

Written Testimony of Reshma Ramachandran, M.D., M.P.P. of Yale School of Medicine

Hearing on “The Path Forward on COVID-19 Immunizations”

House Ways and Means Subcommittee on Health

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Chairman Doggett, Ranking Member Nunes, and distinguished members of the subcommittee, thank you for the invitation to testify today. My name is Reshma Ramachandran. I am a fellow in the National Clinician Scholars Program at Yale School of Medicine and a physician at the West Haven Veterans Affairs Medical Center. I am also a board member of Universities Allied for Essential Medicines North America and co-Chair the Doctors for America Drug Affordability Action Team. I am honored to testify before you today. I am doing so in my own independent capacity. My remarks reflect my own views and not that of the U.S. government, U.S. Department of Veterans Affairs, Yale University, and the organizations I work with.

I understand that the subcommittee is particularly interested in broad perspectives on COVID-19 vaccine pricing. For my patients, price plays an important role. Price is what determines if my patients are able to pick up the treatments I prescribe them or have to abandon them at the pharmacy counter so they can pay for food or rent. Price is what determines whether my patients will be able to live healthily or end up in the emergency room or hospital with a preventable condition. Price even sometimes determines if my patients live or die.

Pricing of COVID-19 vaccines especially matters for our public health programs that strive to protect our patients. For every dollar spent on purchasing vaccines, another will not be spent on other crucial areas such as ensuring equitable distribution of these vaccines, particularly to those vulnerable communities that have been the hardest hit by this deadly disease.

While I understand that Congress has appropriately put in protections so that patients can access the vaccine without the financial barriers of cost-sharing or co-payments¹, these are meant to only last during the current public health emergency. We are beginning to understand that COVID-19 will not disappear, that it will likely be endemic or something that occurs seasonally, and will likely require booster shots to prevent serious disease. It is through this lens that I will outline a few key points for the subcommittee to consider.

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There is no doubt that the record-breaking availability of multiple effective and safe COVID-19 vaccines is an incredible scientific achievement. This would not have been possible without the significant financial support from the American public, whose taxpayer dollars have funded key federal agencies and programs that have catalyzed the rapid development of these vaccines. One such program is Operation Warp Speed, created during this public health emergency period within the Department of Health and Human Services (HHS). This program alone has awarded \$10 billion to manufacturers to develop and produce COVID-19 vaccines.²

The two available vaccine candidates have considerably benefited from this public funding. For the Pfizer vaccine, the National Institutes of Health (NIH) funded scientists at the University of Pennsylvania who developed the vaccine’s underlying mRNA vaccine technology

¹ Centers for Medicare and Medicaid Services, “Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics,” November 13, 2020, <https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics>.

² “COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations” (Washington, D.C.: Government Accountability Office, November 2020), <https://www.gao.gov/assets/720/710691.pdf>.

before being further advanced in collaboration with BioNTech, a German pharmaceutical firm.^{3,4} BioNTech would later partner with Pfizer to manufacture this vaccine. BioNTech also received direct public funding – the German government program Project Lightspeed granted \$445 million to this company for its vaccine development.⁵ For the Moderna vaccine, public funding fully supported its development from laboratory bench to bedside.^{6,7} Janssen’s candidate, whose emergency use authorization by the Food and Drug Administration (FDA) is being discussed by the Vaccines and Related Biological Products Advisory Committee today, received almost \$2 billion just through Operation Warp Speed.⁸ For several vaccine candidates, the American public appears to have underwritten their development and manufacturing costs.^{9,10}

Despite this significant public investment, patients are left uncertain when they will be vaccinated due to continued delays in manufacturing supply. Moreover, review of available agreements between manufacturers and the U.S. government reveals a continued pattern of putting pharmaceutical companies before patients who ultimately funded this work. Essentially, Operation Warp Speed and other government agencies have handed over a blank check of U.S. taxpayer funds to manufacturers without adequate protections to ensure timely, affordable access. Patients across the country are effectively footing the bill three times for COVID-19 vaccines – their taxpayer dollars are not only funding their development and production, but also again to receive these doses.

In order for patients to receive a fair return on their significant investment, Congress must implement the following three measures:

1. full transparency of all public funds and resources for COVID-19 vaccine development and production,
2. full transparency of all agreements between the U.S. government and manufacturers, and
3. the ability to employ all available mechanisms to guarantee that the American public has adequate supply and affordable access.

Transparency of Public Funds for COVID-19 Vaccine Development and Production

To ensure fair return on public investment, we must know exactly how much has been underwritten by the American people across all government agencies towards COVID-19 vaccine development and production. Even before the current public health emergency, patients played a critical role in funding COVID-19 vaccine development. Analysis of the NIH RePORTER database by Public Citizen found that almost \$700 million had been spent on

³ Luis Gil Abinader, “Foundational mRNA Patents Are Subject to the Bayh-Dole Act Provisions,” *Knowledge Ecology International* (blog), November 30, 2020, <https://www.keionline.org/34733>.

⁴ Damian Garde and Jonathan Saltzman, “The Story of MRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race,” *STAT*, November 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/>.

⁵ Joe Miller, “Inside the Hunt for a Covid-19 Vaccine: How BioNTech Made the Breakthrough,” *Financial Times*, November 13, 2020, <https://www.ft.com/content/c4ca8496-a215-44b1-a7eb-f88568fc9de9>.

⁶ Bob Herman, “Moderna Skirts Disclosures of Coronavirus Vaccine Costs,” *Axios*, August 5, 2020, <https://www.axios.com/moderna-barda-coronavirus-funding-disclosure-2775a517-a775-485a-a509-b6906c8535a9.html>.

⁷ Zain Rizvi, “The People’s Vaccine” (Washington, D.C.: Public Citizen), accessed February 23, 2021, <https://www.citizen.org/article/the-peoples-vaccine/>.

⁸ Biomedical Advanced Research and Development Authority, “BARDA’S Rapidly-Expanding COVID-19 Medical Countermeasure Portfolio,” accessed February 20, 2021, <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>.

⁹ Herman, “Moderna Skirts Disclosures of Coronavirus Vaccine Costs.”

¹⁰ Biomedical Advanced Research and Development Authority, “BARDA’S Rapidly-Expanding COVID-19 Medical Countermeasure Portfolio.”

coronavirus R&D since the severe acute respiratory syndrome (SARS) outbreak in 2002.¹¹ This publicly-funded research laid the foundation for current COVID-19 therapies and vaccine candidates. Part of this research that was especially critical for the development of COVID-19 vaccines is the method stabilizing coronavirus spike proteins. This was originally developed and adapted for COVID-19 by scientists at the NIH who later filed patents for this approach.¹² Almost all of the leading COVID-19 vaccine manufacturers use this publicly-funded method to develop and produce these vaccines. It also remains unclear if the NIH licensed this patented technology to manufacturers and what the terms of these licenses, if they exist, are.

During the current pandemic period, vaccine manufacturers have also been able to secure further funding and resources from the U.S. government outside of Operation Warp Speed. Moderna worked closely with NIH's National Institute of Allergy and Infectious Diseases (NIAID) in developing its vaccine through all development stages. In addition to the \$1 billion that Moderna received in taxpayer grants through Operation Warp Speed for its vaccine development, NIAID also provided \$410 million.¹³ A majority of these funds were used for the last stage of clinical trials that would ultimately demonstrate the vaccine's remarkable 94.1% efficacy in preventing symptomatic disease.¹⁴

Besides Moderna, NIH has also provided research support and funding for late-stage clinical trials for other leading vaccine manufacturers including Janssen¹⁵, AstraZeneca¹⁶, and Novavax¹⁷. Besides brief acknowledgement of this contribution within news releases from the manufacturers and NIH, few details are available on the exact amount of funds and resources being allocated from these government agencies to the manufacturer. This further obscures the significant contributions made by the American public towards COVID-19 vaccine development.

Transparency of Agreements Between U.S. Government and COVID-19 Vaccine Manufacturers

Second, in addition to knowing exactly how much the American public has invested into COVID-19 vaccine development and production, we must also understand the conditions under which this taxpayer funding was awarded to companies. Well before COVID-19 vaccines were made available, the U.S. government through Operation Warp Speed entered into various bulk purchasing agreements with individual vaccine manufacturers. This allowed the U.S government to secure hundreds of millions of doses in hopes of being able to rapidly deploy these vaccines upon authorization. Despite significant public investment into COVID-19 vaccine development, obtaining timely access to these contracts has been incredibly difficult. Organizations including

¹¹ Zain Rizvi, "Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model" (Washington, D.C.: Public Citizen, February 19, 2020), <https://www.citizen.org/article/blind-spot/>.

¹² Zain Rizvi, "Leading COVID-19 Vaccine Candidates Depend on NIH Technology" (Washington, D.C.: Public Citizen, November 10, 2020), <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/>.

¹³ Sydney Lupkin, "Prices For COVID-19 Vaccines Are Starting To Come Into Focus," *NPR*, August 6, 2020, <https://www.npr.org/sections/health-shots/2020/08/06/899869278/prices-for-covid-19-vaccines-are-starting-to-come-into-focus>.

¹⁴ Lindsey R. Baden et al., "Efficacy and Safety of the MRNA-1273 SARS-CoV-2 Vaccine," *New England Journal of Medicine* 384, no. 5 (February 4, 2021): 403–16, <https://doi.org/10.1056/NEJMoa2035389>.

¹⁵ National Institutes of Health, "Janssen Investigational COVID-19 Vaccine: Interim Analysis of Phase 3 Clinical Data Released," NIH.gov, January 29, 2021, <https://www.nih.gov/news-events/news-releases/janssen-investigational-covid-19-vaccine-interim-analysis-phase-3-clinical-data-released>.

¹⁶ National Institutes of Health, "Phase 3 Clinical Testing in the US of AstraZeneca COVID-19 Vaccine Candidate Begins," NIH.gov, August 31, 2020, <https://www.nih.gov/news-events/news-releases/phase-3-clinical-testing-us-astrazeneca-covid-19-vaccine-candidate-begins>.

¹⁷ National Institutes of Health, "Phase 3 Trial of Novavax Investigational COVID-19 Vaccine Opens," NIH.gov, December 28, 2020, <https://www.nih.gov/news-events/news-releases/phase-3-trial-novavax-investigational-covid-19-vaccine-opens>.

Knowledge Ecology International¹⁸ and Public Citizen¹⁹ have filed numerous Freedom of Information Act requests for these contracts, which were left unanswered for many months. After repeated unanswered requests for these agreements to better understand how taxpayer funds were being used to develop and deliver COVID-19 vaccines, these organizations filed lawsuits²⁰ to compel release of this information.

In the fall of 2020, months after these contracts had been announced by the Department of Health and Human Services (HHS), the agreements began to be released in a slow trickle – and with continued concealment. In late October, the agreement between the U.S. government and Moderna was released. Despite being fully publicly-funded, transparency to taxpayers of how their funds would be used by Moderna became an afterthought; when the agreement was released, only 14 out of the 53 pages were free from redactions.²¹ Over the following weeks, contracts with other manufacturers were released with similar redactions.²²

Importance of Transparency for the American Public

The American public in both underwriting the development, production, and purchase of COVID-19 vaccines deserve to have immediate access to these agreements. Transparency of these contracts is crucial in allowing taxpayers a clear understanding of how their funds are being used. This also empowers the U.S. government to have adequate oversight of these companies to hold them accountable and ensure that the American people are being prioritized over pharmaceutical company profits. Moreover, transparency of these contracts also clarifies what mechanisms the government can employ, especially during a public health emergency, to protect patients. For example, in their agreement with Novavax, the Department of Defense successfully negotiated to receive the best, lowest price from the manufacturer for the next five years.²³

Another result of transparency is that taxpayers would then know if the U.S. government successfully secured protections for patients. If such safeguards have been included, understanding whether they will last only during the current public health emergency period or for a time beyond will also be critical. Transparency of these agreements will also clarify to the public who owns the vaccine technology and whether it can be shared with other manufacturers to boost supply more quickly. Moreover, as Operation Warp Speed is not only financing the development and purchase of doses, but also supporting the building of production facilities, public availability of these contracts would reveal whether the U.S. government will retain any rights to these factories, even after the current public health emergency.²⁴ Without further clarification of these crucial questions through release of this contracts, future agreements for

¹⁸ “KEI Blogs and Research Notes on COVID-19/Coronavirus,” *Knowledge Ecology International* (blog), accessed February 20, 2021, <https://www.keionline.org/coronavirus.k>

¹⁹ Public Citizen, “HHS Must Release Billion Dollar Coronavirus Vaccine Contracts, Public Citizen Lawsuit Says,” Public Citizen, October 15, 2020, <https://www.citizen.org/news/hhs-must-release-billion-dollar-coronavirus-vaccine-contracts-public-citizen-lawsuit-says/>.

²⁰ James Love, “KEI Sues HHS and the Army over Access to COVID-19 Contracts,” *Knowledge Ecology International* (blog), October 16, 2020, <https://www.keionline.org/34211>.

²¹ Sydney Lupkin, “A Federal Coronavirus Vaccine Contract Released At Last, But Redactions Obscure Terms,” *NPR*, October 24, 2020, <https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t>.

²² Love, “KEI Sues HHS and the Army over Access to COVID-19 Contracts.”

²³ Kathryn Ardizzone, “Novavax and Inovio COVID-19 Vaccine Contracts Limit Prices Companies Can Charge for Their Products,” *Knowledge Ecology International* (blog), January 28, 2021, <https://www.keionline.org/35185>.

²⁴ Public Citizen, “HHS Must Release Billion Dollar Coronavirus Vaccine Contracts, Public Citizen Lawsuit Says.”

COVID-19 vaccines may continue to reflect the interests of the companies, rather than the American public.

Potential Solutions to Ensure Full Transparency to the American Public

Congress can and must ensure the American people full transparency of their contributions to COVID-19 vaccines. First, Congress could require clinical trial sponsors that receive NIH funding including manufacturers as well as universities and the agency itself to report specific clinical trial cost data by individual trial on ClinicalTrials.gov.²⁵ Existing reporting requirements for ClinicalTrials.gov require sponsors of NIH-funded studies to register their clinical trials and submit results in a timely manner. However, through changes to existing law, Congress could go further, asking trial sponsors to also submit cost data once a trial is completed. Additionally, Congress could also request that the NIH itself disclose any cost information it has, either related to its own spending or of its grantees.²⁶ This would help make clear the contributions NIH has made towards COVID-19 vaccine development across several manufacturers.

As the American public's support of COVID-19 vaccines encompasses more than just clinical trial costs and the NIH, transparency of how taxpayer dollars are being spent or used as resources across all government agencies for both development and manufacturing will be crucial in understanding just what was already paid for by the American people. Additionally, access to this information for COVID-19 vaccines and other therapies must be easily accessible – after all, taxpayers have already paid for them, more than once.

One such solution has been outlined by Chairman Doggett in the Taxpayer Research and Coronavirus Knowledge or TRACK Act.²⁷ This bill would create searchable, public database of all federal support for biomedical R&D related to COVID-19. Rather than be redacted and difficult to obtain, all contracts as well as funding and licensing agreements would be readily available. The database would also include clinical trial data as well as specific information on intellectual property. This includes patents and applications including where the U.S. government has any ownership as well as marketing exclusivity periods. The information would be presented in a user-friendly format, made available within one month of the bill's enactment, and updated at least every two weeks. Instead of this information being held only in the hands of lawyers filing complicated Freedom of Information Act requests, investigative journalists, and researchers, everyone would be able to monitor how their hard-earned tax dollars are being spent. Using this information, Congress can take further action to ensure sufficient supply to fairly priced vaccines that reflect the contributions of the American public.

Current COVID-19 Vaccine Agreements Lack Protections for Patients

Examination of currently available COVID-19 vaccine agreements with manufacturers have shown several missed opportunities for the U.S. government to protect patients. Besides Pfizer, several companies received funding for development, production, and purchase of the

²⁵ Ariella Barel, Laurel Boman, and Christopher Morten, "Clinical Trial Cost Transparency at the National Institutes of Health: Law and Policy Recommendations" (Engelberg Center on Innovation Law & Policy: New York University Technology Law & Policy Clinic, August 2020), https://www.law.nyu.edu/sites/default/files/Clinical_Trial_Cost_Transparency_at_the_NIH-Law_and_Policy_Recommendations.pdf.

²⁶ Barel, Boman, and Morten.

²⁷ Lloyd Doggett, "Taxpayer Research and Coronavirus Knowledge Act of 2020," Pub. L. No. H.R. 7288 (2020), <https://www.congress.gov/bill/116th-congress/house-bill/7288/text>.

vaccines regardless of whether their product was authorized or approved by the FDA. This means that the U.S. government paid for the purchase of vaccine doses in addition to their R&D and manufacturing without knowing if they would be safe or effective. Sanofi and GlaxoSmithKline that have also benefited from this public support are facing significant delays and will be unlikely to supply a vaccine this year.²⁸ Merck, which received funds from Operation Warp Speed has exited COVID-19 vaccine development.²⁹

The contracts also gave companies incredible latitude, allowing for flexible delivery schedules with no penalties for delays. We have witnessed this in real time for both currently available vaccines from Pfizer and Moderna when both companies quickly fell behind in meeting their supply benchmarks for the end of 2020.³⁰ In November, just weeks before its vaccine candidate received emergency use authorization, Pfizer disclosed that it would not be able to meet the projected 100 million dose production target. Instead, it stated that it would be able to provide half as many doses. By the end of 2020, the company was only able to provide 20 million doses.³¹ Similar shortfalls in production were also recently announced by Janssen.³²

The contracts also strip the U.S. government of various mechanisms to address these shortages. For all vaccine candidates, manufacturers were able to exclusively retain the intellectual property including patents and production knowledge. As a result, each pharmaceutical company would have the sole discretion to determine how and where the vaccines are manufactured. This had led to a reliance on companies to work with other manufacturers to deliver on orders made. Both Pfizer³³ and Moderna³⁴ have developed partnerships with contract manufacturers to outsource production. Pfizer has also recently announced collaborations with Sanofi³⁵ and Merck³⁶ to help produce vaccines. Yet despite these partnerships, demand continues to outstrip supply worldwide. These agreements between manufacturers have also remained secret, leaving the American people at these companies' will and with little recourse should supply continue to be limited.

Allowing the companies to retain the patents and production knowledge also has ramifications on guaranteeing adequate supply in the future. The United Nations Secretary General recently noted that an estimated 130 countries had not yet started vaccinations.³⁷

²⁸ Leila Abboud and Hannah Kuchler, "Why the Three Biggest Vaccine Makers Failed on Covid-19," *Financial Times*, February 16, 2021, <https://www.ft.com/content/657b123a-78ba-4fba-b18e-23c07e313331>.

²⁹ Merck, "Merck Discontinues Development of SARS-CoV-2/COVID-19 Vaccine Candidates; Continues Development of Two Investigational Therapeutic Candidates," Merck.com, January 25, 2021, <https://www.merck.com/news/merck-discontinues-development-of-sars-cov-2-covid-19-vaccine-candidates-continues-development-of-two-investigational-therapeutic-candidates/>.

³⁰ Isaac Stanley-Becker and Christopher Rowland, "Vaccine Makers Pfizer and Moderna Pledge Massive Boost to U.S. Supply after Sluggish Rollout," *Washington Post*, accessed February 23, 2021, <https://www.washingtonpost.com/health/2021/02/23/vaccine-distribution-pfizer-moderna/>.

³¹ Carl Zimmer, Sharon LaFraniere, and Noah Weiland, "Johnson & Johnson Expects Vaccine Results Soon but Lags in Production," *The New York Times*, January 13, 2021, sec. Health, <https://www.nytimes.com/2021/01/13/health/covid-vaccine-johnson-johnson.html>.

³² Zimmer, LaFraniere, and Weiland.

³³ Jonas Neubert and Cornelia Scheitz, "Exploring the Supply Chain of the Pfizer/BioNTech and Moderna COVID-19 Vaccines," *JonasNeubert.Com* (blog), January 10, 2021, <https://blog.jonasneubert.com/2021/01/10/exploring-the-supply-chain-of-the-pfizer-biontech-and-moderna-covid-19-vaccines/>.

³⁴ Fraiser Kansteiner, "Moderna Teams with Sweden's Recipharm to Rev up EU Vaccine Manufacturing," *FiercePharma*, January 7, 2021, <https://www.fiercepharma.com/pharma/moderna-clinches-fourth-vaccine-manufacturing-tie-up-sweden-s-recipharm>.

³⁵ Sanofi, "Sanofi to Provide Support to BioNTech in Manufacturing Their COVID-19 Vaccine to Help Address Public Health Needs," <https://www.sanofi.com/en/media-room/press-releases/2021/2021-01-27-07-30-00>, January 27, 2021, <https://www.sanofi.com/media-room/press-releases/2021/2021-01-27-07-30-00-2164797>.

³⁶ Merck, "Merck KGaA, Darmstadt, Germany, and BioNTech Extend Strategic Partnership | Merck KGaA, Darmstadt, Germany," February 5, 2021, <https://www.emdgroup.com/en/news/biontech-strategic-partnership-04-02-2021.html>.

³⁷ Associated Press, "'Wildly Unfair': UN Says 130 Countries Have Not Received a Single Covid Vaccine Dose," *The Guardian*, February 18, 2021, sec. World news, <http://www.theguardian.com/world/2021/feb/18/wildly-unfair-un-says-130-countries-have-not-received-a-single-covid-vaccine-dose>.

Manufacturers in maintaining control of publicly-funded vaccine technology and information have prioritized supplying high-income countries leaving billions unvaccinated during an ongoing pandemic with rapidly emerging variants. As these and other variants continue to surface and spread around the world, modified booster doses will be needed, including in the U.S. This next generation of vaccines will be rooted in publicly-funded research that made possible the initial versions. However, without policy measures that allow the U.S. government to lay claim to this foundational work, the American people may face yet another shortfall in supply of COVID-19 vaccines needed to prevent against these variant strains.

Besides controlling the supply of vaccines, the ability of companies to exclusively own both vaccine patents and production knowledge also allows them to set the price. In spite of the ongoing pandemic, both Moderna and Pfizer are anticipating significant profits from the sale of their vaccines.^{38,39} Only a few contracts currently have provisions to ensure reasonable pricing for the U.S. government. In their agreement with Novavax, the Department of Defense included a stipulation that it should receive the lowest, best price for a period of five years for purchase of doses administered in the U.S.⁴⁰ In exchange for \$1.8 billion, Sanofi has been prohibited in its agreement to sell its vaccine to any member of the G7 or Switzerland at a price lower than that negotiated with the federal government. Novavax has yet to complete its final clinical trials⁴¹, whereas Sanofi has stated that it will not have a candidate available this year⁴².

Mechanisms to Ensure Adequate Supply and Affordable Access

In addition to transparency of the funding contributed and the agreements made with manufacturers, the U.S. government must be able to lay claim to the vaccine technology taxpayers have subsidized so that the American public can have sufficient supply at a fair price. The federal government has multiple mechanisms at its disposal to ensure this. First, all licenses awarded by the U.S. government for publicly-funded technology related to COVID-19 must be made open and non-exclusive.⁴³ This will prevent monopolies of COVID-19 vaccine products. With such a license, the U.S. government would have the ability to license vital vaccine technology, especially during a public health emergency, to multiple manufacturers. No one company would therefore have the ability to control supply and additional manufacturers could be recruited to meet demand.

The U.S. government could also require companies to share both the vaccine and manufacturing technology to further increase production. For federally-funded vaccine candidates, the U.S. government could exercise march-in rights -- a tool created under the Bayh-Dole Act of 1980⁴⁴ that allows the government to intervene and ensure that federally-funded research is made available to the public on reasonable terms. By exercising march-in rights, the

³⁸ Hannah Kuchler, "Pfizer Expects \$15bn in Covid Vaccine Revenue This Year," *Financial Times*, February 2, 2021, <https://www.ft.com/content/0f1ab138-401d-40ff-824f-f6879704f10e>.pf

³⁹ Eric Sagonowsky, "Fierce JPM Week: Moderna Could Join Top Vaccine Players by Sales This Year, CEO Says," *FiercePharma*, January 12, 2021, <https://www.fiercepharma.com/pharma/moderna-could-join-ranks-top-vaccine-companies-by-revenue-year-ceo-says-as-covid-19-vaccine>.

⁴⁰ Ardizzone, "Novavax and Inovio COVID-19 Vaccine Contracts Limit Prices Companies Can Charge for Their Products."

⁴¹ Kathryn Ardizzone, "\$1.8 Billion Sanofi Vaccine Contract Contains International Reference Pricing Clause, Preserves Standard IP and Data Rights," *Knowledge Ecology International* (blog), December 2, 2020, <https://www.keionline.org/34776>.

⁴² Reuters Staff, "Sanofi's MRNA COVID-19 Vaccine Candidate Not Ready This Year - CEO," *Reuters*, February 13, 2021, <https://www.reuters.com/article/uk-health-coronavirus-sanofi-vaccines-idUKKBN2ADOPT>.

⁴³ Janice D. Schakowsky, "Make Medications Affordable by Preventing Pandemic Price Gouging Act of 2020," Pub. L. No. H.R.7296 (2020), <https://www.congress.gov/bill/116th-congress/house-bill/7296/text>.

⁴⁴ Birch Bayh and Bob Dole, "Patent and Trademark Law Amendments Act," 35 U.S.C. § 203 (1980), <https://www.law.cornell.edu/uscode/text/35/203>.

government could cancel an exclusive licensing agreement made with the company. The government would then be able to take control of the federally funded technology and coordinate with other manufacturers to produce doses. The company initially awarded the exclusive license would still be able to collect monetary royalties and distribute the vaccine. Pfizer in its contract with the U.S. government has explicitly barred use of this mechanism, asserting that it has received no public support for its R&D.⁴⁵ Within other agreements including that of Janssen and AstraZeneca, the federal government's ability to use march-in rights has been weakened.⁴⁶

Another method the U.S. government could employ to achieve sufficient supply is through Section 1498⁴⁷ coupled with full use of Defense Production Act as outlined by Senator Elizabeth Warren (D-MA) and Representative Katie Porter (D-CA) in their letter last month to the Biden Administration.⁴⁸ Through this, President Biden could compel manufacturers who have developed and are producing the vaccine to share the required technology and information with other companies to fully utilize all available domestic manufacturing capacity. Just as with march-in rights, companies would still receive reasonable compensation as their technology and data are utilized by other firms. Some have argued that there are other supply chain bottlenecks, including the limited availability of specific machines or supplies to produce key materials necessary for vaccine manufacturing. However, the Defense Production Act could also be utilized to facilitate production of these components necessary for manufacturing vaccines. Current analysis of available data has shown that once technology transfer to another company has been announced, manufacturers are typically able to make their first delivery of doses within six months.⁴⁹ This is regardless of the vaccine technology platform as well as the production process step.

Besides enabling multiple manufacturers to produce vaccine doses to ensure adequate supply, the U.S. government could take further action to ensure price controls. The inclusion of reasonable pricing provisions within the contracts of Novavax⁵⁰ and Sanofi⁵¹ demonstrate that this is possible. While the federal government has been able to negotiate prices lower than initially set by manufacturers in their initial orders for doses, these discounts have been modest at best. Instead, the government might take into consideration various factors to determine if a price is reasonable. This might include how such a price might impact patient access as well as public health program budgets including the opportunity costs of procuring a vaccine at a specific price. Additionally, the government might also weigh the vaccine's development and production costs as well as how much the public has already subsidized. By taking into consideration these factors, the U.S. government can prevent manufacturers from profiteering during a pandemic and

⁴⁵ Sydney Lupkin, "Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections," *NPR*, November 24, 2020, <https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections>.

⁴⁶ James Love, "KEI Receives Seven New Contracts for COVID 19 Research from BARDA and DOD, Including Five Using 'Other Transactions Authority' That Weaken or Eliminate Bayh-Dole and FAR Safeguards," *Knowledge Ecology International* (blog), July 1, 2020, <https://www.keionline.org/covid19-ota-contracts>.

⁴⁷ Joseph Adamczyk et al., "§ 1498: A GUIDE TO GOVERNMENT PATENT USE" (New York University Technology Law & Policy Clinic, 2021 2020), <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/60099e3582c53f4f1b6a4a57/1611243061897/P4A+-1498+A+Guide+to+Government+Patent+Use.pdf>.

⁴⁸ Elizabeth Warren and Katie Porter, "Letter to Operation Warp Speed Re: Use of Defense Production Act for Vaccine Manufacturing," January 14, 2021, <https://www.warren.senate.gov/imo/media/doc/2021.01.14%20Letter%20to%20OWS%20re%20Use%20of%20DPA%20for%20Vaccine%20Manufacturing.pdf>.

⁴⁹ Luis Gil Abinader, "Manufacturers of COVID-19 Vaccines Typically Start Delivering in under Six Months after Tech Transfer," *Knowledge Ecology International* (blog), February 22, 2021, <https://www.keionline.org/35364>.

⁵⁰ Ardizzone, "Novavax and Inovio COVID-19 Vaccine Contracts Limit Prices Companies Can Charge for Their Products."

⁵¹ Ardizzone, "\$1.8 Billion Sanofi Vaccine Contract Contains International Reference Pricing Clause, Preserves Standard IP and Data Rights."

intervene to ensure that patients receive a fair and equitable price. Further enforcement mechanisms the federal government could employ to intercede should manufacturers set an excessive price include voiding any FDA-awarded exclusivities and granting an open, non-exclusive license to other firms to produce a more affordable option. These same manufacturers would still be able to receive compensation in the form of royalties.

The Future of COVID-19 Vaccine Pricing

Much of the focus on COVID-19 vaccines has been directed towards issues around supply and pricing during the current public health emergency period. Although not certain, it is highly probable that these vaccines will become a necessary preventative measure beyond the current pandemic period. This is especially likely given the rapid rise and spread of variants. Both immunologists⁵² and manufacturers⁵³ have speculated that vaccination may need to occur at least annually in order to sustain the individual immune response necessary to prevent severe or symptomatic disease. Manufacturers have stated that they have set prices to reflect the current global health emergency.⁵⁴ Moderna also announced that “while the pandemic continues” they would not enforce any COVID-19 related patents against those making vaccines.⁵⁵ However, it remains unclear how this pandemic period is defined. While the U.S. government may consider the end of the pandemic period as when the HHS Secretary officially declares COVID-19 as a Public Health Emergency to be over, manufacturers may not. Internal documents from AstraZeneca have revealed that although the company pledged not to profit from its vaccine during this pandemic period, they also specified that they could declare the pandemic to be over by July 2021.⁵⁶

More alarming, however, are the implications of having little to no protections for patients included in current agreements with vaccine manufacturers to ensure reasonable pricing in the future. Both Pfizer and Moderna CEOs have speculated that the COVID-19 vaccine market may be similar to that of influenza.^{57,58} Like the COVID-19 vaccine, the influenza vaccine was developed with public funding. Even today, further development and manufacturing of seasonal influenza vaccine doses benefit from public funding and resources.^{59,60} As is anticipated for the COVID-19 vaccine, multiple manufacturers produce influenza vaccines that are routinely administered annually. To further understand what future pricing may look like for COVID-19 vaccines, my colleagues and I looked back at the past two decades of the influenza

⁵² Zoe Cormier, “The Second-Generation COVID Vaccines Are Coming,” *Scientific American*, January 20, 2021, <https://www.scientificamerican.com/article/the-second-generation-covid-vaccines-are-coming/>.

⁵³ Meg Tirrell, “Moderna Looks to Test Covid-19 Booster Shots a Year after Initial Vaccination,” *CNBC*, January 14, 2021, sec. Health & Science, <https://www.cnn.com/2021/01/14/moderna-looks-to-test-covid-19-booster-shots-a-year-after-initial-vaccination.html>.

⁵⁴ “Representative Jan Schakowsky Question and Answer Portion of House Oversight and Investigations Hearing on ‘Pathways to a Vaccine: Efforts to Develop a Safe, Effective, and Accessible COVID-19 Vaccine,’” § Oversight and Investigations Committee (2020), <https://www.youtube.com/watch?v=wVbqNZCtLJY&feature=youtu.be>.

⁵⁵ Moderna Inc., “Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic,” October 8, 2020, <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19/>.

⁵⁶ Donato Paolo Mancini, “AstraZeneca Vaccine Document Shows Limit of No-Profit Pledge | Financial Times,” *Financial Times*, October 7, 2020, <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686>.

⁵⁷ Jared S. Hopkins and Matt Grossman, “Pfizer Sees Covid-19 Vaccine Ranking Among Its Top Sellers,” *Wall Street Journal*, February 2, 2021, sec. Business, <https://www.wsj.com/articles/pfizer-lifts-outlook-on-covid-19-vaccine-posts-weaker-profit-11612270628>.

⁵⁸ Tirrell, “Moderna Looks to Test Covid-19 Booster Shots a Year after Initial Vaccination.”

⁵⁹ “Influenza Vaccines | NIH: National Institute of Allergy and Infectious Diseases,” NIH.gov, n.d., <https://www.niaid.nih.gov/diseases-conditions/influenza-vaccines>.

⁶⁰ “FDA’s Critical Role in Ensuring Supply of Influenza Vaccine,” FDA.gov (FDA, September 28, 2020), <https://www.fda.gov/consumers/consumer-updates/fdas-critical-role-ensuring-supply-influenza-vaccine>.

vaccine market.⁶¹ We found that both public and private sector prices rose by 149% and 163% respectively over this twenty year period in spite of having multiple manufacturers on the market and several similar products available. Additionally, contrary to traditional economic principles, prices across both sectors for these vaccines continued to rise over this time period despite a steady increase in the supply distributed and a market for whom the vaccines are recommended. Finally, analysis of the three largest manufacturers by market share (GlaxoSmithKline, Sanofi, and CSL) over the past decade further revealed that their rate of return as measured by compound annual growth rate of their influenza vaccine products outpaced the annual growth rate of the consumer price index for prescription drugs over the same time period.

Our analysis of the influenza market is a warning sign that a similar pattern may occur for COVID-19 vaccines. Although the government has been able to secure slightly discounted pandemic prices for COVID-19 at this time, manufacturers have admitted that they anticipate being able to raise prices in the future for these same vaccines. If so, the impact of continued high prices of these vaccines on public health program budgets will be immense, possibly forcing them to divert funds that could have been spent elsewhere to procure these publicly-funded vaccines.

Current discounts on the prices of COVID-19 vaccines may reflect the purchasing power of the government in buying hundreds of millions of doses. In the future, as with the influenza vaccine, we will likely see other stakeholders besides the federal government including private payors purchasing a majority of doses. Similar to the influenza vaccine, private insurers will likely purchase vaccines at a higher price compared to government health plans. While the Affordable Care Act should prevent insured patients from facing any potential financial barriers to accessing these vaccines such as copayments, these higher prices may be reflected in more costly health plan premiums. Additionally, current reasonable pricing provisions for vaccines are limited to only specific government payors. In the case of Novavax, while the Department of Defense may be able to secure the best, lowest price for their purchases⁶², other payors will be paying higher prices in comparison.

In the past year, I have seen many patients for their “goodbye” visit. Many had lost their jobs or were forced out of work because of other responsibilities at home. Because of this, they also lost their health insurance and would come to my clinic for one last visit before their coverage ended. These are the patients who keep me up at night as I worry and wonder if there will be sufficient supply of booster doses available for them to prevent against rapidly emerging variants next year and beyond when current pandemic protections expire.

Congress must take action to ensure the American people access to an affordable vaccine, especially one they have already paid for multiple times over. To do so, they must make transparent and easily available the significant contributions that taxpayers have already made to develop and produce these vaccines. Congress must also make ensure public access to all agreements between COVID-19 vaccine manufacturers and the U.S. government to allow the American people to oversee how their taxpayer dollars are being spent and hold companies accountable. Finally, and most importantly, Congress must also implement safeguards so that public funds are not given away without guarantees to ensure adequate supply or reasonable pricing. Without further action now, we may enter a period after the current pandemic ends where the lack of an affordable vaccine option could threaten efforts to ensure long-term control of COVID-19.

⁶¹ Reshma Ramachandran et al., “The Future of COVID-19 Vaccine Pricing: Lessons from Influenza,” *Forthcoming*, 2021.

⁶² Ardizzone, “Novavax and Inovio COVID-19 Vaccine Contracts Limit Prices Companies Can Charge for Their Products.”