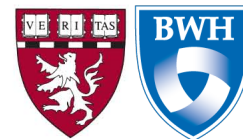




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Taxpayers Paid Billions For It:
So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?

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Committee on Health, Education, Labor, and Pensions
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EXECUTIVE SUMMARY

Moderna's proposed 400% price increase of the NIH-Moderna vaccine, from \$26 to \$110-130 per dose, is unwarranted and egregious. 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 two years, Moderna reported \$37 billion in revenue, a staggering \$20 billion of which was profit. Yet, in 2022, Moderna spent more on stock buybacks 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 US, 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 SARS-coV-2 and provide more opportunities for the virus to mutate. Additionally, if just 50% of American adults received one dose of a booster under the new price, payers would spend more than the total cost of the US 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.

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BIOGRAPHY

I am an Assistant Professor of Medicine at Harvard Medical School and the Assistant Director of the Program On Regulation, Therapeutics, And Law (PORTAL) within the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. I am also a faculty affiliate with the Behavioral Insights Group at the Harvard Kennedy School; the Center for Bioethics at Harvard Medical School; the Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health; the Harvard-MIT Center for Regulatory Science; and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. At the Harvard T.H. Chan School of Public Health, I serve as the Faculty Director of the JD/MPH program and teach public health law.

I completed my undergraduate studies at the University of Virginia, where I was a Jefferson Scholar. I subsequently studied epidemiology at the University of Cambridge, where my doctoral work centered on understanding the progression of a rare autoimmune disease and the effectiveness of treatments for it. After graduating in 2010, I studied law with a concentration in health law at the University of Maryland as a John L. Thomas Leadership Scholar. Since 2013, I have been a member of PORTAL, first as a fellow, then as an instructor, and now as an assistant professor.

My research draws upon my interdisciplinary training as an epidemiologist and lawyer and focuses on the effects of laws and regulations on therapeutic development, approval, use, and related public health outcomes. Over the past decade, I have authored over 120 peer-reviewed articles, written 5 book chapters, and co-developed a massive open online course on prescription drug regulation, cost, and access, for which over 100,000 people worldwide have registered. Among the topics that I have studied and published on are the drivers of the high cost of prescription drugs in the United States and possible reforms,¹ the federal government's contributions to drug development,² and vaccine access.³

¹ See, e.g., Aaron S. Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316(8) J. AM. MED. ASS'N 858 (2016), <https://pubmed.ncbi.nlm.nih.gov/27552619>; Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 STAN. L. & POL'Y REV. 421 (2019), <https://law.stanford.edu/publications/pharmaceutical-policy-in-the-united-states-in-2019-an-overview-of-the-landscape-and-avenues-for-improvement/>.

² See, e.g., Ameet Sarpatwari, Alison K. LaPridus, & Aaron S. Kesselheim, *Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support*, 172(5) ANNALS INTERNAL MED. 348 (2020), <https://pubmed.ncbi.nlm.nih.gov/31986528/>; Ameet Sarpatwari, Jerry Avorn, & Aaron S. Kesselheim, *Accounting for US Public Funding in Drug Development: How Can We Better Balance Access, Affordability, and Innovation?*, 371 BMJ m3841 (2020), <https://pubmed.ncbi.nlm.nih.gov/33032982/>.

³ See, e.g., Ameet Sarpatwari et al., *COVID-19 Vaccine Boosters for All Adults: An Optimal U.S. Approach?*, 175(2) ANNALS INTERNAL MED. 280 (2022), <https://pubmed.ncbi.nlm.nih.gov/?term=Vaccine+boosters+for+all+adults%3A+an+optimal+U.S.+approach%3F&sort=date>.

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 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 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

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

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 Steenhuisen, *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.

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 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.²¹

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.²²

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.”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 10 drugs that enter Phase I testing, approximately 1-2 make it to market.²⁴ The costs of

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>.

¹⁹ Lalani et al., *supra* note 9.

²⁰ *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/>.

²¹ 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/>.

²² *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/>.

²³ 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/>.

²⁴ See CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (April 2021), <https://www.cbo.gov/publication/57126>.

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.²⁵ Late-stage clinical trials are often more expensive, with one study reporting a mean cost of \$240 million.²⁶

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.”²⁷ If the incentives are too low, private companies may not invest in researching these therapeutics, as has been seen in the antibiotics space.²⁸ However, if the incentives are too great, reducing the likelihood of important treatments for ongoing unmet medical need.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.

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 2022.³⁰ This argument is also weak.

²⁵ 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](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext).

²⁶ 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.

²⁷ 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>.

²⁸ See Benjamin Plackett, *Why big pharma has abandoned antibiotics*, 586 NATURE S50 (2020), <https://www.nature.com/articles/d41586-020-02884-3>.

²⁹ 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).

³⁰ 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>.

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.³¹ In 2021, the NIH-Moderna vaccine—the sole company product—made Moderna the sixth most profitable pharmaceutical company in the world.³²

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 \$449.³³ Such growth would be the envy of any biotechnology investor and helped increase Mr. Bancel's personal wealth to \$4.7 billion.³⁴ Moderna co-founders Robert Langer and Noubar Afeyan have seen their net worth rise to \$1.7 billion and \$1.8 billion, respectively.³⁵

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.³⁶ The same year, Moderna structured a \$926 million "golden parachute" for Mr. Bancel in the event of his dismissal.³⁷ Between June and September 2020, numerous Moderna executives sold approximately \$90 million in Moderna shares despite widespread anger.³⁸ 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."³⁹

³¹ 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>.

³² 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>.

³³ Moderna, Inc. *Common Stock (MRNA) Historical Data*, NASDAQ, <https://www.nasdaq.com/market-activity/stocks/mrna/historical> (accessed Mar. 19, 2023).

³⁴ Stéphane Bancel, FORBES, <https://www.forbes.com/profile/stephane-bancel/?sh=97d89463742f> (accessed Mar. 19, 2023).

³⁵ 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).

³⁶ 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>.

³⁷ Spencer Kimball, *Moderna CEO Bancel's Golden Parachute Soared by Hundreds of Millions over the Pandemic*, CNBC (Mar. 10, 2022), <https://www.cnb.com/2022/03/10/moderna-ceos-golden-parachute-soared-by-hundreds-of-millions-over-the-pandemic.html>.

³⁸ 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>.

³⁹ 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/>.

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 between August 2020 and July 2022, the company raised the price of the NIH-Moderna vaccine from \$15 (monovalent) to \$26 (bivalent).⁴⁰

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.⁴¹

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.⁴² 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.”⁴³ A month after the dispute spilled out into the public, Moderna partially backed down by not paying for the patent to be issued.⁴⁴

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.”⁴⁵ However, in August 2022, Moderna broke that promise, suing Pfizer and BioNTech for alleged patent infringement.⁴⁶

As the pandemic raged globally, Moderna failed its obligations to low-income countries. In October 2021, Moderna supplied its doses almost exclusively to wealthy

⁴⁰ 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>.

⁴¹ 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>.

⁴² 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>.

⁴³ Steenhuisen, *supra* note 14.

⁴⁴ 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>.

⁴⁵ 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/>.

⁴⁶ 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>.

nations, more so than any other vaccine manufacturer.⁴⁷ 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.”⁴⁸

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.⁴⁹ 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.⁵⁰ 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.⁵¹ Under the status quo, 27 million uninsured Americans⁵² 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.⁵³ Medicaid will cover the vaccine without cost sharing until September 30, 2024 (if the public health emergency ends on May 11, 2023).⁵⁴

⁴⁷ 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>.

⁴⁸ *Id.*

⁴⁹ 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/>.

⁵⁰ Carrie Teicher, *What Moderna Owes the World*, STAT NEWS (Nov. 4, 2021), <https://www.statnews.com/2021/11/04/what-moderna-owes-the-world/>.

⁵¹ 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>.

⁵² 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/>.

⁵³ *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>.

⁵⁴ *Id.*

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 3 million Americans are enrolled.⁵⁵

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.⁵⁶ 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.”⁵⁷

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

⁵⁵ 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>.

⁵⁶ 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>.

⁵⁷ Kates, Cox, & Michaud, *supra* note 40.

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.⁵⁸

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.⁵⁹

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.⁶⁰

⁵⁸ 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/>.

⁵⁹ *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>.

⁶⁰ 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.