CASE: SM-345
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OPERATION WARP SPEED AND THE COVID-19 VACCINE

In May 2020, COVID-19 had brought the country to its knees. Becca Latha, an MBA1, strolled through the deserted Schwab courtyard and past the chairs and tables draped with "CAUTION" tape. She enjoyed the brief sunshine during the walk around the sunny Stanford campus, breaking up hours of Zoom classes.

"How much longer is this going to last? I can't handle another 4 hours on Zoom," Becca grumbled. Her phone buzzed with the latest headline: "President Trump announces Operation Warp Speed – $10B to accelerate COVID vaccine development." Her mind raced. "Will the vaccine come out by the fall? How are they going to develop a vaccine so quickly? Should I be investing in some pharma companies? The only way to get the economy running again is a vaccine!" That glimmer of hope was what Becca needed, as she pulled out her phone to order something to eat from DoorDash.

HISTORY OF PUBLIC-PRIVATE PARTNERSHIPS

The Organization for Economic Cooperation and Development (OECD) formally defined public-private partnerships (PPP) as "long term contractual arrangements between the government and a private partner whereby the latter delivers and funds public services using a capital asset, sharing the associated risks."[1] PPP in the United States dated back to the 1700s, with most partnerships focused around infrastructure development.[2] For example, private citizen George Washington started the Patowmack Company in 1785 to enable ship navigation and build canals along the

[1] "Recommendation of the Council on Principles for Public Governance of Public-Private Partnerships," OECD, May 2012, https://www.oecd.org/governance/budgeting/PPP-Recommendation.pdf (May 4, 2021).
[2] "A Brief History of Public Private Partnerships," Lorman Education Services, July 19, 2018, https://www.lorman.com/resources/a-brief-history-of-public-private-partnerships-16968 (May 4, 2021).

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Potomac River.[3] These early partnerships primarily involved the construction of highways, bridges, and railroads.

Public infrastructure projects typically involved five key stages: design, build, finance, operate, and maintain.[4] The traditional contracting approach to completing these projects involved the government hiring private firms to perform one of the project stages or an activity within a stage. Through this approach, the financial and operational risk of the project and project completion remained with the government. For example, Boston's "Big Dig" infrastructure project fell behind and costs ballooned from $7.7 billion to $13.6 billion in under a decade.[5]

A PPP approach might still entail public investment, but transfer financial and/or operational risk to the private partner by giving them control and accountability over one or more of the project stages. This risk-sharing approach was intended to align incentives between the public and private sectors to address cost, quality, and timeliness of project completion. For example, a PPP to build a bridge might place the private partner at risk for completing the project with finances based on projected future toll revenue, and leave the private party accountable for cost overruns in design and construction. Some governments would only participate in PPPs if the financial risk was pushed to the private sector.[6]

By 2020 a variety of different PPP models had emerged. A recent development involved asset monetization partnerships—for example, the city of Detroit leased the Detroit-Windsor bridge to a private party, which maintained and operated the bridge while collecting tolls.[7] Another PPP was SpaceX's efforts to build rockets for human space flight for NASA.[8]

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

In September 11, 2001, the United States experienced the largest terrorism attack on its soil, organized by Al Qaeda. Starting a week later, letters were found at multiple sites including the U.S. Congress, which contained a weaponized version of the bacteria Anthrax.[9] Thus, the country faced multiple terrorist threats at once including the new threat, bioterrorism. Lacking countermeasures for these new threats, the Biomedical Advanced Research and Development

[3] "Canal History: George Washington & The Patowmack Company," Canal Trust, https://www.canaltrust.org/about-us/about-the-co-canal/history/canal-history-george-washington-the-patowmack-company/ (May 4, 2021).
[4] "Public-Private Partnerships for Transportation and Water Infrastructure," Congressional Budget Office, January 2020, https://www.cbo.gov/publication/56044 (May 4, 2021).
[5] Pamela Ferdin, "Boston's 'Big Dig' Buried in Cost Overruns," *The Washington Post*, April 12, 2000, https://www.washingtonpost.com/archive/politics/2000/04/12/bostons-big-dig-buried-in-cost-overruns/447054fe-83d2-4acf-bec0-f0c7920302d1/ (May 4, 2021).
[6] "Public-Private Partnerships for Transportation and Water Infrastructure," loc. cit.
[7] Matt Helms, "Terms of Detroit's settlements with FGIC, Syncora," *Detroit Free Press*, October 17, 2014, https://www.freep.com/story/news/local/detroit-bankruptcy/2014/10/17/detroit-settlement-details-syncora-fgic/17384587/ (May 4, 2021).
[8] James Cawley, "NASA and SpaceX Complete Certification of First Human-Rated Commercial Space System," NASA, November 10, 2020, https://www.nasa.gov/feature/nasa-and-spacex-complete-certification-of-first-human-rated-commercial-space-system (May 4, 2021).
[9] "Timeline: How The Anthrax Terror Unfolded," *NPR*, February 15, 2011, https://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded (May 4, 2021).

Authority (BARDA) was established in 2006 within the U.S. Department of Health under the Assistant Secretary for Preparedness and Response.[10] BARDA's mission was to develop the necessary vaccines, drugs, therapies, and diagnostic tools for public health emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, attacks, pandemic influenza, and emerging infectious diseases.[11] Over time, BARDA became more and more involved in pandemic response in response to health threats in the United States and globally (See Exhibit 4).

BARDA's strategic plan highlighted the importance of public-private partnerships in addressing this broad mission: "BARDA's commitment to public private partnerships is deep-rooted and extends across its entire portfolio."[12] BARDA partnered with industry to promote the advanced development of medical countermeasures.[12] For medical products, BARDA was "bridging the valley of death" by providing financing and services similar to venture capital firms, but did not take equity stakes in private companies.[13]

BARDA ran a variety of stockpiling programs for the different components of its broad mission. Some examples of BARDA drug/vaccine development programs included:

1. *Anthrax:* BARDA made investments in 9 different pharmaceutical companies for the research and development of diagnostics, therapeutics, and vaccines for anthrax. Of the investments, five had come to market with the products developed by Emergent BioSolutions becoming part of the national stockpile.[14]

2. *Ebola:* BARDA made investments in 1 vaccine, 1 diagnostic, and 2 treatments that had come to market. This included the development of the first Ebola vaccine developed by Lumos Pharma. The vaccine was announced in December 2019 and brought to market by Merck.[15]

3. *Avian Flu:* BARDA supported the development of vaccines for avian flu, commonly referred to as bird flu. They supported the development of 2 vaccines preemptively against the H5N8 virus in case it developed the ability to transmit to humans.[16]

Another important function of BARDA was the creation of manufacturing capacity for pandemic response. One of the missions of the organization was to support the production of required

[10] "BARDA," U.S. Department of Health and Human Services, https://www.medicalcountermeasures.gov/barda/ (May 4, 2021).
[11] "About BARDA," U.S. Department of Health and Human Services, https://www.phe.gov/about/barda/Pages/default.aspx (May 4, 2021).
[12] "BARDA Strategic Plan 2011-2016," U.S. Department of Health and Human Services, https://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf (May 4, 2021).
[13] "BARDA'S Vision, Mission, and Values," U.S. Department of Health and Human Services, https://www.phe.gov/about/barda/stratplan/Pages/barda-vision-mission-and-values.aspx (May 4, 2021).
[14] "BARDA's Anthrax Medical Countermeasure Strategy and Portfolio," U.S. Department of Health and Human Services, https://www.phe.gov/about/barda/anthrax/Pages/default.aspx (May 4, 2021).
[15] Robert Kadlec, "Making history: the world's first FDA-approved Ebola vaccine," U.S. Department of Health and Human Services, December 19, 2019, https://www.phe.gov/ASPRBlog/Pages/BlogArticlePage.aspx?PostID=370 (May 4, 2021).
[16] Robert Roos, "BARDA: Recent 'universal' flu vaccine proposals fell short," CIDRAP, July 23, 2015, https://www.cidrap.umn.edu/news-perspective/2015/07/barda-recent-universal-flu-vaccine-proposals-fell-short (May 4, 2021).

products in a manner that was timely, reliable, and cost effective. BARDA also supported the construction of new facilities and retrofitting of existing facilities. This effort came into play in the avian flu pandemic of 2009.[17] At the time, most flu vaccine was made in chicken eggs, but avian flu could infect humans and birds. If the chickens died, there would be no ability to produce flu vaccine. Fortunately, this scenario did not occur. However, in response to these concerns, BARDA established a network of manufacturing capabilities for emergency production and distribution of medical countermeasures if and when the needs arose.[18] An example of BARDA's manufacturing strategy was its 2011 partnership with Novartis to build a cell-based pandemic flu vaccine production facility, eliminating the need for chicken eggs in vaccine production.[19] In this case, Novartis argued that without the BARDA investment, the migration to the new, more costly production method required to address pandemic avian influenza would not be justified for seasonal flu vaccine production.

NATIONAL INSTITUTES OF HEALTH (NIH)

The National Institutes of Health, the nation's premier agency focused on advancing basic biomedical and health research, was part of the U.S. Department of Health and Human Services. The 2018 NIH budget was $25.9 billion with 10 percent of these funds allocated to internal (or intramural) research at the NIH. The bulk of the budget was allocated to external (or extramural) grants. Over 80 percent of external grants went to investigators at higher education and research institutions.[20]

In 2018, domestic for-profit businesses received $1.2 billion in NIH funding.[21] Most of the funding directed to for-profit businesses came was through the Small Business Innovation Research (SBIR) program. The goal of this program was to help small businesses conduct early-stage research and development. Most of these grants went to firms developing new drugs and medical devices.[22]

Structurally, the NIH engaged in PPPs through the funding of research institutions. Unlike BARDA, most NIH programs did not necessarily have the end of goal of bringing a product to market, but instead often focused on basic research to further our understanding of biology at the cellular and genetic level. NIH research did lead to the identification of novel biologic targets for the development of new therapies, but NIH did not fund drug development. This could lead to the "Valley of Death"—where novel translational research might no longer be fundable by the NIH, but lacked the robust proof of concept required to secure private investment.

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[17] "The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010," U.S. Centers for Disease Control and Prevention, June 16, 2010, https://www.cdc.gov/h1n1flu/cdcresponse.htm (May 4, 2021).
[18] "HHS Awards $6 million to Create Pediatric Disaster Care Centers of Excellence," U.S. Department of Health and Human Services, September 30, 2019, https://www.phe.gov/Preparedness/news/Pages/pdcc-award-30sept19.aspx (May 4, 2021).
[19] "First U.S. cell-based flu vaccine plant set for dedication," U.S. Department of Health and Human Services, December 12, 2011, https://www.phe.gov/Preparedness/news/Pages/cellflu-111212.aspx (May 4, 2021).
[20] https://www.nih.gov/news-events/news-releases/fact-sheet-impact-sequestration-national-institutes-health
[21] "NIH Awards by Location and Organization," National Institutes of Health, https://report.nih.gov/organizations/extramural/funded-organizations (May 4, 2021).
[22] "Small Business Success Stories," National Institutes of Health, July 13, 2020, https://sbir.nih.gov/stories/ (May 4, 2021).

The National Institute of Allergy and Infectious Diseases (NIAID), headed by Dr. Anthony S. Fauci since 1984, was one of the 27 NIH institutes and centers. Charged with efforts to "identify, diagnose and treat" infectious diseases, NIAID was the lead agency combatting emerging infections including HIV, Ebola, and pandemic viral infections.[23] The scientific response to the emergence of HIV was a true success story of a PPP between the NIH, academia, and industry. In the 1980s, the NIAID response to the emergence of the HIV virus was criticized as inadequate in response to the emerging crisis. By the early 1990s, the NIH pushed funding to intramural and extramural investigators to focus on this emerging pathogen, and coordinated testing of novel HIV therapies that emerged.[24] This leadership and funding effort was the catalyst for the remarkable success in addressing HIV infection, which had been transformed from the number one cause of death for men between 25 to 44 into a manageable chronic disease.[25] Anti-retroviral therapy that emerged from this research effort prevented an estimated 9.5 million deaths worldwide in the 20-year period between 1995 and 2015, with global economic benefits estimated at $1.05 trillion.[26]

OPERATION WARP SPEED

Funding and Goals

In late December 2019, the World Health Organization (WHO) received reports of the identification of a novel cluster of patients with viral pneumonia in Wuhan, China.[27] By April 2, 2020, there were over 1 million cases reported globally.[28] In an effort to halt the spread of the virus, states such as California instituted stay-at-home orders for non-essential personnel.[29] The economic fallout of these lock-downs was widespread. The S&P 500 index fell 34 percent by March 23.[30] Unemployment surged, with 20.5 million people losing their jobs in April 2020.[31]

In response to this crisis, in May 2020 the Trump administration announced the creation of Operation Warp Speed (OWS), a PPP launched by the U.S. government to accelerate the

[23] "Anthony S. Fauci, M.D." National Institutes of Health, March 14, 2021, https://www.niaid.nih.gov/about/anthony-s-fauci-md-bio (May 4, 2021).
[24] "Three Decades of Responding to Infectious Disease Outbreaks," National Institutes of Health, November 14, 2017, https://www.niaid.nih.gov/news-events/three-decades-responding-infectious-disease-outbreaks (May 4, 2021).
[25] "A Timeline of HIV and AIDS," HIV.gov, https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline (May 4, 2021).
[26] Steven S. Forsythe et al., "Twenty Years Of Antiretroviral Therapy For People Living With HIV: Global Costs, Health Achievements, Economic Benefits," *Health Affairs*, Vol. 38, No. 7, July 2019, https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05391 (May 4, 2021).
[27] "Archived: WHO Timeline - COVID-19," World Health Organization, April 27, 2020, https://www.who.int/news/item/27-04-2020-who-timeline---covid-19 (May 4, 2021).
[28] "COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)," Johns Hopkins University, https://coronavirus.jhu.edu/map.html (May 4, 2021).
[29] "Executive Order N-33-20," Executive Department, State of California, March 4, 2020, https://www.gov.ca.gov/wp-content/uploads/2020/03/3.19.20-attested-EO-N-33-20-COVID-19-HEALTH-ORDER.pdf (May 4, 2021).
[30] Julie Jason, "The Coronavirus Stock Market: A Market Gone Wild," *Forbes*, April 8, 2020, https://www.forbes.com/sites/juliejason/2020/04/08/the-coronavirus-stock-market-a-market-gone-wild/?sh=304a7e2ea31f (May 4, 2021).
[31] Anneken Tappe, "Record 20.5 million American jobs lost in April. Unemployment rate soars to 14.7%," *CNN*, May 8, 2020, https://www.cnn.com/2020/05/08/economy/april-jobs-report-2020-coronavirus/index.html (May 4, 2021).

development, manufacturing, and distribution of COVID-19 countermeasures including diagnostics, therapeutics, and vaccines.[32] OWS had a goal to deliver 300 million doses of a COVID-19 vaccine by January 2021.[33]

The initial budget for this effort was nearly $10 billion, of which $6.5 billion was designated for countermeasure development to BARDA, and $3 billion was designated to NIH research.[34] An additional $8 billion was dedicated to OWS in late 2020, with money reallocated from the U.S. Strategic National Stockpile and Centers for Disease Control, to bring total funding for this effort to $18 billion.[35]

Leadership Team

Dr. Moncef Slaoui was named chief advisor for OWS. Slaoui was a venture capitalist, and had a 30-year career at GlaxoSmithKline (GSK) including serving as chairman of global vaccines. During his tenure, he oversaw a portfolio of 48 vaccines including the development of 14 novel vaccines. After he retired from GSK in 2017, he joined Medici Venture Capital, and served as the chairman of the board at Galvani, a bioelectronics R&D company jointly owned by GSK and Verily Life Sciences. He also joined the board of Moderna Pharmaceuticals.[36]

General Gustave F. Perna was named chief operating officer for OWS. Prior to this announcement, General Perna served as commander of the U.S. Army Materiel Command (AMC), responsible for global supply chain and readiness for the U.S. Army. He was tapped to use his expertise to accelerate the development, manufacturing, and distribution of COVID countermeasures.[37]

The head of BARDA, Dr. Rick Bright, was reassigned just before OWS was announced.[38] Dr. Bright cited political clashes with the Trump administration as the reason for his removal, namely the rush to use an untested therapy, the malaria drug chloroquine, to treat COVID patients (clinical trials later found that this therapy was not effective in preventing death from

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[32] "Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,'" U.S. Department of Health and Human Services, May 15, 2020, https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html (May 4, 2021).
[33] Moncef Slaoui, "2020 Great Immigrants Recipient," Carnegie Corporation, https://www.carnegie.org/awards/honoree/moncef-slaoui/ (May 4, 2021).
[34] "Trump Administration Announces Framework and Leadership for "Operation Warp Speed,'" loc. cit.
[35] John Tozzi, Riley Griffin, and Shira Stein, "Trump Administration Dips Into Protective Gear, CDC Funds to Fund Vaccine Push," *Bloomberg,* September 23, 2020, https://www.bloomberg.com/news/articles/2020-09-23/how-much-is-the-trump-administration-spending-on-a-vaccine (May 4, 2021).
[36] "Moderna Congratulates Dr. Moncef Slaoui on His Appointment to Oversee the White House's Operation Warp Speed Initiative," Moderna, May 15, 2020, https://investors.modernatx.com/news-releases/news-release-details/moderna-congratulates-dr-moncef-slaoui-his-appointment-oversee (May 4, 2021).
[37] "Trump Administration Announces Framework and Leadership for "Operation Warp Speed,'" loc. cit.
[38] "Kaitlin Collins, Jeremy Diamond, and Betsy Klein, "Director of key federal vaccine agency says his departure was retaliation," *CNN,* April 22, 2020,https://edition.cnn.com/2020/04/22/politics/rick-bright-barda-trump-coronavirus/index.html (May 4, 2021).

COVID-19).[39] Dr. Gary Disbrow was named the new director of BARDA under OWS, having overseen BARDA's medical countermeasures efforts since 2007.[40]

Vaccine Development

NIAID scientists were able to leverage earlier research into the SARS virus to create a stabilized version of the SARS CoV-2 spike protein as a vaccine target within hours of the virus sequence being reported. NIH signed 21 license agreements with biotechnology and pharmaceutical companies for technologies related to SARS-CoV-2 prefusion stabilized spike proteins to support vaccine development.[41] Based on this target, vaccine development began in earnest.

OWS Investments

A majority of investments made by BARDA centered on vaccine development. Some key investments made were as follows (see Exhibit 3):[42]

- $954 million to Moderna for R&D
- $456 million to Johnson & Johnson for R&D
- $31 million to Sanofi/GSK for R&D
- $38 million to Merck/IAVI for R&D

Of note, Pfizer Inc. refused to accept U.S. government funding for its vaccine R&D efforts. However, BioNTech, Pfizer's partner in vaccine development, received $445 million from the German government. Pfizer cited that it did not want to be caught in the bureaucracy of the American government in taking taxpayer funding for R&D.[43]

Beyond research support, OWS and BARDA also placed large vaccine orders to companies, including Pfizer. The idea of these vaccine orders was to spur the development of manufacturing capacity even before the vaccines were approved by the Food and Drug Administration (FDA). Some of the main vaccine contracts included:

- $6 billion to Pfizer for 300 million doses
- $5 billion to Moderna for 300 million doses
- $1.2 billion to AstraZeneca / Oxford for 300 million doses
- $1 billion to Johnson & Johnson for 100 million doses

[39] "Is chloroquine or hydroxychloroquine useful in treating people with COVID-19, or in preventing infection in people who have been exposed to the virus?" Cochrane, https://www.cochrane.org/news/chloroquine-or-hydroxychloroquine-useful-treating-people-covid-19-or-preventing-infection (May 4, 2021).
[40] "Gary L. Disbrow, Ph.D.," U.S. Department of Health and Human Services, https://www.phe.gov/about/barda/Pages/Disbrow.aspx (May 4, 2021).
[41] "Technology Development Success Stories," National Institute of Allergy and Infectious Diseases, https://www.niaid.nih.gov/research/technology-development-success-stories (May 4, 2021).
[42] "Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021, https://crsreports.congress.gov/product/pdf/IN/IN11560 (May 4, 2021).
[43] Riley Griffin and Drew Armstrong, "Germany funded the development of Pfizer's COVID vaccine—not U.S.'s Operation Warp Speed," *Fortune*, November 9, 2020, https://fortune.com/2020/11/09/pfizer-vaccine-funding-warp-speed-germany/ (May 4, 2021).

- $1.6 billion to Novavax for 100 million doses
- $2 billion to Sanofi/GSK for 100 million doses[44]

In addition to these investments, the NIH partnered with Moderna throughout 2020 to support research and testing of their COVID vaccine.[45] Moderna, founded in 2010 around mRNA technology, had 24 drug development candidates identified by 2019, with 12 in clinical trials, including 8 vaccine programs with 5 in clinical trials. Clinical development included mostly Phase 1 safety studies, and some Phase 2 trials. Moderna had no products that were FDA approved or marketed at the end of 2019.[46]

Licensing and Intellectual Property

Novel intellectual property related to the COVID-19 vaccines could include patents on the vaccine candidates, patents on the manufacturing process, or even use patents. However, patents in the United States are negative rights—they prevent another entity from practicing an invention, but do not give the patent holder freedom to operate. In other words, a company could patent an mRNA COVID-19 vaccine, but would not be able to manufacture the vaccine until it could obtain licenses to the underlying mRNA technology. In mid-2020, Moderna, CureVac, BioNTech, and GSK owned nearly half of all mRNA patent applications.[47]

Under OWS, BARDA retained the right to require its partners to license vaccines internationally, to halt exports if requested by the government, and to have access to the technology on a royalty-free basis.[48] While these provisions were enshrined in the OWS contracts, there was no indication that the U.S. government planned to implement any of these provisions, as doing so could severely disincentivize future industry collaborations.

Pfizer, Moderna, and other recipients of funding were able to create large IP moats for products supported with public funding. There were global calls for waiving patent protection for COVID vaccines to allow others to manufacture the vaccine. Oxford University licensed its vaccine technology to AstraZeneca on a royalty-free basis for the duration of the public health emergency.[49] In turn, AstraZeneca licensed the vaccine to the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, and the Serum Institute of India (SII) at no profit.[50] Initially, the U.S. and E.U. opposed waiving patent rights for the underlying

[44] "Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," loc. cit.
[45] Joe Palca, "COVID-19 Vaccine Candidate Heads To Widespread Testing In U.S.," *NPR,* July 27, 2020, https://www.npr.org/sections/coronavirus-live-updates/2020/07/27/895672859/us-vaccine-candidate-heads-to-widespread-testing-in-people (May 4, 2021).
[46] SEC Form 10-K Moderna, Inc., February 27, 2020, https://sec.report/Document/0001682852-20-000006/ (May 4, 2021).
[47] "Cecilia Martin and Drew Lowery, "mRNA vaccines: intellectual property landscape," *Nature,* July 28, 2020, https://www.nature.com/articles/d41573-020-00119-8 (May 4, 2021).
[48] Moderna Inc. annual report, 2020, U.S. Securities and Exchange Commission, https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c (May 4, 2021).
[49] Rory O'Neill, "LSPN Connect: how COVID crystallised Oxford Uni's licensing mission," *lsipr,* January 2, 2021, https://www.lifesciencesipreview.com/news/lspn-connect-how-covid-crystallised-oxford-uni-s-licensing-mission-4346 (May 4, 2021).
[50] "AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine," June 4, 2020, https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html (May 4, 2021).

vaccine technologies (see Exhibit 1). The requirements for licensure could prevent developing countries from building manufacturing capacity and could lead to major difficulties in vaccine access. This presented a risk of drawing out the pandemic, and also a risk of new variants emerging as the virus continued to spread.[51] In the face of mounting criticism, the Biden administration reversed their position in May 2021.

In an effort to potentially stave off compulsory licensure, Moderna publicly stated that it would not enforce its patent during the COVID pandemic and was willing to license its technology to others for the COVID vaccine after the pandemic was over.[52]

In the end, there remains an open question of whether intellectual property rights are really a barrier to vaccine access when manufacturing capacity has emerged as a much larger question.

Vaccine Pricing

Governments were the main purchasers of COVID vaccines. The U.S. government procured vaccines at prices negotiated with Moderna, Pfizer, and other partners. The prices countries paid for vaccines varied in mid-2021—the E.U. paid $14.70 for a Pfizer dose while the U.S. paid $19.50. However, the U.S. paid less for Moderna, $15/dose, while the E.U. paid about $18. Moderna charged the U.S. government less in recognition of the U.S. investment in the development of its vaccine. Similarly, the E.U. supported the development of the Pfizer vaccine.

During a U.S. House of Representatives committee hearing, Moderna and Merck were asked if they would sell their vaccines at cost—and both indicated that they would not. Johnson & Johnson and AstraZeneca, on the other hand, indicated that they would not profit during the pandemic. Post-pandemic, the prices for these vaccines were likely to jump significantly. However, the key debate centered on the question of whether and by how much these companies should be allowed to profit off of a federally funded initiative, especially as it appeared that COVID vaccination might become an annual health requirement.

Manufacturing and Distribution

In addition to investments in vaccine development, BARDA played an active role in bolstering the vaccine manufacturing capacity. BARDA formed partnerships with advanced facilities, specifically in Texas at Texas A&M (in partnership with FujiFilm), and Maryland at Emergent BioSolutions, to provide capacity to its federal vaccine partners to quickly manufacture vaccines.[53]

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[51] Johnathan Shaffer, "Biden should use emergency powers to license Covid-19 vaccine technologies to the WHO for global access," STAT News, March 25, 2021, https://www.statnews.com/2021/03/25/biden-use-emergency-powers-license-covid-19-vaccines-for-global-access/ (May 4, 2021).

[52] "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 (May 4, 2021).

[53] "HHS Reserves and Rapidly Expands Manufacturing Capacity for COVID-19 Vaccines at Texas Center for Innovation in Advanced Development and Manufacturing," U.S. Department of Health and Human Services, July 27, 2020, https://www.hhs.gov/about/news/2020/07/27/hhs-reserves-and-rapidly-expands-manufacturing-capacity-for-covid-19-vaccines-at-texas-center.html (May 4, 2021).

BARDA also made investments in manufacturing for ancillary supplies needed for vaccine distribution. For example, they provided $204 million to Corning to create Valor Glass vials for vaccines and $31 million to Cytiva to expand manufacturing capacity of products essential to creating the vaccines.[54,55]

While BARDA made investments to support vaccine manufacturers, much of the decision making around investments in building capacity was left to Pfizer, Moderna, and other vaccine manufacturers. In addition, product launch and marketing were left to the individual companies and states.[56] Moderna, for example, cited marketing as being a new area where the company was working to develop expertise.[57]

Transparency and Conflicts of Interest

One of the core criticisms of OWS was the opaque nature of BARDA's decision-making process. Criteria for choosing the size and recipients of specific investments, and the terms of the investments, were not disclosed to the public. These issues were at the center of Senate oversight hearings.[58] For example, BARDA took a major risk in supporting novel mRNA technology. The rationale for this approach was not articulated to the public, and it remained unclear where accountability would lie if this approach had not proved successful. Despite these initial concerns, the mRNA technology was successful. It is unclear if a more transparent process would have ended up selecting such a risky technology. Looking beyond just the U.S. market, the mRNA vaccines were likely to be very difficult to administer on a global level, given the need for specific cold chain storage. This suggested the American public could be at risk for COVID variants emerging in populations that were not vaccinated. In retrospect, it remained an open question whether the U.S. population would have been better served with a broader portfolio of vaccine technology approaches. Another fallout from the lack of transparency around OWS were a number of rumors circulating that fueled conspiracy theories in the general public, and contributed to vaccine hesitancy.

Confounding the lack of transparency in OWS were conflict of interest concerns surrounding the role of Dr. Slaoui. Dr. Slaoui was on the Board of Moderna prior to being appointed to his role in OWS. Further, he held shares in Moderna, GSK, and Lonza Group, the latter a company that partnered with Moderna to manufacture their COVID vaccine. All of these pharmaceutical companies clearly benefited from the investments made by OWS. In addition to Dr. Slaoui,

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[54] "Operation Warp Speed ramps up U.S.-based manufacturing capacity for vials for COVID-19 vaccines and treatments," U.S. Department of Health and Human Services, June 11, 2020, https://www.hhs.gov/about/news/2020/06/11/operation-warp-speed-ramps-up-us-based-manufacturing-capacity-for-vials-for-covid-19-vaccines-and-treatments.html (May 4, 2021).

[55] "Trump Administration Expands Manufacturing Capacity with Cytiva for Components of COVID-19 Vaccines," U.S. Department of Health and Human Services, https://www.hhs.gov/about/news/2020/10/13/trump-administration-expands-manufacturing-capacity-cytiva-components-covid-19-vaccines.html (May 4, 2021).

[56] Stacy Wood and Kevin Schulman, "Beyond Politics - Promoting Covid-19 Vaccination in the United States," *The New England Journal of Medicine*, February 18, 2021, https://www.nejm.org/doi/full/10.1056/nejmms2033790 (May 4, 2021).

[57] Moderna Inc. annual report, 2020, U.S. Securities and Exchange Commission, loc. cit.

[58] Jon Cohen, "Operation Warp Speed's opaque choices of COVID-19 vaccines draw Senate scrutiny," *Science,* July 2, 2020, https://www.sciencemag.org/news/2020/07/operation-warp-speed-s-opaque-choices-covid-19-vaccines-draw-senate-scrutiny (May 4, 2021).

three other leaders of OWS were found to have conflicts of interest due to holdings in Pfizer and Teva Pharmaceuticals.[59] Overall, these conflicts raised concerns about the vetting process for appointment to OWS, the enforcement of U.S. federal ethics rules for OWS personnel, and the decision-making process at OWS.

After the 2020 election, Dr. Slaoui was asked to resign at the request of the Biden administration.[60] He was replaced in OWS by former FDA Commissioner Dr. David Kessler.[61]

Another concern that arose within OWS was the role of Emergent BioSolutions in the BARDA program. In 2012, Emergent BioSolutions was awarded a contract by BARDA to maintain a plant in Baltimore reserved for producing vaccines for pandemic response.[62] As a condition of the agreement, Emergent was required to demonstrate the readiness of the plant by producing 50 million doses of a pandemic influenza vaccine by June 2020. However, Emergent failed to complete this test.

Despite this failure, in June 2020 the federal government awarded Emergent BioSolutions $628 million to produce COVID vaccines for OWS at the Baltimore plant.[63] In the end, OWS assigned the Baltimore plant's capacity to the Johnson & Johnson and AstraZeneca vaccines.

In March 2021, Johnson & Johnson announced that workers at the Emergent facility had contaminated 15 million doses of vaccine by mixing ingredients intended for the AstraZeneca vaccine with the Johnson & Johnson vaccine.[64] The *New York Times* reported that a series of outside audits dating back to 2020 reported that Emergent did not meet basic industry manufacturing quality standards and had insufficient trained manufacturing personnel.[65] After a nine-day audit of the plant, the FDA noted "unsanitary conditions, paint peeling off of the walls and floors, residue on equipment, improperly trained staff, and numerous opportunities for

[59] "Documents Reveal Potential Unresolved Conflicts Of Interest Among Top Operation Warp Speed Advisors," September 22, 2020, https://coronavirus.house.gov/news/press-releases/documents-reveal-potential-unresolved-conflicts-interest-among-top-operation (May 4, 2021).
[60] Kristen Holmes, Sarah Mucha, and Gregory Lemos, "Head of US vaccine effort resigns at request of incoming Biden administration but will stay through transition," *CNN*, January 13, 2021, https://edition.cnn.com/2021/01/13/politics/moncef-slaoui-operation-warp-speed-resigns-biden-administration/index.html (May 4, 2021).
[61] Sheila Kaplan and Sheryl Gay Stolberg, "Biden Picks Former F.D.A. Chief to Lead Federal Vaccine Efforts," *The New York Times*, January 15, 2021, https://www.nytimes.com/2021/01/15/health/covid-vaccine-kessler.html (May 4, 2021).
[62] Chris Hamby, Sharon LaFraniere and Sheryl Gay Stolberg, "U.S. Bet Big on Covid Vaccine Manufacturer Even as Problems Mounted," *The New York Times*, April 6, 2021, https://www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html (May 4, 2021).
[63] Kyle Blankenship, "Emergent BioSolutions, BARDA reach $628M deal to manufacture COVID-19 vaccine hopefuls," Fierce Pharma, June 1, 2020, https://www.fiercepharma.com/manufacturing/barda-emergent-biosolutions-reach-628m-contract-to-manufacture-covid-19-vaccine (May 4, 2021).
[64] Sharon LaFraniere and Noah Weiland, "Johnson & Johnson's vaccine is delayed by a U.S. factory mixup," *The New York Times*, March 31, 2021, https://www.nytimes.com/2021/03/31/world/johnson-and-johnson-vaccine-mixup.html (May 4, 2021).
[65] Sheryl Gay Stolberg, Sharon LaFraniere and Chris Hamby, "Top Official Warned That Covid Vaccine Plant Had to Be 'Monitored Closely,'" *The New York Times*, April 7, 2021, https://www.nytimes.com/2021/04/07/us/emergent-biosolutions-coronavirus-vaccine.html (May 4, 2021).

vaccine products to be contaminated."[66] Johnson & Johnson announced it would "exercise its oversight authority to ensure that all of FDA's observations with respect to the Emergent facility are addressed promptly and comprehensively."[67]

The key question became why, even though audits in 2020 showed poor results, Emergent was awarded the contract to manufacture COVID vaccines? A congressional investigation was launched into the role of Trump administration officials in awarding the sole source manufacturing contract to Emergent. This investigation included a specific focus on the role of Dr. Robert Kadlec, who had worked as a consultant for Emergent before being appointed to the Department of Health and Human Services.[68] Also of concern was the sale of $10 million in Emergent shares by the company's CEO, Robert Kramer, before the Johnson & Johnson manufacturing announcement on vaccine contamination was made public.[69]

ALTERNATIVE MODELS TO OWS

Globally, other organizations also funded COVID vaccine development through a variety of partnerships. The U.S. government chose not to collaborate with these international groups, instead launching OWS.

The European Union (E.U.) and World Health Organization (WHO) raised $8 billion across 40 countries to spearhead efforts for rapid vaccine development.[70] The Gates Foundation additionally contributed $1.75 billion to vaccine development, with $250 million going to the E.U. and WHO coalition, with other funding going to infrastructure in developing markets.[71]

The E.U. funding for vaccine development adopted a clear, transparent approach for criteria used to evaluate grants. The committee in charge of decision making included representatives from all E.U. member states. Clear financing criteria was established, including evaluation of technology used, cost, speed, and manufacturing capacity.[72] All documentation and contracts

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[66] Beth Mole, "Contractor that ruined 15M doses of J&J vaccine hiked price of another by 800%," arsTechnica, April 22, 2021, https://arstechnica.com/science/2021/04/contractor-that-ruined-15m-doses-of-jj-vaccine-hiked-price-of-another-by-800/ (May 4, 2021).
[67] "Johnson & Johnson Statement on FDA Observations at Emergent BioSolutions (Updated 4/30)," Johnson & Johnson, April 30, 2021, https://www.jnj.com/johnson-johnson-statement-on-fda-observations-at-emergent-biosolutions (May 4, 2021).
[68] Rich Mendez, "Congressional investigation launched into Emergent BioSolutions' federal vaccine contracts," *CNBC,* April 20, 2021, https://www.cnbc.com/2021/04/20/congressional-investigation-launched-into-emergent-biosolutions-federal-vaccine-contracts-.html (May 4, 2021).
[69] Noah Higgins-Dunn, "Emergent CEO sold more than $10M in stock before scrapping J&J COVID-19 vaccine doses: report," Fierce Pharma, April 26, 2021, https://www.fiercepharma.com/pharma/emergent-ceo-sold-more-than-10-million-stock-before-j-j-doses-were-scrapped-report (May 4, 2021).
[70] Damon Wake, "EU Spearheads $8 Billion Virus Fundraiser," Yahoo Finance, May 4, 2020, https://finance.yahoo.com/news/eu-hosts-virus-telethon-seeking-first-7-5-003500556.html (May 4, 2021).
[71] "Bill and Melinda Gates call for collaboration, continued innovation to overcome challenges of delivering COVID-19 scientific breakthroughs to the world," Gates Foundation, December 9, 2020, https://www.gatesfoundation.org/Media-Center/Press-Releases/2020/12/Bill-and-Melinda-Gates-call-for-collaboration-innovation-to-deliver-COVID-19-breakthroughs (May 4, 2021).
[72] "EU Vaccines Strategy," European Commission, https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en (May 4, 2021).

with funding recipients—including Pfizer and BioNTech, the most well-known recipients—were publicly available.

Other countries also contributed funding towards local companies and programs. The Indian Parliament pledged $365 million to the Department of Health Research in India in 2021 to fund virology institutes and studies on highly infectious pathogens.[73] Russia's sovereign wealth fund, the Russian Direct Investment Fund, funded research on the Sputnik V vaccine.[74] The exact amount of funding from the Chinese government to develop the Sinopharm and Sinovac vaccines, along with a dozen or so other vaccine candidates, has not been publicly disclosed.[75]

Additionally, the Serum Institute in India, the world's largest vaccine producer, made significant investments in spring 2020 to bolster its vaccine capacity. Before any vaccines were approved, the Serum Institute made a gamble to manufacture and stockpile four different vaccine candidates, including the AstraZeneca vaccine. This gamble paid off, resulting in India being one of the leading suppliers of COVID vaccines globally.

COVID VARIANTS

For much of 2020, scientists tracking the pandemic were reporting on the remarkable genetic stability of the COVID-19 virus. These data provided reassurance that the vaccines being developed to attack the spike protein would be effective in terms of providing widespread protection for the population. Unfortunately, by the end of 2020, scientists discovered that the virus had begun to evolve. In South Africa, the 501Y.V2 was described in October, and quickly spread across the country. In the U.K., the B.1.1.7 was described on December 14, a variant that was able to spread more rapidly and had the potential for more severe infections. In Brazil, the P.1 variant was reported in January 2021.[76] By April 2021, the South Africa variant was reported in 68 countries, the U.K. variant had been reported in 114 countries, and the Brazil variant in 36 countries.[77]

Scientists were alarmed at the emergence of these new variants. In laboratory studies, results suggested that the variants were having an impact on vaccine efficacy, with the AstraZeneca vaccine efficacy reduced by 86 percent for the South African variant.[78] These results reinforced the need for continued genomic surveillance of the virus, but also highlighted that over the long term, there would be no global relief from the COVID-19 pandemic while the virus continued to

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[73] T. V. Padma, "India budget pledges billions for virus research amid COVID pandemic," *Nature*, February 4, 2021, https://www.nature.com/articles/d41586-021-00298-3#:~:text=The%20pledges%2C%20unveiled%20in%20the,%25)%20over%20last%20year's%20budget (May 4, 2021).

[74] Chris Baraniuk, "Covid-19: What do we know about Sputnik V and other Russian vaccines," *The British Medical Journal*, March 18, 2021, https://www.bmj.com/content/372/bmj.n743 (May 9, 2021).

[75] Flynn Murphy, "Inside China's response to COVID," *Nature*, December 2, 2020, https://www.nature.com/articles/d41586-020-03361-7 (May 4, 2021).

[76] "New SARS-CoV-2 Variants — Clinical, Public Health, and Vaccine Implications," Letter to the Editor, *The New England Journal of Medicine*, March 24, 2021, https://www.nejm.org/doi/full/10.1056/NEJMc2100362 (May 4, 2021).

[77] "Global Report Investigating Novel Coronavirus Haplotypes," Pango Lineages, https://cov-lineages.org/global_report.html (May 4, 2021).

[78] "New SARS-CoV-2 Variants — Clinical, Public Health, and Vaccine Implications," loc. cit.

circulate and mutate. Over time, new vaccines would have to be developed to address the emergence of these genetic variants (this was not uncommon; annual influenza vaccines, for instance, were designed to address multiple different variants circulating globally). U.S. experts suggested a schedule of annual COVID boosters might be required in the future. Scientists also suggested that further research into other vaccine targets or a combination of targets could yield a "universal" COVID vaccine.[79]

QUESTION FOR THE FUTURE

By the end of 2020, Pfizer, Moderna, Johnson & Johnson, and AstraZeneca had produced COVID-19 vaccines faster than a novel vaccine had ever been developed previously. To PPP proponents, this dramatic success served as a proof point for the potential benefits of PPPs. In this case, public investment supported the private sector in vaccine development and manufacturing, de-risking private investment of the pharmaceutical partners. The early investment in manufacturing capacity, before the vaccines had been approved, was especially salient in terms of having a supply of vaccine to respond to the public health emergency. From the perspective of those involved with OWS, this effort was an overwhelming success. By spring, 2021, OWS was also able to contrast the readily available vaccine supply in the United States with that in Canada and the European Union by as further evidence of the success of the program.

Despite this remarkable achievement, critics of OWS and PPPs raised questions about this conclusion. They questioned whether public investments really were required by the global pharmaceutical industry to achieve this amazing milestone. Pfizer publicly raised concerns about the involvement of the federal government in vaccine development, and reported significant pressure when the Trump administration attempted to have the company apply to the FDA for Emergency Use Authorization before analysis of the clinical trials had been completed.[80] They question the central role of Moderna in this effort, a company was that did not have any FDA approved and marketed products before OWS, and that lacked clinical trial and manufacturing expertise. They also highlight the relationship of OWS with Emergent Biosciences, which strongly suggests the influence of politics and lobbying in decision making by BARDA. Critics also highlight the focus on vaccine manufacturing to the exclusion of vaccine distribution and promotion. Finally, they cite the short-sighed focus on the US vaccine supply in the midst of a global pandemic, where vaccine availability may provide an illusion of safety while deadly variants emerge in populations that lack access to a vaccine.

[79] Wayne C. Koff and Seth F. Berkley, "A universal coronavirus vaccine," *Science*, February 19, 2021, https://science.sciencemag.org/content/371/6531/759 (May 4, 2021).
[80] Jon Cohen, "Fact check: No evidence supports Trump's claim that COVID-19 vaccine result was suppressed to sway election," *Science*, November 11, 2020, https://www.sciencemag.org/news/2020/11/fact-check-no-evidence-supports-trump-s-claim-covid-19-vaccine-result-was-suppressed (May 4, 2021).

DISCUSSION QUESTIONS

1. Did COVID-19 vaccine development require a PPP? What benefits did this structure provide? What risks did it entail?

2. Transparency and a means to address conflicts of interests were major issues in the implementation of OWS. Are these elements required for a PPP? What are the risks of a PPP with and without these elements?

3. OWS had a U.S. focus. What were the implications of this focus on the U.S., on the E.U., and on the developing world in terms of the global response to the pandemic? Did the U.S. population benefit from this approach?

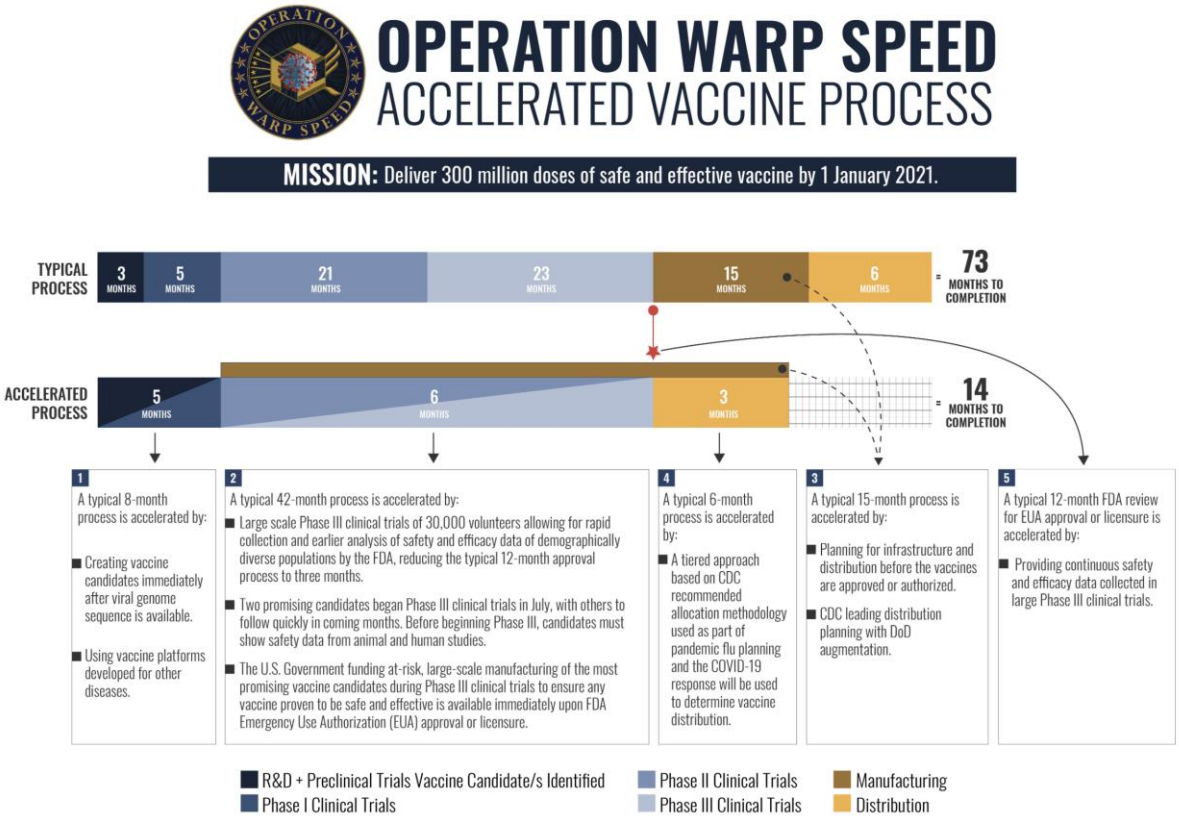
4. In considering a portfolio of vaccine technologies, did the PPP crowd in or crowd out other possible solutions for vaccine development?

5. Should we measure success of this PPP by the time required for vaccine development, or the time required to achieve herd immunity through vaccine deployment? If the latter was the measure of success, was OWS successful? If we had the latter measure, would you have allocated more resources to building the U.S. public health infrastructure instead of OWS?

Exhibit 1
International Positions on COVID Patent Rights

Source: https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations

Exhibit 2
Operation Warp Speed Timeline



Source: U.S. Department of Defense,
https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.JPG.

Exhibit 3
Operation Warp Speed Funding

Table 1. Vaccine Candidates Supported by BARDA and Other Federal Agencies

Company	Type	Contract Value	Specifications	Doses per Person	Current Phase (Preliminary Effectiveness – U.S. Strain)[a]	Storage
Pfizer/BioNTech	mRNA[b]	$5.97B	300 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna	mRNA	$4.94B $954M	300 million doses Development	2	Phase III (94.5%) EUA Issued	Cold storage (6 mos, -20° C) Refrigerator (30 days, -2° to -8° C)
AstraZeneca/ Oxford Univ.	Viral Vector[c]	$1.2B	300 million doses	2	Phase II/III (70%)	Refrigerator (-2° to -8° C)
Johnson & Johnson (Janssen Pharmaceuticals)	Viral Vector	$1B $456M	100 million doses Development	1	Phase III (72%) EUA Issued	Refrigerator (3 mos, -2° to -8° C)
Novavax	Protein[d]	$1.6B	100 million doses	2	Phase III (95.6%)	Refrigerator (-2° to -8° C)
Sanofi/GSK	Protein	$2.04B $30.8M	100 million doses Development	2	Phase I/II	Refrigerator (-2° to -8° C)
Merck/IAVI[e]	Viral Vector	$38M	Development[f]	1	DISCONTINUED	N/A

Sources: https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine; https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/.

Note: Current as of March 1, 2021.

a. This data reflect vaccine effectiveness against only the predominant strain of COVID-19 in the United States. Vaccines have different efficacies against the UK and South Africa variants respectively, and vaccine makers are considering creating booster shots to improve immunity to these strains.

b. Messenger RNA (mRNA) vaccines contain harmless virus genetic material that codes for a protein that is found on the virus's surface. The body recognizes this protein as foreign and initiates an immune response.

c. Viral vector vaccines contain a weakened version of the live virus that has most of the harmful parts of the COVID-19 genetic code removed.

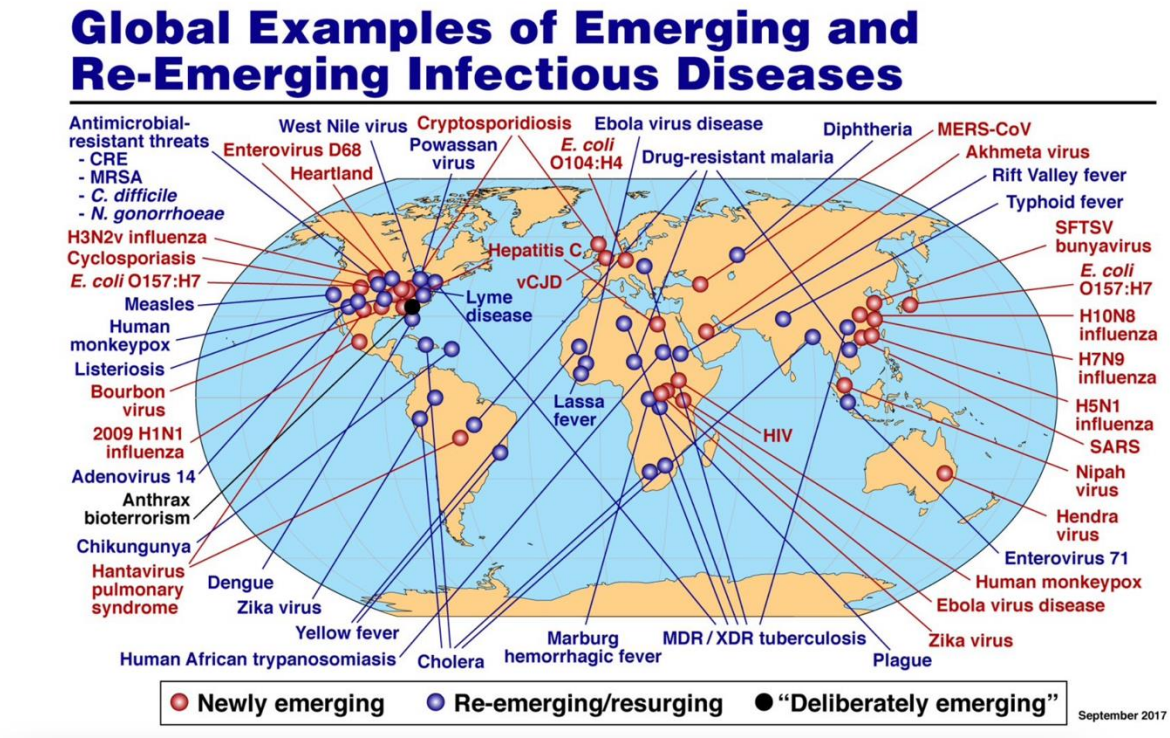
d. Protein subunit vaccines contain harmless pieces of the COVID-19 virus (protein), which the body recognizes as foreign and mounts an immune response against.

e. The Merck/IAVI vaccine candidate was discontinued due to lack of demonstrated efficacy. It was supported by BARDA, not by OWS.

f. Only Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI received funding from the federal government to support vaccine development. The remaining candidates participated in federal purchase of vaccine doses only.

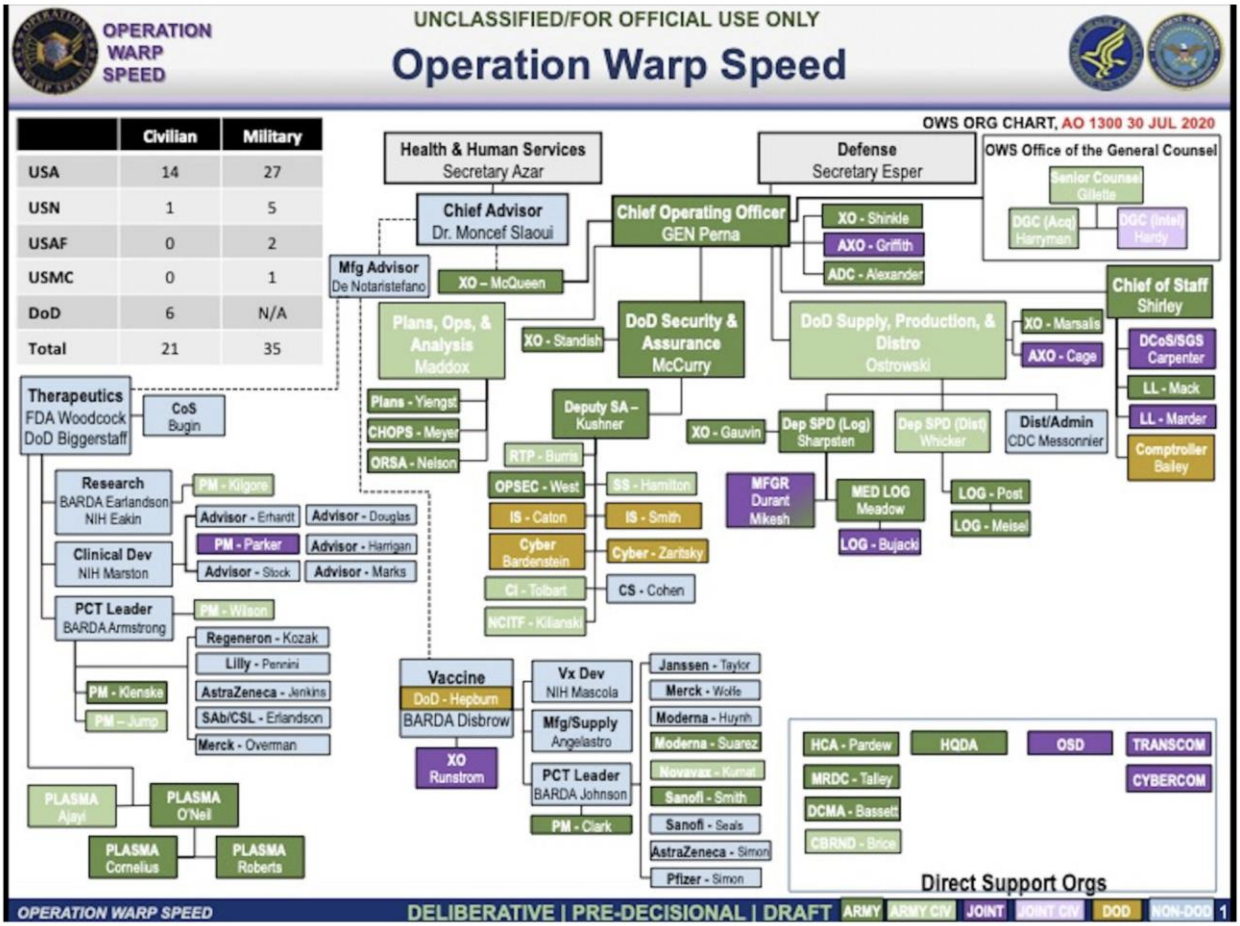
Source: "Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials," Congressional Research Service, March 1, 2021, https://crsreports.congress.gov/product/pdf/IN/IN11560#:~:text=Operation%20Warp%20Speed%20(OWS)%20is,of%20COVID%2D19%20medical%20countermeasures.

Exhibit 4
Global Emerging Diseases



Source: National Institute of Allergy and Infectious Diseases, https://www.niaid.nih.gov/news-events/three-decades-responding-infectious-disease-outbreaks.

Exhibit 5
Operation Warp Speed Organizational Structure

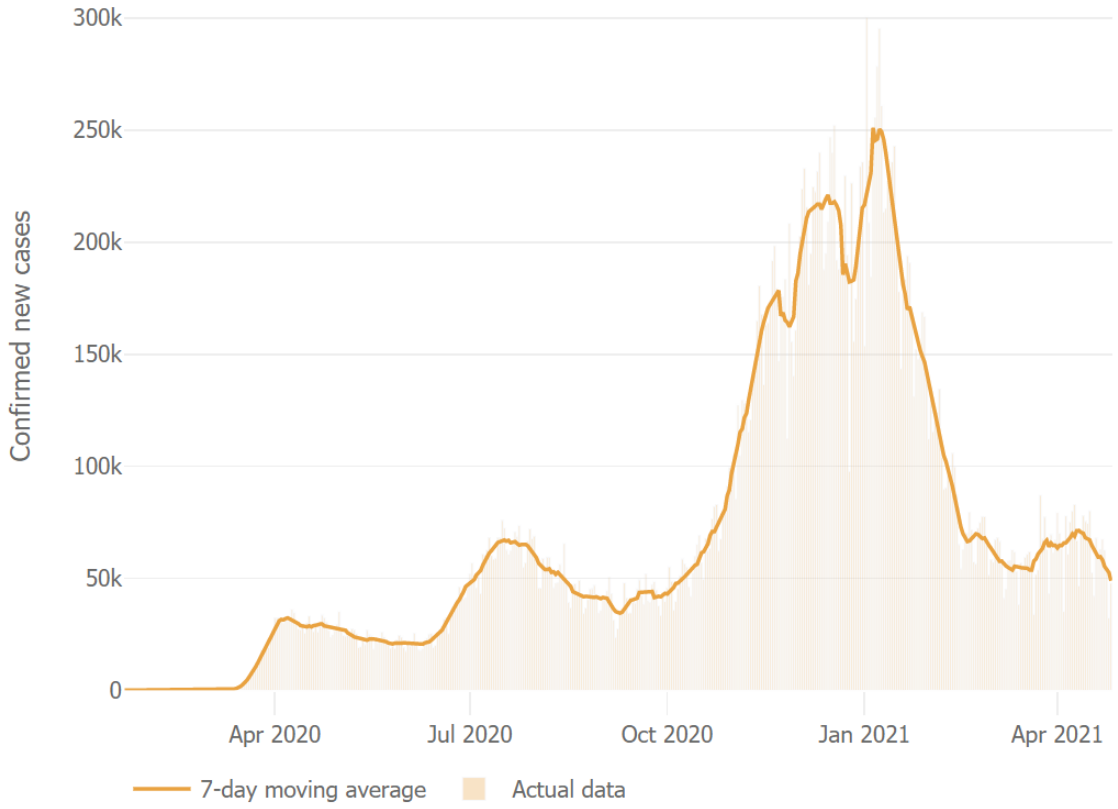


Source: The Chart as outlined by Stat News, September 28th, 2021. (https://www.statnews.com/2020/09/28/operation-warp-speed-vast-military-involvement/).

Exhibit 6
Novartis Holly Springs Plant

Source:https://www.newsobserver.com/latest-news/nnpe65/picture7524923/alternates/FREE_768/I2B0G.So.156.jpeg

Exhibit 7
U.S. COVID-19 Data



Source: Johns Hopkins University Coronavirus Resource Center, https://coronavirus.jhu.edu/data/new-cases.

Exhibit 8
Moderna Financials

MODERNA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Years Ended December 31,		
	2020	2019	2018
Revenue:			
Grant revenue	$ 528,905	$ 12,173	$ 12,556
Product sales	199,872	—	—
Collaboration revenue	74,618	48,036	122,512
Total revenue	803,395	60,209	135,068
Operating expenses:			
Cost of sales	7,933	—	—
Research and development	1,370,339	496,309	454,082
Selling, general and administrative	188,267	109,620	94,252
Total operating expenses	1,566,539	605,929	548,334
Loss from operations	(763,144)	(545,720)	(413,266)
Interest income	24,715	38,530	27,023
Other (expense) income, net	(6,084)	(7,526)	1,835
Loss before provision for (benefit from) income taxes	(744,513)	(514,716)	(384,408)
Provision for (benefit from) income taxes	2,551	(695)	326
Net loss	(747,064)	(514,021)	(384,734)
Reconciliation of net loss to net loss attributable to common stockholders:			
Premium paid on repurchase of preferred stock	—	—	(4,127)
Cumulative preferred stock dividends	—	—	(12,996)
Net loss attributable to common stockholders	$ (747,064)	$ (514,021)	$ (401,857)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.96)	$ (1.55)	$ (4.95)
Weighted average common shares used in net loss per share attributable to common stockholders, basic and diluted	381,333,059	330,802,136	81,114,183

Source: Moderna Inc. Form 10-K, 2020, https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c.

Exhibit 9
Emergent Financials

	Year Ended December 31,				
(in millions, except per share data)	2020	2019	2018	2017	2016
Statements of operations data:					
Revenues:					
Product sales	$ 989.8	$ 903.5	$ 606.5	$ 421.5	$ 296.3
Contract development and manufacturing services	450.5	80.0	98.9	68.9	49.1
Contracts and grants	115.1	122.5	77.0	70.5	143.4
Total revenues	1,555.4	1,106.0	782.4	560.9	488.8
Total operating expenses	1,121.6	991.9	692.6	436.6	383.3
Income from operations	433.8	114.1	89.8	124.3	105.5
Net income from continuing operations	305.1	54.5	62.7	82.6	62.5
Net loss from discontinued operations	—	—	—	—	(10.7)
Net income	$ 305.1	$ 54.5	$ 62.7	$ 82.6	$ 51.8
Net income per share-basic	$ 5.79	$ 1.06	$ 1.25	$ 1.98	$ 1.29
Net income per share-diluted	$ 5.67	$ 1.04	$ 1.22	$ 1.71	$ 1.13
Weighted average number of shares — basic	52.7	51.5	50.1	41.8	40.2
Weighted average number of shares — diluted	53.8	52.4	51.4	50.3	49.3

Source: Emergent BioSolutions Inc. Form 10-K, 2020, https://investors.emergentbiosolutions.com/static-files/139a4191-2e9e-4db8-a6bc-0d3e9340adf9.