OPERATION WARP SPEED

Innovating Vaccine Development While Addressing a National Crisis

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TOP LINES

- Operation Warp Speed (OWS), a bold and innovative public-private partnership pioneered under the Trump Administration, led to the unprecedented emergency use authorization of a COVID-19 vaccine just 11 months after the viral genetic sequence was made available to researchers.
- The conventional approach to vaccine development is sequential, allowing developers to make informed decisions about their financial risks and likelihood of success before proceeding with the next step.
- The OWS strategy utilized a parallel rather than sequential vaccine development process whereby large up-front investments and guaranteed purchase amounts mitigated traditional financial risks.
- The persistent underinvestment in infectious-disease vaccines before COVID-19 also manifested in a delayed uptake of new vaccine technology, particularly between 2010 – 2020.
- The lessons learned from OWS, namely strategic investments in public-private partnerships, should be applied to future pandemic preparedness plans and other pressing national challenges.

INTRODUCTION

The rapid development and deployment of COVID-19 vaccines represent not only a historic breakthrough in medicine but also a new chapter in public-private partnerships and federal support for American innovation. The process to develop a new vaccine, which historically took 7-10 years due in part to the sequencing of different clinical trials, was accelerated to meet the urgency of a global pandemic. The Pfizer and Moderna vaccines currently being administered rely on messenger RNA (mRNA), a new approach developed years ago but authorized for the first time in the context of inoculating against COVID-19. Moreover, the vaccination of millions of Americans per day enabled by robust cooperation between the federal government, state and local partners, and the private sector is facilitating an end to the pandemic in the U.S.

To appreciate these advances in medicine, it is critical to understand their origins in the strategy of the previous administration's unprecedented investment in Operation Warp Speed (OWS) and its focus on supporting innovation to achieve results on behalf of the American people in a timely and effective manner—two key criteria amid a national emergency. OWS shattered the status quo. Its impact can only be fully understood when viewed in the context of where the country and the medical community were in terms of vaccine development and pandemic planning when COVID-19 struck.

A 2019 White House Council of Economic Advisers (CEA) report on pandemic influenza and vaccine innovation found that longstanding underinvestment in new or better vaccine technologies was largely due to a lack of private market incentives and advocated for an increased role for public-private partnerships to correct this trend (CEA, 2019). Their findings are not dissimilar from those in a report from scientific advisors to President Obama in 2010 that found shortcomings in the Nation's response to the 2009 H1N1 influenza pandemic and recommended better utilization of public-private partnerships to optimize vaccine production in the U.S. (PCAST, 2010) That two separate reports with such similar recommendations were issued by the two different administrations 9 years apart indicates a missed opportunity to implement lessons learned during those intervening years. A 2008 report on bioterrorism noted that whereas "the nuclear age began with a mushroom cloud…the life sciences community has never experienced a comparable iconic event" and so "security awareness has grown slowly, lagging behind the emergence of biological risks and threats"(Graham et al., 2008, p. xvii).

When it came to federal government preparations, the Trump Administration inherited 2 decades of pandemic planning focused almost entirely on influenza—given the Nation's century of experiences to date—and a public health infrastructure ill-equipped to mount a nationwide effort to protect the American public from a previously-unknown pathogen. A Department of Health and Human Services (HHS) report on the 2009 response to the H1N1 outbreak noted that "serendipity played a role" in the fact that the outbreak was so geographically limited, and explained that "[I]f the health care system had been tested to its limits, serious problems may have emerged…"(HHS, 2012, p. 95).

As the COVID-19 pandemic is relegated to the history books with U.S. vaccination efforts made possible by the success of OWS, the Nation faces a new set of questions, including global distribution strategies, the protection of intellectual property, and the role for continued innovation through public-private partnerships in non-pandemic periods. This paper offers a retrospective of how OWS disrupted in positive ways the vaccine development, manufacturing, and distribution space; reflect on previous pandemic responses, particularly the 2009 H1N1 response; and considerations for how future administrations can adjust their pandemic preparedness plans to protect the American people from outbreaks of unknown pathogens.

VACCINE DEVELOPMENT IN CONTEXT

According to a study of 21 novel vaccines approved by the Food and Drug Administration (FDA) from 2010 to 2020, the time from clinical testing to approval was about 8 years (Puthumana et al., 2021). This does not include the basic research, discovery, and pre-clinical studies required before clinical studies can begin. Standard clinical trials involve three phases before approval and a fourth phase that consists of post-approval monitoring and research. In each phase of clinical trials, an increasing number of human subjects are added to determine safety and efficacy, and, resultingly, each phase also increases in time and costs (CDC, n.d.-a). The conventional approach is sequential development, allowing vaccine developers to make informed decisions about their financial risks and likelihood of success before proceeding with the next step.

Two recent studies evaluated the probability of success of new vaccines for infectious diseases. McGill University researchers found a 10 percent probability of progressing from phase 2 to licensure within 10 years. Massachusetts Institute of Technology (MIT) researchers, using a dataset of vaccine and non-vaccine programs targeting infectious diseases over 20 years (January 1, 2020, through January 7, 2020), estimated an overall probability of success of 39.8 percent in industry-sponsored vaccine development programs but only a 6.8 percent probability of success in non-industry-sponsored vaccine development programs (Lo et al., 2020; MacPherson et al., 2021). When performing disease-specific analysis, Lo et al. observed only one development path for the severe acute respiratory syndrome (SARS) in each of the industry- and non-industry-sponsored development program categories (Lo et al., 2020). By comparison, there were 640 industry-sponsored vaccine development programs researching respiratory infections in the 20-year period (Lo et al., 2020). Further, in discussing the implications of their findings, the MIT research team posited that because the technical success rate for vaccine development outperforms other therapeutic groups, such as cancer drugs, the overall underinvestment in infectious disease vaccines is in part due to the perceived lack of financial incentives rather than the risk of technical failure.

This persistent underinvestment in infectious disease vaccines also manifested in a delayed uptake of new vaccine technology. The influenza vaccine best exemplifies this. Human seasonal influenza A viruses circulate regularly, and U.S. seasonal vaccines are designed each year to include the three or four virus strains thought most likely to cause illness during the next flu season. (CDC, n.d.-b) In the U.S., that decision is typically made in February for the fall/winter season, and the process of production then begins. The majority of influenza vaccines are produced with a 70-year-old technology involving chicken eggs. The egg-based technique involves injecting candidate vaccine viruses in fertilized hen's eggs for several days before the virus is harvested to proceed with the remainder of vaccine production. It can take 6 months to deliver substantial amounts of vaccines. There is always the potential for the circulating viruses to mutate during that time rendering the vaccine less effective (CEA, 2019). The egg-based method also makes vaccine production dependent on the supply of chicken eggs and facilities that can complete the production process. These problems can

generally be managed for seasonal influenza, but they become a major issue during an influenza pandemic.

There have been four influenza pandemics in the last 100 years—1918, 1957-58, 1968, and 2009—with the 2009 H1N1 pandemic being the most informative regarding updating vaccine technologies. In a 2010 report to President Obama outlining the influenza vaccine production challenges regarding the 2009 H1N1 pandemic, the President's Council of Advisors on Science and Technology (PCAST) found the following:

> Due to difficulties in producing vaccine, initial doses became available only after about 26 weeks, sufficient doses to cover half the population became available at 38 weeks and supply adequate to protect the entire Nation would have taken approximately 48 weeks to produce. This timeline was far too slow, by approximately 3 to 5 months (PCAST, 2010, p. v-vi).

This prompted research and approval of new technologies for the influenza vaccine over the next 10 years that also proved foundational to the development a SARS-CoV-2 vaccine.

The same 2010 report to President Obama identified two other mechanisms for vaccine production that could improve vaccine availability in pandemic influenza: growing viruses in cultured cells and using proteins produced by recombinant DNA technology (PCAST, 2010). At the time of the report, neither method was approved for use by the FDA, and both economic and regulatory hurdles for the new technologies were identified, leading to a recommendation for the federal government to "take a mission-driven approach to reengineering the vaccine enterprise" (PCAST, 2010).

The private sector identified similar problems with outdated influenza vaccine production and used the delayed vaccine availability in the 2009 H1N1 pandemic as a springboard for innovation. In 2012 and 2013, researchers reported the success of new vaccine technology in mice models that utilized mRNA, which has a cellular function of providing instructions for protein production, to stimulate the immune system to form antibodies to viral proteins (Hekele et al., 2013; Petsch et al., 2012).

The first cell-based vaccine platform was licensed for use in the U.S. by the FDA in 2012, and the first recombinant protein-based influenza vaccine was licensed in 2013 (Rockman et al., 2020). By September 2019, however, these new vaccine platforms still had not overtaken egg-based vaccines for seasonal influenza, and mRNA influenza vaccine research had progressed to only one Phase 1 clinical trial from Moderna Therapeutics (CEA, 2019; Feldman et al., 2019). While the U.S. had demonstrated forward progress since the 2009 H1N1 influenza pandemic, a report by CEA in September 2019 found the country was still ill-equipped to mitigate health and economic losses of a repeat influenza pandemic with the most commonly used vaccine production technologies (CEA, 2019).

In response to the CEA report, President Trump issued Executive Order 13887 on September 19, 2019, titled "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health," which included direction to reduce reliance on egg-based influenza vaccine production and expand the domestic capacity of alternative methods that allow more rapid responses to emerging influenza viruses (EOP, 2019). The executive order also instructed the Secretary of HHS to:

> evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships, including, in emergency situations, the transfer of technology to public-private partnerships—such as the HHS Centers for Innovation and Advanced Development and Manufacturing or other domestic manufacturing facilities—in advance of a pandemic, in order to be able to ensure adequate domestic pandemic manufacturing capacity and capability (EOP, 2019, p.49937).

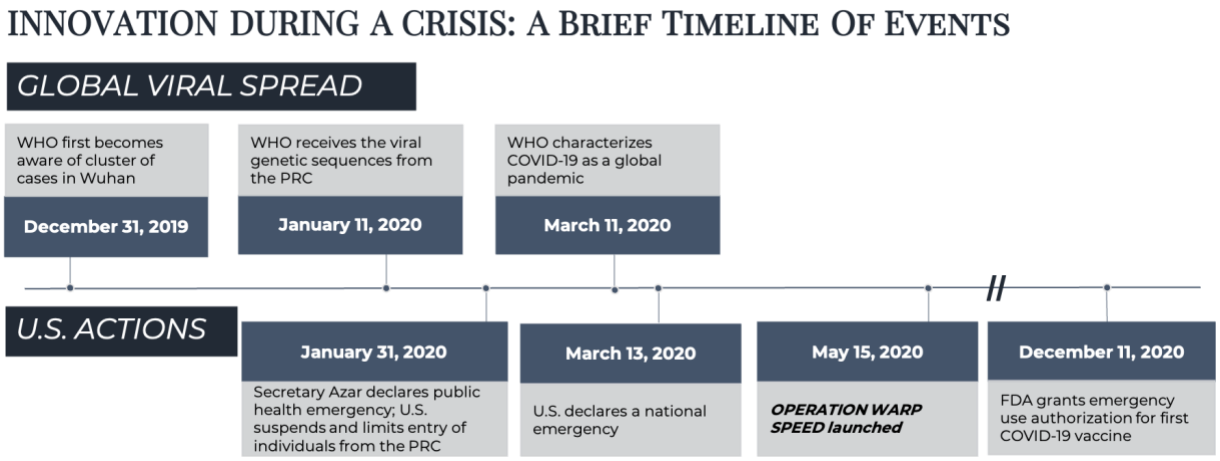
The Trump Administration did not realize in September 2019 that its efforts to modernize the influenza vaccine, in combination with a decade of work on vaccine research from the public and private sectors, would set the groundwork for one of the greatest scientific achievements in American history.

The Arrival of COVID-19

On December 31, 2019, the World Health Organization (WHO) first became aware of a cluster of cases of viral pneumonia in Wuhan, People's Republic of China (PRC), and by January 9, 2020, the cause of the outbreak was determined to be a novel coronavirus (WHO, 2020). On January 11, 2020, Chinese media reported the first death from the novel coronavirus, and the WHO reported receiving the genetic sequences for the virus from the PRC (WHO, 2020). HHS Secretary Alex Azar declared a public health emergency on January 31, 2020, and the U.S. issued a proclamation suspending and limiting the entry of individuals from the PRC (HHS, 2020a; EOP, 2020a) on that same day. On February 11, 2020, the novel coronavirus was officially labeled as SARS-CoV-2, and the disease it caused was named COVID-19. On March 11, 2020, the WHO characterized COVID-19 as a global pandemic, and President Trump declared a national emergency on March 13, 2020, thus marshaling the full resources of the U.S. federal government. (EOP, 2020b; WHO, 2020). On December 11, 2020—exactly 9 months after the global pandemic declaration and 11 months after the genetic sequence became available to researchers—the first COVID-19 vaccine received emergency use authorization from the FDA (FDA, 2020). These remarkable results were largely made possible through the Trump Administration's strategic and unprecedented investment in innovation through OWS.

Though the federal government announced initial investments in private-sector vaccine candidates on March 30, 2020, it was the launch of OWS on May 15, 2020, that created the historic public-private and intergovernmental partnerships to address the economic and scientific process barriers to vaccine development previously discussed (Slaoui & Hepburn, 2020; DOD, n.d.). The FDA regulatory processes for vaccine authorization were separate from

OWS. While the agency did provide guidance to vaccine developers and expedited reviews compared to a non-pandemic setting, a separate analysis of the successes and shortcomings of the FDA's approach to COVID-19 is needed, particularly regarding processes for vaccine authorization during a pandemic (Kuter et al., 2021).



STRATEGIC APPROACH OF OPERATION WARP SPEED

According to Dr. Moncef Slaoui and Dr. Matthew Hepburn, OWS chief advisor and vaccine development lead, respectively, OWS was developed to fundamentally restructure how the U.S. government supports vaccine development, manufacturing, and distribution (Slaoui & Hepburn, 2020). The OWS objectives were outlined in a New England Journal of Medicine article:

> The initiative set ambitious objectives: to deliver tens of millions of doses of a SARS-CoV-2 vaccine—with demonstrated safety and efficacy, and approved or authorized by the FDA for use in the U.S. population—beginning at the end of 2020 and to have as many as 300 million doses of such vaccines available and deployed by mid-2021 (Slaoui & Hepburn, 2020, p.1701).

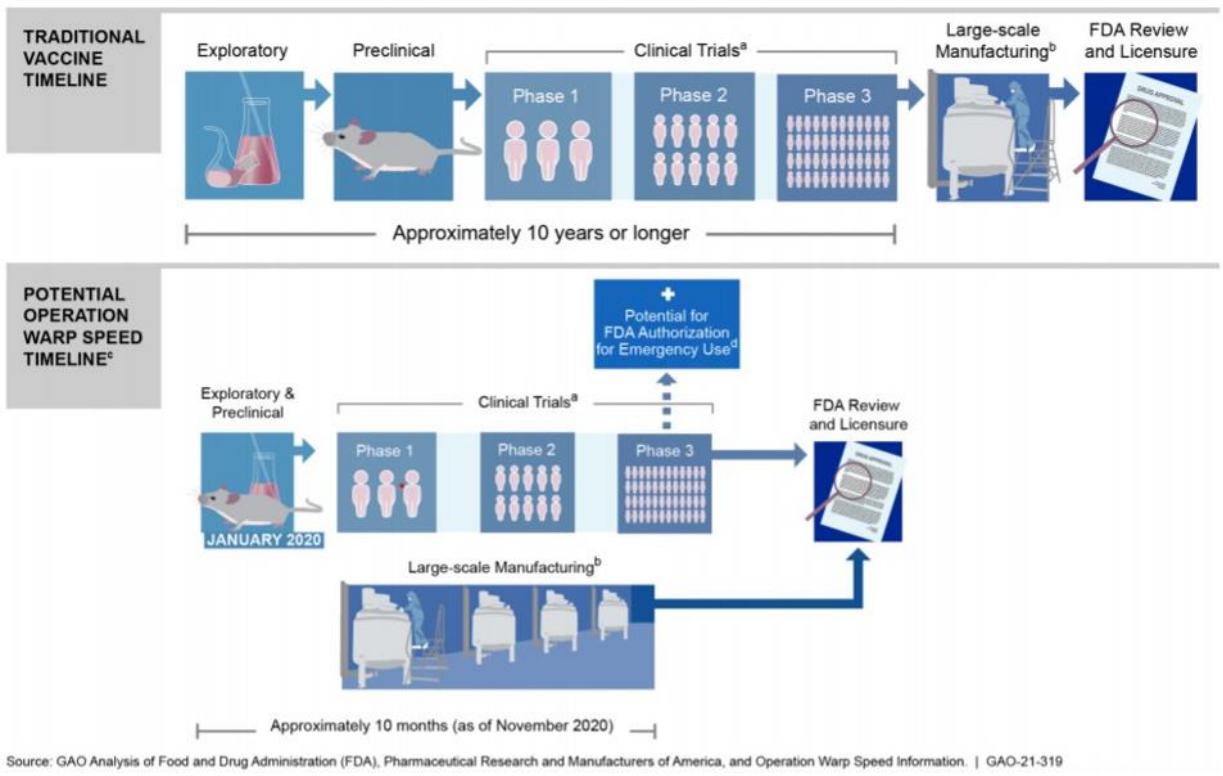
The Government Accountability Office (GAO) reports that, by the end of 2020, the Department of Defense (DOD) and HHS had obligated approximately $13 billion to help achieve this goal (GAO, 2021). The strategic plan to defray financial risk for vaccine developers and promote innovation in vaccine science, clinical trial design, and mass manufacturing demonstrated a federal government that understood the potential of private sector partnerships and a commitment to meeting the needs of the American people.

In addition to creating public-private partnerships and financial investments, OWS made multiple other strategic decisions that facilitated the success of the vaccine development programs and are described in detail below.

Parallel Development Approach

The OWS strategy utilized parallel rather than sequential vaccine program development whereby clinical trials, process development to meet regulatory standards, and manufacturing scale-up happened simultaneously. Large up-front investments and guaranteed purchase amounts mitigated traditional financial risks associated with these aspects of vaccine development (Slaoui & Hepburn, 2020). A GAO report on OWS illustrated the sequential and simultaneous approaches and noted an order of magnitude decrease between the two—from approximately 10 years to approximately 10 months (GAO, 2021).

Figure 1: Traditional Vaccine Development Timeline Compared to Potential Operation Warp Speed (OWS) Timeline

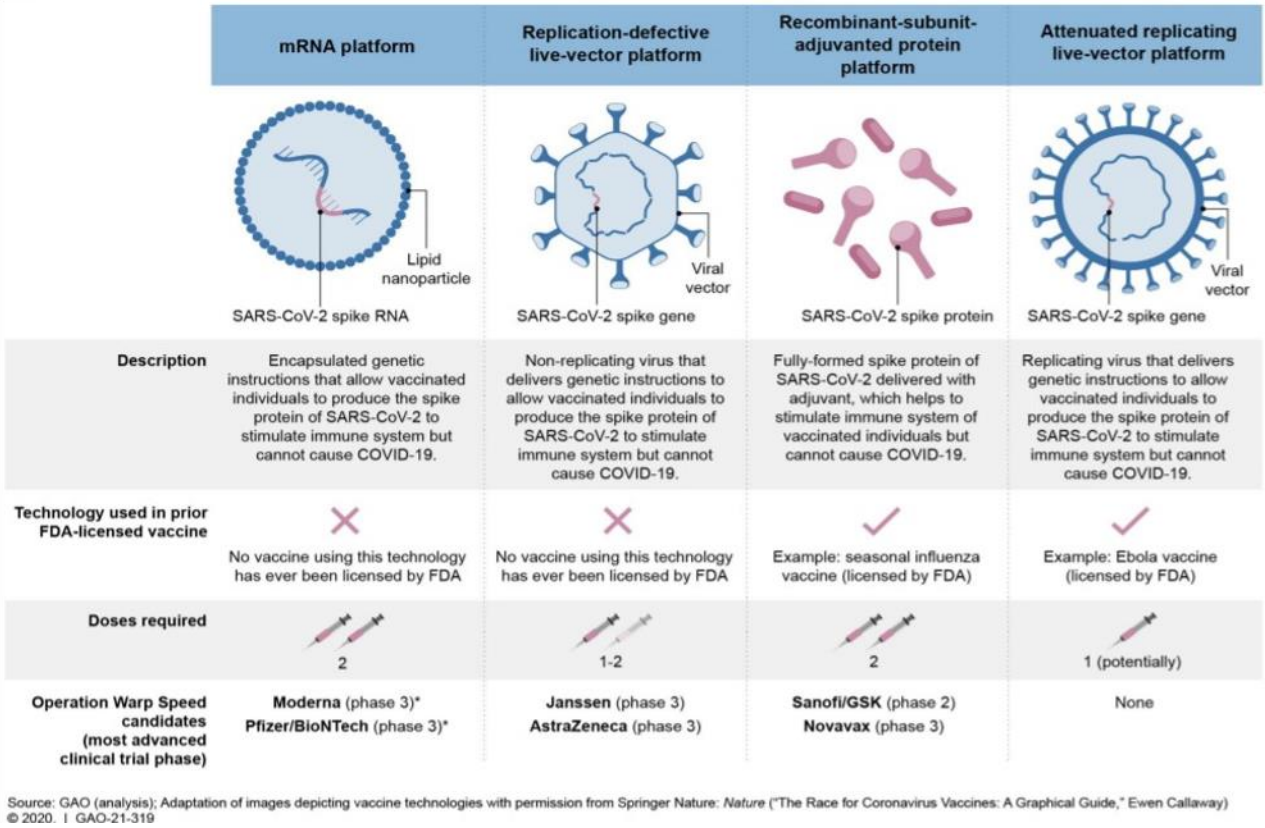


Source: GAO Analysis of Food and Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America, and Operation Warp Speed Information. | GAO-21-319

Multiple Platforms

OWS also deployed a strategic approach to new vaccine technologies by specifying that candidate vaccines had to use one of four platforms thought most likely to yield a safe and effective vaccine, with one being an mRNA platform, to minimize the risk that failure in one platform would fail the entire operation (Slaoui & Hepburn, 2020). Another GAO illustration best summarizes these four proposed platforms and the candidate vaccines supported by OWS in three of the platforms.

Figure 2: Overview of the Four Vaccine Platform Technologies Considered by Operation Warp Speed, as of January 2021



Source: GAO (analysis); Adaptation of images depicting vaccine technologies with permission from Springer Nature: *Nature* ("The Race for Coronavirus Vaccines: A Graphical Guide," Ewen Callaway)
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Clinical Trials

As previously discussed, clinical trials are one of the largest drivers of the high cost and prolonged timeframe in the traditional vaccine development process because this is the step that ensures safety and efficacy. In addition to financial support, OWS facilitated fast and high-quality vaccine research through:

- collaborations including the COVID-19 Prevention Network (CoVPN), which utilized existing federal government clinical-trial networks resulting in maximization of phase 3 trial study sizes,

- a master study protocol through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership,

- aligned phase 3 trial endpoints for all vaccine candidates, and

- optimized trial site selection using data modeling made possible in large part by the newly established HHS Protect system of real-time clinical data (Kuter et al., 2021; Slaoui & Hepburn, 2020; CEA, 2021a).

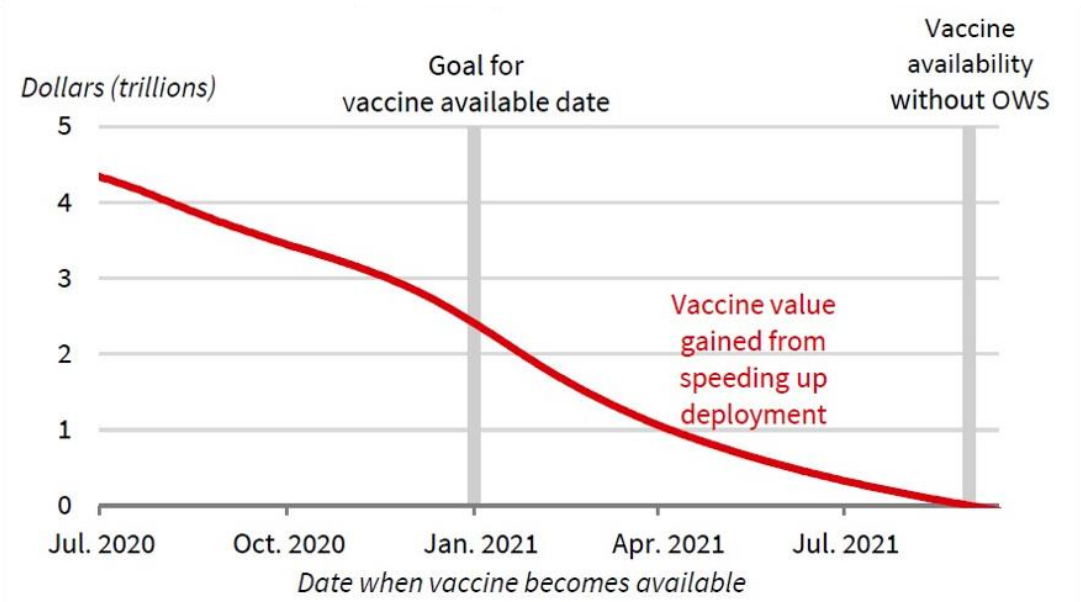
Manufacturing

While OWS allowed vaccine developers to start large-scale manufacturing during the clinical trials, the GAO report identified previous issues related to manufacturing that included: limited capacity, disruptions to supply chains, and gaps in the available workforce (GAO, 2021). OWS implemented multiple solutions throughout 2020 and January 2021, including utilizing Biomedical Advanced Research and Development (BARDA) and the Army Corps of Engineers to increase manufacturing capacity, determining common critical supply needs among vaccine developers, and executing 18 supply contracts under the Defense Production Act (GAO, 2021).

PUBLIC HEALTH AND ECONOMIC IMPACT

In a mid-November 2020 report, CEA estimated the value of faster vaccine development with OWS compared to an internal HHS projection of September 2021 without OWS. CEA estimated that developing and deployment of a COVID-19 vaccine by the end of 2020 would save $2.4 trillion in economic and health costs (CEA, 2021a, p. 122).

Figure 3: Value of Speeding Up a COVID-19 Vaccine Starting September 1, 2021



Sources: Institute for Health Metrics and Evaluation; Centers for Disease Control and Prevention; Congressional Budget Office; CEA calculations.
Note: OWS = Operation Warp Speed.

VACCINE DISTRIBUTION

Vaccine distribution is one of the most difficult aspects of any pandemic response because it requires clear identification and prioritization of the most vulnerable population groups and effective communication and coordination to ensure doses are distributed promptly and that the American people are willing to receive them. The latter requires not only

information about the location of vaccination sites but also education to ensure the American people have enough trust in the vaccine to want to take it.

With new vaccine development costing several billion dollars, the stakes for successful distribution during a pandemic are particularly high (CEA, 2019). Timely access to a new vaccine during a pandemic affects the confidence American people have in government pandemic planning and response, as well as the incentives for pharmaceutical companies to prioritize their work on new vaccines (GAO, 2011, Lo et al., 2020). As COVID-19 demonstrated, even if vaccine surpluses are stored in the Strategic National Stockpile, there is no guarantee that those same vaccines will be useful for a novel pathogen, which indicates that the distribution of new vaccines must be part of pandemic planning.

In designing an approach for accelerating vaccine development, approval, and distribution, the Trump Administration began by looking at the country's most recent experience in addressing a national pandemic outbreak.

Recent Frames of Reference

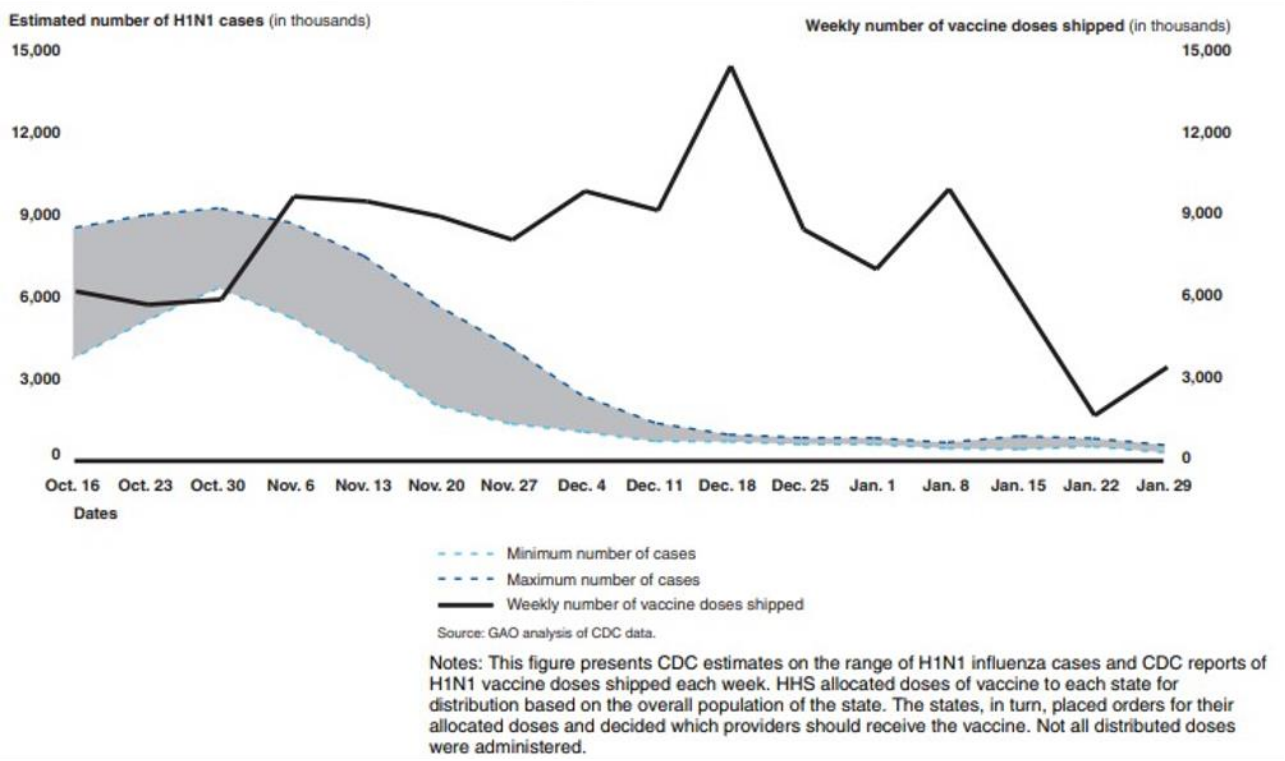
The most recent experience for vaccine development and distribution—and the first national-scale effort undertaken after the creation of specific agencies like BARDA and the Office of the Assistant Secretary for Preparedness and Response (ASPR) tasked with vaccine development and distribution—was the response to the H1N1 influenza outbreak in 2009. Fortunately, that virus was far less severe than COVID-19. The testing for the virus was also far less precise and less consistent, with the Obama Administration halting testing altogether at one point (Re, 2020). As such, the true number of individuals infected and the full extent of the virus's spread remains unknown to this day. The depiction of "virus activity" in the chart below (as cited in GAO, 2011, p. 26) comes with a dose of imprecision and uncertainty.[1] Given that the vaccine for seasonal influenza was not effective for H1N1, the Obama Administration needed to produce unique vaccines for H1N1, with the added objective of vaccinating the American public during flu season with two different strains of influenza (CDC, n.d.-c). A report on lessons learned from the H1N1 response noted that "[t]he credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials" (GAO, 2011, p. 27). The report went on to describe:

> During the summer of 2009, HHS conveyed to state and local jurisdictions, and to the public, that a robust H1N1 vaccine supply, about 120 million to 160 million doses, was expected to be available in October 2009. Ultimately, only about 23 million doses of H1N1 vaccine were allocated for ordering by states and local jurisdictions at the end of October 2009, and because of the time required to order and ship the vaccine, fewer than 17 million doses were shipped out that month (GAO, 2011, pp. 27-28).

[1] The CDC estimates that from "April 12, 2009 to April 10, 2010…there were 60.8 million cases (range: 43.3-89.3 million), 274,304 hospitalizations (range: 195,086-402,719), and 12,469 deaths (range: 8868-18,306) in the United States due to the (H1N1)pdm09 virus" (CDC, n.d.-c).

The failures in vaccine distribution in 2009 resulted in a loss of trust by both state and local governments and the American public in the federal government's ability to protect them from the virus. The same report describes that "[c]onsequently, the public had an unfavorable view of the federal government's ability to provide the country with the H1N1 vaccine," and cites a Gallup poll that found that "54 percent of adults said the federal government was doing a poor (41 percent) or very poor (13 percent) job of providing the country with adequate supplies of the vaccine," and a report that found "loss of government credibility was also a concern at the state level" (GAO, 2011, p. 28).

Figure 4: H1N1 Influenza Activity and Vaccine Availability, October 2009 through January 2010



Source: GAO analysis of CDC data.

Notes: This figure presents CDC estimates on the range of H1N1 influenza cases and CDC reports of H1N1 vaccine doses shipped each week. HHS allocated doses of vaccine to each state for distribution based on the overall population of the state. The states, in turn, placed orders for their allocated doses and decided which providers should receive the vaccine. Not all distributed doses were administered.

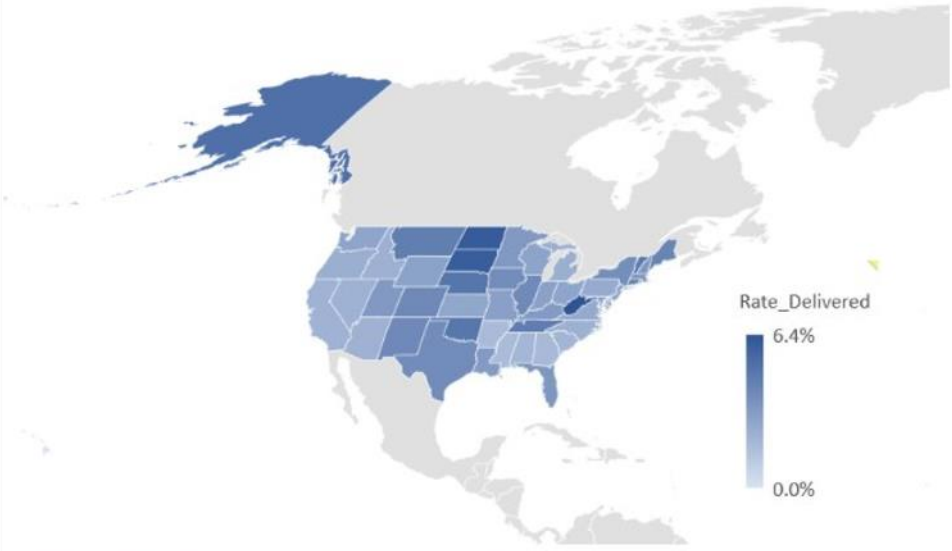
Charting a New Course

Left with an obsolescent model of vaccine distribution and faced with a novel and highly contagious virus, the Trump Administration needed to fundamentally rethink how distribution should take place to most rapidly and efficiently vaccinate the American people. OWS assigned primary responsibility for vaccine distribution to the DOD—one of the key intragovernmental partners— because of its expertise in logistics and capacity to engage in a mission-focused, nationwide mobilization of personnel and resources. Additionally, U.S. agencies that could have been considered were fulfilling other roles in the response. The Federal Emergency Management Agency (FEMA), whose planning and strategies are designed for an all-hazards response, was mobilized on a nationwide scale early in the pandemic to lead the overall COVID-19 operational response, relying on its logistical and tactical expertise from more than2 decades of responding to large, often weather-related, disasters (FEMA, 2021a). ASPR, established in 2006, does not have the relative Cabinet-level

seniority, and mobilization of this scale would likely have been challenging as the majority of its $2.6 billion fiscal year 2021 budget was already allocated to other critical aspects of the response— BARDA and the Strategic National Stockpile (Dornauer, 2020). The Public Health Service Commissioned Corps were mobilized during the COVID-19 response with a primary focus on clinical response efforts, including augmentation of hospital and public health department resources and provision of medical attention to those in need of testing, vaccination, or treatment (PHSCC, 2021). General Gustave Perna, a four-star Army general with four decades in logistics management, brought specialized experience to OWS vaccine distribution planning (Senate Armed Services Committee, 2020). Under his leadership, the DOD created a COVID-19 vaccine distribution program with the help of a custom-built technology platform and ran training and rehearsal exercises with states to refine their distribution planning (Simunaci, 2020). This ensured that the moment vaccines were approved, they would reach those individuals that needed them most urgently. On December 14, the Monday after Pfizer's COVID-19 vaccine received emergency use authorization from the FDA, Reuters reported that 141 out of 145 of the identified destinations received vaccine shipments and vaccinations successfully commenced (O'Donnell & Spalding, 2020).

Exactly 1 year from the WHO receipt of the viral genetic sequences, the U.S. had succeeded in vaccinating 7.7 million Americans, which was the highest vaccination rate among all G20 nations. The daily vaccination rate of 1 million per day was rapidly accelerating according to plan. This great American success story of grit and innovation was largely due to the effective public-private partnerships pursued by OWS (WHO, 2020; CEA, 2021b).

Figure 5: Percent of Vaccines Administered to Population Aged 18 and Above



Source: Operation Warp Speed; CEA Calculations
https://trumpwhitehouse.archives.gov/articles/operation-warp-speed-delivers-best-early-vaccination-rate-g20/

Two key assets in the distribution effort were HHS Protect and Tiberius, both data platforms developed by Palantir specifically for OWS's mission.

HHS Protect was designed as a comprehensive portal for detailed health data down to the hospital level to monitor health system conditions, forecast the pandemic, and serve as a platform to facilitate coordination of the entire COVID-19 response between federal agencies and state and local partners (HHS, n.d., Simunaci, 2020). For example, HHS Protect was used by the Trump Administration to identify regions and health systems under stress, rapidly deploy resources, and facilitate high enrollment in vaccine trials. Further, a team from the COVID Tracking Project at *The Atlantic* reported that 96% of U.S. hospitals submitted every data point to HHS in the last week of December 2020 and have found the data is harmonized with state-reported hospitalization metrics (Glassman et al., 2020; Madrigal, 2021). The data is now publicly available as a resource for all levels of government, hospitals, and all Americans, which lays essential groundwork for the level of data transparency needed to end the pandemic and build better health data infrastructures moving forward.

Tiberius, the technology platform developed by DOD, launched over Labor Day Weekend 2020 and was designed for the government to be able to "manage the various vaccine data and identify any issues that could prevent Americans from getting shots" (Loftus & Winkler, 2020). The platform aggregated data submitted by states and other sources (all without personal health or identifying information), assessed the demand of vaccine relative to the supply within manufacturing supply chains and was able to map out and identify at a zip code level where vaccines needed to get sent to most urgently (Simunaci, 2020). A recent *Nature Medicine* article found that 36 of 64 U.S. jurisdictions were using Tiberius as of March 2021, which is facilitating the use of CDC's Social Vulnerability Index to increase equitable vaccine distribution (Schmidt et al., 2021). Despite variable utilization of Tiberius by jurisdictions, it appears to be filling an important information gap and could still be expanded to facilitate efforts to get vaccines to all Americans who want them, particularly the most vulnerable.

As Tiberius came on board in September 2020, OWS released public strategic documents for its distribution plans to help guide states and jurisdictions to ensure efforts were coordinated. The distribution plan, "From the Factory to the Front Lines," outlined three "key components" of distribution:

> Partnerships with state, local and tribal health departments, territories, Tribes, and federal entities to allocate and distribute vaccines, augmented by direct distribution to commercial partners.
>
> A centralized distributor contract with potential for back-up distributors for additional storage and handling requirements.
>
> A flexible, scalable, secure web-based IT tracking system for ongoing vaccine allocation, ordering, uptake, and management (HHS, 2020b, p. 3).

The Interim Playbook for Jurisdiction Operations (Interim Playbook), released simultaneously, stated as the goal of the U.S. government "to have enough COVID-19 vaccine for all people in the United States who wish to be vaccinated," and that the playbook would help jurisdictions "plan and operationalize a vaccination response to COVID-19 within their jurisdictions" (CDC, 2020, p. 5). The Coronavirus Response and Relief Supplemental Appropriations Act of 2021, which was enacted on December 27, 2020, provided CDC with $8.7 billion to support the distribution of vaccines (CDC, 2021a). Out of a total of $4.29 billion of that amount reserved for states, territories, and localities, $3 billion was awarded in January 2021 (CDC, 2021a). Of that $3 billion, $300 million is "focused on high-risk and underserved populations, including racial and ethnic minority populations and rural communities" (CDC, 2021a). The remaining $4.25 billion of the $8.7 billion is reserved for the storage and handling of vaccines and supporting the data analysis and monitoring of vaccine distribution (CDC, 2021a). In tandem with this financial support and guidance from the Trump Administration to jurisdictions, the administration partnered with CVS and Walgreens to provide vaccines for free to those in long-term care facilities (De Lea, 2020). In November 2020, the Trump Administration entered into agreements with pharmacies across the country to augment the distribution of vaccines (Weixel, 2020; HHS, 2020c). With 7.7 million Americans having received the first dose by January 11, 2021, the Trump Administration announced that the partnership would expand to 40,000 pharmacies across the county to accelerate the vaccine distribution further (Roubein, 2021, Weixel, 2021, CEA, 2021b).

Accounting for Two Administrations

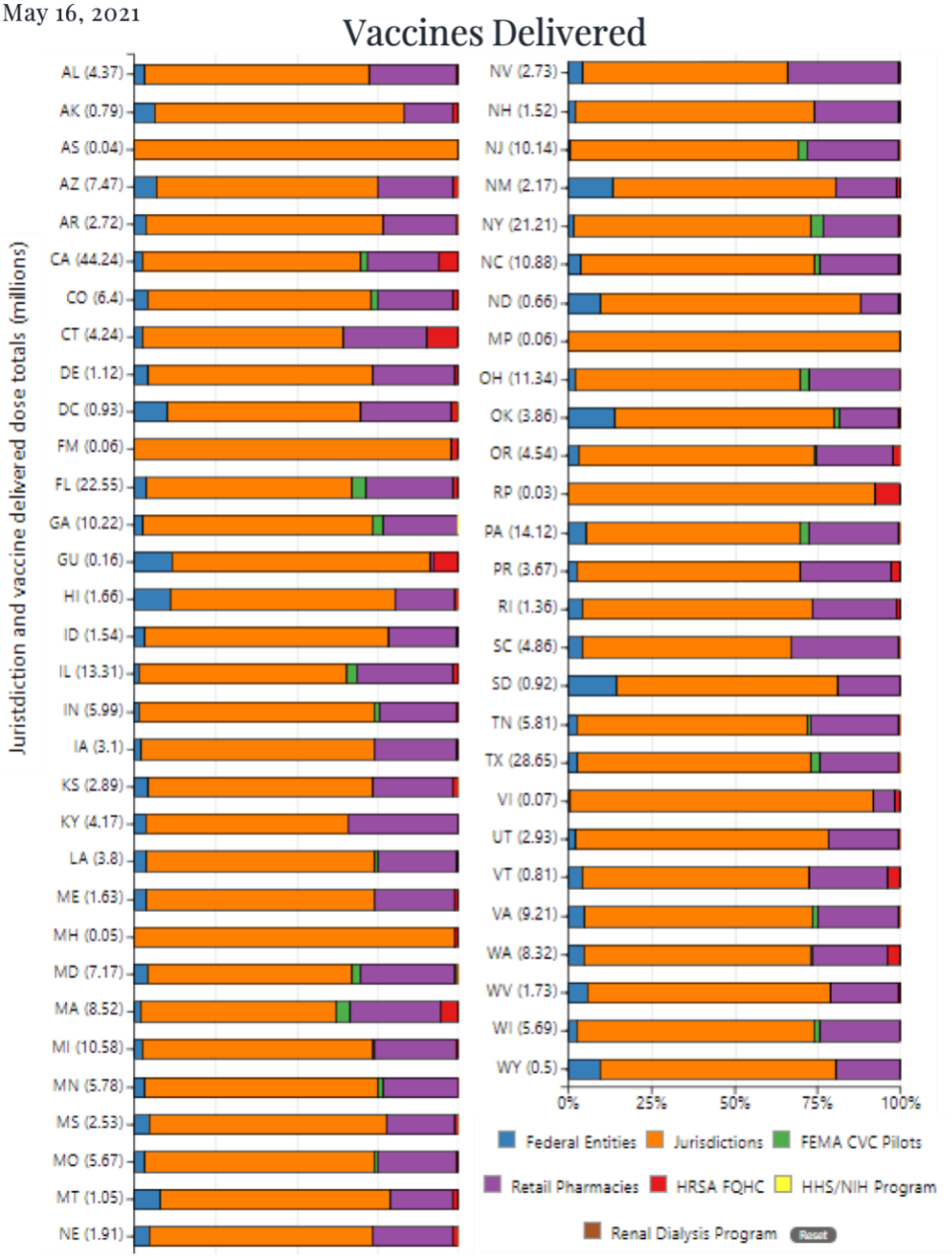
The COVID-19 vaccine distribution has evolved in a particularly unique way as it took place across two presidential administrations, which shared many elements in common but differed to an extent regarding the degree of vaccine distribution centralization by the federal government. While both administrations stated their chief goal was to support states, the Trump Administration took a traditional federalist approach where states informed and played a large part in the decisions regarding how and where distribution should occur. The Interim Playbook provided states with templates, and states submitted vaccine distribution plans to the CDC for review (CDC, 2020). The CDC then provided iterative feedback to state and local partners to help refine their plans. The White House Coronavirus Task Force served as a convening force for interagency partners but maintained that its primary role was to provide resources to support state and local leaders—particularly through the nearly 50 calls between senior federal leaders, including the vice president, governors, and their teams—as they made vaccine distribution plans (The White House, 2021). This included providing data and expertise to those best positioned to make dynamic decisions on how to succeed in addressing the priority needs of their most vulnerable communities.

A media report recently highlighted a difference in the level of leadership engagement and regular communication between governors and the White House, with governors noting that the Nation's top leaders were readily accessible in the Trump Administration (the vast

majority of calls were led by former Vice President Mike Pence, who had previously served as the Governor of Indiana) (Wegmann, 2021). This level of engagement has not continued in the current administration, leading some governors to express frustration about communication gaps and lack of access to the top decision-makers (Wegmann, 2021).

The Biden Administration has largely carried on many of the operational components of OWS, including nearly the same vaccine rollout plan with a target of all adults having access to the vaccine by the end of May—a one day difference from the OWS goal of making 300 million doses available by June 1, 2021 (Florko, 2021). They have also demonstrated a continued reliance on or expansion of the public-private partnerships outlined above while adding some centralized components to vaccine distribution, primarily through FEMA (FEMA, 2021b). With these components, the federal government determines and prioritizes vaccination site locations, emphasizing a mass-vaccination campaign augmented by the domestic deployment of military personnel. FEMA has reported large financial and personnel investments in federal programs in recent months (FEMA, 2021b). Still, CDC data through May 16, 2021, demonstrates that only a small fraction of vaccinations have occurred through federal entities, while jurisdictions (state, territory, freely associated state, tribe, or local entity) are the largest recipients of vaccine deliveries, followed by retail pharmacies (CDC, 2021b).

Figure 6: U.S. COVID-19 Vaccination Program: Vaccine Channel Portfolio by Jurisdiction Updated
May 16, 2021



Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/jurisdiction-porfolios.html

NEW QUESTIONS

In a March 2021 viewpoint, members of the Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force who represent 10 countries, questioned how OWS vaccines would be used for COVID-19 prevention in global health settings (Kim et al., 2021). While recognizing its benefit, the authors described OWS as a form of "so-called vaccine nationalism" because it prioritized the needs of the U.S. over others in need. That sentiment, however, is an

incomplete picture of the U.S. approach outlined in an Executive Order from December 8, 2020, which stated:

> It is the policy of the United States to ensure Americans have priority access to free, safe, and effective COVID-19 vaccines. After ensuring the ability to meet the vaccination needs of the American people, it is in the interest of the United States to facilitate international access to United States Government COVID-19 Vaccines (EOP, 2020c, p. 79777).

The question now is how the U.S. can best contribute to global COVID-19 vaccination. One path is through multilateral channels such as the COVID-19 Vaccine Global Access (COVAX) program, which is co-led by the Coalition for Epidemic Preparedness Innovations, Gavi, the Vaccine Alliance, and WHO. The other option is one that prioritizes bilateral agreements and the types of private-sector solutions that have proven critical to the success of the U.S. vaccination drive over the past 6 months (So & Woo, 2020). The latter approach was favored by the Trump Administration, which opted not to engage with COVAX but did work directly with other countries on vaccine distribution arrangements (AP, 2020, So & Woo, 2020). In a shift from the previous administration, the Biden Administration has pursued a more multilateral route, having made a $4 billion commitment to COVAX, although the initiative has not met its objectives thus far (Kim et al., 2021, Steinhauser et al., 2021).

The Biden Administration has also supported a World Trade Organization (WTO) proposal that would temporarily waive the intellectual property rights of COVID-19 vaccine makers to potentially allow others to manufacture their COVID-19 vaccines using the breakthrough technology that was accelerated by OWS (USTR, 2021). This decision has been heavily criticized, as commandeering intellectual property rights from U.S. companies after the fact may undermine the willingness of the private sector to engage in future public-private partnerships with governments at any level (WSJ Editorial Board, 2021a, Borio & Gottlieb, 2021). Moreover, even ignoring future ramifications, this action alone will not yield immediate results due to the lead-time required to establish manufacturing facilities for the new vaccine technology (WSJ Editorial Board, 2021b). Further, many of the global distribution strategies outlined above were already being executed before the Office of the United States Trade Representative announcement. While the U.S. continues to discuss how to best contribute to global vaccine distribution, it cannot be understated that American investment in innovation through OWS benefitted the world by addressing the COVID-19 pandemic and accelerating vaccine research a decade.

When the COVID-19 pandemic ends, the U.S. and the world will have to determine the new "steady-state" for vaccine research, innovation, and development for pandemic preparedness. OWS demonstrated what is possible with singularly focused research, strategy, and resources. Private-market incentives, however, are likely to recede to pre-pandemic levels unless new models are embraced, or novel approaches such as a nonprofit public utility approach described by Liljenquist and co-authors are implemented (Liljenquist et al., 2021).

WAY FORWARD

The implementation of OWS was unusual not only because it took place amid a pandemic but also because it took place across two different presidential administrations. Though COVID-19 messaging strategies differed between administrations—with the Trump Administration maintaining a more federalist approach centered on the principle of a "locally executed, state managed, federally supported" response—the Biden Administration is utilizing many of the same plans, on-the-ground personnel, and agreements as OWS. The current administration has implemented an increased role for a federally centralized component that has, to date, only accounted for a small fraction of the total vaccinations. In short, the current COVID-19 vaccine delivery system in the U.S. appears to rely heavily on the operational models established by OWS for public-private partnerships and jurisdiction-led vaccine efforts, with the new federal programs providing additional contributions on the margin. As such, it is not surprising that the current trajectory of administered vaccines also matches the outlined goals and projections of OWS, though conclusive takeaways about vaccine deployment that would have proceeded under the continuation of the previous federal approach are not feasible.

As far as vaccine development and approval, the experience of OWS raises several considerations for future pandemic planning and pharmaceutical development in general. The first and most foundational reflects the very reasons the administration initiated this effort: the existing government agencies tasked with accelerating vaccine development and distribution, namely BARDA and ASPR, could not rise to the task to facilitate these processes at the scale COVID-19 demanded. How successful would vaccine development have been, and what would have been the impact on stopping the pandemic, had the previous administration only relied on those government agencies created for these purposes?

When designing future pandemic preparedness plans, these issues on the optimal location of innovation and the ideal balance of centralized versus locally executed, state managed, federally supported approaches to the development and distribution of COVID-19 vaccines should be at the forefront, alongside foundational questions about designing effective public-private partnerships to address Americans' most urgent needs. Lessons learned from the innovative OWS approach, much of which was adopted by the Biden Administration, are transferrable to addressing other pressing national challenges, such as cybersecurity. These lessons could also inform the associated budgetary lines and bureaucratic processes, including intellectual property protections to maximize effectiveness. As exemplified by OWS, the measure of success of future responses will ultimately rest on the speed and quality of the effort to protect the public. Moreover, the American people now know that unprecedented, successful innovation that can reverse the tide of a pandemic is possible through investment, public-private partnerships, dynamic leadership, and a "whole-of-America" response.

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