



A Comprehensive COVID-19 Vaccine Plan

Efficient Manufacturing, Financing,
and Distribution of a COVID-19 Vaccine

By Topher Spiro and Zeke Emanuel

July 2020

Contents

- 1 Introduction and summary**

- 4 Accelerate development of alternative vaccine technologies**

- 6 Coordinate and expand manufacturing capacity**

- 15 Public financing to ensure widespread vaccination**

- 17 Ensure efficient and equitable distribution**

- 23 Establish governance and accountability mechanisms**

- 24 Conclusion**

- 25 About the authors**

- 26 Endnotes**

Introduction and summary

Several COVID-19 vaccines have shown promising results in early stages of development. This summer and fall, several vaccines will enter Phase III clinical trials to determine their efficacy and safety. Some experts believe the U.S. Food and Drug Administration (FDA) could authorize a vaccine within six months.

But this timeframe is not when most Americans can expect to be vaccinated. The time between FDA authorization of a vaccine and widespread availability can take many months. For example, in 2009, the first doses of the H1N1 vaccine were administered on October 5. Only 124 million doses were available by the end of January 2010, four months later.¹

Shortening this time by even weeks could save tens of thousands of American lives. Moreover, experts believe at least 70 percent of the population must be vaccinated to achieve herd immunity—when enough of the population is immune to protect the others by stopping spread of the virus. The sooner this target can be reached, the sooner the economy can fully reopen and a normal way of life can resume.

Accelerating this timeframe will require unprecedented government action and coordination. As Dr. Anthony Fauci and his colleagues observed, “Cost, distribution system, cold chain requirements, and delivery of widespread coverage are all potential constriction points in the eventual delivery of vaccines to individuals and communities.”² Experts believe two doses of vaccine will be needed,³ requiring the manufacturing, financing, distribution, and administration of 462 million doses to achieve herd immunity and 660 million doses for the entire U.S. population.

Unfortunately, the Trump administration’s effort so far has been plagued by needless delays, questionable decisions, and a lack of planning and transparency. According to the whistleblower complaint of Dr. Rick Bright, the ousted former director of the Biomedical Advanced Research and Development Authority (BARDA), “Lack of leadership and action ... has placed the health and safety of all Americans at risk of not being protected from the deadly coronavirus even when a vaccine becomes available.”⁴ To date, the administration has not released a comprehensive vaccine plan.

To develop a comprehensive vaccine plan, we interviewed representatives of vaccine manufacturers, manufacturers of vaccine supplies, pharmacies, and other experts and reviewed all publicly available information. But we were limited in the information that we could obtain because we are not government officials, and some information is proprietary or confidential. Accordingly, policymakers should use this assessment as a guide to seeking additional information and to inform planning efforts.

To ensure efficient manufacturing and distribution of a COVID-19 vaccine, the executive branch and Congress urgently need to:

- Accelerate development of alternative vaccine technologies
- Map the nation's manufacturing and fill-finish capacity, including manufacturing capacity for brewing equipment
- Invest up to \$400 million to retrofit four existing facilities for the production of 50 million doses per facility
- Invest \$100 million to expand the capacity of manufacturers of brewing equipment
- Invest up to \$1.4 billion to build two new manufacturing facilities
- Use the Defense Production Act (DPA) to coordinate vaccine manufacturing capacity and supply chains
- Map the nation's manufacturing capacity for vaccine supplies and materials, including vials, syringes, needles, stoppers, adjuvants, and cold storage
- Use the DPA to coordinate manufacturing capacity for glass vials, syringes, and needles
- Immediately invest an additional \$70 million to expand manufacturing capacity for syringes and needles
- Expand the supply of more rapid sterility and potency tests
- Use the Vaccines for Children Program as a model to bulk purchase 660 million doses
- Appropriate \$20 billion for the purchase of COVID-19 vaccines and related supplies for the U.S. population
- Set a maximum administration fee and require government programs and private insurance plans to cover the fee
- Appropriate \$1.5 billion for the cost of administration for uninsured individuals
- Issue guidelines for states on how to target distribution and operationalize targeting
- Leverage the CDC's centralized distribution for publicly financed vaccines
- Contract with a technology company to upgrade the Vaccine Tracking System
- In partnership with state health departments and the private sector, establish 7,300 community vaccination clinics
- Appropriate \$10 billion for community vaccination clinics

- Plan a massive vaccination campaign by recruiting medical experts, sports stars, celebrities, and community leaders and partnering with grassroots organizations and medical organizations
- Appropriate \$7.2 billion for the World Health Organization's (WHO) international financing mechanism for low- and middle-income countries and secure commitments from U.S. allies
- Establish governance and accountability mechanisms and release a comprehensive vaccine plan

As this report demonstrates, a massive coordinated effort is needed and there is little evidence that the Trump administration is adequately preparing now. Rapid manufacturing, financing, distribution, and administration of a COVID-19 vaccine will require unprecedented government planning, action, and coordination at both the federal and state levels. Tens of thousands of lives, millions of livelihoods, and a normal way of life are at stake.

Accelerate development of alternative vaccine technologies

Globally, more than 165 vaccines are in development and four vaccines are already in Phase III large-scale trials.⁵ These vaccines use a variety of technologies—some traditional, some cutting edge—each with advantages and disadvantages.⁶ These vaccines fall into five main categories:

- **Live, weakened virus vaccines** use the virus itself, but weaken it so that it does not cause disease. Licensed vaccines have used this technology and a single dose may be possible. However, these vaccines are very slow to produce and require extensive safety testing. Codagenix, based in New York, is developing this type of vaccine.
- **Inactivated virus vaccines** inactivate the virus so that it is not infectious. Licensed vaccines have used this technology. However, this technology poses the risk of enhancement of an infection, which is what happened with the SARS vaccine. As a result, this vaccine requires extensive safety testing. Sinovac, based in China, is developing this type of vaccine.
- **Viral vector vaccines** use a different virus, such as the adenovirus, to carry COVID-19 protein spikes that provoke an immune response. The vector virus is weakened and can be either replicating or nonreplicating within cells. The replicating types use technology that licensed vaccines use, such as the measles and Ebola vaccines. Production of these vaccines can be scaled quickly and a single dose may be possible. However, the nonreplicating types use technology that no licensed vaccine has used. In addition, preexisting immunity to the vector virus could reduce their effectiveness. Oxford University and AstraZeneca, Johnson & Johnson, and Merck are developing these types of vaccines.
- **Protein vaccines** use a protein fragment of the virus to provoke an immune response. Several licensed vaccines use this technology, such as the hepatitis B, influenza, and HPV vaccines. Production of these vaccines can be scaled quickly. However, they may require adjuvants and multiple doses. GlaxoSmithKline, Sanofi Pasteur, Novavax (based in Maryland), and Baylor College of Medicine (based in Texas) are developing these types of vaccines.

- **Nucleic acid vaccines** use genetic DNA or RNA to program replication of the protein spike, which provokes an immune response. Production of these vaccines can be scaled quickly because no culture or fermentation is required. However, this technology is unproven; no licensed vaccine uses it. In addition, these vaccines require cold storage and their temperature stability is a challenge. Moderna (based in Massachusetts), Pfizer, and Inovio (based in Pennsylvania) are developing these types of vaccines.

The Trump administration established Operation Warp Speed to speed the development of COVID-19 vaccines. This program coordinates the component agencies of the Department of Health and Human Services (HHS), the Department of Defense, private industry, and other federal agencies for the development, manufacturing, and distribution of COVID-19 vaccines.⁷ Operation Warp Speed initially selected the Moderna (RNA), Pfizer (RNA), Johnson & Johnson (nonreplicating vector), and Oxford/AstraZeneca (nonreplicating vector) vaccines for federal support. Recently, Operation Warp Speed selected the Novavax (protein) vaccine as well.⁸

These selections provide federal support for clinical trials and manufacturing. However, Operation Warp Speed did not consult the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic and Interventions and Vaccines committee, a key group of scientific experts.⁹ The five selected vaccines use three different technologies; only one of them uses a technology that a licensed vaccine uses (the Novavax vaccine). Remarkably, no U.S. vaccine uses traditional inactivated-virus technology, and only one Operation Warp Speed vaccine uses traditional protein-based technology.

The federal government should accelerate the development of additional vaccine technologies. The portfolio of U.S. vaccines must be diversified to ensure that at least one vaccine is safe and effective. Moreover, it is unlikely that the first vaccine authorized by the FDA will be the best vaccine, and some vaccines may be inappropriate for certain populations. If the virus becomes endemic and immunity wanes, several vaccines will be needed. Since the U.S. is currently relying heavily on vaccines that use unproven technologies, it is critical that additional vaccines that use traditional technologies be developed as a hedge.

Coordinate and expand manufacturing capacity

Pharmaceutical manufacturers are scrambling to secure supply chains and manufacturing capacity in an uncoordinated race, locking up manufacturing capacity. It is unclear whether manufacturers would voluntarily use their facilities and contracted capacity to produce another manufacturer's vaccine. There is little visibility for manufacturers up and down the supply chain—let alone for the general public and policy-makers—into manufacturing capacities. One industry expert told us, “We don't know what the government's needs are.”¹⁰ Without such visibility, planning and coordination will remain suboptimal.

Assess and expand manufacturing and fill-finish capacity

Once bulk vaccine is produced, fill-finish is the process of filling vials and syringes and packaging them in highly sterile conditions. After rapid mass production of the H1N1 vaccine encountered challenges, President Barack Obama's Council of Advisors on Science and Technology concluded that fill-finish “is a major hurdle on the path to vaccine distribution” and that it “generally proves to be a major rate-limiting step in the process of delivering vaccine, especially under pandemic conditions.”¹¹ Accordingly, Dr. Anthony Fauci and his colleagues concluded, “There is an immediate need to fund the necessary bio-manufacturing infrastructure, including the fill-finish steps that provide vialled vaccine products for distribution.”¹²

Unfortunately, it can take up to five years to build a new manufacturing facility. This timeline could be accelerated but not to less than three years. In the United Kingdom, the government began funding a Vaccines Manufacturing and Innovation Centre in March 2018 and its completion will be accelerated to summer 2021.¹³ This facility will have capacity to produce enough doses for the U.K. population within four to six months of opening.¹⁴ Although it is too late for the United States to build new facilities for production in 2021, existing manufacturing capacity can be coordinated, and several existing facilities could be retrofitted. Since COVID-19 vaccines will likely be needed for many years, the United States should also begin construction of new manufacturing facilities.

Assess existing contracts and capacities of all U.S. pharmaceutical manufacturers and contract development and manufacturing organizations (CDMOs)

The federal government and pharmaceutical manufacturers have already lined up some manufacturing capacity in a haphazard manner, forming an overlapping web of contracts. These capacities must be mapped so that they can be coordinated when the most successful vaccines are selected.

In June, BARDA issued a task order to Emergent BioSolutions for manufacturing and expansion of fill-finish capacity. Emergent's Bayview facility has capacity to produce up to 300 million doses.¹⁵ Under the task order, Emergent will also expand its fill-finish capacity, adding a third line to its Camden, Maryland, facility and a second line to its Rockville, Maryland, facility.¹⁶ The Department of Defense also has a contract with Novavax for 10 million doses.¹⁷

Johnson & Johnson and Novavax also have contracts with Emergent BioSolutions for manufacturing.¹⁸ Johnson & Johnson expects Emergent to produce 750 million to 1 billion doses in 2021, and Novavax has a contract with Emergent for 100 million doses by the first quarter of 2021.¹⁹ It is unclear how these contracts line up with Emergent's actual capacity.

Moderna has also lined up manufacturing and fill-finish capacity. Moderna has a contract with Swiss-based Lonza for 500 million doses in 2021, but it is unclear how many of these doses will be produced at its U.S. facility.²⁰ Moderna also has a contract with Catalent for fill-finish capacity for 100 million doses in the third quarter of 2020.²¹ Johnson & Johnson also has a contract with Catalent for fill-finish capacity for 75 million vials per year.

Among the large, established U.S. vaccine manufacturers, Pfizer is adding shifts to its plants, stockpiling its current drugs, and shifting production of drugs to Catalent, Lonza, and Thermo Fisher Scientific to free up its own manufacturing capacity.²² Merck's capacity and plans to secure capacity are unknown.

There is evidence that some fill-finish capacity remains untapped. For example, Argonaut Manufacturing Services launched a new fill-finish line in January and announced the immediate availability of fill-finish capacity in March.²³

The federal government should immediately complete a comprehensive assessment of manufacturing and fill-finish capacities of all U.S. pharmaceutical manufacturers and CDMOs. Manufacturers should be required to submit detailed information on their manufacturing and fill-finish capacities, including any existing contracts. They should also assess whether production of other drugs can be shifted to contract manufacturers.

Assess the operational readiness of the Centers for Innovation in Advanced Development and Manufacturing (CIADMs) and Fill-Finish Manufacturing Network (FFMN)

After the manufacturing industry encountered challenges in rapid mass production of the H1N1 vaccine, the Obama administration recommended investment in surge vaccine manufacturing capacity for a pandemic.²⁴ In 2012, BARDA awarded \$400 million to establish three Centers for Innovation in Advanced Development and Manufacturing (CIADMs).²⁵ These centers are public-private partnerships between small biotech firms, academic institutions, and large pharmaceutical manufacturers. They were tasked with building capacity to produce 50 million doses each in four months by the end of 2020.

The operational readiness of the CIADMs is unclear. In 2013 and 2015, BARDA used the CIADMs to produce the H7N9 avian influenza vaccine and an Ebola drug.²⁶ But in October 2018, a joint BARDA-Department of Defense team concluded, “Operational capability has not been adequately developed and must be prioritized going forward with a goal of ever increasing competency to meet biodefense MCM mission requirements.”²⁷

Based on public reports, the known status of the three CIADMs is as follows:

- **Emergent (Maryland).** This CIADM appears to be fully operational; it is the manufacturer that has contracts with BARDA, Johnson & Johnson, and Novavax for hundreds of millions of doses.
- **Holly Springs (North Carolina).** This CIADM was originally operated by Novartis, which built a vaccine manufacturing facility that has been able to produce a commercial scale pandemic influenza vaccine since 2011.²⁸ In 2016, Novartis sold the facility to Seqirus.²⁹ In 2018, Seqirus had capacity for 20 million doses and began an expansion, which is expected to be completed in 2022 or 2023, with a target of 40 million doses per year.³⁰ It is unclear whether this expansion could be accelerated and whether capacity will be locked up for Seqirus’s new flu vaccine, which the FDA recently approved.
- **Texas A&M University System (Texas).** This CIADM has an existing “current Good Manufacturing Practices” (cGMP) vaccine bulk manufacturing facility operated by Fujifilm Diosynth Biotechnologies.³¹ It is accelerating construction of a new facility, which will be completed by the end of 2020. The center’s leadership has said that after receipt of a task order from BARDA, production can begin within 3 months to 6 months. This time is needed for the tech transfer and to order raw materials.³² BARDA should immediately assess whether an additional investment could accelerate completion of the new facility.

In 2013, BARDA awarded \$40 million to establish four fill-finish sites that comprise the Fill-Finish Manufacturing Network (FFMN).³³ This network was tasked with building capacity to package up to 117 million doses in 12 weeks. In April, Dr. Rick Bright, then the director of BARDA, said that these manufacturers “are prepared to begin manufacturing vaccine if needed.”³⁴ Based on public reports, the known status of these sites is as follows:

- **Bloomington, Indiana.** Cook Pharmica sold this site to Catalent, which completed an expansion for automated, high-speed packaging.³⁵ As noted, Catalent has contracts with Johnson & Johnson and Moderna for fill-finish capacity.
- **Greenville, North Carolina.** Pantheon Pharmaceuticals sold this site to Thermo Fisher Scientific.³⁶ In 2019, Thermo Fisher Scientific began to add new vial filling lines at the Greenville site.³⁷ It is unclear whether this expansion has been completed or could be accelerated.
- **Parsippany, New Jersey.** JHP Pharmaceuticals sold this site to Par Pharmaceuticals.³⁸
- **Alachua, Florida.** Nanotherapeutics changed its name to Ology Bioservices.³⁹ Earlier this spring, this site was 6 months to 9 months from operational readiness.⁴⁰ The Department of Defense has a contract with Ology Bioservices to manufacture the Inovio vaccine.⁴¹

In 2016, BARDA added two sites:

- **Advanced BioSciences Laboratories (ABL) (Rockville, Maryland).** ABL has active fill-finish capacity that meets the FDA’s GMP requirements for live and vector vaccines.⁴² In April, ABL announced that it had completed fill-finish for a COVID-19 vaccine.⁴³
- **IDT Biologika Corporation, (Rockville, Maryland).** This site is also active. In 2019, the National Institute of Allergy and Infectious Diseases awarded the manufacturer a task order for the production of an RSV vaccine.⁴⁴

The federal government should immediately complete a comprehensive assessment of both the CIADMs and the FFMN.

Accelerate expansion of manufacturing and fill-finish capacity

The federal government should immediately assess whether any existing CIADM facilities or other facilities can be quickly retrofitted to expand capacity. For example, industry experts report that the Alachua, Florida, site has a facility that requires the installation of equipment, which is why it was 6 months to 9 months from operational readiness this spring. Pfizer is retrofitting existing facilities at a cost of about \$40 million per facility. Other industry experts estimate that the cost of upgrades could be up to \$100 million per facility.

BARDA should invest up to \$400 million to retrofit four existing facilities for the production of 50 million doses each. These facilities should be upgraded to ensure that they have the capability to produce multiple types of vaccines.

Industry experts are concerned that there is a bottleneck in the production of the brewing equipment that is needed to expand capacity, estimating that it takes 6 months to 8 months to fill orders.⁴⁵ The two U.S. manufacturers of this equipment are MilliporeSigma, based in Danvers, Massachusetts, and Thermo Fisher Scientific, based in Waltham, Massachusetts. In addition to traditional stainless steel tanks, these companies produce disposable plastic bags for processing a vaccine. The federal government should immediately complete a comprehensive assessment of this critical part of the manufacturing supply chain. BARDA should invest \$100 million to expand the capacity of these manufacturers.

Once brewing equipment is obtained, it can take a few months to install it. The federal government should use the DPA to accelerate installation. Under section 303(e) of the DPA, the federal government can require installation of equipment in existing facilities.

Since it is likely that mass production of COVID-19 vaccines will be needed for many years, the federal government should form a public-private partnership with the private sector to build new manufacturing facilities. These facilities should have the capability to produce multiple types of vaccines. For Pfizer, the cost to build a new manufacturing facility was \$600 million, and experts estimate that the cost could be up to \$700 million per facility.⁴⁶ Congress should appropriate \$1.4 billion for the construction of two new manufacturing facilities.

Coordinate U.S. manufacturing capacity

The manufacturing capacities of every pharmaceutical manufacturer and contract manufacturer in the U.S. should be viewed as a network that must be coordinated for mass production of the most successful vaccines. Scientific experts at the NIH, FDA, and their advisory committees should assess which vaccine or combination of vaccines is the safest and most effective. The nation's manufacturing capacity should be freed up and harnessed for mass production of these vaccines.

To effectuate this coordination, the federal government must use the Defense Production Act aggressively.⁴⁷ Under section 303(a) of the DPA, BARDA should contract directly with pharmaceutical manufacturers and contract manufacturers for the production of at least 660 million doses. Although BARDA has started to enter into such contracts, it will need to adjust its portfolio once the most successful vaccines

are determined. Under section 101(a) of the DPA, manufacturers should be required to accept these contracts and should be required to prioritize these contracts over preexisting contracts. In this manner, the web of contracts described above can be overridden so that manufacturing capacity can be coordinated.

Under Title VII of the DPA, the federal government should allow manufacturers to transfer technology and share information on capacities and supply chains without fear of violating intellectual property or antitrust law.

It is critical that the DPA be invoked early so that the federal government's intentions are clear and time and resources are not wasted in an attempt to coordinate capacities without use of the DPA. The lack of clear, decisive coordination will result in significant delays that unnecessarily prolong the pandemic and cost thousands of lives.

Assess and expand manufacturing capacity for vaccine supplies

Even if the U.S. secures enough manufacturing capacity for the vaccines themselves, their distribution and administration could be significantly hampered by a shortage of supplies. These include vials, syringes, needles, rubber stoppers for vials, plungers for syringes, and alcohol wipes. The U.S. has suffered in its ability to ramp up diagnostic testing due to a shortage of swabs and chemical reagents. The shortage of vaccine supplies similarly threatens to delay the time when most Americans can expect to be vaccinated. As with vaccine manufacturing capacity, the federal government should use the DPA to coordinate manufacturing capacity for glass vials, syringes, and needles by establishing contracts that are prioritized over preexisting contracts.

Assess and expand manufacturing capacity for glass vials

A shortage of medical glass for vials is of particular concern. Glass for vials is specialized, containing chemicals that stabilize the temperature. The major U.S. manufacturer of glass vials is Corning, which had capacity for millions of vials per month before the pandemic. Corning is expanding capacity to reach a target of 3 to 4 times existing capacity, which suggests 10 million to 25 million vials per month.⁴⁸ BARDA has a contract with Corning to expand capacity to 164 million vials per year, but it is unclear when this will be possible.⁴⁹ Production of glass tubing and vials will scale up at facilities in Durham, North Carolina; Big Flats, New York; and Vineland, New Jersey. Pfizer also has a long-term contract with Corning, but it is unclear for how many vials.⁵⁰

Globally, the other major manufacturers of glass vials include Schott AG, a German company, and Stevanato Group (Ompi), an Italian company. BARDA has not yet approached Schott AG, whose chairman recently said, “We have been very much surprised by this reaction from the [U.S.] government.”⁵¹ Stevanato Group has facilities in Italy, Slovakia, Mexico, China, and Brazil, and it is considering building a new plant in the United States.⁵² Johnson & Johnson has a contract with this company for 250 million vials.⁵³ BARDA should assess whether Stevanato Group could build a plant in the United States within one year with funding to accelerate construction.

BARDA should also immediately invest in research and development to determine whether multidose vials are feasible. If one vial can package five or even 10 doses, the number of vials needed would be exponentially reduced. Johnson & Johnson is working on a five-dose vial with Catalent.⁵⁴ Packaging a vaccine in multidose vials could speed up delivery by several weeks, potentially saving thousands of lives.

Assess alternatives to glass vials

The federal government is relying heavily on alternatives to glass vials—plastic vials and plastic prefilled syringes—which are unproven. More oversight over progress in developing these new technologies is urgently needed.

The Department of Defense and BARDA have a contract with SiO₂ Materials Science for plastic vials: 40 million in June, 80 million in September, and 120 million in November.⁵⁵ These plastic vials have a microscopic glass coating, and according to SiO₂, can be manufactured in a quarter of the time of glass vials. In March, SiO₂ was producing only 14 million vials per year; it is unknown whether SiO₂ hit its June production target.⁵⁶

Under Project Jumpstart, the Department of Defense and HHS have a contract with ApiJect Systems America for plastic prefilled syringes: 100 million by the end of 2020, and 500 million in 2021.⁵⁷ These syringes could be significantly cheaper and more rapidly scaled than glass vials.⁵⁸ However, they require testing and validation because plastic may interact differently with the vaccine and may not be able to control temperature. Since vaccines may work differently with different devices, additional clinical studies and regulatory approvals may be necessary. The FDA has not approved these syringes, and ApiJect has only manufactured prototypes to date.

Assuming the technology can be validated, BARDA should assess whether to contract with existing blow-fill-seal (BFS) facilities to expand filling lines or allocate capacity from these facilities to ApiJect. BARDA would have the authority to do so under section 101

of the DPA. Expanding capacity in this manner could produce 30 million plastic prefilled syringes per month.⁵⁹ The federal government should also assess whether it is possible to retrofit facilities that produce eye drop containers to produce these syringes.

Assess and expand manufacturing capacity for syringes and needles

BARDA has estimated that 650 million to 850 million syringes and needles will be needed and that it would take up to two years to produce them.⁶⁰ The U.S. market is comprised of Becton Dickinson & Company (BD), Cardinal Monoject, McKesson, Smiths Medical, and Retractable Technologies Inc. (RTI), which produce 663 million injection devices per year.⁶¹ Since these devices are for current needs, such as flu vaccinations, the industry will need to roughly double its production for COVID-19 vaccinations.

Until July, BARDA was relying on two unproven companies for the production of 320 million syringes and needles by April 30, 2021.⁶²

- BARDA has a contract with RTI, which has a current capacity of only about 40 million per year. In addition, 83 percent of RTI's products are manufactured in China and potentially subject to export restrictions.
- BARDA also has a contract with Marathon Medical. This company is a distributor—not a manufacturer—and is subcontracting this order.

BD, based in New Jersey, is the largest manufacturer of needles and syringes in the world and accounts for 58 percent of U.S. production. In July, BARDA finally entered into contracts with BD for 140 million needles and syringes, the majority of which will be delivered by the end of 2020.⁶³

BARDA also has a contract with BD to build three new manufacturing lines in Nebraska.⁶⁴ These new lines will provide capacity for 320 million doses per year but will take about 12 months to build. Although BD has indicated that it could install even more lines, BARDA has not yet acted.

If RTI manages to double its capacity, at this time next year, the U.S. supply of syringes and needles would only total about 220 million: 40 million from RTI in 2020, 40 million from RTI in 2021, and 140 million from BD in 2020-2021.

The federal government should immediately assess whether the capacities of U.S. manufacturers can be expanded. BARDA should immediately invest an additional \$70 million to build two manufacturing lines by July 2021. As recommended by Dr. Rick Bright, BARDA should also invest in research to identify alternatives to syringes and needles, such as nonspecialized needles, jet injectors, and nasal sprayers.

Assess supply chains for other vaccine supplies and raw materials

The federal government should also immediately complete a comprehensive assessment of raw materials and ancillary materials needed for vaccines, syringes, and stoppers.

- **Stoppers.** The major U.S. manufacturer is West Pharmaceutical Services, based in Pennsylvania.⁶⁵ Its capacity is unknown. The federal government should immediately assess its capacity and provide funding to expand capacity if needed.
- **Adjuvants.** Protein vaccines require adjuvants. Adjuvants can boost immunity and reduce the number of doses required.
- **Cold storage.** Merck's vaccine may require storage in cold freezers and RNA vaccines require cold storage. The federal government should assess whether to use the DPA for the production of refrigerators.
- **Lipids.** RNA vaccines require lipids to coat the RNA. As Dr. Anthony Fauci and his colleagues observed, "The scalability of these lipid nanoparticles and their temperature stability are issues that need to be addressed."⁶⁶
- **Raw materials for syringes and stoppers.** Polypropylene is required for syringes and rubber or silicone is required for stoppers and plungers. The federal government should help identify new supply chains for raw materials, such as glass and plastic manufacturers outside of the health care industry.

There is currently no public visibility into any of these supply chains, which could be serious bottlenecks. Under section 101(a) of the DPA, the federal government should assist manufacturers in providing funding or coordination to secure U.S. supply chains.

Expand the supply of more rapid sterility tests and potency tests

Vaccines must be tested to ensure that they are not contaminated with bacteria or fungi. The current test, which uses horseshoe crab blood, takes about two weeks.⁶⁷ New assays can shorten this time to five days.⁶⁸ The European Pharmacopeia has approved an alternative test, the recombinant factor C (rFC) test. The FDA should assess whether to grant Emergency Use Authorization of the rFC test.

Potency tests measure the amount of antigen that reacts with antibodies. The reagents are sheep antibodies that can take 8 weeks to 12 weeks to produce.⁶⁹ President Obama's Council of Advisors on Science and Technology concluded "problems with making potency reagents are a well-known source of delays in manufacturing seasonal influenza vaccines, since serious bottlenecks in production and delivery can occur if effective reagents are not available when vaccine materials are ready for testing and packaging."⁷⁰ BARDA should invest in research and development for an alternative potency test that does not require producing new antibodies.

Public financing to ensure widespread vaccination

To achieve herd immunity, at least 70 percent of the population needs to be vaccinated. Successful vaccination campaigns always provide vaccinations for free.

- In the 1950s, the National Foundation for Infantile Paralysis (now the March of Dimes), founded by Franklin D. Roosevelt, funded free polio vaccines for children.⁷¹
- In 1991, the U.S. had a measles epidemic because half of children had not been immunized. Congress, responding to the leadership of Hillary Clinton, established the Vaccines for Children (VFC) Program to provide free vaccinations to uninsured, underinsured, and Medicaid-eligible children.⁷²
- In 2009, the federal government bulk purchased the H1N1 vaccine and related supplies and provided them for free to vaccination sites.⁷³

There are myriad benefits of public financing of vaccines. First, public financing promotes mass vaccination due to widespread knowledge that it is free. Second, public financing eliminates gaps in insurance coverage, the cost of insurance billing, confusion, and unfair price disparities. There is huge variation in the prices for COVID-19 diagnostic testing: Medicare pays \$100 per test, while some insurers pay more than \$2,000 per test.⁷⁴ The list prices at large hospitals vary from \$20 to \$850 per test.⁷⁵ Third, public financing can minimize or eliminate profiteering of the pharmaceutical industry. It is estimated that the average profit margin for vaccines is about 20 percent.⁷⁶ Fourth, public financing allows for coordination of U.S. manufacturing capacity, as described above. Lastly, public financing allows for centralized, efficient distribution, as described below.

The CDC's VFC Program and Section 317 Immunization Program provide free vaccinations to children (as described above); adults who are uninsured or underinsured; and fully insured individuals during public health emergencies.⁷⁷ By bulk purchasing vaccines, these programs reduce the private sector prices of vaccines by an average of 27 percent for pediatric flu vaccines; 30 percent for adult flu vaccines; 32 percent for other pediatric vaccines; and 41 percent for other adult vaccines.⁷⁸

The federal government should utilize this model to bulk purchase one or more COVID-19 vaccines. Currently, the average CDC price per dose is \$14 for flu vaccines; \$55 for other pediatric vaccines; and \$61 for other adult vaccines. There is evidence that COVID-19 vaccines can be priced well within this range. In July, Pfizer agreed to supply the federal government with 100 million doses for \$1.95 billion, or \$19.50 per dose.⁷⁹ At this price level, the cost would be \$13 billion for 660 million doses.

To be safe, Congress should appropriate \$20 billion for the purchase of COVID-19 vaccines and related supplies for the U.S. population. The CDC or BARDA should contract with vaccine manufacturers and contract manufacturers using the same process as the CDC's VFC and Section 317 programs. As part of this process, manufacturers should submit data on their Cost of Goods Sold (COGS). Prices per dose should not exceed the COGS by more than the average percentage that current CDC prices exceed the COGS.

As discussed above, the federal government should use section 303(a) of the DPA to make these contracts, and if necessary, section 101(a) to require manufacturers to accept these contracts. Since there is no current domestic market price for COVID-19 vaccines, the federal government should waive the requirement that the price be the current domestic market price under section 303(a)(7).

The federal government should also set maximum fees that providers can charge for administration of COVID-19 vaccines. The average fee charged for administration of vaccines under the VFC Program is \$21.80.⁸⁰ Providers should be required to accept this amount of payment for administration of COVID-19 vaccines. Government programs and private insurance plans should be required to cover this amount at no cost to enrollees. Administration at community vaccination clinics, as discussed below, should be free, regardless of insurance coverage.

For uninsured individuals, Congress should appropriate funding for the cost of administration. According to the Urban Institute, the number of uninsured will rise to 34 million assuming an unemployment rate of 15 percent.⁸¹ Assuming two doses will be needed, Congress should appropriate about \$1.5 billion for the cost of administration for each uninsured individual.

Ensure efficient and equitable distribution

The CDC, with its experience operating vaccine distribution programs, should take the lead in distribution of COVID-19 vaccines. The agency should issue guidance for state and local public health departments and convene a White House summit on COVID-19 vaccination. Although Operation Warp Speed envisions using the Department of Defense to assist with distribution and administration, this involvement could undermine public confidence in vaccination. The Department of Defense's involvement should be strictly limited to assistance with transport and logistics management.

Assess how to target distribution

Since 660 million doses will not be immediately available, groups must be prioritized for vaccination. The CDC's Advisory Committee on Immunization Practices (ACIP), which has always weighed the benefits of vaccines for various populations, should issue guidelines for states. The ACIP should assess the degree of targeting needed based on the projected supply of vaccine; research on the effects of the virus on various populations; and evidence of the effectiveness of a vaccine for various populations.

As a sample, targeting tiers could be recommended as follows:

- **Tier 1: first responder health care workers**
 - Inpatient hospital and emergency department workers
 - Nursing home and home health workers
 - Federal, state, and local public health officials
 - EMS workers
 - Vaccine administrators
 - Vaccine manufacturing workers

- **Tier 2: essential workers**
 - Other health care workers
 - Teachers and school staff
 - Staff of child care facilities
 - Food processing workers
 - Grocery store workers
 - Postal and shipping workers
 - Public transportation workers
 - Police and firefighters
 - Deployed and mission critical national security personnel

- **Tier 3: high-risk populations**
 - Pregnant women
 - High-risk children
 - High-risk nonelderly adults
 - Adults older than 65 years old

- **Tier 4: general population**

The CDC, working with state health departments, should also carefully assess how to operationalize this targeting. The first distributions of a vaccine should be to sites that are well-suited to screen for the tiers. For example, vaccines could be distributed to hospitals for tier 1; state health departments for tier 2; and providers and community vaccination clinics for tier 3. These sites must agree to follow the targeting guidelines and document vaccinations. If two doses are required, vaccinated individuals must return to the same site.

Leverage the CDC's centralized distribution for publicly financed vaccines

For the VFC Program and Section 317 Immunization Program, the CDC uses the Vaccine Tracking System (VTrckS) to track orders, demand needs, inventory, dosages administered, and safety in real time.⁸² The federal government should immediately contract with a technology company to assess what upgrades are needed to expand capacity. This system should prompt vaccination sites to send reminders to individuals for any second doses needed. Together with the Vaccine Adverse Event Reporting System, it should track any adverse events carefully among the first 3 million doses.

The CDC currently uses one private distributor (McKesson) with two national depots for the VFC Program.⁸³ This centralized distribution reduces inventory and distribution costs, maintains the chain of cold storage, and reduces loss or damage of vaccines. In 2009, the CDC contracted with McKesson for centralized distribution of the H1N1 flu vaccine.⁸⁴

Every year, the CDC distributes more than 75 million doses of vaccines to health departments and providers.⁸⁵ Given the need for 660 million doses in 2021, the CDC should assess the capacities of all three major distributors: McKesson, Cardinal Health, and AmerisourceBergen. Each distributor has established networks and information systems with different pharmacy chains. For example, CVS uses Cardinal Health, while other pharmacies use the other distributors. The CDC could use one distributor for large vaccination sites and all three distributors for pharmacy chains.

As under the VFC Program, COVID-19 vaccines should be allocated to states in proportion to their populations. Consistent with these allocations, vaccination sites should order vaccines via VTrckS, and vaccine manufacturers should send bulk shipments to the CDC distributor. The CDC distributor should then distribute vaccines and supplies directly to vaccination sites.

As discussed, initial distributions should be reserved for vaccination sites that can implement the targeting guidance. The CDC should also assess whether distributions should be made to large vaccination sites first, including state health departments, hospital systems, and the community vaccination clinics discussed below. State health departments would run school clinics and designate other sites. Smaller vaccination sites would include workplaces, physician offices, and pharmacies. In 2009, distributions to pharmacies began about three months after the first orders of the H1N1 vaccine.

Establish community vaccination clinics across the United States

Based on CDC estimates, the categories that comprise sample tiers 1 and 2 amount to about 22 million people.⁸⁶ To achieve herd immunity, at least 70 percent of the U.S. population, or 231 million people, need to be vaccinated as quickly as possible. Once the population of tiers 1 and 2 are vaccinated, that leaves 209 million people who need access to a vaccine within a month of general availability.

To meet this need, the federal government, in partnership with state health departments and the private sector, should establish 7,300 community vaccination clinics. The targets for these clinics could be 30 doses per hour per vaccinator, with four vaccinators per clinic, for a total of 28,800 doses per month. These clinics should include outdoor sites, such as a track oval or stadium; large indoor sites that can maintain social distancing, such as large gymnasiums, auditoriums, and conference centers; and drive-through sites in large parking lots.

Staffing for a community vaccination clinic could include: four vaccinators; four vaccine preparers; a nurse medical screener; four staffers to provide and review information and forms; four staffers for medical records and data entry; a clinic manager; and two security guards. Several staffers should be multilingual. Under this sample staffing, each clinic would require nine registered nurses and eight medical assistants.

According to the Bureau of Labor Statistics, the average annual wage is \$77,460 for a registered nurse; \$35,720 for a medical assistant; \$115,160 for a health services manager; and \$33,030 for a security guard.⁸⁷ If a community vaccination clinic operates for six months, the wage costs could be about \$580,000 per clinic—or \$4.2 billion for 7,300 clinics. However, many clinics could recruit volunteers or be created by supplementing existing community health centers or pharmacies. Clinics would need personal protective equipment, seating, tables, computers, internet access, handwashing stations, portable latrines, and waste disposal. With this scale in mind, Congress should appropriate \$10 billion for community vaccination clinics.

For many community vaccination clinics, state and federal governments should form public-private partnerships with retail pharmacies such as Walmart and CVS. These pharmacies already administer tens of millions of flu vaccines. For example, CVS administers up to 22 million flu vaccines and could expand capacity to 70 million vaccinations. Walmart currently operates 200 community testing centers that could be converted to community vaccination clinics. CVS currently operates 1,400 testing sites and plans to expand to 3,000 sites, which could be converted to community vaccination clinics.

Plan a massive vaccination campaign

A massive campaign is needed to educate the public about the benefits of COVID-19 vaccination. According to a recent poll, only about half of Americans say they would get a COVID-19 vaccine, although about one-third are unsure.⁸⁸ Only 25 percent of African Americans and 37 percent of Hispanics say they would get vaccinated; alarmingly, 40 percent of African Americans say they would not get a COVID-19 vaccine, perhaps because of the Tuskegee study that lasted for decades, ending in 1972.⁸⁹

In 1956, public health officials recruited Elvis Presley to get a polio vaccine on the Ed Sullivan Show.⁹⁰ Newspapers and magazines followed with photos of Elvis getting his shot. In six months, the vaccination rate for teens skyrocketed from 0.6 percent to more than 80 percent.

Similarly, state and federal governments should recruit medical experts, celebrities, and community leaders to post on social media when they receive a COVID-19 vaccine. These role models could include actors, musicians, sports stars, country music stars, NASCAR drivers, and faith leaders. Since people trust medical experts, pamphlets and posters should be distributed to physician offices throughout the country. Such educational materials should be culturally and linguistically diverse. State and federal governments should engage medical organizations such as the American Medical Association, the American Academy of Pediatrics, Planned Parenthood, the National Medical Association, the National Hispanic Medical Association, the Association of American Indian Physicians, and the National Black Nurses Association.

As it did for H1N1 vaccination, HHS should partner with the Ad Council to launch nationwide public service announcements. The president should proclaim the first month of general availability as National COVID-19 Vaccination Month. State and federal governments should also engage grassroots and membership organizations such as the NAACP, the Movement for Black Lives, UnidosUS, and AARP.

Cooperate with international organizations and invest in global production

The U.S. goal should not just be herd immunity for the U.S. population but also herd immunity for the global population. In addition to fulfilling humanitarian values, equitable global access to COVID-19 vaccines is in the U.S. national security and public health interest. Large outbreaks could destabilize nations, depress the global economy, and seed outbreaks in the United States over time.

International organizations have started to finance global production of a COVID-19 vaccine. The Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi the Vaccine Alliance (Gavi) have a contract with AstraZeneca for 300 million doses of the Oxford vaccine.⁹¹ AstraZeneca also has a contract with the Serum Institute of India for 1 billion doses of the Oxford vaccine for low- and middle-income countries.

The WHO launched the Access to COVID-19 Tools Accelerator (ACT Accelerator)—a collaboration of organizations, including CEPI, Gavi, and the Gates Foundation—to ensure equitable global access to COVID-19 vaccines.⁹² The ACT Accelerator’s target is delivery of 2 billion vaccines by the end of 2021. The group’s funding target is \$18.1 billion for vaccines; so far, only \$2.6 billion (14 percent) has been raised.⁹³

Congress should appropriate \$7.2 billion, or 40 percent of the target, for the ACT Accelerator. The U.S. Department of State should simultaneously negotiate with Europe, Canada, Japan, South Korea, Australia, and New Zealand to provide the remaining funding. In addition to meeting critical needs, this funding and diplomacy would go a long way toward restoring goodwill toward the United States worldwide.

Establish governance and accountability mechanisms

As noted, Operation Warp Speed has suffered from delays, questionable decisions, and a lack of transparency and accountability. The co-director, Dr. Moncef Slaoui, is a former pharmaceutical executive who has not disclosed his financial interests, with the approval of the inspector general.⁹⁴ With this governance structure, there is a risk that undue political or industry influence will influence decisions.

In 2010, President Obama's Council of Advisors on Science and Technology recommended a governance structure for pandemic vaccine production.⁹⁵ Consistent with these recommendations, authority and accountability for vaccine manufacturing and distribution should be centralized within HHS. HHS should manage day-to-day operations, with a senior White House staffer providing accountability. Within HHS, the assistant secretary for preparedness and response (ASPR) should manage HHS agencies: BARDA, the CDC, the NIH, and the FDA. The ASPR should establish a technical advisory committee comprised of representatives of state and local health departments; vaccine manufacturers; contract manufacturers; manufacturers of vaccine supplies; distributors; and retail pharmacies.

To date, Operation Warp Speed has not released a comprehensive vaccine plan. This Center for American Progress report—obtaining information from interviews and public news reports—should not be necessary. Congress should require the administration to release a comprehensive plan for manufacturing, financing, and distribution and hold subsequent hearings on the plan. This unprecedented endeavor requires visibility for the public, Congress, state and local health departments, and manufacturers.

Conclusion

Finding a vaccine that works effectively and ensuring that the vaccine is mass distributed are two different challenges. Rapid manufacturing and distribution of a COVID-19 vaccine will rank as one of the most challenging government initiatives ever undertaken. Lives—and a normal way of life—are at stake. But with aggressive planning, management, and funding, a strong and competent federal government has an opportunity to prove that it can be an extraordinary force for good in people's lives.

About the authors

Topher Spiro is vice president for Health Policy at the Center for American Progress. He is also a senior fellow for Economic Policy at the Center. Spiro served as a senior adviser to Sen. Ted Kennedy and Sen. Tom Harkin, assisting in the drafting of the Affordable Care Act.

Zeke Emanuel is a senior fellow at the Center for American Progress and vice provost for Global Initiatives at the University of Pennsylvania. Emanuel served as special adviser for health policy to the director of the White House Office of Management and Budget under President Barack Obama.

Endnotes

- 1 Executive Office of the President President's Council of Advisors on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise To Meet the Challenges of Pandemic Influenza" (Washington: 2010), available at <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>.
- 2 Lawrence Corey and others, "A Strategic Approach to COVID-19 Vaccine R&D," *Science* 368 (6494) (2020): 9548-9550, available at https://science.sciencemag.org/content/368/6494/948?utm_campaign=fr_sci_2020-05-14&et rid=143961329&et_cid=3326744.
- 3 Fatima Amanat and Florian Krammer, "SARS-CoV-2 Vaccines: Status Report," *Immunity* 52 (2020): 583-589, available at [https://www.cell.com/immunity/pdf/S1074-7613\(20\)30120-5.pdf](https://www.cell.com/immunity/pdf/S1074-7613(20)30120-5.pdf).
- 4 CNN, "READ: Rick Bright's Full Whistleblower Complaint," May 5, 2020, available at <https://www.cnn.com/2020/05/05/politics/rick-bright-full-complaint/index.html>.
- 5 David Kirkpatrick, "Three Coronavirus Vaccine Developers Report Promising Initial Results," July 20, 2020, available at <https://www.nytimes.com/2020/07/20/world/covid-coronavirus-vaccine.html?referringSource=articleShare>.
- 6 Fatima Amanat and Florian Krammer, "SARS-CoV-2 Vaccines: Status Report"; Lawrence Corey and others, "A Strategic Approach to COVID-19 Vaccine R&D"; Ewen Callaway, "The Race for Coronavirus Vaccines: A Graphical Guide," *Nature*, April 28, 2020, available at <https://www.nature.com/articles/d41586-020-01221-y>; Nicole Lurie and others, "Developing COVID-19 Vaccines at Pandemic Speed," *New England Journal of Medicine* 2020 (382): 1969-1973, available at <https://www.nejm.org/doi/full/10.1056/NEJMp2005630>.
- 7 U.S. Department of Health and Human Services, "Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,'" Press release, May 15, 2020, available at <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.
- 8 Katie Thomas, "U.S. Will Pay \$1.6 Billion to Novavax for Coronavirus Vaccine," *New York Times*, July 7, 2020, available at <https://www.nytimes.com/2020/07/07/health/novavax-coronavirus-vaccine-warp-speed.html>.
- 9 Jon Cohen, "Top U.S. Scientist Left Out of White House Selection of COVID-19 Vaccine Shortlist," *Science Magazine*, June 4, 2020, available at <https://www.sciencemag.org/news/2020/06/top-us-scientists-left-out-white-house-selection-covid-19-vaccine-shortlist>.
- 10 Personal communication with author via phone, July 2020.
- 11 Executive Office of the President President's Council of Advisors on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise To Meet the Challenges of Pandemic Influenza."
- 12 Lawrence Corey and others, "A Strategic Approach to COVID-19 Vaccine R&D."
- 13 PA Media, "Government to Invest £93m in UK Vaccine Manufacturing Centre," *The Guardian*, May 16, 2020, available at <https://www.theguardian.com/society/2020/may/17/government-to-invest-93m-in-uk-vaccine-manufacturing-centre>.
- 14 Sara Marley, "AstraZeneca Aims for 30 Million U.K. Vaccine Doses by September," *Bloomberg*, May 17, 2020, available at <https://www.bloomberg.com/news/articles/2020-05-17/astrazeneca-aims-for-30-million-u-k-vaccine-doses-by-september>.
- 15 Emergent BioSolutions, "Emergent BioSolutions Signs Agreement to be U.S. Manufacturing Partner for Johnson & Johnson's Lead Vaccine Candidate for COVID-19," Press release, April 23, 2020, available at <https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-signs-agreement-be-us-manufacturing>; Emergent BioSolutions, "Emergent BioSolutions Joins U.S. Government's Warp Speed Program in Landmark Public-Private CDMO Partnership for COVID-19 Vaccine Development and Manufacturing," Press release, June 1, 2020, available at <https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-joins-us-governments-warp-speed-program>.
- 16 Emergent BioSolutions, "Emergent BioSolutions Joins U.S. Government's Warp Speed Program in Landmark Public-Private CDMO Partnership for COVID-19 Vaccine Development and Manufacturing."
- 17 Globe Newswire, "Novavax Awarded Department of Defense Contract for COVID-19 Vaccine," Press release, June 4, 2020, available at <https://www.globenewswire.com/news-release/2020/06/05/2044076/0/en/Novavax-Awarded-Department-of-Defense-Contract-for-COVID-19-Vaccine.html>.
- 18 Emergent BioSolutions, "Emergent BioSolutions Signs Agreement to be U.S. Manufacturing Partner for Johnson & Johnson's Lead Vaccine Candidate for COVID-19."
- 19 Emergent BioSolutions, "Emergent BioSolutions Signs Agreement with Novavax to Manufacture NanoFlu," Press release, March 31, 2020, available at <https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-signs-agreement-novavax-manufacture>.
- 20 Moderna, "Moderna Advances Late-Stage Development of its Vaccine Against COVID-19," Press release, June 1, 2020, available at <https://investors.modernatx.com/news-releases/news-release-details/moderna-advances-late-stage-development-its-vaccine-mrna-1273>.
- 21 Moderna, "Moderna and Catalent Announce Collaboration for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate," Press release, June 25, 2020, available at <https://investors.modernatx.com/news-releases/news-release-details/moderna-and-catalent-announce-collaboration-fill-finish>.
- 22 Carl O'Donnell and Michael Erman, "Pfizer to Outsource Some Drug Production, Focus on Coronavirus Vaccine," Reuters, May 8, 2020, available at <https://www.reuters.com/article/us-health-coronavirus-pfizer-vaccine/pfizer-to-outsource-some-drug-production-focus-on-coronavirus-vaccine-idUSKBN22K2ZS>.
- 23 PRNewswire, "Immediate COVID-19 Vaccine & Therapeutic Fill/Finish Production Availability Announced by Argonaut Manufacturing Services," Press release, May 23, 2020, available at <https://www.prnewswire.com/news-releases/immediate-covid-19-vaccine--therapeutic-fillfinish-production-availability-announced-by-argonaut-manufacturing-services-301027920.html>.
- 24 U.S. Department of Health and Human Services, "The Public Health Emergency Medical Countermeasures Enterprise Review" (Washington: 2010), available at <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>.

- 25 Government Accountability Office, "National Preparedness HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect" (Washington: 2014), available at <https://www.gao.gov/assets/670/662120.pdf>; https://www.medicalcountermeasures.gov/media/8922/aspa_0411_20120613_aspr_pr_countermeasures_centers_approved_formatted-508new.pdf.
- 26 U.S. Department of Health and Human Services, "Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committee FY 2019" (Washington: 2019), available at <https://www.hhs.gov/sites/default/files/fy-2019-phssec-cj.pdf>.
- 27 David Willman, "Federal Vaccine Development Sites Ill-Suited to Counter COVID-19 Epidemic," *Washington Post*, March 15, 2020, available at https://www.washingtonpost.com/investigations/federal-vaccine-development-sites-ill-suited-to-counter-covid-19-epidemic/2020/03/15/34e8586c-63c4-11ea-acc4-80c22bbe96f_story.html.
- 28 Robert Roos, "Novartis Says Cell-Based Flu Vaccine Facility Ready to Produce," Center for Infectious Disease Research and Policy, December 13, 2011, available at <https://www.cidrap.umn.edu/news-perspective/2011/12/novartis-says-cell-based-flu-vaccine-facility-ready-produce>.
- 29 Government Accountability Office, "Biological Defense Additional Information That Congress May Find Useful as It Considers DOD's Advanced Development and Manufacturing Capability" (Washington: 2017), available at <https://www.gao.gov/assets/690/685889.pdf>.
- 30 Eric Sagonowsky, "Seqiris to Spend \$140M, Add 120 Jobs At U.S. Plant As It Takes Cell-Based Vaccines Global," *Fierce Pharma*, November 19, 2018, available at <https://www.fiercepharma.com/vaccines/seqirus-to-spend-140m-add-120-jobs-nc-flu-vaccine-plant-expansion>.
- 31 Texas A&M University Center for Innovation in Advanced Development and Manufacturing, "Facilities," available at <https://ciadm.tamhsc.edu/facilities/index.html> (last accessed July 2020).
- 32 The Eagle, "COVID-19 The Texas A&M System Responds – Episode 9," June 4, 2020, available at https://theeagle.com/news/a_m/tamus/covid-19-the-texas-a-m-system-responds---episode-9/video_c27bbb0e-2304-5daa-a559-1ed785bf12f9.html.
- 33 U.S. Department of Health and Human Services Public Health Emergency, "HHS Boosts National Capacity to Produce Pandemic Flu Vaccine New Fill and Finish Manufacturing Network Strengthens Pandemic Readiness," Press release, September 25, 2013, available at <https://www.phe.gov/Preparedness/news/Pages/finish-fill-130930.aspx>;
- Government Accountability Office, "National Preparedness HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect" (Washington: 2014), available at <https://www.gao.gov/assets/670/662120.pdf>;
- U.S. Department of Health and Human Services Public Health Emergency Medical Countermeasures, "Fill Finishing Manufacturing Network (FFMN)," available at <https://www.medicalcountermeasures.gov/barda/core-services/finish-fill-manufacturing-network/> (last accessed July 2020).
- 34 Olivia Rubin, Katherine Faulders, and Matthew Mosk, "When Coronavirus Vaccine Arrives, Experts Worry US Not Ready to Mass Produce," *ABC News*, April 16, 2020, available at <https://abcnews.go.com/Health/vaccine-arrives-experts-worry-us-ready-mass-produce/story?id=70167459>.
- 35 Cook Group, "Cook Group Completes Sale of Cook Pharmica," Press release, October 24, 2017, available at <https://www.cookgroup.com/cook-group-completes-sale-of-cook-pharmica/>; *Pharmaceutical Business Review*, "Moderna and Catalent Announce Collaboration for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate," June 26, 2020, available at <https://www.pharmaceutical-business-review.com/news/moderna-and-catalent-announce-collaboration-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-candidate/>.
- 36 Pantheon, "Why did Thermo Fisher Scientific Acquire Pantheon?" available at <https://patheon.com/resource-library/webinars/1-year-later-why-did-thermo-fisher-scientific-acquire-patheon/> (last accessed July 2020).
- 37 Dan Stanton, "Thermo Fisher Injecting \$150M in Patheon Fill & Finishing Plants," *Pitt County Development Commission*, March 19, 2019, available at <https://locateincarolina.com/news/thermo-fisher-injecting-150m-in-patheon-fill-finish-plants/>.
- 38 PR Newswire, "Par Pharmaceutical to Acquire JHP Pharmaceuticals," Press release, January 21, 2014, available at <https://www.prnewswire.com/news-releases/par-pharmaceutical-to-acquire-jhp-pharmaceuticals-241264801.html>.
- 39 Business Wire, "Nanotherapeutics Announces Name Change to Ology Bioservices, Reflecting the Company's Ongoing Transformation Into One of the Top Contract Development and Manufacturing Organizations of Vaccines and Biologics," Press release, October 2, 2017, available at <https://www.businesswire.com/news/home/20171002005452/en/Nanotherapeutics-Announces-Change-Ology-Bioservices-Reflecting-Company%E2%80%99s>.
- 40 Personal communication with author via phone, July 2020.
- 41 PR Newswire, "Ology Bioservices, Inovio Partner to Manufacture COVID-19 DNA Vaccine With \$11.9 Million Department of Defense Grant," Press release, March 24, 2020, available at <https://www.prnewswire.com/news-releases/ology-bioservices-inovio-partner-to-manufacture-covid-19-dna-vaccine-with-11-9-million-department-of-defense-grant-301028626.html>.
- 42 Advanced Bioscience Laboratories, "ABL Awarded BARDA Contract to Fill Live Virus-Based Medical Countermeasures," available at <https://ablinc.com/about-abl/news/news-item/abl-awarded-barda-contract-fill-live-virus-based-medical-countermeasures/> (last accessed July 2020).
- 43 Advanced Bioscience Laboratories, "ABL, Inc. Supports Fill/Finish of SARS-CoV-2 (COVID-19) Vaccine Candidate," Press release, April 15, 2020, available at <https://ablinc.com/about-abl/news/news-item/abl-inc-supports-fill-finish-of-sars-cov-2-covid-19-vaccine-candidate/>.
- 44 Business Wire, "IDT Biologika Awarded New Task Order in the Scope of 10-Year NIH Contract to Manufacture Vaccines and Biologics for Infectious Diseases," Press release, November 5, 2019, available at <https://www.businesswire.com/news/home/20191105005003/en/IDT-Biologika-Awarded-New-Task-Order-Scope>.
- 45 The authors reached out to MilliporeSigma twice but did not receive a response.
- 46 Stanley Plotkin and others, "The Complexity and Cost of Vaccine Manufacturing – An Overview," *Vaccine* 35 (33) (2017): 4064-4071, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/>
- 47 The Defense Production Act of 1950, as amended, 50 U.S.C. App. section 2061 et seq. (October 1, 2009), available at <https://www.fema.gov/media-library/assets/documents/15666>; Congressional Research Service, "The Defense Production Act of 1950: History, Authorities, and Considerations for Congress (Washington: 2020), available at <https://fas.org/sgp/crs/natsec/R43767.pdf>.

- 48 Bill Bostock, "Inside the U.S. Government's \$347 Million Plan to Fight the Global Glass Vial Shortage Ahead of a Coronavirus Vaccine Rollout," *Business Insider*, June 22, 2020, available at <https://www.businessinsider.com/coronavirus-vaccine-glass-shortage-operation-warp-speed-corning-sio2-2020-6>.
- 49 U.S. Department of Health and Human Services, "Operation Warp Speed Ramps Up U.S.-Based Manufacturing Capacity for Vials for COVID-19 Vaccines and Treatments," Press release, June 11, 2020, available at <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>.
- 50 Manojna Maddipatla and Manas Mishra, "Pfizer Ties Up With Glass Maker Corning for Vial Supply," *Reuters*, May 28, 2020, available at [https://www.reuters.com/article/us-pfizer-corning/pfizer-ties-up-with-glass-maker-corning-for-vial-supply-idUSKBN2342IC#~:text=\(Reuters\)%20%2D%20U.S.%20drugmaker%20Pfizer,the%20companies%20said%20on%20Thursday](https://www.reuters.com/article/us-pfizer-corning/pfizer-ties-up-with-glass-maker-corning-for-vial-supply-idUSKBN2342IC#~:text=(Reuters)%20%2D%20U.S.%20drugmaker%20Pfizer,the%20companies%20said%20on%20Thursday).
- 51 Bill Bostock, "Inside the U.S. Government's \$347 Million Plan to Fight the Global Glass Vial Shortage Ahead of a Coronavirus Vaccine Rollout."
- 52 Christopher Rowland, "A Race Is On to Make Enough Small Glass Vials to Deliver Coronavirus Vaccine Around the World," *Washington Post*, July 13, 2020, available at <https://www.washingtonpost.com/business/2020/07/13/coronavirus-vaccine-coming-glass/>.
- 53 Jared S. Hopkins and Drew Hinshaw, "Coronavirus Vaccine Makers Are Hunting for Vital Equipment: Glass Vials," *Wall Street Journal*, June 16, 2020, available at <https://www.wsj.com/articles/coronavirus-vaccine-makers-are-hunting-for-vital-equipment-glass-vials-11592317525>.
- 54 David E. Sanger and others, "Profits and Pride at Stake, the Race for a Vaccine Intensifies," *New York Times*, May 2, 2020, available at <https://www.nytimes.com/2020/05/02/us/politics/vaccines-coronavirus-research.html>.
- 55 U.S. Department of Health and Human Services, "Operation Warp Speed Ramps Up U.S.-Based Manufacturing Capacity for Vials for COVID-19 Vaccines and Treatments;" Healthcare Packaging, "SiO2 Materials Science Receives \$143 Million Contract from U.S. Government," June 13, 2020, available at <https://www.healthcarepackaging.com/covid-19/news/21137193/sio2-materials-science-receives-143-million-contract-from-us-government>.
- 56 Christopher Rowland, "A Race Is on to Make Enough Small Glass Vials to Deliver Coronavirus Vaccine Around the World."
- 57 U.S. Department of Defense, "DOD Awards \$138 Million Contract, Enabling Prefilled Syringes for Future COVID-19 Vaccine," Press release, May 12, 2020, available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2184808/dod-awards-138-million-contract-enabling-prefilled-syringes-for-future-covid-19/source/GovDelivery/>.
- 58 Sarah Fitzpatrick, Adiel Kaplan, and Didi Martinez, "Trump Administration Unveils Plan to Ramp Up Syringe Production for Future COVID-19 Vaccine," *NBC News*, May 12, 2020, available at <https://www.nbcnews.com/news/us-news/trump-admin-unveils-plan-ramp-syringe-production-future-covid-19-n1204436>.
- 59 Ben Hargreaves, "US Strikes \$138M Deal to Ensure Enough Syringes for COVID-19 Vaccine," *BioPharma Reporter*, May 13, 2020, available at <https://www.biopharma-reporter.com/Article/2020/05/13/US-funds-extra-syringe-production>.
- 60 CNN, "READ: Rick Bright's Full Whistleblower Complaint."
- 61 U.S. GHX Market Data for Calendar 2019.
- 62 Jennifer Haberkorn, "Syringes Are Key to Coronavirus Vaccine Delivery. Trump Is Relying On Two Untested Suppliers," *Los Angeles Times*, July 8, 2020, available at <https://www.latimes.com/politics/story/2020-07-08/trump-coronavirus-vaccine-strategy-syringe-providers>; Martha Mendoza and Juliet Linderman, "U.S. Bets on Small, Untested Company to Deliver COVID-19 Vaccine," *PBS*, July 10, 2020, available at <https://www.pbs.org/newshour/health/u-s-bets-on-small-untested-company-to-deliver-covid-19-vaccine>.
- 63 BD, "BD Partners with U.S. Government on \$70 Million Manufacturing Infrastructure Project for Mass Vaccination Campaigns," Press release, July 8, 2020, available at <https://www.bd.com/en-us/company/news-and-media/press-releases/2020-07-08-bd-partners-with-u-s-government-on-70-million-manufacturing-infrastructure-project-for-mass-vaccination-campaigns>; BD, "BD Receives Additional Orders For 177 Million Injection Devices For U.S., Canada COVID-19 Vaccine Preparations," Press release, July 21, 2020, available at <https://news.bd.com/2020-07-21-BD-Receives-Additional-Orders-For-177-Million-Injection-Devices-For-U-S-Canada-COVID-19-Vaccine-Preparations>.
- 64 Ibid.
- 65 Sarah Owerhohle, "The 'Biggest Challenge' Won't Come Until After a Coronavirus Vaccine Is Found," *Politico*, May 11, 2020, available at <https://www.politico.com/news/2020/05/11/coronavirus-vaccine-supply-shortages-245450>.
- 66 Lawrence Corey and others, "A Strategic Approach to COVID-19 Vaccine R&D."
- 67 James Gorman, "Tests for Coronavirus Vaccine Need This Ingredient: Horseshoe Crabs," *New York Times*, June 3, 2020, available at <https://www.nytimes.com/2020/06/03/science/coronavirus-vaccine-horseshoe-crabs.html> (last accessed July 2020).
- 68 U.S. Department of Health and Human Services, "Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committee FY 2019."
- 69 Executive Office of the President President's Council of Advisors on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise To Meet the Challenges of Pandemic Influenza."
- 70 Ibid.
- 71 Smithsonian National Museum of American History, "What Ever Happened to Polio? Medical Philanthropy," available at <https://amhistory.si.edu/polio/virusvaccine/medphil.htm> (last accessed July 2020).
- 72 Centers for Disease Control and Prevention, "Vaccines for Children Program (VFC), available at <https://www.cdc.gov/vaccines/programs/vfc/about/index.html> (last accessed July 2020).
- 73 Centers for Disease Control and Prevention, "Questions and Answers on 2009 H1N1 Vaccine Financing," available at https://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm (last accessed July 2020).
- 74 Sarah Kliff, "Most Coronavirus Tests Cost About \$100. Why Did One Cost \$2,315?," *New York Times*, June 16, 2020, available at <https://www.nytimes.com/2020/06/16/upshot/coronavirus-test-cost-varies-widely.html>.
- 75 Kaiser Family Foundation, "Analysis Finds List Prices for COVID-19 Tests Range from \$20 to \$850 at Large Hospitals Nationwide," Press release, July 15, 2020, available at <https://www.kff.org/health-costs/press-release/analysis-finds-list-prices-for-covid-19-tests-range-from-20-to-850-at-large-hospitals-nationwide/>.

- 76 Executive Office of the President President's Council of Advisors on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise To Meet the Challenges of Pandemic Influenza."
- 77 Centers for Disease Control and Prevention, "Questions Answered on Vaccines Purchased with 317 Funds," available at <https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html> (last accessed July 2020).
- 78 Centers for Disease Control and Prevention, "CDC Vaccine Price List," available at <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html> (last accessed July 2020).
- 79 Pfizer, "Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2," Press release, July 22, 2020, available at https://www.businesswire.com/news/home/20200722005438/en/Pfizer-BioNTech-Announce-Agreement-U.S.-Government-600?feedref=JjAwJuNHystnCoBq_hl-WBj9Oi60kFTomUxRDB8jhBsNpnJw7dvSFTyni2B-OVIOrCOi9QzgjCezTS3Nw_X6kUrp5Bm-Hav1w-UkdSIG3nDIC87j5HoE75BMeA8LaVacVJefZly-gqxRRsuxHCTK2w%3D%3D&utm_source=dlvr.it&utm_medium=twitter.
- 80 Centers for Medicare & Medicaid Services, "Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration Under the Vaccines for Children Program; Final Rule," November 6, 2012, available at <https://www.federalregister.gov/documents/2012/11/06/2012-26507/rin-0938-aq63>
- 81 Bowen Garrett and others, "How the COVID-19 Recession Could Affect Health Insurance Coverage," The Urban Institute, May 2020, available at https://www.urban.org/sites/default/files/publication/102157/how-the-covid-19-recession-could-affect-health-insurance-coverage_0.pdf.
- 82 Centers for Disease Control and Prevention, "Vaccine Tracking System (VTrckS), available at <https://www.cdc.gov/vaccines/programs/vtrcks/index.html> (last accessed July 2020).
- 83 McKesson, "CDC Expands Existing Vaccine Distribution Partnership with McKesson to Include H1N1 Flu Vaccine," Press release, August 10, 2009, available at <https://www.mckesson.com/about-mckesson/newsroom/press-releases/2014/cdc-expands-existing-vaccine-distribution-partnership-with-mckesson-to-include-h1n1-flu-vaccine/>; Centers for Disease Control and Prevention Vaccine Tracking System (VTrckS), "Vaccine Management Business Improvement Project (VMBIP), available at <https://www.cdc.gov/vaccines/programs/vtrcks/vmbip.html> (last accessed July 2020).
- 84 Business Wire, "CDC Expands Existing Vaccine Distribution Partnership with McKesson to Include H1N1 Flu Vaccine," Press release, August 10, 2009, available at <https://www.businesswire.com/news/home/20090810005445/en/CDC-Expands-Existing-Vaccine-Distribution-Partnership-McKesson>.
- 85 Centers for Disease Control and Prevention, "Pandemic Vaccine Program Distribution, Tracking, and Monitoring," available at <https://espanol.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf> (last accessed July 2020).
- 86 Centers for Disease Control and Prevention, "Interim Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic" (Atlanta: 2018), available at <https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf>.
- 87 U.S. Bureau of Labor Statistics, "Occupational Employment Statistics," available at https://www.bls.gov/oes/current/oes_stru.htm#33-0000 (last accessed July 2020).
- 88 Lauren Neergard and Hannah Fingerhut, "AP-NORC Poll: Half of Americans Would Get a COVID-19 Vaccine," AP News, May 27, 2020, available at <https://apnews.com/dacd8bc428dd4df6511bfa259cfec44>.
- 89 Centers for Disease Control and Prevention, "The Tuskegee Study, 1932-1972," available at <https://www.cdc.gov/tuskegee/index.html> (last accessed July 2020).
- 90 Karen Harris, "The Day Elvis Helped Fight Polio," History Daily, October 28, 2019, available at <https://historydaily.org/the-day-elvis-helped-fight-polio>.
- 91 AstraZeneca, "AstraZeneca Takes Next Steps Toward Broad and Equitable Access to Oxford University's Potential COVID-19 Vaccine," Press release, June 4, 2020, available at <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>.
- 92 World Health Organization, "Access to COVID-19 Tools (ACT) Accelerator," April 24, 2020, available at <https://www.who.int/publications/m/item/access-to-covid-19-tools-act-accelerator>.
- 93 Ben Hargreaves, "WHO Seeks \$31bn in Next 18 Months to Combat COVID-19," BioPharma Reporter, June 29, 2020, available at <https://www.biopharma-reporter.com/Article/2020/06/29/WHO-seeks-billions-in-funding-for-vaccine>.
- 94 Christopher Rowland, "Chief of White House's Operation Warp Speed Vaccine Effort Can Keep Investing in Pharma Firms, Under IG Ruling," *Washington Post*, July 14, 2020, available at <https://www.washingtonpost.com/business/2020/07/14/chief-white-houses-operation-warp-speed-vaccine-effort-can-keep-investing-pharma-firms-under-ig-ruling/>.
- 95 Executive Office of the President President's Council of Advisors on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise To Meet the Challenges of Pandemic Influenza."

Our Mission

The Center for American Progress is an independent, nonpartisan policy institute that is dedicated to improving the lives of all Americans, through bold, progressive ideas, as well as strong leadership and concerted action. Our aim is not just to change the conversation, but to change the country.

Our Values

As progressives, we believe America should be a land of boundless opportunity, where people can climb the ladder of economic mobility. We believe we owe it to future generations to protect the planet and promote peace and shared global prosperity.

And we believe an effective government can earn the trust of the American people, champion the common good over narrow self-interest, and harness the strength of our diversity.

Our Approach

We develop new policy ideas, challenge the media to cover the issues that truly matter, and shape the national debate. With policy teams in major issue areas, American Progress can think creatively at the cross-section of traditional boundaries to develop ideas for policymakers that lead to real change. By employing an extensive communications and outreach effort that we adapt to a rapidly changing media landscape, we move our ideas aggressively in the national policy debate.

