2010–2016 relied to some degree on research funded by an NIH grant. [16] This fact has led many activists and policymakers to contend that the NIH is "responsible" for bringing these products to market and therefore should be required to demand price concessions as part of their patenting activity. [17] Some have gone as far as to say that the NIH should exercise its "march-in rights" and seize the patents of products which are deemed to have prices that are too high. [18]. While such policies might lend themselves to attractive slogans and sound bites, the reality is far more complicated than is often discussed.

Understanding the pitfalls of proposals to strengthen the role of the NIH in pricing requires thinking more carefully about the government's role in drug development in the first place. At a broad level, advances in basic science that improve the understanding of how diseases work or the mechanisms of action driving the efficacy of potential products are relatively hard to successfully protect with our existing intellectual property tools. As a result, firms worry they will be unable to appropriate the value of investments in developing novel advances in basic science. In effect, despite various intellectual property protection regimes, investments in basic science still suffer from many of the public good-related market failures that would plague an entirely unrestricted pharmaceutical market. Firms that do not reasonably believe they can profit from investments will not make them, and as a result there is a fear that basic science research will be under-provided. Given its lack of profit incentives, the NIH is ideally situated to solve this public goods problem by stepping into the market and funding the basic science that otherwise would not occur.

That said, without significant additional investments in drug development, this government-funded basic science research would not result in treatments that address unmet needs in the market and increase economic welfare. In the current market, these additional investments are provided by private firms that undertake additional research and development to commercialize the NIH-funded basic science. The appropriate economic framework for understanding these government investments in basic science is one where this research is a *complement to* rather than a *substitute for* research funded by private risk capital. When you consider government funding as a complement to private research, it becomes clear that our goal

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[15] It should be noted that these high drug costs could impact premiums and the ability to buy insurance. Heavily insured markets can create an incentive for higher drug prices and could result in decreasing welfare in situations where insurance is sold for generic and branded products as a bundle.

[16] E. Galkina Cleary, J. Beierlein, N. Surjit Khanuja, L. McNamee, F. D. Ledley, "Contribution of NIH funding to new drug approvals 2010–2016," *Procedures of the National Academy of Sciences*, March 2018, 115(10).

[17] L. Zhou, "The new bipartisan Senate bill aimed at making Big Pharma lower drug prices, explained," *VOX*, July 31, 2019.

[18] M. Mezher, "Lawmakers Urge HHS to Exercise 'March-in' Rights to Fight Higher Drug Costs," *RAPS.org, January 11, 2016*.

should be to attract as many private firms as possible to leverage these NIH investments in basic science. This would provide the most "bang for the buck" for our government dollars. Currently, this is accomplished by placing relatively few constraints on partnerships between the NIH and private firms. Given the benefits to society from moving basic science from the bench to the bedside—this policy of few constraints should remain.

I.B. The Decentralization of Early Stage Drug Development

Proponents of strict price regulation point to the fact that the savings from such efforts could be redirected back to the NIH and offset any expected decline in innovation. This belief, however, ignores the current assets and activities of the NIH—which is to evaluate and fund *basic science* and not undertake drug development and commercialization activities. While there are a small number of examples of the NIH taking part in more advanced stages of drug development, these are certainly the exception rather than the rule—as would be expected given the purpose of the NIH is to solve the public goods problem for basic science research. To move into a primary drug development role, the NIH would need to transform into something that more closely resembles a private firm. It is not simply a question of providing more funding for the NIH's current system, but transforming in many ways the purpose and activities of the current NIH.

While it is possible the NIH could complete this transformation, this would mean it is no longer primarily solving the public goods problem of basic science and instead would attempt to determine which potential opportunities to commercialize this science should come to market. This effectively involves introducing more central planning to the development of new products where a single firm is undertaking both basic science and drug development activities. In considering the wisdom of such a strategic shift, we should consider that it would run counter to the recent decisions of the major players in the private market. In recent years, large pharmaceutical firms are *decreasing* the degree to which they singularly dictate the path of research through internally funded R&D programs. Instead, the world of biotech drug development involves large numbers of small startups that are increasingly funded by venture capital firms. The most promising and successful of these firms are generally acquired by the larger market participants that then guide the product through the FDA approval process and handle the post approval sales and marketing strategies.

The fact that so much early stage innovation is done by small private firms that do not ultimately commercialize the product has led many to claim that regulators have the freedom to decrease prices without harming innovation. After all, since the firms currently selling the product didn't actually undertake the costly investments in early stage R&D, those early innovative activities are not driven by the eventual profits of these more established firms. This couldn't be further from the truth. The ultimate goal of the providers of private risk capital for early stage firms (e.g. venture capital investors) is a profitable "exit" for their funds. This traditionally happens in the form of an acquisition, though increasingly we are also seeing early stage biotechnology firms going public through an initial public offering (although this trend has reversed in recent years given existing market conditions). The financial terms of these eventual exits are dictated by the potential revenues of the product in the market and thus would be affected by regulated prices that decrease average returns.

In this way, the access and innovation tradeoff is perhaps even greater in the modern world of venture capital backed early stage drug development. This private funding is inherently mercenary in nature and in search of the highest returns. If potential returns from biotech investments fall, investors will simply redirect their funds from the pharmaceutical sector toward the next best option.[19] In this way, policies which decrease the potential profits will lower investments in early stage investments and the resulting increase in profits. While we might think that the NIH could step into the role of venture capital firms and provide funding to early stage biotech firms, there is little evidence they would be effective at this role. At a minimum, we must acknowledge that it is a vastly different enterprise than they are currently engaged in and therefore requires more than simply additional funding for their current activities.

[19] While it is true that there are a number of venture capital firms that focus entirely on the biopharmaceutical sector, they are primarily investing other people's funds and those investors are targeting areas of the economy that provide the greatest returns.

Again, we may find it optimal to limit the flow of innovation in exchange for greater access to the smaller number of products. However, this must be a reasoned calculation and not one based on the false belief that the efforts of even a better-funded NIH or the better angels of a scientist's nature will somehow fill the void vacated by the venture capitalists. This reasoned choice must consider the overall value created by innovation over the long term compared to the relatively short period of exclusivity where access is diminished because of high prices but is certainly not reduced to zero.

II. The Role of Government in Limiting Welfare Losses During Period of Market Exclusivity

For the reasons discussed above, determining the parameters of the access and innovation tradeoff is difficult. That said, there is clearly a role for the government in attempting to limit (to the extent possible) the loss of welfare that occurs during periods of market exclusivity. This can be done both by ensuring the existence of robust competition among therapeutic substitutes and supporting the operation of well-functioning insurance markets. There are four areas where the government could do more in these areas: (1) promoting competition at the indication level when products can treat multiple conditions; (2) supporting a robust system for evaluating patents; (3) creating a modern infrastructure for regulating competition between biosimilars and reference products; and (4) developing strong incentives for price competition between products in government insurance programs.

II.A. Promoting Competition at the Indication Level when Multiple Indications are Present

When products are able to treat multiple conditions the time period for the market entry of competing generic or biosimilar products can become muddled. Innovative products often contain various types of patents and exclusivity related to the underlying molecule, its production, and its method of use. Even in the situation where all of these are valid, it can be difficult for firms to navigate this large set of patents (a concern that I also discuss in the following section).

We want to provide the incentives for firms to find multiple uses for existing products. After all, society has already invested meaningful resources to show that such products are safe and provide efficacy in at least one condition. This includes both clinical trial evidence but also valuable real world evidence about safety from patient populations that are often much larger than those in the original trials.

That said, we also do not want these additional indications to shield firms from appropriate generic competition for the original uses of these drugs. For this reason, existing regulations allow generic firms to enter with a "skinny label" that only allows them to market the product for indications that no longer have patent protection or other forms of exclusivity. However, existing regulations also require that the label for a generic product matches the existing reference product's label. Recently, a Federal court ruled that certain information that is required to be on the label could be viewed as an inducement to infringe on the reference products method of use patents.[20]

This ruling creates an untenable tension in current law where we want generic firms to enter with a skinny label, but existing regulatory requirements could apparently require such firms to include information on their label that would result in them infringing on some of the patents held by the manufacturers of the reference products. Regardless of future court decisions in this area, it is imperative that Congress consider future legislation that offers a clear path to market for generic firms at the indication level.

II.B. Negotiations Over Patent Infringement

Market exclusivity is governed by a variety of governmental institutions. Central to this system are the intellectual property protections provided by patents. Patents offer protection for firms developing novel products. During the time period of patent protection, firms are safe from competition arising from a new entrant selling an exact copy of their innovative product. After patents expire, the intention is for other firms to swiftly enter the market and sell copies of the patented product, with the resulting competition lowering prices and increasing access.

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[20] *https://www.supremecourt.gov/DocketPDF/22/22-37/222237/20220429174452402-Scanned%20Application.pdf.*

Obviously, there is a clear role for government involvement in this area. After all, the initial granting of patents and other forms of intellectual property protection is solely a government action. Governments also regulate the challenges to such patents and the process by which competitors enter the market as exclusivity expires.

Potential entrants observe the rules created by governments and weigh the potential costs and benefits of attempting to enter into competition with a branded product. Increasingly, this includes navigating a myriad of patents related to the underlying pharmaceutical product, the various uses of the product, and its production process. Given the requirement that patents be narrow and specific to a particular invention, modern complex products are often covered by a wide range of patents. Critics claim this large number of patents reflects an attempt by innovative firms to create a "patent thicket" that raises the costs of entry. These critics believe that rather than reflecting intellectual property, the large number of patents is solely intended to create a costly entry barrier that decreases the number of potential entrants and extends the length of market exclusivity. Given this concern, some critics have gone as far as to suggest that each branded product should be limited to a single patent. [21]

While it is surely true that some firms engage in such a "thicketing" strategy to deter entry, the mere existence of even a very large number of patents is not, on its own, evidence of a nefarious strategy. As the complexity of the production process increases, it is reasonable to assume that these processes will also involve the creation of important and necessary intellectual property. All else held equal, this would result in a greater number of patents per product.

Beyond the complexity of production, pharmaceutical products are increasingly used to treat multiple conditions. Discovering potential new uses for these existing drugs requires additional expenditures on scientific discovery and clinical trials. The incentives to invest in those activities stems from the ability to appropriate some of the value created. Given there are great benefits to society from firms developing new uses for existing products, we should encourage firms to investigate whether products which have already been determined to be safe could be used for additional indications. A system that limits the number of patents that can exist for a product would diminish the financial incentives for firms to invest resources to determine these new uses.

That said, the existence of large numbers of patents creates a more difficult path for generic and biosimilar entry. The heart of this concern, however, should not be about the *number* of patents pertaining to a particular product but instead about the underlying *validity* of those patents. Ultimately, this is a question about the efficacy and rigor of the patent approval process undertaken by the Patent and Trademark Office (PTO). If the PTO is granting a large number of relatively weak patents to firms that are deterring entry, this is something that should be addressed directly. It could be that this is the result of the growth in demand for patents on potential new innovations outstripping the resources available to the PTO. Academic research has shown that resource constraints affect the accuracy of patent examiners, with more time-constrained examiners issuing patents that were more likely to be later invalidated. [22] Rather than making sweeping rules about the number of patents, policymakers should more directly examine increased resources in an efficiently run PTO.

One potential model to provide greater resources for the PTO is a process similar to the Prescription Drug User Fee Act (PDUFA) which provides vital additional resources to the FDA that flex with the level of regulatory demand. It is possible that pharmaceutical patents could be assessed additional fees that could be used to increase resources in this area.

The large number of patents creates a further concern about negotiations between branded firms and potential entrants about the timing and manner of entry. Under our existing system, an economically meaningful fraction of generic entrants come to the market by challenging some of the underlying patents of the branded product. Given the potential cost and complexity of these lawsuits, these firms often settle on a negotiated date of entry. These negotiated dates are invariably before the formal end of every related patent but after the date indicated by the earliest patent affecting the product in question. There are valid concerns that such negotiations are a ruse to extend the exclusivity period for branded firms. Effectively, the con-

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[21] R. Feldman, "One-and-done' for new drugs could cut patent thickets and boost generic competition," *STAT News*, Feb 11, 2019.

[22] Frakes MD, Wasserman MF. *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*. National Bureau of Economic Research; 2020.

cern is that the brand and potential entrant are colluding to split the surplus resulting from the lack of competition. Such concerns are correctly heightened when branded firms transfer something of value to the potential entrant. While the oft-discussed *Actavis* decision stops firms from transferring money in exchange for delayed entry, that has not eliminated concerns that settlements detailing entry could be a source of concern.

That said, such settlements are an expected result of a system where we rely on potential entrants to use "Paragraph IV" challenges to effectively police the validity of patents granted by the PTO. Litigation is costly, uncertain, and distracting to the main business activities of firms. For this reason, firms in all markets often attempt to settle lawsuits out of court rather than taking them to trial. Rather than attempt to cast all settlements as attempts to manipulate the market, I would encourage policymakers to revisit the policies that govern such challenges. Over time, Paragraph IV challenges under Hatch-Waxman have become a very common feature of the entry of new products. Even unmeritorious challenges are expensive for the system. It is possible that various features of the market, including but not limited to the 180 day exclusivity for the first-to-file generic firm and the 30 month stay for patent challenges, may be an inefficient means of policing and operating an intellectual property protection system.

One potential avenue to consider is the Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act of 2019. This proposed act would eliminate the 30-month delay for generic entry that is automatically triggered when a patent is challenged. Importantly, this would only apply to patents that are not the main product patent. Without the automatic 30 day stay, a generic firm would be free to enter "at risk," i.e. if they are later found to be infringing on a valid patent they would owe damages to the patent holder. The economic incentives here would result in firms only entering when they believe that the patent is truly weak, i.e. firms would be unlikely to enter at risk against strong patents because they would be afraid of having to pay damages. In that way this would eliminate the protections for weak patents that are currently created by automatic 30 month stay.

II.C. Biosimilar Adoption and Rebates

While rebates serve a vital function in drug price negotiations, there are also situations where the structure of the rebate contract can potentially create a barrier to entry for new competing products. For example, rebate contracts sometimes reference rival products, particularly with respect to a rival's placement on the formulary. Depending on the economic context, such rival-referencing contracts could be either anti-competitive or pro-competitive. For example, a manufacturer may offer larger rebates if its product is the only one in a therapeutic area on the preferred tiers of the formulary. If there are many potential products that are competitors for the entire market, such a contract could be efficient. In fact, these types of contracts are at the heart of the PBM strategy. In describing his strategy, the Chief Medical Officer of Express Scripts said, "So we went to the companies, and we told them, we're going to be pitting you all against each other. Who is going to give use the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products."[23] Since 2012, there has been marked growth in the use of these exclusion lists.

In situations where manufacturers are competing for access to the PBM's entire patient population, these types of contracts can be pro-competitive, leading to large discounts and increased welfare. However, for some types of products, large portions of the market are not truly contestable, i.e., the PBM will not be able to effectively move a fraction of the patients to the low-price product. For example, patients who are currently using a biologic product may be unlikely to be willing to switch to a competing biosimilar at almost any price. In addition, PBMs might find that payers would not be happy with strategies that forced their patients to move across biologic products in this manner.[24]

In a situation where a new entrant cannot effectively compete rapidly for a large fraction of patients, a rebate contract for the incumbent product that is contingent on the absence of the rival entrant on the formulary can serve as an almost impenetrable barrier to entry. This situation is sometimes referred to as a rebate "wall" or "trap." Effectively, the new entrant finds that it cannot offer the PBM a large

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[23] Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." Managed Care. April 5.

[24] Plan sponsors are not simply looking for the *lowest* cost plan, but instead the plan that best balances costs and benefits for their customers or employees.

enough rebate on its products (which represent a relatively small share of sales) to overcome the lost rebate dollars from the incumbent (which represents a majority of the market). In such a situation, the new entrant would find it quite hard to ever gain meaningful market share. Perhaps more concerning, realizing the existence of these rival-referencing contracts, potential biosimilar manufacturers may never choose to attempt to create products in the first place. Concerns about the use of rebates in this manner have been raised by many individuals, including FDA Chairman Scott Gottleib and the CEO of Novartis Vas Narasimhan.[25],[26] They are also the subject of antitrust litigation between reference products and biosimilar firms, which is winding its way through the court system and should provide additional guidance about the legality of these practices.[27],[28]

Given the potential for the rebates contingent on rival products to block potential entrants, regulators should consider more careful oversight and monitoring of rebate contracts that reference rivals. In situations where a large portion of the market is not contestable by the new entrant—for example, in the case of the first biosimilar entering against a reference product—it may be advisable for regulators to create additional restrictions on the ability of rebate contracts to reference the position of rival products on the formulary. In particular it may be necessary to consider separate rules or tests for contracts and rebates based on whether patients are treatment-niave or medically stable on a particular biologic product or biologic products.

In considering why government intervention may be necessary to address these contract structures, it is important to note that even if exclusive contracts limit entry and raise market wide prices, each PBM may have an incentive to demand a bid from a manufacturer for exclusive formulary placement. This could maximize the rebate for the PBM and allow for a more competitive PBM and/or health insurance product. Any individual PBM would benefit from such a contract and may not be able to influence the individual entry decision for any particular product. This could result in a "tragedy of the commons" problem that might be best solved by government action.

II.D. Creating Stronger Incentives for Negotiation in Government Programs

Supporting a competitive market for prescription drugs is made even more complicated by the heavy role of government in the procurement of healthcare for vulnerable populations such as the indigent, elderly, and disabled. Given the fact that healthcare is a unique product for which society places particular value on an individual's ability to access services regardless of their ability to pay, the U.S. has developed a series of social insurance and transfer programs to help vulnerable populations access care. Over time these programs have grown, and public spending now accounts for just over half of all healthcare spending in the United States—a fact that makes healthcare markets distinct from the rest of the economy.

Given the economically meaningful role of the public sector in the healthcare market, the ability to maintain a competitive market inherently relies, at least in part, on government policies and regulations. Ultimately, healthcare is our Nation's most meaningful public-private partnership. This has become even more apparent as the United States increasingly relies on private firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and the Affordable Care Act—which I've previously noted is perhaps the most conservative, market-based approach to the provision of health insurance for such a large number of low-income individuals.[29] Private firms are being used to provide these services because, at their core, they have the strong incentive to respond to consumer demand in a quest to maximize profits. These incentives allocate resources in ways that increase welfare. It is unlikely that a govern-

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[25] Liu, Yanchun. 2018. "FDA chief says pharmas use rebates to block biosimilar competition." MarketWatch. July 19.

[26] Narasimhan, Vas. 2018. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs." Forbes. April 12.

[27] Biosimilars Council. 2018. "Brief Of The Biosimilars Council As Amicus Curiae In Opposition To Defendants' Motion To Dismiss." Civil Action No. 2:17-cv–04180-JCJ. United States District Court For The Eastern District Of Pennsylvania, January 26. Accessed March 4, 2019. *https://www.accessiblemeds.org/sites/default/files/2018-01/AAM-Amicus-Brief-Pfizer-vs-J%26J-1-26-18.pdf*.

[28] United States District Court for the Eastern District of Pennsylvania. 2017. "Complaint, Case 2:17-cv–04180-JCJ." September 20. Accessed March 4, 2019. *https://www.courtlistener.com/recap/gov.uscourts.paed.534730.1.0.pdf*.

[29] Garthwaite, Craig. 2017. "Why replacing Obamacare is so hard: It's fundamentally conservative." The Washington Post. July 10.

ment entity could achieve a similar result, and therefore optimal healthcare policy harnesses market forces while maintaining no illusions about the motivations of the firms it employs to efficiently provide goods and services.

However, successfully managing these public-private partnerships requires establishing rules that enhance rather than inhibit competition. While the existing Medicare Part D program involves a large amount of price negotiation, there are still many drugs paid for by Medicare that effectively involve no direct price negotiation by a payer and instead attempt indirectly benefit from private market negotiations. These drugs are administered by providers and covered under the Medicare Part B benefit. Rather than use private firms to directly negotiate prices for these products, Medicare operates under a "buy and bill" system. Physicians purchase these drugs and then are reimbursed a fixed percentage above the average sales price (ASP) of the product—a price measure intended to account for rebates paid by manufacturers to payers. The purpose of this reimbursement system is to provide doctors with simplicity and predictability of reimbursement. These attractive features, however, come at a meaningful cost for the entire system, as the Part B procurement rules increase prices for the public and private markets while also shifting share at the margin to more expensive treatment options.

In order to understand the widespread effects of Part B, consider the motivations of a pharmaceutical manufacturer negotiating with PBMs and payers to determine its optimal price. Given that these firms are attempting to maximize profits, they set prices that are expected to earn the greatest profits. Once those profit-maximizing prices are set, higher prices will, by definition, decrease the firm's total profits. This occurs because the increased margin will not make up for the lost quantity (and related profits) that comes from a greater use of prior authorization, step therapy, increased cost sharing, or other utilization management tools.

By linking public and private prices, the Part B purchasing rule distorts the optimal pricing decision in the private market. Firms are willing to increase private prices, and suffer declining profits in the private market, because they know they can make up those lost profits and more from the public market. In addition, because they know that physicians earn more money from administering a higher-priced drug, they have an additional incentive related to Part B for raising prices.

The combination of these factors means that the Part B procurement rules create the incentives for firms to offer fewer discounts in the private market, resulting in a higher ASP and greater profits from the public market. As a result, the current Part B rules for purchasing physician-administered drugs result in higher prices in both the public and the private markets. These incentives increase with Medicare's market share in each drug—a larger Medicare market means the potentially higher reimbursement from the public payers is more important for determining profits than the lost sales in the private market. Given the age and disease profile of Part B enrollees, there are a large number of high-cost drugs for which Medicare has a meaningfully large market.

As we look for policy solutions to address the lack of competition created by the Part B reimbursement rules, we must confront two areas of concern. Part B can cause higher prices both because physicians have an incentive to prescribe higher priced drugs (because they earn more for administering such products) and because manufacturers have an incentive to raise private prices to influence the public market. In attempting to address physician incentives, we must be careful not to create perverse incentives to inappropriately prescribe lower-cost drugs. We also must be careful about creating a situation where it is no longer economically viable for physicians to practice in particular areas or in particular organizational forms. For example, attempts to reform the Part B procurement rules that switch to simply paying physicians a flat fee for each administered drug ignore the fact that physicians can face meaningful inventory costs for stocking and maintaining a large volume of high-cost drugs. Many of these costs are likely a function of the acquisition cost of the product. These costs could be particularly acute for small practices, which may lack sufficient liquidity to maintain sufficient stock of medications and may make prescription choices to limit these costs. At the extreme, this could push further consolidation of the provider market.

Congress should consider policies that adopt a vendor model for the distribution of physician-administered drugs that would transform that market from the existing "buy and bill" system to one where physicians have little financial incentive to prescribe particular medications. The details of such a fundamental shift in the market are important and must be worked out. In doing so, Congress should investigate why previous attempts to establish a similar model under the Competitive Acquisition Program (CAP) did not successfully attract vendors and providers. Certainly,

part of this failure results from the fact that many providers are currently dependent on the revenues they earn from the buy-and-bill system. Thus, any successful reform must figure out a way to attract those physicians and other providers into the system. In addition, such a program would need to be sufficiently attractive to vendors to attract entrants to the market. This would likely require empowering vendors with the ability to walk away from particular drugs in order to secure greater discounts. This may limit the access of Medicare patients to some products, but we must be honest and adamant that some degree of reduced access is a necessary part of any true price negotiation process.

While there are many details to work out in this area, I would strongly encourage policymakers to follow the policy lead of Part D and find ways to utilize private-sector vendors to negotiate lower prices for Part B, rather than accepting this portion of Medicare as being a price taker. Failing to do so will continue to perpetuate a policy that increases spending across the system.

III. The Role of Government in Supporting a Robust Small Molecule Generic Market

As discussed above, the access-innovation tradeoff involves granting firms a time-limited period of market exclusivity. At the conclusion of this period, it is in the best interest of society for products to be sold in a robust and competitive market. Our existing system of follow-on competition has largely worked well since the passage of the Hatch-Waxman Act in 1984. However, the complexity of the modern drug market has created a new set of challenges for this previously well-functioning process.

Markets for generic small molecule products are intended to have fierce price competition facilitated by the automatic substitution of prescriptions toward less-expensive generic products. In a well-functioning generic market, firms compete primarily on price and therefore profits are determined by a firm's ability to manufacture products at the lowest marginal cost. This fierce price competition means that successful entrants must be able to produce enough to reach the minimum efficient scale (MES) of their production process. Absent sufficient quantity, entrants realize they will find themselves at a perpetual cost disadvantage to incumbent firms and therefore will rationally decline to enter the market. For sufficiently small markets, there is only enough demand for a single manufacturer to reach MES—and the incumbent firm is a natural monopolist that maintains meaningful pricing power.

In recent years, several firms appear to have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. This was perhaps best personified by the pricing strategies of Turing Pharmaceuticals, but aspects of this strategy have been implemented by other firms and thoroughly documented in several media outlets.[30] The ability for these firms to charge monopoly prices for generic products is not the result of the above-discussed tradeoff between access today and innovation tomorrow - society has long since paid for the innovation from any of these products. Instead, the high prices represent firms taking advantage of a market failure created by the small patient population. While large pharmaceutical firms were historically either unwilling to exploit this pricing power or unaware of this financial strategy, the practice of firms charging high prices without fear of entry in small generic markets is now widespread throughout the industry (albeit the strategy is typically employed by smaller firms with fewer invested assets in the industry). If Congress hopes that for-profit firms will simply avoid this pricing strategy going forward, they will be sorely mistaken. Instead, solutions to market failures for small-market generics will need to come either from firms being harmed by this practice or through government action.

For some of these products, private firms are stepping forward with market-based solutions. Specifically, a consortium of hospitals led by Intermountain Healthcare has created CivicaRx—a joint venture designed to address the high prices charged for many generics that are administered in a hospital setting.[31] For products administered in the inpatient hospital setting, providers are unable to pass the in-

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[30] *Hopkins, Jared S., and Andrew Martin. 2018. "These New Pharma Bros Are Wreaking Havoc on Prescription Drug Prices." Bloomberg. April 6. Pollack, Andrew. 2015. "Drug Goes From $13.50 a Tablet to $750, Overnight." The New York Times. September 20*. Rockoff, Jonathan D., and Ed Silverman. 2015. "Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices." The Wall Street Journal. April 26.

[31] Abelson, Reed, and Katie Thomas. 2018. "Fed Up With Drug Companies, Hospitals Decide to Start Their Own." The New York Times. January 18.

creased costs along to patients or payers and have therefore decided to vertically integrate and manufacture the products themselves.

While vertical integration in this setting is an efficient response by hospitals in response to a market failure in their supplier market, CivicaRx will likely not find it valuable to undertake the manufacturing of products that are sold directly to patients through retail or specialty pharmacies or administered in an outpatient setting. Those products do not impact the financial health of the hospitals involved in the joint venture. Therefore, solutions for these other products must come from new government policies that either reduce the number of natural monopoly markets or use economic tools to more directly intervene in the natural monopoly markets that remain.

If high fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential policy solution is to lower these fixed costs. This would decrease the quantity required for a new entrant to reach MES and compete with the incumbent manufacturer. In recent years, the FDA has been focused on programs to accomplish this goal. For example, there have been efforts to streamline and harmonize the generic application process across developed countries.[32] There have also been attempts to increase the speed and efficiency of the ANDA process, which would decrease barriers to entry and potentially increase the number of markets that could support multiple firms.[33]

I would encourage the FDA to continue to evaluate the approval process to look for additional efficiencies that would decrease entry costs. However, even the most efficient process for entering a generic market will require some expenditures to demonstrate the safety and bioequivalence of the product—and this will always represent a meaningful fixed-cost investment. Therefore, another potential solution to promote entry is to attempt to increase the size of some generic markets. While this can't be accomplished within any geographic boundary (i.e., we are unlikely to uncover more patients with these types of conditions), I would encourage Congress and regulators to consider a broader system of importation across developed countries with similar safety and regulatory systems (i.e., the countries the FDA is currently empowered to turn to in the case of drug shortages). Aggregating demand across these markets would increase total quantity and the number of products that could successfully be produced by multiple manufacturers. Some have argued the FDA could implement this strategy today by considering generic products with large price hikes to be a situation of shortage.[34] However, it is likely that congressional investigation and debate are needed before we implement such an important change to the sourcing of generic medications.

Even after efforts to decrease costs and increase market sizes, there likely will remain some markets that still cannot support multiple firms. In this case, further regulations are likely necessary to reach an efficient outcome. Senator Elizabeth Warren has previously proposed that the government step in to manufacture generic drugs when products have small market sizes and large drug price increases.[35] I understand and appreciate the motivation for Senator Warren's proposal and think that it is a potentially viable policy option for addressing this particular market failure, i.e., the lack of competition in markets for generic products without sufficient size to support multiple firms.

However, I fear that a government entity will likely fail at being an efficient producer of these products—after all, this is not an enterprise in which they specialize. As a result, the marginal costs of a government producer would likely be higher than for a private firm with experience in drug production. Before the government undertakes such a new and complicated economic activity, I would propose a private-sector solution in which Congress empowers the FDA to provide a new form of market exclusivity for generic products with market sizes that do not support multiple competitors.

The exact specifics of such an exclusivity would need to be worked out, but a first step would be for Congress to ask the FTC to examine how many potential patients

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[32] Gottlieb, Scott. 2018. "Advancing Toward the Goal of Global Approval for Generic Drugs: FDA Proposes Critical First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs." FDA. October 18.

[33] Elvidge, Suzanne. 2018. "FDA sets another record in 2018 for generic drug approvals." BioPharma Dive. October 12.

[34] Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. 2016. "Role of the FDA in Affordability of Off-Patent Pharmaceuticals." JAMA 315 (5): 461–462. doi:10.1001/jama.2015.18720.

[35] Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." The Washington Post. December 17.

are necessary for a market to support multiple generic firms. While most generic prescriptions are likely for molecules that can support multiple competitors, there are potentially a large number of molecules with small patient populations that can't support multiple manufacturers. For example, there has been an increase in the number of exits by ANDA holders in recent years, with many firms citing a lack of profitability. The median generic market currently has only two manufacturers, and approximately 40 percent have a single manufacturer—which likely is the result of limited market potential for these molecules.[36] That said, the current number of firms participating in the market in equilibrium does not provide sufficient information to understand whether the market could ultimately support multiple firms. After all, it is the threat of entry and not actual entry that disciplines profits. Inferring the number of firms that a particular generic market could support based on the number of current firms could be particularly problematic given the ongoing allegation of collusion in this market.[37] Therefore, it is important for economists at the FTC to determine the exact market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possesses significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and potentially increasing the market size to include some limited foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, I would propose the FDA be required to undertake a request for proposal (RFP) process for those markets. Under this RFP process, any private firm could apply for the rights to be the exclusive manufacturer of a natural monopoly generic medicine at a certain fixed percentage above manufacturing costs. As part of this RFP process, firms would compete on the amount of margin they would require to serve the market. The winning firm would possess the exclusive rights to sell the drug at this regulated price for a time period sufficient to recover the fixed costs of entry. At that time, the FDA would have the option of re-auctioning off the market exclusivity. In order to ensure the efficient operation of this process, it may also be necessary for the FDA to set a maximum percentage that they will accept before they will turn to a non-profit or government supplier for the product. This will limit any ability of firms to collude to divide up the markets they choose to enter.

I would encourage Congress to immediately investigate solutions in the area of small-market generics, as this problem will only grow in importance. Recent scientific advances have allowed for an increasing personalization of medicine. Along with co-authors, I have documented the rising share of clinical trials involving a patient-specific biomarker to determine either efficacy or safety.[38] Almost by definition, personalized medicine will involve products with limited patient populations, and for many of these products we should be worried about whether robust generic or biosimilar competition will ever emerge.[39] Therefore, while the problem of small-market generics is not a dominant feature of today's market, it will only grow in importance. It will likely be far easier to address the problem now than it will be when the number of powerful interests manufacturing such products increases.

The CHAIR. Thank you very much. Let me begin by asking Dr. Morten and Dr. Sarpatwari their assessment of Mr. Bancel's remarks. Dr. Morten.

Dr. MORTEN. Thank you, Senator. There is a lot in Mr. Bancel's remarks. I might start with his claim that the U.S. Government has already been repaid somehow by Moderna for its contributions to the NIH Moderna vaccine.

I think I heard Mr. Bancel say that we have already received something like $2.9 billion in benefit from the company. He describes it as a discount that was granted to the American public

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[36] Berndt, Ernst R., Rena M. Conti, and Stephen J. Murphy. 2017. "The Landscape of U.S. Generic Prescription Drug Markets, 2004–2016." NBER Working Paper No. 23640.

[37] Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.

[38] Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

[39] The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

back in 2020 and 2021 when we were purchasing hundreds of millions of doses. This is revisionist history.

This is sort of a new telling that Moderna has come up with, I think since this Committee called this hearing. At the time that we cut these deals, these were negotiated prices between a buyer and a seller.

Moderna sold its doses for about $20 a dose similar to what Pfizer sold its doses for similar to what Moderna sold its own product for overseas. And so, to view it as a discount I think is artificial and very much post-hoc——

The CHAIR. Thank you. Let me go to Dr. Sarpatwari. Mic——

Dr. SARPATWARI. Thank you. I would also like to touch upon the issue of the discount. I don't believe it was a discount in return for the Government's contribution to drug development.

Moderna was a smaller company. It was a company in which if invested in, then there was more risk. The actual guarantee that Moderna got was a guaranteed purchase, even if the product was unapproved. That differs from other purchases under Operation Warp Speed.

Mr. Bancel has at times attempted to justify the price increase on the grounds of increased costs. It seems to me a little bit improbable that 100-fold increase cost would be there with distribution systems that already exist.

But that is not really what irks me so much. What irks me is that at times he justifies it on the basis of cost. At times he justifies it on the basis of value. He can't have his cake and eat it, too. I think that what we are seeing here is the privatization of gain and the socialization of risk, which is not a sustainable way to operate.

The CHAIR. I want to ask both of you, pick up on a point that Dr. Garthwaite and many others have made. In the world right now and in our Country, there are people who are suffering and dying because they cannot afford the high cost of prescription drugs.

That is true in the United States. It is certainly true in poor countries around the world. Correct me if I am wrong, but there are probably millions of people dying of preventable, curable diseases simply because the price of medicine is too high. In your judgment, is there another model out there?

That addresses the issue of making sure that when a drug is developed, a lifesaving drug, its goal is not just to make huge profits for the drug company, but to make it accessible to people all over the world.

What am I missing in saying that there is something cruel and immoral of people dying and suffering in America and all over the world who cannot afford medicine, which often costs, as in the case of this vaccine, a few dollars to produce, really cheap.

What do you think about the morality, and give me alternatives to saying, hey, I got to make billions, I don't care if you die. Is there another model that will create the drugs—Dr. Garthwaite talked about the need to create new drugs.

We all want to do that. It is not the only model to say, the only way to do it is to make millions of people die. Is there another model out there? Who wants to take a response—Dr. Morten?

Dr. MORTEN. Sure, I will start. Senator, that is a truly essential question I think in this moment. I will respectfully disagree with my colleague, Professor Garthwaite. I think he said something like, if we decrease spending, we will get fewer products. It suggests a kind of a zero-sum game.

I think that is a false tradeoff. I think there are genuinely transformative options available. The NIH Moderna vaccine proves this. The NIH Moderna vaccine is not a story of the triumph of the free market, is the story of the triumph of public science and public, private partnership.

We have incredible resources at the NIH and other scientific agencies. We can unleash these. We can do public sector, pharmaceutical R&D, development, manufacturing, and we can cut better deals with industry when they come to NIH and other agencies to take some of our great technology to market.

The CHAIR. Dr. Sarpatwari. What is your thought?

Dr. SARPATWARI. There definitely are other models the rest of the world use them. So, one model that I am thinking about is just to actually gauge the value of the product and base the price off of that.

Two-thirds of drugs that have been approved in one past year that we took a look at were actually rated by health technology assessment committees as offering no greater value than what exists today. So, what we need to do is not treat innovation as a blank word. Innovation needs to mean clinically meaningful.

In that case, when something is clinically meaningful, I think we do owe—we do owe manufacturers a good profit on their development. And I think that in those cases, we need to make sure that insurance is there to make sure that millions of Americans can afford these therapies.

I do see it as a moral failure, and I think that we do have an obligation that we are failing the American people.

The CHAIR. Dr. Garthwaite, I used your name. You can respond. Do you see any other model, any other choice other than saying you are going to become a billionaire but people can't afford your product? Is there another model to get this science and innovation to people who need it all over the world?

Dr. GARTHWAITE. We could certainly have the NIH increase its funding of drugs. I know right now the NIH doesn't actually bring drugs to market. They do early stage development. As my colleague Dr. Morten pointed out, the NIH did partner with Moderna. But they did however much we want to sort of downplay Moderna's role here, there was $3 billion spent on getting a platform up and running for them.

There is a role for the private market to work together. I will note, though, that the NIH currently spends a mere fraction of what the private capital markets supply to drug developers, something in the order of like one-fourth of what the private market has.

You would have to have the Government step in and then the Government be—able to allocate that capital in a way Government has never shown it is able to do.

The CHAIR. But if the result was, taking your point, if the result was that we took that product after the companies made their fair share of profits and provided it to the world, everybody in this country at an affordable rate, don't you think from a social and moral perspective, that would be a huge step forward.

Dr. GARTHWAITE. I believe I was pretty clear in my testimony that we could have had that conversation with Moderna before we gave——

The CHAIR. I am not talking about Moderna.

Dr. GARTHWAITE. We can have a conversation with anyone beforehand, Senator, but you want to come back now after you give people money with no restrictions and then relitigate the deal, and that means people won't trust the Government anymore.

The CHAIR. Okay.

Dr. GARTHWAITE. That matters. And I think it should matter to you.

The CHAIR. Okay.

Senator Cassidy.

Senator CASSIDY. Yes. Before I start, Senator Paul asked I submit these documents for the record. I ask unanimous consent that these documents related to myocarditis associated with the COVID–19 vaccine be entered into the record.

The CHAIR. Without objection.

[The following information can be found on page 138 in Additional Material:]

Senator CASSIDY. Okay, gentlemen, I have now learned in academia, you better have a beard.

[Laughter.]

Senator CASSIDY. That is the one thing that seems to unite you all. It is interesting—I will start with you, Mr. Garthwaite. I actually think that the Federal Government actually copied best practices from the private sector in the development of the vaccine. I spoke to some people once involved with angel investing in venture capital, etcetera.

They find a clinical problem. They find the researcher that has done the best work. They work backward and fund that researcher, and that researcher on that problem identified as essential, think ALS, which they are currently doing, then develops a product from which the investors make a return, which is essentially what we did with the COVID vaccine.

We got an issue, who can do the work? We are going to fund you. Then we are going to bring it forward. Is that a fair statement?

Dr. GARTHWAITE. Yes, I think—in many ways you can think of it operating like a venture capital or an angel investing firm where we had like a very specific target we needed to hit, and the Government could be the venture capitalist for that.

As the world gets more complicated, as we think about different pathways for treating diseases and different diseases, I just question whether the Government is going to be a good venture capitalist, given all of the other——

Senator CASSIDY. I accept that. You don't have to argue that with me, brother.

Dr. GARTHWAITE. I was worried for a second but——

Senator CASSIDY. Not at all. Dr. Morten, Dr. Sarpatwari, you are—when I read your testimony, you are trying to build a case that the Government has a right to march in or to dictate a price.

Did they or did they not collaborate effectively or efficiently or whatever on the development of the science, etcetera? But that really goes beyond passes, if you will, the point that Dr. Garthwaite makes and what the CEO of Moderna made.

If you are going to negotiate some limitation on the price when we commercialize, then do it beforehand. Don't come back afterwards and ask to negotiate. Do it beforehand. That is just really the crux of the matter.

When I read your testimonies, it seems as if you are building a rationale to circumvent that crux. Dr. Morten, I will start with you. And your thoughts—be brief because I have got limited time.

Dr. MORTEN. Yes, thanks, Senator. I think it is regrettably true that in 2020, the U.S. Government, the Trump administration, did not extract from Moderna a clear contractual obligation to share control with NIH or to set affordable prices. But it is clear from the record that NIH and Moderna were partners. They had an understanding——

Senator CASSIDY. But that is beside the point. Well, that is—so sorry, and I don't mean because your testimony is all about that, but that is really beside the point. They did not negotiate before. And so—I have limited time. I am sorry. Dr. Sarpatwari—I am sorry if I am not getting your name correct. I apologize.

Dr. SARPATWARI. Sarpatwari——

Senator CASSIDY. Sarpatwari.

Dr. SARPATWARI. Thanks for the question, Senator. I agree that we need to do a better job upstream in negotiating contracts that would have avoided difficulty in this case. But I think there was an understood agreement here that in turn, for all the late-stage de-risking that was done, that a more—Americans would have affordable access to this.

Senator CASSIDY. No, you can't say that it is not affordable if there is going to be no out-of-pocket exposure for someone despite their coverage.

Dr. SARPATWARI. Affordable in two ways, I think is slightly what I mean. So first of all, we know——

Senator CASSIDY. By the way, I am sorry to interrupt—that unspoken agreement, probably should have been put on paper. I am not going to argue with that we need to have affordable drugs, but to come back and say it was unspoken is really a wish. It is not something which you can take to a court.

By the way, we can also argue whether the Trump administration failed. I was there and feces were hitting the fan and we were trying to get things done as rapidly as possible. And it is very easy to 2020 retrospectively look at things. But anyway, go back to your point. I am sorry.

Dr. SARPATWARI. Sure. And so, in terms of affordable, we need to look at the patients who are going to fall through the cracks through the patient assistance programs, which happen.

Senator CASSIDY. Now you are presuming, because it has happened with other PAPs, it is going to happen with this one.

Dr. SARPATWARI. Yes, I am.

Senator CASSIDY. But the testimony is that they are already working with advocates for the homeless in order to make sure the homeless who are often drug addled and cannot fill out paperwork, can get it completed, that sort of thing. So, you are prejudging guilt, if you will.

Dr. SARPATWARI. No, I don't think so. I am making an educated assessment based on a vast amount of evidence about these programs. I think second, when we talk about affordable, we need to think about what public payers are paying for these products because that will limit, in the case of Medicaid, what it can spend in other places. And in the case of Medicare, that is going to result in higher premiums.

Senator CASSIDY. Well, there is two things about that. And by the way, if we want to talk about capping block granting, the states are doing a per capita cap on state Medicaid program. Right now, they have kind of an unlimited budget.

Obviously that is a problem for the FISC. Dr. Garthwaite, there has been kind of a sense of, is there a new paradigm by which we could bring things to market? By the way, I hope I got your name correctly, too.

Senator CASSIDY. Can we bring things to market with a new paradigm? But I am told that prior to 2019—prior to the passage of Bayh-Dole, only 5 percent of basic research was being translated to clinical practice.

By Bayh-Dole, which basically said to universities, NIH has funded your research, but the university is going to now own the license to the patent. And you can work with private industry if you wish.

That was catalytic to dramatically increase the translational research of the basic science that NIH was funding. Is that a fair interpretation of history?

Dr. GARTHWAITE. Yes. I mean, I think we have a pretty clear sense that we are now able to commercialize things from what we often refer to as the bench to the bedside.

That basic science done sort of at universities, of which a lot of my colleagues who are much smarter than me do, is great, but it is only great when it comes to patient welfare to the extent it turns into a drug you can take. And so, Bayh-Dole provides a mechanism by which we can commercialize that science, yes.

Senator CASSIDY. Basically, at that point, we waived the white flag and we said to depend upon a Federal Government basic science researcher, and that is not what she or he is interested in, to commercialize or translate the science is not going to happen.

Dr. GARTHWAITE. Well, it is just a capital question, right. All of this is about, like who is going to pay for those next steps and who is going to make the choices about what we select to move forward.

Where there is this difference in what is good science and what could be a good product. Venture capital is a really good job of taking things out of universities and figuring out what we should commercialize going forward.

Senator CASSIDY. In which case they get to set a price, which we may not like, but nonetheless, that is part of the deal.

Dr. GARTHWAITE. Yes, I would rather they set price on a drug that exists than have people like my mother-in-law and others who have died of cancer because there is no treatment that exists for them.

Senator CASSIDY. With that, I yield.

The CHAIR. Okay. Let me thank our witnesses. Good discussion. Would like to go on further. I got to vote. Senator Cassidy has another engagement. So, this is the end of our hearing today. And thank you again. And we thank Dr. Bancel—Mr. Bancel, once more.

For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, April 5th by 5.00 p.m.

I ask unanimous consent to enter the record a statement from a stakeholder group about the cost of COVID vaccines, as well as a letter from the NIH about its inventorship of the COVID vaccine and evidence about public funding of Moderna.

[The following information can be found on page 135 in Additional Material:]

The CHAIR. The Committee stands adjourned.

ADDITIONAL MATERIAL

PREPARED STATEMENT OF KAISER PERMANENTE

Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for the opportunity to provide a statement for the record on behalf of Kaiser Permanente.[1] As the largest private, integrated health care system in the United States, Kaiser Permanente provides pharmacy services and coverage

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the Nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 700 other clinical facilities; and Permanente the Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members. As the largest private integrated health care delivery system in the United States, Kaiser Permanente delivers care to more than 12.6 million members in eight states and the District of Columbia. We are committed to providing high-quality, affordable care and improving the health of our members and the communities we serve. *https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609.*

to over 12.6 million people.[2] Our integrated model of care combines both a health plan and a care delivery system. Because payer, direct purchasing, pharmacy, and provider operations are all part of the Kaiser Permanente system, we have a unique perspective on drug prices and pharmacy benefits. Our mission for pharmacy, and all the services we provide, is to deliver high-quality, affordable care and to improve the health of our members and the communities we serve.

Kaiser Permanente greatly appreciates the Committee's attention to drug prices—and particularly troubling reports that drug manufacturers plan to increase the price of their COVID–19 vaccines nearly 400 percent as the country transitions these products to commercial markets. We have long been deeply concerned about the crippling burden high drug prices impose on our members and our ability to carry out our mission as a nonprofit organization. As the country emerges from a pandemic, manufacturers are proposing significant unjustified increases to the price of these COVID–19 vaccines, placing further pressure on health care costs and affordability.

As COVID–19 variants continue to emerge, vaccines will likely continue to play a crucial role in curbing deaths and serious illness. Therefore, these vaccines must be affordable and accessible for everyone. Kaiser Permanente understands that commercialization of COVID–19 vaccines is appropriate, but it must be done thoughtfully and methodically, with enough lead time to transition all necessary arrangements, including contracting with manufacturers and making distribution arrangements. However, given manufacturers' recent pricing announcements, we are concerned that commercialization is simply becoming a process for those manufacturers to extract excessive profits at the expense of the rest of the health care system.

Reports indicate manufacturers intend to charge up to $130 per dose, which is 5 times the current price paid by the Federal Government. These vaccines received substantial financial investment and other support from the Federal Government, including initial investments of $10 billion in taxpayer dollars to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. In the summer of 2020 alone, $1.95 billion went to Pfizer for the government to purchase and deliver 100 million doses,[3] and $2.4 billion went to Moderna for research, manufacturing, and the government purchase of 100 million doses.[4],[5],[6] Since then, billions more have been spent on advance-purchase agreements. By making up-front investments, the Federal Government took on the risk of vaccine development, thereby removing the bulk of financial risk from manufacturers as they developed their products.

Manufacturers have already recouped their investments in bringing these vaccines to market; in fact, they have made billions of dollars on their COVID–19 vaccines. In 2021, Pfizer's COVID–19 vaccine, known as Comirnaty, became the highest revenue-generating drug ever in a single year, generating $36.8 billion in sales.[7] In 2022, their vaccine generated $37.8 billion in sales.[8] Moderna, the other leading COVID–19 vaccine manufacturer in the United States, generated approximately $18.4 billion in revenue for their vaccine, known as Spikevax, in 2022.[9]

Given the significant taxpayer investment and profitability already experienced by these companies, it is unreasonable to accept price increases up to 400 percent over the price paid by the Federal Government during the pandemic. According to ana-

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[2] Within our footprint, we maintain a primarily internalized pharmacy system, including over 550 outpatient, hospital, infusion, specialty, and mail order pharmacy sites, staffed by over 14,000 pharmacy personnel. Kaiser Permanente spends approximately $10 billion annually on pharmaceuticals. Our Permanente Medical Group (PMG) physicians and other authorized practitioners prescribe, and our pharmacies, dispense over 90 million prescriptions annually. *https://apnews.com/article/science-health-business-covid-medicare-1a5d65356ebc7b5bc76524ae99deb55e.*

[3] *https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600.*

[4] *https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Award-from-U.S.-Government-Agency-BARDA-for-up-to-483-Million-to-Accelerate-Development-of-mRNA-Vaccine-mRNA-1273-Against-Novel-Coronavirus/default.aspx.*

[5] *https://endpts.com/moderna-begins-first-us-pivotal-covid-19-vaccine-study-lands-472m-more-from-barda/.*

[6] *https://www.reuters.com/article/us-moderna-stocks/moderna-shares-jump-on-1-5-billion-u-s-contract-for-covid-19-vaccine-idUSKCN2581SW.*

[7] *https://www.fiercepharma.com/special-reports/top-20-drugs-worldwide-sales-2021#c9635227-c325-40d3-8595-efd3a8db5181.*

[8] *https://billion.html.*

[9] *https://www.fiercepharma.com/pharma/moderna-covid-vax-scarfed-sales-184b-2022-company-says.*

lysts, Pfizer's proposed price hikes could add around $2.5-$3 billion in annual revenue. [10] Moderna expects to reach at least $5 billion in sales in 2023. [11]

Windfall pricing such as this will negatively impact consumers and add costs to the already strained health care system. Public and private payers will continue to cover the price of the vaccine with no cost-sharing for most patients with coverage, but the cost will still be borne by those payers. Manufacturers should not abuse policies that require $0 cost-sharing by shifting the substantial financial liabilities to the health system, taxpayers, and employers and individuals who pay the cost of health coverage. When a drug or vaccine that received substantial taxpayer funding for development is priced egregiously high, the government should use every tool it has to recoup its investment and ensure the health system and public directly benefit and don't have to pay for the same innovation twice.

It is inevitable that these price gouging practices will disproportionately impact uninsured individuals. Pharmaceutical manufacturers may announce patient assistance programs promising uninsured individuals access to "no-cost" vaccines. However, these programs will not result in sufficient vaccine uptake if individuals are required to navigate a complex application or reimbursement process. Uninsured individuals need easy access to vaccines without navigating bureaucratic obstacles. Moreover, while patient assistance programs may appear to be a step in the right direction, they will be nothing more than a fig leaf attempting to hide a gross injustice if nothing is done to address the unacceptably high list price.

When the government and industry partner to develop critical public health products, with substantial research support and financial risk mitigation by the government, it is fundamentally inappropriate for manufacturers to price their products to simply maximize profits, just as it is inappropriate for retailers to freely raise prices on basic necessities during a period of emergency. The prices paid directly by the government clearly demonstrate adequate profitability at much lower prices, even as demand has waned. At Kaiser Permanente, we are committed to ensuring everyone has affordable access to life-saving vaccines; however, we cannot ignore the significant burden astronomical list prices place on the health system, taxpayers, and patients. We call on manufacturers to do their part and reconsider their egregious prices.

Thank you for considering our perspective on these important issues. We look forward to working with you to advance meaningful solutions.

NATIONAL INSTITUTES OF HEALTH,
BETHESDA, MD.
March 17, 2023

Hon. BERNIE SANDERS, *Chairman*,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
428 Dirksen Senate Office Building,
Washington, DC.

DEAR CHAIRMAN SANDERS:

I am writing to provide additional information regarding the scientific contributions of the National Institutes of Health (NIH), and specifically scientists at the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center (VRC), that were made to the development of Moderna's mRNA–1273 vaccine against COVID–19. Below are several facts relevant to NIH's determination that Drs. Barney Graham, Kizzmekia Corbett, and John Mascola (VRC scientists at the time this work was done) are co-inventors of certain disputed patent applications. NIH has communicated these and additional details of NIH's contributions to Moderna on multiple occasions.

VRC and Moderna had collaborated since 2016 on a variety of projects including HIV, RSV, HMPV, HPIV3, Zika, MERS-CoV, and Nipah vaccines. This collaboration was formalized under agreements focused on prototype pathogen vaccine development for coronaviruses and paramyxoviruses using MERS-CoV and Nipah as the prototypes for those pathogens. The parties regularly meet to discuss collaborative projects.

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[10] *https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-covid-vaccine-price-hike-seen-giving-revenue-boost-years-2022-10-921/*.

[11] *https://www.fiercepharma.com/pharma/moderna-covid-vax-scarfed-sales-184b-2022-company-says*.

Longstanding NIAID support for intramural and extramural research enabled the development of versatile vaccine platforms and the use of structural biology tools including cryo-electron microscopy to design specific proteins—called immunogens—that powerfully stimulate the immune system. Prior to the COVID–19 pandemic, scientists at the NIAID VRC and their academic collaborators made the critical scientific discovery of how to mutationally stabilize—in a highly immunogenic form—viral proteins that coronaviruses use to infect human cells. This strategy facilitated the design of vaccine candidates that generate robust protective immune responses. As soon as the sequence of SARS-CoV–2 was made available in early January 2020, NIAID VRC researchers rapidly generated a stabilized SARS-CoV–2 spike protein for use in COVID–19 vaccine development. This crucial breakthrough in structure-based vaccine design led to the development of safe and effective COVID–19 vaccine candidates, several of which are now authorized or approved by the FDA, and built across a range of vaccine platforms including the highly successful mRNA platform.

Moderna has publicly discussed the collaboration between the NIAID VRC and Moderna on COVID–19 vaccine development. On January 23, 2020, Moderna issued a press release announcing a "new collaboration to develop an mRNA vaccine against the novel coronavirus" and stating that "The Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, collaborated with Moderna to design the vaccine."[1] On June 15, 2020, Mr. Bancel noted in an interview with Bloomberg Business that VRC and Moderna had co-developed mRNA-1273.[2] In the interview Mr. Bancel states "so what we did is we. the NIAID team, they spent a few days looking at the genetic sequence of a virus online, they read some 3-D modeling to understand the structure of the protein of the virus and then we jointly decided with NIAID what vaccine we were going to design, that took three days. And we never had access to a virus, physically. It was all information on computers."

Based on this and other information, NIH and VRC scientists emphatically believe that they were integral members of a collaborative team of scientists working to design and produce the mRNA-based SARS-CoV–2 vaccine now known as mRNA–1273.

Further, through sustained support for fundamental research underlying the vaccine concepts and the establishment and utilization of an extensive clinical trials network, NIAID helped advance the development of six candidate COVID–19 vaccines. In addition to making available the technology that enabled the development of COVID–19 vaccines, NIAID supported the Phase 3 clinical trials for three vaccines that were made available for use in the United States, including the mRNA–1273 vaccine that was developed through a collaboration between the NIAID VRC and Moderna, Inc. This support included provision of U.S. Government funds to clinical trial sites; contribution of clinical trial design, harmonization, infrastructure, and management; and delivery of in-kind resources to support the rapid assessment of these vaccine candidates.

Sustained research investments by NIH over decades prior to the emergence of SARS-CoV–2 up until today have allowed, and continue to allow, for the unprecedented pace of COVID–19 vaccine development.

Sincerely,

TARA A. SCHWETZ, PH.D.
ACTING PRINCIPAL DEPUTY DIRECTOR,
National Institutes of Health

LINKS TO INFORMATION SUBMITTED BY SENATOR PAUL

Vaccine Safety Datalink, October 2022: *https://www.acpjournals.org/doi/full/10.7326/M22-2274*.

Vaccine Safety Datalink, January 2023:*https://www.sciencedirect.com/science/article/pii/S0264410X22015419*.

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[1] Press Release: Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus (Jan. 23, 2020), *https://s29.q4cdn.com/435878511/files/doc—news/2020/01/23/moderna-announces-funding-award-cepi-accelerate-development.pdf*.

[2] *Leadership Live With David Rubenstein: Moderna CEO Stephane Bancel*, BLOOMBERG (June 15, 2020, 8:42 PM), *https://www.bloomberg.com/news/videos/2020-06-16/leadership-live-with-david-rubenstein-moderna-ceo-stephane-bancel-video*. See video beginning at the 9:30 time point.

Review article: Knudsen and Prasad, December 2022:*https://onlinelibrary.wiley.com/doi/10.1111/eci.13947*.

Israeli study, May 2021: *https://www.sciencedirect.com/science/article/pii/S0264410X21006824*.

Vaccine Safety Datalink, August 2021: *https://stacks.cdc.gov/view/cdc/109493*.

Vaccine Safety Datalink, October 2021: *https://stacks.cdc.gov/view/cdc/110921*.

The Washington Post

Our Law Helps Patients Get New Drugs Sooner

BY: BIRCH BAYH AND BOB DOLE

April 11, 2002

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every $1 spent in government research on a project, at least $10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to 7 years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

The writers are, respectively, a former Democratic Senator from Indiana and a former Republican Senator from Kansas.

Democrat's Proposed Price Controls for Prescription Drugs Could Mean Postponing a Cure for Alzheimer's Disease by Decades

BY: U.S. SENATOR ROGER MARSHALL, M.D.

FOX News

August 6, 2022

We are entering the most exciting time of biomedical innovation and advancement in American history. Our growing understanding of human genetics and the promise of personalized medicine will advance the race to cure cancer and treat or prevent Alzheimer's disease. However, this progress will be erased if Congress passes government drug price controls, which will end the promise of innovation and prevent patients from seeing the benefits of the next generation of cures.

Americans enjoy unprecedented access to new, novel treatments. Of the 460 new medicines approved globally since 2012, 85 percent are available to Americans compared to just 59 percent in U.K. and 44 percent in Canada. Of the 123 new lifesaving cancer drugs, 93 percent are available in the U.S. compared to just 69 percent in the U.K. and 59 percent in Canada. It's baked in that, in order for government price controls to work, these countries must deny and ration care to their citizens.

Our system thrives on access and innovation. Government bureaucrats don't get to decide whether we have access to medicine. The market provides solutions, and Americans freely utilize them.

Of course, no system is perfect. Our health system needs real reforms, not feel-good gestures that create more long-term problems, and net no true savings on drug prices.

Democrat proposals typically just shift costs around so that they can mask who pays for what. For example, the Affordable Care Act hasn't reduced health spending, it just shifted more costs of health care to taxpayers and raised the cost of insurance for people who are insured through their employer. Moreover, the latest reconciliation bill raids Medicare "savings" from the price control provision to pay for ACA subsidies for wealthy individuals.

Under this same proposal, we would see at least 15 percent fewer drugs developed and brought to market in the next 17 years. Do you want to accept delaying the cure for Alzheimer's disease by a decade or more? In a few days, Democrats are going to force us to accept, that instead of breakthrough medicines, we'll just have to settle for end-of-life care.

There are more than 6 million Americans living with Alzheimer's. We all know and love someone impacted by this relentless disease. It's estimated to cost our health system $321 billion this year, and by 2050, it will exceed $1 trillion. Of the total costs spent for seniors with Alzheimer's, barely 10 percent is spent on prescription drugs. Everything else is hospital and long-term care. Without many of these medicines, we would be spending much more on hospitalizations, and be living shorter, worse quality lives. So what is the human value, let alone the monetary value of such a cure?

While it's politically easy to demonize pharmaceutical companies, Democrats need to remember that this industry bailed us out of the pandemic, developed miracle gene therapies that put terminal cancers in complete remission, and cured Hepatitis C. This industry did all of this and more because we allow them to fail and try again. None of the above happened overnight. It was decades in the making.

There are basic economics on why we're first and best in this industry. First, this industry spends more on R&D—it totaled $120 billion just last year. It's a long game though, often taking 15 years to see that investment make it to the pharmacy counter. But 90 percent ultimately fail.

All of that money is spent at great risk—investors don't know what will work and what won't. If the Federal Government eliminates incentives to make a risky investment, R&D spending will dwindle.

Look at the EU: once that governing body took control of the pharmaceutical industry, venture capital, patent registrations, and other key factors that demonstrate a strong industry, declined significantly. Meanwhile, the U.S. continues to grow with proof by the numbers and at our local pharmacy.

The pain for us is at the pharmacy with increasing out-of-pocket costs. Unlike other health care categories, retail prescription drugs account for only 8 percent of our Nation's health spending. While list prices have grown less than inflation, drug price negotiators have pocketed more discounts, but are forcing patients to pay more

out-of-pocket. In fact, these kickbacks for the middlemen have exceeded 50 percent of the list price for many prescription drugs. Those kickbacks must go to patients and we need a solution to this shortcoming in our system.

Republicans have solutions. I joined Senator Michael Crapo, R-Idaho and my colleagues in introducing the Lower Costs, More Cures Act, which includes more than 20 policies to address shortcomings in drug pricing. Just like the new laws the Ensuring Innovation Act and the ACT for ALS, which we helped author and support, which helped drive down drug prices, this legislation promotes competition, innovation, and safe more efficient paths toward approval for novel treatments.

There is common ground on making medicines more affordable for Americans, on preserving our R&D pipeline for future cures, and on the president's goal of curing cancer. However, progress will never be made if the will and the incentive to innovate is decimated.

Republican Roger Marshall, M.D., represents Kansas in the U.S. Senate. Previously he was the Congressman for Kansas' 1st District. Prior to Congress, Dr. Marshall was a practicing obstetrician and gynecologist in Great Bend, Kansas. He received his M.D. at the University of Kansas School Of Medicine in 1987.

[Whereupon, at 12:54 p.m., the hearing was adjourned.]

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