

Public Returns on Public Investment: Moderna's Violation of the Social Contract

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Abstract: In January 2023, Moderna announced its intent to increase the price of the COVID-19 vaccine it co-developed with the National Institutes of Health (NIH) by 400%. The federal government should pressure Moderna to change course and resume buying doses for all Americans, leveraging its purchasing power to obtain a fair price.

In January 2023, Moderna announced that it was considering increasing the price of its COVID-19 vaccine by about 400% in the United States, from \$26 to \$110-130 per dose.¹ One month later, on February 15, the manufacturer stated that it would launch a patient assistance program for under- and non-insured Americans and ensured that the NIH-Moderna vaccine would also be available “at no cost for insured people,” absent additional details.² With approximately 2,100 weekly COVID-related deaths and 3,750 COVID-related ICU admissions still transpiring in the country at the time³ and the extensive contributions of the federal government to the development and manufacturing of the NIH-Moderna vaccine widely known,⁴ Moderna's plans elicited wide-

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spread anger,⁵ culminating in Moderna's CEO being called to testify before the Senate Committee on Health, Education, Labor, and Pensions on March 22, 2023.⁶ This article summarizes Moderna's arguments in defense of its planned price increase — specifically, the value of the NIH-Moderna vaccine, the need to support ongoing research and development, and the purported minimal impact the price increase would have on Americans — and explains their shortcomings. The article then offers policy for how the US government could respond to Moderna's announcement and prevent price gouging for necessary therapeutics in future pandemics.

Extensive Federal Government Contribution to Development and Manufacturing

Moderna's first justification for its proposed price increase — the value of the NIH-Moderna vaccine⁷ — is without merit. 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 paid for by US taxpayers.

The development of the NIH-Moderna vaccine is an incredible public funding achievement. 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 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 NIH-Moderna 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 (HHS) and the Department of Defense to support the development of COVID-19 medical countermeasures,

cle technology via the government's patent use rights, which it has asserted in ongoing lawsuits with the companies Arbutus and Alnylam.²¹

Comments from key US officials highlight 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.²²

Moncef Slaoui, then-head of Operation Warp Speed and a former member of the Moderna Board of Directors, was more direct, stating, "We held Moderna by

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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 the 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 By March 2022, BARDA and NIH had provided Moderna with \$1.7 billion and \$490 million, respectively, for clinical trials.¹⁹

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.²⁰ Under the terms of the contract, Moderna claims that it was also provided protection from possible patent infringement for the use of lipid nanoparti-

the hand on a daily basis."²³

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 ten drugs that enter Phase I testing, approximately one to two make it to market.²⁴ The costs of vaccine development through the end of early clinical safety and efficacy testing, including the possibility of failure, have been estimated to be between \$84 and \$112 million.²⁵ Late-stage clinical trials are often more expensive, with one study reporting a mean cost of \$240 million.²⁶

Drug manufacturers are rewarded for shouldering these at-risk costs with market exclusivity for approved therapeutics and, thus, the ability to charge monopoly prices for a fixed time. As two scholars have 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."²⁷ If the incentives are too low, private companies may not invest in researching these therapeutics, as has been seen with

antibiotics.²⁸ However, if the incentives are too great, it may result in unnecessarily high prices that reduce the likelihood of treatment for vulnerable populations with unmet medical needs.²⁹ 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.

Self-Enrichment Over Research and Development

Another argument that has been made to support the proposed price increase of the NIH-Moderna vaccine is that higher prices will lead to additional revenue that is needed to support investment in research and development, which for Moderna totaled just under \$3.3 billion in 2022.³⁰ This argument is also weak.

Ample Revenue Available for Research and Development

Moderna has already secured ample revenue for research and development. Following the essential contributions of the federal government, Moderna received emergency use authorization for its COVID-19 vaccine in January 2021. Over the course of the next two years, Moderna earned \$37 billion in revenue, \$20 billion of which was profit.³¹ In 2021, the NIH-Moderna vaccine — the company's only commercialized product — made Moderna the sixth most profitable pharmaceutical company in the world.³²

This success translated to rising share prices. Between January 31, 2020 (World Health Organization declaration of the pandemic) and September 10, 2021 (peak price), Moderna's share price increased 2038%, from \$21 to \$449.³³ Such growth would be the envy of any biotechnology investor and helped increase the personal wealth of the company's chief executive, Stéphane Bancel, to \$4.7 billion.³⁴ Moderna co-founders Robert Langer and Noubar Afeyan saw their net worth rise to \$1.7 billion and \$1.8 billion, respectively.³⁵

Flush with cash, however, Moderna and its executives elected to maximize short-term gain over investing in research and development. In 2022, Mr. Bancel made \$398 million on actual realized gains of stock exercised and sold, a pay package that was reportedly "likely to be one of the largest in health care for 2022."³⁶ The same year, the company spent \$3.3 billion on share buybacks to further enrich its investors—more than it spent on research and develop-

ment³⁷ — in addition to structuring a \$926 million "golden parachute" for Mr. Bancel in the event of his dismissal.³⁸ In light of these actions, Moderna's claim that a price increase is needed to support its research and development enterprise rings hollow.

A Troubling Pattern of Behavior

Moderna's proposed fourfold price increase of the NIH-Moderna vaccine represents an escalation of an already troubling pattern of behavior. 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 had already increased the price of the vaccine before the recent announcement. Over the course of five orders with the federal government between August 2020 and July 2022, the company raised the price of the NIH-Moderna vaccine from \$15 a dose (monovalent) to \$26 a dose (bivalent).³⁹

Moderna has also engaged in extensive patent gamesmanship. Unlike other manufacturers, Moderna resisted paying NIH and partnering universities for the use of the patented technique to develop the prefusion-stabilized SARS-CoV-2 spike protein. Only in January 2023, after years of negotiation, did the company relent and agree to pay NIH a \$400 million "catch-up" payment and a running royalty.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 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.”⁴⁹ For the US government to give in to Moderna’s proposed price increase would only incentivize this type of behavior.

Public Health Implications

If implemented, the proposed price increase will harm public health and place considerable strain on payers, including Medicare and Medicaid. In Fall 2023, the US government will stop purchasing and distributing vaccines directly for all Americans, and the cost of vaccines at their higher prices will fall on insurers and individuals. For the insured, this shift raises concerns over possible co-pays and their effects. As KFF noted: “A wide range of studies find that even relatively small levels of cost sharing, in the range of \$1 to \$5, are associated with reduced care, including necessary services.”⁵⁰

Some potential harms of this shift in coverage will be mitigated.⁵¹ Medicaid will cover the vaccine without cost-sharing until September 30, 2024.⁵² 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 standards to cover the vaccine without cost-sharing. However, the requirement would not extend to short-term plans, in which an estimated three million Americans are enrolled.⁵³

For the 25–30 million uninsured or underinsured Americans, the picture is particularly worrisome. In July 2023, the CDC announced its intentions to launch the Bridge Access Program for COVID-19 Vaccines. Under this program, the CDC will provide free vaccines to this population but only until December 2024. Moderna’s proposed patient assistance program, which will likely be the sole source of support

afterward, 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.⁵⁴

Given the barriers associated with patient assistance plans, it is likely that many 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.

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 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 centralized purchasing power to obtain a fair price. Finally, Congress can authorize the Centers for Medicaid and Medicare Services (CMS) to impose a price for the NIH-Moderna vaccine based on the same factors CMS has to consider when negotiating drug prices under the Inflation Reduction Act. These include the comparative effectiveness of the drug, federal financial support for its development and testing, and unit costs of production and distribution.⁵⁵

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 voiced in response 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 the NIH-Moderna vaccine, while its research and development expenses were de-risked and accompanied by substantial public investment. 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, it is likely Moderna would 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.⁵⁶

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. The return on this investment should be affordable access for all Americans. Moderna's attempt to increase the price of the vaccine four-fold shatters this social compact; Congress should make every effort to fight for a fair price.

Note

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