Written Statement of Christopher J. Morten, J.D., Ph.D.
Associate Clinical Professor of Law, Columbia Law School

Before the United States Senate
Committee on Health, Education, Labor & Pensions (HELP)

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

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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

[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

[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]

[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

[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* r*VSV-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

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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.