

THE PEOPLE'S VACCINE

Zain Rizvi

Access to Medicines Program

June 11, 2020



ACKNOWLEDGMENTS

This report was written by Zain Rizvi, law and policy researcher in Public Citizen's Access to Medicines Program. It was edited by Peter Maybarduk, director of the Access to Medicines Program.

ABOUT PUBLIC CITIZEN

Public Citizen is a national non-profit organization with more than 500,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues including consumer rights in the marketplace, product safety, financial regulation, worker safety, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.

Contact Public Citizen

Main Office
1600 20th Street NW
Washington, D.C. 20009

Capitol Hill
215 Pennsylvania Avenue SE, #3
Washington, D.C. 20003

Texas Office
309 E 11th Street, Suite 2
Austin, Texas 78701

Phone: 202-588-1000

Phone: 202-546-4996

Phone: 512 477-1155

For more information, please visit www.citizen.org.

© 2020 Public Citizen

TABLE OF CONTENTS

Introduction 4

The People’s Vaccines 5

 AstraZeneca/Oxford 5

 Moderna/NIH 7

 Johnson & Johnson 8

 Merck/IAVI 9

 Pfizer/BioNTech 10

INTRODUCTION

Congress has appropriated nearly ten billion dollars to support development and manufacturing of COVID-19 diagnostics, treatments and vaccines.¹ Governments around the world are spending billions more.² In this report, we use five case studies to trace the role of public funding for COVID-19 vaccines. We focus on the corporations that the Trump Administration has reportedly selected as the most likely to produce a COVID-19 vaccine.

The stories are remarkably similar. To varying degrees, the public has helped fund new ways of designing vaccines (“platform technologies”). These technologies are now being used to develop COVID-19 vaccines, with significant taxpayer support each step along the way.³ The public is paying for research, development, and manufacturing— with no strings attached. More funding is imminent.⁴ Yet unless the government requires these corporations to make these vaccines essentially public goods, a proven vaccine may not reach everyone who needs it.

Last month, more than 140 world leaders and luminaries called for a people’s vaccine against COVID-19.⁵ In a letter organized by Oxfam and UNAIDS, the leaders noted that “Access to vaccines and treatments as global public goods are in the interests of all humanity. We cannot afford for monopolies, crude competition and near-sighted nationalism to stand in the way.” The vast amount of public funding for COVID-19 vaccine candidates only adds to the urgency of this call.

¹ Alex M. Azar, Secretary Azar White House Remarks on Operation Warp Speed, U.S. Department of Health and Human Services (May 15, 2020), <https://www.hhs.gov/about/leadership/secretary/speeches/2020-speeches/secretary-azar-white-house-remarks-on-operation-warp-speed.html>

² Francesco Guarascio, Global fundraising for COVID-19 vaccine, drugs exceeds \$10 billion, EU says, Reuters (May 26, 2020), <https://www.reuters.com/article/us-health-coronavirus-eu-vaccine/global-fundraising-for-covid-19-vaccine-drugs-exceeds-10-billion-eu-says-idUSKBN23217Z>

³ Much remains unknown about how they money is being directed, with the terms of critical contracts shrouded in secrecy.

⁴ Noah Weiland and David E. Sanger, Trump Administration Selects Five Vaccine Candidates as Finalists, NY Times (June 3, 2020) <https://www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html?action=click&module=Top%20Stories&pgtype=Homepage> (“Their selection as finalists. . . will give all five companies access to additional government money, help in running clinical trials and financial and logistical support for a manufacturing base that is being built even before it is clear which if any of the vaccines in development will work.”)

⁵ World leaders unite in call for a people’s vaccine against COVID-19, Oxfam International (May 14, 2020), <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>

Table 1: U.S. Biomedical Advanced Research and Development Authority (BARDA) COVID-19 Vaccines Funding

Organization	Product	Description	Amount
AstraZeneca (Oxford)	AZD1222 (formerly ChAdOx1 nCoV-19 vaccine)	"The AZD1222 vaccine consists of the replication-deficient simian adenovirus vector ChAdOx1, containing the structural surface glycoprotein (Spike protein) antigen of the SARS CoV-2 (nCoV-19)"	\$1,200,000,000
Moderna (NIH)	SARS-CoV-2 mRNA-1273 vaccine	"mRNA based SARS-CoV-2 vaccine encoding a pre-fusion stabilized Spike protein"	\$483,298,520
Johnson & Johnson	Viral Vector Vaccine for COVID-19	"Support development to licensure of a vaccine to combat COVID-19 using Janssen's established Adenovirus 26 platform."	\$456,237,081
Merck (IAVI)	rVSVΔG-CoV2	"Recombinant vesicular stomatitis virus (VSVΔG)-vectored vaccine expressing the spike protein of SARS-CoV-2."	\$38,033,570
Pfizer (BioNTech)	BNT162 program	SARS-CoV-2 RNA vaccine candidates against COVID-19	N/A
Emergent BioSolutions	N/A	Supporting vaccine and therapeutics manufacturing of Warp Speed Candidates ⁶	\$628,000,000
TOTAL			\$2,805,569,171

Note: This table only captures direct BARDA funding for COVID-19 candidates reportedly prioritized by the Trump Administration. It does not include other sources of public funding. Funding for Emergent BioSolutions, a contract manufacturer, may support the production of a range of vaccine candidates.

THE PEOPLE'S VACCINES

AstraZeneca/Oxford

AstraZeneca licensed a COVID-19 vaccine candidate from the University of Oxford, which had jointly worked on the project with a spin-out company. The Oxford vaccine was developed using technology that had earlier received funding from an international public and private collaboration, the Coalition for Epidemic Preparedness Innovations (CEPI). In 2018, CEPI awarded Oxford \$18 million to develop a vaccine against other viruses, including an earlier coronavirus, MERS.⁷

⁶ HHS Adds \$628 Million to Contract with Emergent BioSolutions to Secure CDMO Manufacturing Capacity for Operation Warp Speed, U.S. Department of Health and Human Services (June 1, 2020), <https://tinyurl.com/y7haul92>

⁷ Oxford University vaccine against COVID-19 starts clinical tests, CEPI (April 23, 2020), https://cepi.net/news_cepi/oxford-university-vaccine-against-covid-19-starts-clinical-tests/

After the emergence of the new coronavirus, CEPI redirected Oxford funding to the new coronavirus “to support the manufacture of vaccine materials required for preclinical and phase 1 testing.”⁸ Oxford is now running the Phase I/II trial, with funding from the U.K. government, CEPI and the Chinese government. Many partners did preclinical testing, including the U.S. National Institutes of Health (NIH).⁹ Notably, AstraZeneca is so far not listed as a partner on the clinical or preclinical testing.¹⁰

In late April, AstraZeneca announced a partnership with University of Oxford to further develop and to manufacture at scale the COVID-19 vaccine candidate.¹¹ The U.K. government also gave \$25 million (£20 million) to support Oxford’s vaccine research and clinical trials.

Last month, AstraZeneca announced a new \$1.2 billion partnership with the U.S. government. The company “received support of more than \$1bn from the US Biomedical Advanced Research and Development Authority (BARDA) for the development, production and delivery of the vaccine, starting in the fall. The development programme includes a Phase III clinical trial with 30,000 participants and a paediatric trial.”¹² Notably, the company said its announcement to scale production “is not anticipated to have any significant impact on the Company’s financial guidance for 2020; expenses to progress the vaccine are anticipated to be offset by funding by governments.”¹³

On June 4th, AstraZeneca announced a \$750 million agreement with CEPI and Gavi, the Vaccine Alliance, to support the manufacturing, procurement and distribution of the vaccine.¹⁴

⁸ Oxford University vaccine against COVID-19 starts clinical tests, CEPI (April 23, 2020), https://cepi.net/news_cepi/oxford-university-vaccine-against-covid-19-starts-clinical-tests/

⁹ COVID-19 Oxford Vaccine Trial: Sponsors and Partners, University of Oxford, <https://www.covid19vaccinetrial.co.uk/sponsors-and-partners>

¹⁰ *Id.*

¹¹ Landmark partnership announced for development of COVID-19 vaccine, University of Oxford (April 30, 2020), <http://www.ox.ac.uk/news/2020-04-30-landmark-partnership-announced-development-covid-19-vaccine> and AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine, AstraZeneca (April 30, 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html>

¹² AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford’s potential new vaccine, AstraZeneca (May 21, 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html>

¹³ *Id.*

¹⁴ AstraZeneca takes next steps towards broad and equitable access to Oxford University’s COVID-19 vaccine, AstraZeneca (June 4, 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html>

Moderna/NIH

Moderna is advancing a new approach to vaccines that uses mRNA. The company's founders partly developed the idea in a scientific paper that relied on public funding.¹⁵ Many investors initially considered the idea too speculative.¹⁶ But the Department of Defense took significant risk early-on.¹⁷ In 2013, the agency awarded the corporation \$25 million to test the approach. In 2016, BARDA awarded Moderna \$125 million to develop a Zika vaccine, which helped increase confidence in the new technology.¹⁸ NIH was recently working with Moderna to develop a vaccine for another kind of coronavirus, helping jumpstart the new response.¹⁹

When the new coronavirus emerged in December, an international public and private collaboration, the Coalition for Epidemic Preparedness Innovations (CEPI), provided funds to develop the vaccine for COVID-19.²⁰ NIH scientists then began testing the vaccine and ran a Phase I trial.²¹ Moderna was recently awarded a \$483 million BARDA contract to support further vaccine testing and to scale-up manufacturing to enable large-scale production.²²

¹⁵ Warren L, Manos PD, Ahfeldt T, et al. Highly efficient reprogramming to pluripotency and directed differentiation of human cells with synthetic modified mRNA. *Cell Stem Cell*. 2010;7(5):618-630. <https://pubmed.ncbi.nlm.nih.gov/20888316/>

¹⁶ Steve Usdin, DARPA's gambles might have created the best hopes for stopping COVID-19, *BioCentury* (March 19, 2020), <https://www.biocentury.com/article/304691/darpa-jump-started-technologies-behind-some-of-the-leading-covid-19-vaccine-and-antibody-hopes>

¹⁷ *Id.*

¹⁸ mRNA Strategic Collaborators: Government Organizations, Moderna, <https://www.modernatx.com/ecosystem/strategic-collaborators/mrna-strategic-collaborators-government-organizations> <https://www.biospace.com/article/moderna-s-zika-virus-vaccine-data-supports-covid-19-vaccine-approach/>

¹⁹ NIH clinical trial of investigational vaccine for COVID-19 begins, NIH (March 16, 2020), <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins> (“VRC and Moderna scientists already were working on an investigational MERS vaccine targeting the spike, which provided a head start for developing a vaccine candidate to protect against COVID-19.”)

²⁰ Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus, Moderna (Jan. 23, 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-funding-award-cepi-accelerate-development>

²¹ Moderna expects to coordinate with NIH again on Phase III trials. SEE: Moderna Announces First Participants in Each Age Cohort Dosed in Phase 2 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus, Moderna (May 29, 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-first-participants-each-age-cohort-dosed-phase>

²² 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, Moderna (April 16, 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million>

Johnson & Johnson

J&J is developing a COVID-19 vaccine using technologies it has used before. Those methods benefited from public funding. For example, on March 13th, J&J announced it was collaborating with the Beth Israel Deaconess Medical Center (BIDMC), a teaching hospital of Harvard Medical School to find suitable COVID-19 candidates.²³ The release noted

The company is leveraging its proven vaccine technology that it is also using to develop its investigational Ebola (which also utilizes its MVA-BN® technology), Zika, RSV and HIV vaccines. Research and collaboration on preclinical work for our Zika and HIV vaccine candidates at the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center was foundational to developing these vaccines.

The press release quoted Dan Barouch, the director of a virology center at BIDMC. According to a NIH database, Dr. Barouch has received \$45 million in taxpayer funding, most of it focused on developing vaccines.²⁴ J&J has also received at least \$200 million from BARDA to develop its Ebola vaccine.²⁵

In 2017, J&J entered into a contract with BARDA to advance products to treat or prevent infectious diseases. Before COVID-19, J&J had received \$82 million from that contract alone.²⁶

In February, J&J announced it was collaborating with BARDA to develop a COVID-19 vaccine candidate. The announcement stated J&J and BARDA would “both contribute to the research and development costs.” BARDA would “provide funding to support accelerated development of a vaccine candidate into Phase 1 clinical studies, with options for additional funding to progress a promising candidate.”

²³ Johnson & Johnson Announces Collaboration with the Beth Israel Deaconess Medical Center to Accelerate COVID-19 Vaccine Development, Johnson & Johnson (March 13, 2020), <https://www.jnj.com/johnson-johnson-announces-collaboration-with-the-beth-israel-deaconess-medical-center-to-accelerate-covid-19-vaccine-development>

²⁴ NIH RePORTER Database, NIH, https://projectreporter.nih.gov/reporter_SearchResults.cfm?icde=50289508

²⁵ HHS Contract Summaries, USA Spending, https://www.usaspending.gov/#/award/CONT_AWD_HHSO100201500008C_7505_-NONE_-NONE_- and https://www.usaspending.gov/#/award/CONT_AWD_HHSO100201700013C_7505_-NONE_-NONE_-

²⁶ HHS Contract Summaries, USA Spending, https://www.usaspending.gov/#/award/CONT_IDV_HHSO100201700018C_7505 and <https://www.phe.gov/Preparedness/news/Pages/janssen-flu.aspx>

A month later, J&J announced an expansion of its partnership with BARDA, pledging to commit over a billion dollars together for its COVID-19 vaccine candidate.²⁷ The candidate was developed “through collaborations with scientists at multiple academic institutions.”²⁸ J&J and BARDA will “co-fund vaccine research, development, and clinical testing.”²⁹ BARDA has so far awarded J&J \$456 million for vaccine development, and \$150 million for a new antiviral.

On April 23, J&J announced a new \$135 million agreement with Emergent BioSolutions for large-scale manufacturing.³⁰ The Emergent facility is a part of public-private partnership with HHS, known as Center for Innovation in Advanced Development and Manufacturing. The public spent \$163 million to setup this facility.³¹ Notably, BARDA recently announced a *separate* agreement with Emergent worth \$628 million for COVID-19 vaccine and treatment manufacturing. J&J's candidate may benefit from this.

Merck/IAVI

Merck is using the recombinant vesicular stomatitis virus (rVSV) technology that formed the basis of an Ebola vaccine to develop a COVID-19 vaccine. The Ebola vaccine—which was the first rVSV vaccine approved for use in humans—is rooted in public funding. In 2002, researchers at Canada's National Microbiology Laboratory discovered the vaccine for Ebola. Canadian scientists then worked with US Army scientists to develop the vaccine. Merck eventually acquired the license to the vaccine from a small biotechnology company. With clinical trials supported by millions of dollars of public funding, Merck was able to get the Ebola vaccine approved.³²

²⁷ Johnson & Johnson Announces Collaboration with U.S. Department of Health & Human Services to Accelerate Development of a Potential Novel Coronavirus Vaccine, Johnson & Johnson (Feb. 11, 2020), <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>

²⁸ Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use, Johnson & Johnson (March 30, 2020), <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use>

²⁹ *Id.*

³⁰ Emergent BioSolutions Signs Agreement to be U.S. Manufacturing Partner for Johnson & Johnson's Lead Vaccine Candidate for COVID-19, BioSolutions (April 23, 2020), <https://www.biospace.com/article/releases/emergent-biosolutions-signs-agreement-to-be-u-s-manufacturing-partner-for-johnson-and-johnson-s-lead-vaccine-candidate-for-covid-19/>

³¹ Department of Health and Human Services' Centers for Innovation in Advanced Development and Manufacturing, Medical Countermeasures, <https://www.medicalcountermeasures.gov/barda/core-services/ciadm/>

³² Matthew Herder, Janice E Graham, Richard Gold, From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine, *Journal of Law and the Biosciences*, , Isz019, <https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/Isz019/5706941>

IAVI, a nonprofit organization, has been using rVSV technology to develop candidates for HIV and viral hemorrhagic fevers.³³ For example, CEPI granted IAVI up to \$54.9 million for its Lassa Fever vaccine.³⁴ The U.S. Department of Defense is supporting development of its Marburg Virus vaccine.³⁵ In 2018, IAVI received \$43 million from governments and \$35.5 million from foundations.³⁶

On May 26, Merck announced its COVID-19 partnership with IAVI. IAVI scientists will design and engineer the SARS-CoV-2 vaccine candidate. IAVI and Merck will work together to advance development. Merck also announced it received \$38 million in BARDA funding “to provide initial funding support for this effort.” IAVI has said that the Japanese government, in partnership with the World Bank, will contribute to its work on COVID-19 vaccines.³⁷

In addition, Merck also recently acquired Themis, which was developing another COVID-19 vaccine candidate using the technology developed at the non-profit Institut Pasteur, with funding from CEPI.³⁸

Pfizer/BioNTech

Pfizer is working with a German biotechnology company called BioNTech to develop a COVID-19 vaccine. Like Moderna, BioNTech is advancing a new approach to vaccines that uses mRNA. BioNTech was founded by academics based at German universities who worked for years on developing new approaches to treat cancer, including through mRNA.³⁹ The German government provided critical seed funding to launch the biotech in 2008, awarding the academics—and then the company—a prize from its GO-Bio competition, totaling more than \$5 million (€4 million).⁴⁰

³³ IAVI Fact Sheets, IAVI, <https://www.iavi.org/newsroom/fact-sheets-publications>

³⁴ CEPI Partners with IAVI to Advance Lassa Fever Vaccines, IAVI (May 21, 2018), <https://www.iavi.org/newsroom/press-releases/2018/iavi-cepi-partner-for-emergency-lassa-fever-vaccines>

³⁵ Coronavirus vaccine program, IAVI (February 2020), <https://www.iavi.org/fact-sheets-download?download=227:coronavirus-vaccine-program>

³⁶ IAVI Annual Report 2018, IAVI (August 2019), <https://www.iavi.org/fact-sheets-download?download=201:iavi-2018-annual-report>

³⁷ Coronavirus vaccine program, IAVI (February 2020), <https://www.iavi.org/fact-sheets-download?download=227:coronavirus-vaccine-program>

³⁸ Themis Approach, Themis, <https://www.themisbio.com/technology/themis-approach/> and Merck to Acquire Themis, Merck (May 26, 2020), <https://investors.merck.com/news/press-release-details/2020/Merck-to-Acquire-Themis/default.aspx>

³⁹ Research papers authored by Ugur Sahin, Google Scholar, <https://scholar.google.com/citations?user=MzVQ-OMAAAAJ&hl=en>

⁴⁰ Development of innovative vaccines against cancer, Germany's Federal Ministry of Education and Research (April 10, 2006), <https://www.go-bio.de/en/development-of-innovative-vaccines-against-cancer-1733.html>. (At the 2009 average conversion rate of 1 USD = 1.25 Euro.)

In 2018, BioNTech entered into a partnership with researchers at the University of Pennsylvania to develop mRNA vaccines for infectious diseases. The NIH-funded academics had previously shown the potential of mRNA vaccines against pathogens.⁴¹

Last year, the European Investment Bank provided \$56 million (€50 million) in financing to BioNTech, with the company saying it would “use the funds for research and development, market access and the expansion of manufacturing capabilities for its mRNA-based product candidates.”⁴² The Gates Foundation also invested \$55 million—in a grant that could reach up to \$100 million—to expand the company’s work in infectious diseases, namely HIV and tuberculosis.⁴³

On March 16, Pfizer announced it would jointly develop a COVID-19 vaccine with BioNTech.⁴⁴ On June 11, the European Investment Bank provided BioNTech a \$114 million (€100 million) loan to support the development and manufacturing scale-up of the COVID-19 vaccine.⁴⁵

⁴¹ Pardi, N., Parkhouse, K., Kirkpatrick, E. *et al.* Nucleoside-modified mRNA immunization elicits influenza virus hemagglutinin stalk-specific antibodies. *Nat Commun* 9, 3361 (2018), <https://www.nature.com/articles/s41467-018-05482-0#Ack1>, <https://tinyurl.com/ybkdac4q>

⁴² Germany: EIB provides funding of EUR 50 million to BioNTech as part of the Investment Plan for Europe, European Investment Bank (Dec. 17, 2019), <https://tinyurl.com/ybd87q8n> (At the 2019 average conversation rate of 1 USD = 1.12 Euro.)

⁴³ BioNTech Announces New Collaboration to Develop HIV and Tuberculosis Programs, BioNTech (Sept. 4, 2019), <https://investors.biontech.de/news-releases/news-release-details/biontech-announces-new-collaboration-develop-hiv-and>

⁴⁴ Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine, Pfizer (March 16, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_to_co_develop_potential_covid_19_vaccine

⁴⁵ Investment Plan for Europe: European Investment Bank to provide BioNTech with up to €100 million in debt financing for COVID-19 vaccine development and manufacturing (June 11, 2020), <https://www.globenewswire.com/news-release/2020/06/11/2046651/0/en/Investment-Plan-for-Europe-European-Investment-Bank-to-provide-BioNTech-with-up-to-100-million-in-debt-financing-for-COVID-19-vaccine-development-and-manufacturing.html> (“In recent years the EIB has become a unique player in supporting highly innovative venture-stage biotech and medtech companies in their research and development of vaccines, therapeutics and diagnostics solutions, and we are doing everything we can to step up our support in the current crisis.”)



www.citizen.org

© 2020 Public Citizen