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Can Operation Warp Speed Serve as a Model for Accelerating Innovations Beyond Covid Vaccines?

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Executive Summary

Operation Warp Speed (OWS) was a roughly \$18 billion program undertaken by the U.S. government to accelerate the development, production, and administration of vaccines in the heat of the COVID-19 pandemic. The success of the program in shortening the typical development cycle by an order of magnitude—using a completely new delivery technology (mRNA) no less—has led to calls for using programs modeled after OWS for other innovations that would potentially have great social value.

The various elements of the OWS we detail can be synthesized into two maxims concerning spending to avert an existential crisis: spend prodigiously, leaving no stone unturned; spend effectively, cutting red tape. The rollout of vaccines under OWS experienced fewer hiccups than therapeutics and diagnostics rolled out outside of the program, suggesting the maxims have some merit. However, the large OWS budget was spent with fewer checks and balances traditionally in place to minimize waste, fraud, and abuse, suggesting that the OWS model for accelerating innovation involves risks and thus presents a tradeoff. The strongest cases for the OWS model are emergencies checking three boxes—scale, speed, and spillovers. These three boxes are obviously checked by wars, pandemics, global warming, and other existential crises.

In cases in which some but not all boxes are checked, such as Alzheimer's, devastating as this endemic disease is, it may not be necessary to abandon traditional markets and legislative processes to incentivize innovation. Still, there may be scope for improving incentives by adopting elements of OWS that do not require relaxing checks and balances—such as encouraging multiple shots on goal, even some long shots, or reallocating some funding from push to pull.

I. Introduction

Operation Warp Speed (OWS) was a large-scale public-private partnership among the Department for Health and Human Services, the Department of Defense, and commercial manufacturers to mitigate the COVID-19 pandemic by advancing vaccine, therapeutic, and diagnostic candidates between May 2020 and February 2021. OWS resulted in the development, manufacturing, and deployment of Moderna’s and Pfizer’s vaccines across the United States in 2020, along with the Johnson & Johnson vaccine in 2021. Focusing on programmatic execution, the ambitious timeline and scope of OWS was “unprecedented”, especially compared to previous public health emergency response efforts such as the West African Ebola virus epidemic in 2014 (Slaoui and Hepburn 2020). The scale of the program has led to comparisons to other innovative government programs like the Manhattan Project and the Apollo Program.

It is estimated that within six months, OWS-funded vaccines saved the lives of 140,000 Americans and delivered nearly \$2 trillion in economic benefits (Gupta et al. 2021). For context, between 2020 and 2021, the pandemic resulted in a \$26 billion loss a day (Baker et al. 2021). By contrast, OWS cost around 12-hours’ worth of COVID-19 daily costs (Baker et al. 2021). While an OWS-style program would not be feasible for every science and technology challenge, specific elements could be applied more broadly.

One basis of OWS was a memorandum of understanding between HHS and DoD, which highlighted five areas of effort, vaccines, therapeutics, diagnostics, supply, production and distribution and security assurance. The OWS senior leadership team was led by Dr. Moncef Slaoui, General Gustave Perna, Paul Mango, and the directors of the five areas of focus.

To determine how features of the OWS program can be harnessed to address current science and technology challenges, this paper identifies seven key programmatic features that depending on the context could be institutionalized more broadly and reviews current OWS-style successor efforts. This paper proposes how a future “Operation Warp Speed for pandemic prevention” could institutionalize key programmatic features by creating a Pandemic Prevention Task Force to routinely exercise capacity and a special projects ARPA-H Office to institutionalize OWS-style high-risk high-reward investment. Together, these efforts would help shift the pandemic prevention paradigm away from panic and neglect and towards keeping critical capabilities and infrastructure warm. Lastly, these efforts are contrasted with the reusability of OWS to address challenges such as Alzheimer’s Disease.

II. Background on the OWS Episode

OWS, like other innovative government programs such as the Manhattan Project and the Apollo Program, took lessons from the World War II-era Office of Scientific Research and Development (OSRD), which focused on applied research and technology.¹ The creation of the OSRD marked a period of technological collaboration between the military and scientific community, and resulted in innovations from radar-controlled glide bombs to the antimalarial quinacrine (Boyce 1947, Tognotti 2009). Like OWS, OSRD addressed the full spectrum of research, development, manufacturing, and implementation, and operated with a committed buyer. Other similarities between OSRD and OWS include the emphasis on speed, use of parallel funding, and taking on manufacturing risk (Gross and Sampat 2022).

Additionally, all three of these programs were well resourced in manner that allowed for the flexibility needed to enable their ambitious visions. By 1945, the Manhattan Project cost approximately \$2.2 billion in nominal terms, or \$37 billion in 2023 dollars (Metcalf 2023). The Apollo Program cost an estimated \$25.8 billion, equivalent to \$257 billion in 2020 (Dreier 2022). By comparison, OWS cost around \$18 billion (Tozzi, Giffin, and Stein 2023).

Unlike its predecessors, OWS focused less on discovery and more on programmatic execution. Strategic principles behind the program to accelerate development included, having a diverse portfolio to lessen likelihood of failure whether from manufacturability, safety, or efficacy, accelerating the programmatic timeline without compromising safety by using parallel workstreams despite financial risk, increasing the phase 3 trial populations for each vaccine candidate to increase safety and efficacy data, providing support to the private sector for phase 3 trial preparations as phase 1 applications were submitted, harmonizing phase 3 trial clinical endpoints, and proactively scaling-up manufacturing capacity and stockpiling vaccine doses (Slaoui and Hepburn 2020).

Structurally, OWS was a public-private partnership that included a program lead from industry. Rather than a traditional taskforce, OWS was a whole-of-government response to a crisis. Additionally, OWS relied on broad executive authorities reserved for emergencies. Moreover, the ability of OWS to meet its mission was dependent on three key pieces of additional context, there had been a previous SARS epidemic, the COVID-19 infection fatality rate is lower compared to other emerging infectious diseases (Wilder-Smith 2021), and there had been decades of investment in mRNA research and development.²

OWS relied on the Defense Production Act (DPA) to prioritize producing vaccine components, for instance by scaling up production of vaccine vials when faced with shortages (Bostock 2020; Siddalingaiah 2021; Nocera and McLean 2023). The current version of the Defense Production Act was reauthorized in 2019, empowering the president to restrict the hoarding of key supplies, allocate “materials, facilities, and services,” and require companies to prioritize government orders to maintain national defense through executive order (Siripurapu 2021). The Defense Production Act also provides antitrust protection, allowing companies to coordinate. It permits the president to make purchase commitments, loan guarantees, prevent exports, and install equipment. During the COVID-19 pandemic, President Trump used the Defense Production Act to require General Motors to produce ventilators, prevent the export of personal protective equipment, prevent the hoarding of key resources, and declared meat processing plants “critical infrastructure” in response to concerns of plant closures. Through OWS, President Trump used the Defense Production Act 18 times by the end of 2020.³ President Biden also used the Defense Production Act, such as to equip two manufacturing facilities to ensure timely production of the Johnson & Johnson vaccine (Lupkin 2021).

III. The Economics of Key OWS Elements

In this section, we identify and discuss seven elements of the OWS model contributing to its success in accelerating the rollout of vaccines during the pandemic. After presenting this “laundry list” of elements, we draw out common themes from them and discuss which might be the most readily reusable for future programs.

A. Prodigious Funding

Initially, OWS received around \$10 billion in supplemental funding through the CARES Act, directing \$6.5 billion to the Biomedical Advanced Research and Development Authority for the development of medical countermeasures and \$3 billion to the National Institute of Health for research.⁴ Bloomberg News reported that additional funding was reallocated to OWS from other public health programs, totaling OWS’s budget to the \$18 billion (Tozzi, Griffin, and Stein 2023). Examples include reallocating \$6 billion from the Strategic National Stockpile to acquire PPE and ventilators and \$700 million from the Center for Disease Control, \$300 million of which was

intended for an advertising campaign.⁵ These transfers highlight OWS’s reliance on flexible funding to meet its ambitious timeline allowed for in emergency appropriations.

B. Multiple Shots on Goal

The goal of OWS was to obtain a safe and effective vaccine that could be widely rolled out to the population to protect citizens’ health and provide reassurance that would allow schools and the economy to reopen. While having multiple successful vaccines to choose from is “nice to have,” most of the benefit—the “must have”—comes from having *some* vaccine to roll out in the population. OWS did not pursue just one candidate to obtain that one success. To increase the chance of scoring quickly, it is worth taking multiple shots on goal. Historically, success in bringing individual vaccines through clinical trials to approval is far from certain (Lo et al. 2020), too low to bank the health of the nation on one shot.

That OWS was taking multiple shots on goal provided an environment in which it could invest in a portfolio of technologies. The technologies covered by OWS included mRNA (Moderna and Pfizer), viral vector (Janssen and AstraZeneca), and adjuvanted protein (Sanofi/GSK and Novavax) vaccine candidates. Failure risks are correlated within technologies: a given technology may simply not be suited to combat the given pandemic pathogen, and so if one fails it may be an indication that every candidate in its technology class might also fail. Pursing different technologies reduces the correlation in the failure risk and improves the probability that some candidate succeeds.

To illustrate these points, it is instructive to work through a much-simplified exercise of investing the optimal portfolio of vaccine candidates. Table 2 in Athey et al. (2022) presents a list of 20 of the most promising candidates in development when OWS was making its decisions. The authors estimated probabilities of success of individual candidates and the correlation in failure rates among them based on the modeling work of Ahuja et al. (2021). Their model generates correlation in failure by assuming that failures can be generated at various levels, and failure at any one level spells failure for the product, as in Kremer’s (1993) O-ring theory of product development. There is a chance that no vaccine will work for COVID-19, then a chance that a given technological platform might fail (inactivated virus, viral vector, mRNA, DNA, etc.), then subcategories within a platform. Even if no failure is experienced at higher levels in the hierarchy,

individual candidates within a subcategory can always fail, more likely the earlier in the development pipeline.

Consider forming a portfolio of four vaccines out of this list of 20 to maximize the probability of at least one success. According to the model, four candidates had the highest probability of success (estimated to be 29%) because they were already far along in clinical trials (phase 3) and used traditional delivery technologies for vaccine delivery (inactivated virus and viral vector). If one assumes, counterfactually, that failures are independent events across the four candidates, the probability of at least one success equals the complement to the probability that all four fail: $1 - (1 - 0.29)^4 = 75\%$. But the failures are not independent events. Three of the candidates happen to use the same inactivated-virus delivery platform. All may fail if that delivery platform happened not to work for COVID-19. According to model estimates, which take into account the correlation in failures, the probability of at least one success in the portfolio of the four candidates that have the highest standalone probabilities of success is only 63%. (see Figure 2 in Athey et al. 2022).

Selecting the candidates with the highest probability of success does not lead to the optimal portfolio in this case. The portfolio of four candidates can be improved by substituting the most promising mRNA candidate for one of the three using the inactivated-virus delivery platforms. Even though the mRNA candidate was ascribed a lower standalone probability, 22%, lower because its delivery platform had never been used before in vaccines, it would still be better to include it because its failure is less correlated with the other vaccines in the portfolio than a third with the same delivery technology as others. Including the mRNA technology increases the probability of at least one success in the portfolio of four vaccines up to 66%. A three-percentage-point increase may seem small, but when multiplied by the trillions of dollars of surplus from mitigating pandemic harm with a successful vaccine, it is a nontrivial improvement.

The OWS portfolio did include two mRNA vaccines despite pessimism among some scientists about whether the technology would ever prove practical, based in part on a decade previous disappointing experience with the related DNA technology (Hwang 2024). It turned out to be fortunate that mRNA vaccines were included. Pfizer and Moderna's mRNA vaccines ended up being the dominant vaccines distributed in the United States. Some of the other technologies that received approval were found to have side effects among especially younger patients, which, despite being extremely rare, led their use to be curtailed. Taking multiple shots on goal not only

increases the chance of some success but also increases the chance of multiple successes, which generate additional benefits when some of the apparent successes do not pan out or when there is heterogeneity in effects so that different candidates may produce more benefits in different situations (say different candidates are better for certain populations by age, gender, race, or location).

Competitive forces on their own may not lead to the optimal spread of firms across technologies, and there may be systematic reasons why the optimal portfolio should include an array of technologies including some that initially appear less promising. Hopenhayn and Squintani (2021) develop a theoretical model in which a fixed stock of researchers allocate themselves across project areas with different private returns. The free flow of researchers ends up equalizing average returns across different areas. Owing to congestion externalities, arising from researchers cannibalizing some of the returns from others in the same area, marginal social returns may remain quite unequal across areas despite the equalization of average private returns. Put simply, researchers tend to overcrowd the most promising areas, to the detriment of social welfare and overall innovation.

Adapting Hopenhayn and Squintani's (2021) model to the OWS setting, in which the same revenue would be obtained by a safe and effective vaccine whatever the underlying technology, the difference in firms' private returns would be driven by differences in cost and probability of success. The logic of the model would suggest that firms predictably overcrowd traditional technologies with more initial promise, leaving more difficult/speculative technologies such as mRNA underexploited. The marginal social returns for mRNA candidates may be higher than traditional candidates, providing a rationale for at least giving a second look to non-traditional candidates in the portfolio, not *despite* but precisely *because* they are more difficult/speculative. Of course there is a limit to the argument: while difficult/speculative technologies may deserve a second look, there may be some with so little promise as not to be worth funding.

OWS could have saved money by taking the multiple shots on goal sequentially rather than simultaneously. Once one succeeded, further investment in other candidates could be saved. The urgency involved in pandemic response precluded a sequential approach. Supposing optimistically that each candidate could be developed within a year from start to finish, the last candidate in a portfolio of four of them would take four years to get to, the last in a portfolio of five would take five years to get to, and so forth, while the population would suffer for lack of a vaccine if no

earlier candidates did not generate a success. On the other hand, if developed in parallel, a portfolio of arbitrary size could be accomplished in the same year (or whatever development period is required for a single candidate). Parallel development might even experience economies of scope from conducting clinical trials of several candidates together, since they could use the same control group, and so require fewer total subjects.

Our toy example above considered constructing the optimal portfolio of four vaccine candidates. OWS was more ambitious, sponsoring not four but six candidates. As ambitious as the program was, some commentators urged even more shots on goal. The op-ed by Athey et al. (2020) called for the United States to invest \$70 billion in 15 to 20 candidates. The marginal improvement in probability of some success obtained by including the 20th candidate might just be a fraction of a percentage point, but, again, a small chance of saving trillions of dollars of harm is worth additional investment, even in the billions of dollars.

During the Manhattan Project, a key bottleneck in building the atomic bomb was enriching enough uranium to supply the needed amount of fissile material. As discussed in Hewlett and Anderson, Jr.'s (1962) history of the Project, it undertook not one but three approaches to enriching the uranium needed for the atomic bomb (magnetic field, gaseous diffusion, and liquid thermal diffusion). The Project built three large-scale production plants using each of the technologies despite none ever having been tried before. Although the Project was keenly interested in the success of some technology, it ended up expediting the construction of the atomic bomb by using a bit of enriched uranium from each plant, just as the availability of multiple approved vaccines during OWS could expand the supply of vaccines, expediting their rollout to the population.

The more shots on goal a program takes, the costlier it will be. Taking many expensive shots on goal necessitates spending prodigiously. Thus, the element of OWS discussed in this subsection is not independent of the element discussed in the previous subsection; the subsections are closely interrelated. This subsection also anticipates some of the material in the next: taking multiple shots on goal enables taking some long shots. The next subsection is more of a shift in focus than an introduction of a new element of the OWS program. Rather than focusing on the number of candidates in the optimal portfolio, it focuses on explaining why the portfolio might include some long shots.

C. Taking Long Shots

The previous section hinted at some reasons for taking long shots in a crisis setting like a pandemic. As mentioned, the Athey et al. (2020) op-ed called for a much larger portfolio than OWS ultimately included, as many as 15 to 20 candidates rather than six. Presuming that candidates with the most promise would already have been selected for smaller portfolios, the marginal candidates added to form increasingly larger portfolios would start to include increasingly longer shots. According to the estimates shown in Table 2 of Athey et al. (2022), the marginal candidates added to the optimal portfolio of size 20 include a vaccine with an 9% standalone probability of success (owing to its use of the speculative DNA technology platform) and another with an 8% standalone probability of success (owing to its being very early in preclinical development). Those marginal candidates contribute less than a half a percentage point to the overall probability of at least one success in the portfolio. Yet a case can be made for expanding the optimal portfolio to include those candidates because even a tiny increase in the probability of program success when multiplied by the enormous losses that might be averted by a successful vaccine justify even the expenditure of billions of dollars of investment in the marginal candidates, “spending billions to save trillions” as Athey et al. (2022) paraphrase.

The heavy investment by OWS in the mRNA vaccines can be viewed as a long shot taken by the program ultimately crucial for its success. That they became the “go to” candidates for COVID-19 primary series and boosters can lead one to forget the initial doubt expressed by some scientists and industry managers whether the technology was at all viable, never having been used for a vaccine in human history (Hwang 2023). The estimates in Athey et al. (2022) put the standalone probability of success of the most promising mRNA vaccines at 21%, but more skeptical experts put the estimate roughly at 0%. Outside a pandemic, it is not hard to justify holding off investing in excessively speculative technologies. During a pandemic, the tradeoff changes, and it becomes harder to justify not investing in speculative approaches, especially those that are less correlated with traditional approaches.

The enormous losses experienced during the pandemic rationalized another long shot that would rarely be undertaken under ordinary circumstances: at-risk capacity building. Under ordinary circumstances, a pharmaceutical firm would wait until its product received regulatory approval before undertaking any large capacity investments that would be wasted if the product fails to be approved. But in a pandemic, the social returns to having the vaccine faster are

potentially enormous. Installing vaccine capacity can be time consuming. Whether the capacity is coming from repurposing existing contract manufacturers' facilities to produce pandemic vaccine or greenfield construction of new facilities, installing vaccine capacity is complex, expensive, and time consuming. Regulators have to verify that the facilities are using good manufacturing processes (GMP). The lag from plan to production can take months or years. Time can be saved if firms expand capacity in parallel with clinical trials before regulatory approval. The drawback is that the expenditures on scaling up capacity will turn out to have no return (wasted in that sense) if the product fails to be approved. But the gain from speeding up vaccine by having vaccine ready to rollout not long after the approval date may be worth the risk of that wasted expenditure. At-risk capacity investment is a long shot that is hard to justify under ordinary circumstances but hard not to justify in a pandemic. Even if billions of dollars end up being expended on capacity for failed candidates, that expenditure is well worth even a modest chance of accelerating the availability of vaccines in a pandemic.

According to the estimates in Ahuja et al. (2021), if one credits the at-risk investment strategy with accelerating the availability of the OWS capacity by just three months, that credit translates into a \$390 billion reduction in pandemic harm in the United States. The benefit from at-risk investment (measured in level terms) scales with the amount of capacity involved. Had OWS installed the capacity found by the Ahuja et al. (2021) analysis to be optimal—about twice that installed under OWS—the benefit to the United States of using the at-risk strategy to accelerate the availability of that capacity by three months would have been \$560 billion. The benefit to the world from accelerating optimal world capacity by three months was estimated to be \$3.4 trillion.

D. Combining Push and Pull Funding

The innovation process can be thought of as a pipeline leading from inventors' initial ideas through many stages including the development of prototypes, engineering refinements, through scale up of capacity for widespread production. Various policies can try to boost innovation incentives by adding funds at either end of the pipeline. The policy of picking promising innovators at the start and funding their costs as they proceed through the pipeline, typically via grants, is called “push” funding. An alternative funding mechanism, “pull” funding, dangles a reward for success at the end of the pipeline, whether in the form of a patent promising a lucrative commercial market, a

lump-sum prize for solving a puzzle, or a purchase contract for producing a certain quantity of a product meeting a technical profile. Push pays for attempts; pull pays for success. Each form of funding has pros and cons. The conditions under which push or pull is optimal is still under investigation, but the answer will undoubtedly build on the prior theoretical literature of optimal innovation policy, including such seminal work as Wright (1983) and Weyl and Tirole (2012).

In a pandemic, when the risk of not developing a vaccine is much more damaging to society than spending a billion dollars too much, the perspective is not so much “either or” as “both and.” Uncertain as to whether push or pull would provide the best incentives, OWS used both. Except for Pfizer, which rejected push funding (presumably to avoid any government claims on its intellectual property), the rest of the firms funded by OWS received push funding, paying R&D expenses as well as some of the expenses involved in scaling up at-risk capacity. All the firms received push funding from OWS provided push funding in the form of advance procurement contracts, signed before firms even had approved products, promising a per-dose payment for a specified quantity upon the authorization of the U.S. Food and Drug Administration (FDA).

Athey et al. (2022), expanding on the insights in Ahuja et al. (2021), discuss some of the virtues of using a mix of push and pull for funding innovation in crises. As we have discussed, crises call for multiple shots on goal some of which may be long shots. To use pull funding to induce the investment of marginal candidates—the long shots—can be quite expensive, and the need to offer that contract to inframarginal candidates as well only multiplies the expense. Push funding can economize on some of that expense, as can be demonstrated by a simple numerical example.

Suppose that a program wants to invest in a portfolio of the five candidates with probabilities of success, to use some round numbers, of 50%, 40%, 30%, 20%, and 10%. Suppose that bringing a candidate through the development pipeline to approval and at-risk capacity investment amounts to \$1 billion per firm. To simplify, normalize production costs and the required rate of return on capital both to zero, so that we will assume a firm is willing to participate as long as the revenue it expects from the pull contract exceeds \$1 billion, covering its up-front investment. Since firms only obtain the pull-funding revenue if they succeed, to break even, revenue must equal the up-front cost times the reciprocal of its probability of success. The firm with 40% probability of success must earn at least \$2.5 billion conditional on success. The firm with 10% chance must earn at least \$10 billion, which a uniform program would pay not just to

that firm but would set the price that a uniform program would pay to any successful candidate. The expected outlay from that pull-funding program is \$15 billion, equal to the \$10 billion paid to any successful firm times the sum of the probabilities that firms succeed: $50\% + 40\% + 30\% + 20\% + 10\% = 150\%$.

Consider an alternative program that funds firms' investments via push. Assume that a firm is willing to invest as long as grant funding covers its \$1 billion up-front expense. A push-funding program inducing all five firms to participate would cost \$5 billion, a third of the expense we computed for the pull-funding scheme.

Push also transfers some of the risk of sunk investment from the firm to the funder. This may have an advantage if the funder has some ability to control the risk (say the government can relax the approval guidelines to increase the probability of success or can follow through on its procurement promises). It may reduce the firm's need to raise capital that may be quite costly if it reflects an unusually large risk premium that may have to be covered in a crisis situation with at-risk investment in the presence of a low probability of success and uncertain norms about overcharging in a pandemic. There may be a limit to how much capital a small pharmaceutical company like Moderna can access in a short time, which might fall well short of the substantial amount needed to take a vaccine through the large clinical trials necessary and to spin up the capacity necessary to cover a substantial fraction of the U.S. population.

Directing the firm to invest at-risk and agreeing to cover its expenses if so may be the most direct way to induce firms to undertake the at-risk strategy, which the previous subsection argued has such high social value but is how commercial firms ordinarily behave.

Thus, push can thus incentivize speed simply by directing firms to make early investments that the funder pays for. Incentivizing speed with pull raises some difficulties. If the contract does not specify delivery dates, firms could save money by installing limited capacity and delivering doses over an extended period. Incentives for speed could come from specifying a target date and adding bonuses for early delivery or penalties for late delivery. But the ability to meet a target date may depend on events outside of the firms' control. Bonuses and penalties may increase risk and consequently the firms' cost of capital. As Castillo et al. (2021) note, a penalty reflecting the social harm from delayed vaccine availability in a pandemic may be higher than most firms are willing to pay.

Push funding has its own drawbacks, leading Ahuja et al. (2021) to endorse the use of a mix of push and pull, as OWS did, not purely one or the other. Pure push funding might run into an adverse-selection problem if the funder does not have a good idea of who the serious innovators are. The funder may end up wasting grant funding on researcher pet projects rather serious attempts. The funder may miss some serious attempts that it happens not to be aware of on the other. Push funding might also run into moral-hazard problems, with firms overstating their funded costs or moving overhead and expenses from other lines of business as funded-program expenses.

Perhaps the key benefit of pull relative to push is the powerful incentive it provides to achieve the ultimate goal of OWS. Development and approval of a vaccine were just milestones along the way to the ultimate goal of the widespread rollout of a safe and effective vaccine to the population. Specifying a generous payment per dose provides powerful incentives to develop a practical vaccine that can be produced at scale and to operate facilities that carry out that production. Push funding and milestone payments do not provide as powerful incentives to achieve that clear commercial goal. In certain cases, it may be impossible to sign procurement contracts before the product even exists. There may be too much uncertainty to determine a suitable target product profile. In the case of OWS, the product was known (vaccines), the pathogen was identified (COVID-19), and the suitable dosage, safety, and efficacy could be specified to accord with FDA regulatory standards. By contrast, it is hard to imagine specifying a technical product profile much in advance for the complex products generated by the Manhattan Project or Apollo Mission, so pull funding would have been impractical in those settings. Also, those projects were not seeking production of millions of units distributed to individuals but one-off products that would be used by the government. Widescale production was not a goal of those programs as it was with OWS.

Ahuja et al. (2021) recommended defraying paying most of the firms' program costs, say 85%, leaving the residual 15% to be incentivized via pull funding. This small residual may leave the firm with enough "skin in the game" to mitigate adverse-selection and moral-hazard problems. Although the residual percentage recommended to be covered by push is small, it may still account for considerable program expense. For example, returning to the simple example with five firms having 50%, 40%, 30%, 20%, and 10% probabilities of success, one can show that a funding program that covers 85% of the investment cost with push funding and 15% with pull would cost an expected \$6.5 billion, with more than a third of expected expense coming from pull. Pull is

disproportionately more expensive than the cost it defrays for the reasons explained above. Pull is disproportionately expensive because the high revenue required to pull in the marginal firm facing a relatively low probability of success sets the amount paid to all firms, including inframarginal firms which would have been willing to participate for less. By tying payments to firms' audited expenditures, push funding can limit what Laffont and Tirole (1993) call the "information rent" accruing to inframarginal firms.

E. Streamlining Regulation

Another unprecedented feature of OWS was its willingness to bypass traditional regulatory bureaucracy in a safe and effective manner. Typically, FDA communication with industry sponsors is limited and formally structured. During OWS, communication was more frequent and at times informal, which streamlined the regulatory process. FDA also issued public guidance documents in record time. In one instance, it took two weeks to move from a letter to guidance, compared to the usual one-year timeline. By including standardized clinical endpoints in its guidance, the FDA made its expectations fully transparent with industry. Lastly, the FDA allowed concurrent and combined clinical trial phases, enabling preclinical animal studies to occur while conducting human trials.⁶

Why not streamline the approval process in this way for all pharmaceuticals? The FDA does not have the resources to cut its response time from one year to two weeks for every product it reviews. When speed was of the essence in the COVID-19 pandemic, the FDA concentrated its available resources on reducing its response time for vaccines.

Collaborating closely with industry presumably also took FDA manpower and resources, again it would be easier to justify streamlining regulatory review during a pandemic than during ordinary times. The FDA may wish to preserve more of an arms' length relationship with regulated firms during ordinary times to avoid regulatory capture. During the pandemic, the tradeoff between speed and regulatory independence tips toward speed. Furthermore, the public's and press' attention was focused on the FDA and the approval of vaccines during the pandemic, so there was less danger of corruption going unnoticed.

D. Coordinating Government Agencies

Rather than operating as a traditional U.S. government task force or interagency working group, OWS was an integrated group, with representatives from all mission-critical government agencies. Adopting a whole-of-government approach early on was critical to the success of OWS.

According to an interview of OWS leader Paul Mango (Dutton 2022), they had a direct line to the West Wing, which encouraged quick decisions and bypassed red tape. Second, the urgency of the crisis brought HHS and DoD together. Partnering with DoD was especially important given HHS's constraints in contracting and purchasing. Military leadership provided critical logistical support, including through deploying the Army Corps of Engineers to manufacturing facilities and using military cargo planes to transport key machinery (Lopez 2020).

There are good reasons that the U.S. government's standard operating procedure is not to bring together numerous government agencies and have them coordinate. Small projects or projects that do not require the expertise of multiple agencies can be handled in a single one. When speed is not of the essence, even if multiple agencies are involved, they can provide their input sequentially without having to be in the same room together. Only a large crisis requiring multiple agencies which need to act quickly would justify the resources required by the whole-of-government approach. Just as ships wait until emergencies to sound an "all hands on deck" alarm, the same applies to a call for a whole-of-government approach.

G. Cooperate with Industry

Unlike in other public-private partnerships where the U.S. government is purely a subsidizer, during OWS, the U.S. government took on the role of a flexible partner with industry. One example is the assistance with phase 3 trial design and participant recruitment (Slaoui and Hepburn 2020). Specifically, the Department of Veterans Affairs assisted in coordinating and centralizing phase 3 trial recruitment and enrollment for the different vaccine candidates through its medical centers (McClure et al. 2023). OWS additionally met the different needs of both larger firms such as Pfizer which needed advance purchase agreements as well as smaller firms like Moderna that required assistance in conducting clinical trials.

The working level "person in plants" model provided the OWS team with real-time manufacturing updates on the ground (Mango 2022). This allowed logistical challenges to be addressed in real time, helping OWS meet its ambitious mission and timeline.

Ordinarily, government does not have the resources to delve into the work of the private sector. Even if it did, the government might want to maintain an arm’s length relationship with industry to avoid corruption or the appearance of corruption.

H. Summary

What seems like a laundry list of elements can be synthesized into two maxims concerning spending to avoid an existential crisis: spend prodigiously (“leave no stone unturned”) and spend effectively (“cut red tape”).

Table 1: Synthesizing OWS features

OWS feature	Leave no stone unturned	Cut red tape
Prodigious spending	✓	
Multiple shots	✓	
Long shots	✓	
Push and pull	✓	
Streamline regulation		✓
Integrate agencies		✓
Cooperate with industry		✓

The first OWS feature, “prodigious spending,” is an umbrella for all the other elements that require extensive resources. Taking multiple shots on goal, including some long shots, requires resources for each shot. Using both push and pull funding does not necessarily involve more resources if the two are drawn from a restricted budget but does if both are fully funded as if they were standalone programs.

The last three OWS features share the theme of cutting red tape. Streamlining regulation and having agencies cooperate with each other and with industry can speed decision making and authorization. They are not independent of the level of resources, however. Regulation was streamlined by moving COVID-19 vaccines to the top of the queue, moving all the other pharmaceuticals back. Whatever needed FDA resource was presumably called on, day or night, to provide advice to industry, agree on a trial protocol, and evaluate the data. Presumably the FDA would require orders of magnitude bigger budget and staff to offer similar service to evaluate typical products. Getting multiple government agencies together draws on the resources of each.

It would be difficult to get their ordinary business done with their leadership distracted by a joint project like OWS, but the emergency demanded it. Close coordination with industry required meetings and attention and in some cases could lead to a cozy relationship that might increase the chance of capture, high contract prices, and thus the expenditure of more resources than usual. Thus, cutting red tape is not a “free lunch” but likely involves more spending as all the features of OWS in Table 1.

The OWS features summarized in Table 1 most obviously carry over to emergencies when the tradeoff between avoiding overspending versus mitigating social harm from the emergency tips to mitigating social harm. Some of the features can be at least partially separated from the need for extensive resources and could be considered for innovation programs outside of emergencies. Combining push and pull does not have to mean spending every possible resource to fully fund push and pull. Outside of an emergency, innovation programs could consider complementing the typical instinct to fund innovation via grants to consider whether it might not be better to earmark some or all of those funds for push. The program budget does not necessarily need to be increased.

As long as the innovation program is large enough to take several shots at the problem, the principle of considering the correlation in probability of success/failure across the approaches might be considered and, in some cases, a long shot favored that is less correlated with the portfolio than others. This might increase the probability of successful innovation and combat the tendency of firms to congest certain technology approaches.

This can be done even without increasing the number of shots.

IV. Secondary Arms of OWS

A. Diagnostics

The diagnostics side of OWS was executed through the NIH Rapid Acceleration of Diagnostics (RADx) program.⁷ The program adopted a shark tank approach to supporting promising diagnostics, with awards focusing on bringing different types of tests to market, including development, manufacturing, and validation. The initial program funding was \$1.5 billion through the Paycheck Protection Program and Health Care Enhancement Act in order to both increase

testing capacity before the 2020 flu season and invest in innovative diagnostics (Tromberg et al. 2020).

Due to laboratory testing shortages, during the early weeks of the COVID-19 pandemic the CDC had strict guidelines for which patients were eligible for polymerase chain reaction (PCR) tests. This led to the public four-day delay in testing the first American hospitalized case of community transmission (Abdalla 2020). Additionally, the CDC's own PCR test kits were contaminated resulting in false-positive results (Willman 2020). For comparison, the first case of COVID-19 was detected in the United States and South Korea on January 21, 2020. By March 17, 2020, the U.S. had tested 125 per million for COVID, while South Korea had tested more than 5,000 per million (Stapp 2020).

To rectify this trajectory, a key goal of RADx was to have at-home COVID-19 tests available across the country and see infection rates in real-time, specifically the program sought to test 6 million Americans per day by December 2020. Programmatically, RADx had four key components (Tromberg et al. 2020):

- accelerate availability of at-home tests by fall 2020 (RADx-tech),
- scale-up advanced diagnostic technologies (RADx-ATP),
- support cutting-edge testing and sequencing methods (RADx-rad),
- foster community partnerships to increase testing access (RADx-UP).

RADx developed an “innovation funnel” approach to evaluate technologies. The first stage was an open call, followed by phase 0 which was the shark-tank weeklong intensive selection process, phase 1 was a month-long validation and testing phase, and phase 2 included regulatory approval, clinical testing, and scaling up manufacturing. Advanced technologies were fast-tracked to phases 1 and 2 (Tromberg et al. 2020). RADx also had a diverse range of private sector participants, including academic laboratories, small businesses, start-ups, mid-larger size businesses, and nonprofit laboratories.

While RADx did change the diagnostics market, Americans did not get multiplexed at-home tests as quickly or abundantly compared to other countries due to cultural factors at FDA and CDC rather than technological barriers. Unlike the vaccine side of OWS, RADx only used push funding and at \$1.5 billion, spent less money. RADx did support multiple simultaneous shots on goal through its shark tank approach, including molecular and antigen test platforms and

sequencing technologies. Between late 2020 and 2021, the RADx program resulted in 32 EUAs and the commercial availability of over 840 million tests.⁸

However, RADx did not streamline regulation in a similar manner as OWS did for vaccines and to a lesser extent therapeutics. Prior to COVID-19, the FDA had only approved one pathogen-specific at-home test in 2012 for HIV (McMeil, Jr. 2012). During the COVID-19 pandemic the FDA did provide proactive guidance for pathogen-specific at-home tests,⁹ however regulatory uncertainty persisted with respect to test validation and the lack of a clear regulatory path for multiplexed at-home tests. RADx did create a program to act as an intermediary between private forms and the FDA to streamline test validation and improve access to clinical samples.¹⁰ However, FDA regulation of at-home testing did not consider the broad public health benefits, such as measuring infectiousness, focusing solely on the risk and benefits to an individual such as false-positive results, which bottlenecked regulation. These bottlenecks were especially true for multiplexed tests. For example, the company Lucira filed for bankruptcy the same day as the FDA approved its at-home test for both flu and COVID-19, citing prolonged FDA approval as a contributing factor (Olsen 2023). The United States is yet to have available abundant at-home multiplexed rapid tests for COVID-19, influenza, and RSV which are abundant in other countries like Europe and Australia (Miller 2024).

B. Therapeutics

To meet the ambitious timeframe, OWS selected therapeutics that were in trials for other indications or therapeutics that have already been approved by FDA (Slaoui et al. 2020). In evaluating which therapeutics to support, OWS leadership considered the likelihood of receiving approval or an EUA by the end of 2020, robust science, and manufacturability at scale. The Accelerating COVID-19 Therapeutic Interventions and Vaccines Initiative (ACTIV) program at NIH was a public-private partnership used to assess comparisons between therapies and interventions using a total of six master protocols.¹¹ Streamlining the trial process by using master protocols allowed ACTIV to evaluate multiple interventions across different studies and within the same trial. By November 2020, OWS had four therapeutic EUAs: for remdesivir, for COVID-19 convalescent plasma, for bamlanivimab, and for hydroxychloroquine (the additional authorization for chloroquine was revoked two months after granting).¹² Currently, there are two

oral antivirals (Paxlovid and Lagevrio) for COVID-19 as well as the IV antiviral, Veklury (remdesivir).¹³

Compared to the vaccine and diagnostic areas of focus, OWS was less impactful in pushing novel approaches, seeking instead to mitigate the effects of the pandemic in the interim before a safe and effective vaccine was available at scale. One area of focus was antibody therapies of which monoclonal antibodies were promising due to their manufacturability, scalability, and ability to be used to prevent infection and serve as treatment in both inpatient and outpatient settings (Slaoui et al. 2020). OWS built on prior DARPA efforts in antibody discovery platforms and similar to its vaccine efforts supported the scaled manufacturing of monoclonal antibodies before the completion of clinical studies. OWS used multiple shots on goal by supporting different monoclonal antibody candidates and used primarily pull funding, such as an award to Regeneron of \$450 million to manufacture 70,000 to 300,000 doses of monoclonal antibody treatments (Slaoui et al. 2020).

V. Application of OWS Principles Currently Underway

A. Requested Authorities

The Department of Health and Human Services (HHS) has asked Congress for OWS-style expanded “other transaction authorities” to flexibly partner with industry without relying on Department of Defense (DoD) as contracting support. According to HHS officials, between 2020-2023, HHS relied on DoD to execute \$90 billion in contracts. To better procure and acquire products, HHS is looking for similar authorities to DoD’s general procurement and acquisition authority and innovative general procurement and acquisition authority. To catalyze the industrial base, HHS is asking for authorities similar to the Defense Production Act Title III, as these capabilities would help commercialize key R&D investments for emerging threats.¹⁴

Increased regulatory capacity and flexibility were critical to OWS’ ambitious timeline. A FY24 legislative priority for FDA has been establishing an Emerging Pathogens Preparedness Program within the Center for Biologics Evaluation and Research.¹⁵ This program would allow FDA to be more responsive to emerging outbreaks by increasing personnel, expediting review of both novel countermeasures and repurposing of existing countermeasures, accelerating recommendations and guidance, and enhancing FDA’s post-market surveillance programs. Having

a dedicated office to address emerging threats would create warm-base regulatory capacity that could be exercised during non-emergencies to maintain OWS-style expedited review during the next Public Health Emergency.

B. Programs

The Department of Health and Human Services coordination Operations and Response Element (H-CORE) institutionalizes the logistical lessons learned from DoD during OWS.¹⁶ Key initiatives include vaccine and therapeutic development coordination, which includes distributing COVID-19 vaccines and monoclonal antibodies, and supplying test to treat sites.¹⁷ H-Core also leads the distribution of N95 masks and at-home COVID rapid tests, and coordinates primarily with other HHS counterparts (the Biomedical Advanced Research and Development Authority [BARDA] and the Strategic National Stockpile). However, H-CORE is underfunded, and would require extra support to mount an emergency response.¹⁸ H-CORE is also not directly tied into other relevant USG stakeholders, but the new Office of Pandemic Preparedness and Response Policy could facilitate between HHS and DoD to ensure a robust whole-of-government emergency response.¹⁹

Project NextGen, the Biden Administration's successor to OWS, launched in April 2023 to accelerate next-generation medical countermeasures.²⁰ The program is run jointly by BARDA and NIAID, and has awarded around \$2 billion of its \$5 billion budget. Project NextGen has three program areas: strengthen (develop next-generation COVID-19 vaccines that reduce transmission and protect longer), treat (improve COVID-19 treatment options), and enable (invest in alternative vaccine delivery technology and manufacturing capacity).

While OWS took an end-to-end approach, Project NextGen seeks to de-risk pandemic preparedness through more traditional funding awards, rather than through advance market commitments. However, to catalyze innovation in vaccine patch technology, Project NextGen has awarded Luminary Labs \$100 million for a five-year initiative to design and implement two prize competitions.²¹ While Project NextGen has clear medical countermeasure targets with an overall focus on bringing agnostic products to licensure, the program is susceptible to mission creep, with its broad scope and limited resources.

VI. Future Opportunities for the OWS Approach

With uncertainty around what threat might cause the next pandemic, perhaps some as unknown pathogen termed Disease X,²² institutionalizing some of the key OWS infrastructure can be used to routinely address pandemic prevention. Increasing pandemic prevention capacity would require all seven OWS features, however during non-emergencies prodigious spending would be limited. While R&D challenges require multiple layered goals to be achieved, much of pandemic prevention at the federal level is a challenge of execution. Clear product goals include investing in existing medical countermeasure bottlenecks, such as reducing transmission or more durable immunity. Robust pandemic prevention will also rely on a broad portfolio approach to take multiple and long shots on emerging technologies and platforms. With no sustainable private market for pandemic prevention, the U.S. government could use pull funding mechanisms (such as milestone payments or challenges) to accelerate innovation in critical capabilities. While push funding should be utilized, pull funding has the additional accountability benefit of requiring firms to meet certain benchmarks to receive funding. As pandemic prevention efforts are siloed across the federal government, successful efforts will require a clear command and control structure to ensure the necessary integration of agencies that only happens with a whole-of-government approach.

The newly established White House Office of Pandemic Preparedness and Response Policy (OPPRP) will be the central leader for preparing and responding to known and unknown biological threats and pathogens, coordinating, and implementing across the federal government.²³ The goal of this agile office is to integrate across the biodefense enterprise, identify duplicative efforts, and determine what efforts to better resource. The OPPRP intends to work closely not just across the interagency but also with industry partners.

As the biodefense enterprise is cross-jurisdictional, OPPRP is uniquely positioned to serve a coordinating function, an essential feature of OWS (Nocera and McLean 2023). Additionally, as pandemic prevention is not solely a health issue, it requires a whole-of-government response with agile partnerships. Similar to OWS, the OPPRP has the backing of senior White House leaders and can act as a strong command and control during emergencies. Being a White House office, it is insulated from the cycles of panic and neglect that typically govern prevention efforts. However, OPPRP does not have influence over agency budgets, which can limit its influence.

While OPPRP institutionalizes a clear U.S. government czar of pandemic prevention, efforts to complement OPPRP can ensure prevention gaps, once identified, are promptly addressed. Two efforts could be: establishing an OWS-style Pandemic Prevention Task Force co-led by a civil servant and private sector expert, and creating an office within ARPA-H that takes OWS-style high-risk bets on new prevention capabilities and can make procurement agreements. Together, these efforts would help shift the pandemic prevention paradigm away from panic and neglect and towards keeping critical capabilities and infrastructure warm.

A. Pandemic Prevention Task Force

The Pandemic Prevention Task Force would be an agile multi-disciplinary interagency group made up of representatives from key agencies (such as ASPR, DoD, and FDA) that would serve on assignment for 2-4 years. Having mixed leadership would allow the taskforce to both incentivize industry engagement and interagency coordination, two features critical to OWS' success. The Pandemic Prevention Task Force would routinely exercise a whole-of-government response by integrating across agencies to bridge existing silos and maintain communication infrastructure, which was critical to OWS. Additionally, the Pandemic Prevention Task Force would have a budget that bundles prevention and response funding and would be empowered during public health emergencies.

Primarily, the Task Force would address the need to routinely exercise federal prevention efforts. Prior to the COVID-19 pandemic, most disaster relief and response capabilities involved idle capacity that atrophied. One example is the Public Health Emergency Response Fund, which had no funding available during the acute phase of the COVID-19 pandemic (Alton and Carlin 2020). To limit the need for future emergency supplementals during periods of crisis, Congress authorized the Public Health Emergency Rapid Response Fund in 1983 to have funding ready to go once a Public Health Emergency is declared. This fund was supposed to promote a rapid response by supporting deployment of response personnel, development and deployment of medical countermeasures and diagnostic tests, grantmaking, and public health emergency investigations. However, no funds had been appropriated since FY1999 and the fund has had a zero balance since around 2012 (Katz et al. 2017).

Another example of atrophied capacity is the state of the Strategic National Stockpile during the acute phase of the COVID-19 pandemic (Frontz 2023). While the stockpile allocated

and distributed resources across the country, there were many instances of communities receiving expired masks or broken ventilators (Rubin 2020; Murray and Glover 2020). Additionally, during the Mpox outbreak it became apparent that the stockpile had let around 20 million life-saving vaccine doses expire (Goldstein 2022).

To avoid needless expirations and waste of costly medical countermeasures and capabilities, the Pandemic Prevention Task Force could help the federal government transition from a static stockpile to a functioning reconfigurable stockpile, where products are cycled through different public health settings rather than expiring unused in a warehouse. A reconfigurable stockpile would invest in critical components like swaps, packaging, and platform-based technologies that can be reconfigured to a target specific threat when needed. For example, the Task Force could work to shift the current medical countermeasure enterprise from dependence on the one-bug-one-drug paradigm and towards agile broad-spectrum platform therapeutics for prevention and treatment.²⁴ In non-public health emergencies these diagnostic and therapeutic platforms could be easily reconfigured and deployed to address endemic diseases like seasonal flu. This type of change would increase the stockpile's responsiveness to unknown biological threats with Disease X products and would keep the biomanufacturing base warm.

The Pandemic Prevention Task Force would exercise pandemic prevention and operational capabilities by addressing challenges identified by OPPRP. For instance, OPPRP could pitch five problems and the Task Force would leverage its multidisciplinary and interagency background to select one problem to work through every year. To be an OWS-style taskforce, problems would need to have clear deliverables, and could range from ways to increase personnel capacity during nation-wide emergencies or work to address supply-chain chokepoints, to routinely exercise different capacity or capability muscles.

Other challenges the Task Force could work to remedy include addressing current regulatory bottlenecks ahead of time, such as clarifying the FDA animal rule, which is used in some cases when approvals are based on animal data.²⁵ The Task Force could help ensure cases where regulatory guidelines were streamlined are the rule rather than the exception. For example, the JYNNEOS vaccine used in the Mpox response was approved based on a non-inferiority trial.²⁶ Thus, regulators, while uncertain about the durability of vaccine protection, still authorized its use (Kupferschmidt 2022).

Establishing clear regulatory pathways is key for next-generation pandemic prevention tools as many innovative solutions do not fit traditional FDA pathways and can get lost in regulatory ambiguity. This has been especially true for diagnostics (Gibbs and Javitt 2021). The day the first at-home test for both COVID-19 and flu received its Emergency Use Authorization, the company Lucira filed for bankruptcy (Olsen 2023). The company is just one example of a diagnostic company that produced a timely next-generation diagnostic during the COVID-19 pandemic only to be a casualty of regulatory uncertainty.

The Task Force could also meet its mission by exercising with other bioeconomy challenges that keep prevention capabilities warm, like manufacturing larger mRNA molecules at scale for personalized cancer vaccines, or next-generation treatments for cardiovascular disease or diabetes (Dolgin 2023; Rosa et al. 2021).

B. ARPA-H Office for Pandemic Prevention

The U.S. government might consider institutionalizing an OWS-style high-risk high-reward approach through a dedicated ARPA-H Office to address key pandemic prevention and response gaps, with the ambitious goal of disarming infectious diseases. An ARPA-H Office would be uniquely positioned to drive innovation and maintain agility, with a flat management structure geared to empower project managers to take multiple and long shots while avoiding mission creep (Russell 2023, Azoulay et al. 2019). An ARPA-H Office for pandemic prevention would be a temporary office structured with funding for five to ten years. The Office would be similar to the DARPA special projects offices, which are temporary efforts focused on coordinating, developing, or deploying critical national security capabilities on an accelerated timeline.²⁷ While ARPA-H is statutorily limited to eight program offices, the Director may establish additional special project offices.²⁸ This Office would also serve as a federal owner for innovative prevention capabilities with a distinct mission from other efforts across the medical countermeasure enterprise.

The overall ambitious mission of a dedicated ARPA-H Office would be to accelerate capabilities that disarm all infectious diseases such that there would be no seasonal cold and flu, and new outbreaks would be promptly identified and mitigated before they become epidemics. This mission compliments existing ARPA-H efforts such as the APECx program, which seeks to develop next-generation vaccines that target viral families to eliminate viral disease.²⁹ ³⁰ To advance its mission, the Office would focus on addressing problems that exercise different

prevention, preparedness, and response muscles by streamlining the status quo to run sprints. These sprints would focus on a particular OWS muscle like manufacturing capacity or speed, as what worked in the case of the OWS vaccines may not be generalizable in the next emergency. An example would be testing the manufacturing capacity of producing a universal flu vaccine every eight years or scaling novel antibiotic candidates in a year.

To execute its mission and encourage the next generation of prevention and response (through sprints) capabilities, the APRA-H Office would need to take both multiple and long shots, use push and pull mechanisms, as well as cooperate closely with industry. A defining feature of the office would be its OWS-style ambition. Programs would be encouraged to have around a 5% chance of success (Russell 2023). The 2011 DARPA's ADEPT program was similarly high risk, but resulted in critical advances in mRNA vaccine technology and is now touted as a critical DARPA success.³¹ To encourage high-risk programs, the Office would prioritize technical failure and would use it as an indicator of program manager's risk taking (Russell 2023). To complement the emphasis on ambitious bets, the Office would incorporate probabilistic forecasting at the program manager level to generate data on predictions of success (whether that is technology spillover or likelihood of reaching certain program progress) and anticipate unintended consequences downside. To be successful, the Office would have to be a combination of taking blue sky bets, use push and pull funding, but also have a clear pathway for procurement to generate industry interest.

Similar to the OWS leadership, the Office would require program managers with industry and management expertise (Reinhardt 2020). To best support the ambitious mission, program managers would need clearances to keep apprised of the threat landscape as well as ability to maintain strong relationships with the emerging biotechnology industry. The Office would need contracting managers as well to ensure smooth capability transition and procurement, a challenge for ARPA agencies (Azoulay et al. 2019). ARPA-H has been successfully addressing this challenge with its Project Accelerator Transition Innovation Office (PATIO), which focuses on ensuring smooth technology transition and commercialization.³² PATIO would support the ARPA-H Office by proactively mapping out a transition model at the beginning of a program, identifying potential challenges as well as potential customers, and engaging the necessary federal stakeholders (such as CMS or FDA) throughout the lifespan of the program to ensure a robust end-to-end approach.³³

C. Applying OWS Model to Hepatitis C

The Pandemic Prevention Task Force could exercise federal prevention efforts by also addressing persistent public health challenges. One such challenge could be elimination of the Hepatitis C virus, which currently infects around 2.2 million Americans according to Lewis et al. (2023). Complicating public health intervention, only around two out of five infected Americans are aware they are positive for Hepatitis C (Collins 2023). Adding to the need for a coordinated response, viral hepatitis is projected to cause more deaths in 2040 than HIV, malaria and tuberculosis combined (Foreman et al. 2018). While countries such as Egypt have eliminated Hepatitis C, a dedicated federal effort could put the United States on track to elimination before the burden increases further (Collins 2023).

As a public health challenge, Hepatitis C satisfies all of the previously identified OWS criteria. Currently, direct acting antivirals are available, but preclinical vaccine candidates face several challenges. By addressing Hepatitis C, the Pandemic Prevention Task Force would exercise a federal response including, ensuring multiple and long shots, using push and pull funding, integration among both federal and local agencies, cooperation with industry, promoting regulation innovation, as well as strengthening deployment and uptake partnerships.

In determining a clear Hepatitis C mission, the Pandemic Prevention Task Force could encourage a range of different vaccine candidate technologies due to high uncertainty of what might work. In clarifying its mission, the Pandemic Prevention Task Force would need to decide if it would be striving towards a vaccine that prevents infection that could be used as a prophylactic or a vaccine that prevents chronic infection.

While there are some preclinical vaccine candidates, private funders' interest is limited due in part to an unclear pathway for Hepatitis C vaccine development. Additionally, many firms have invested in direct-acting antivirals and have little incentive to pursue a vaccine that could potentially disrupt markets for these treatments. The Pandemic Prevention Task Force would focus on a vaccine as it would be critical to mitigating increasing incidence of the virus as well as help drive elimination. The Pandemic Prevention Task Force could also experiment with what combination of push and pull funding best incentives a range of vaccine candidate technologies, which could inform applied science in other areas of viral hepatitis research.

Hepatitis C presents several regulatory challenges which would maintain the Pandemic Prevention Task Force's agility in this area. The two key challenges are no established correlates

of protection and the lack of a good animal model as humans are the only natural reservoir (Berggren 2020). Similar to OWS, the Pandemic Prevention Task Force would need to coordinate with the FDA to standardize correlates of protection and even put out proactive guidance on what constitutes an effective immune response, as individuals with chronic Hepatitis C can have broadly neutralizing antibodies (Bukh 2022). There would also need to be coordination to determine what experimental substitutes or surrogates could be used in lieu of traditional animal model evidence. By focusing on this challenge, the Pandemic Prevention Task Force would also help research efforts in other areas where animal model evidence is a bottleneck. Additional options could include requiring just chimpanzee immunogenicity data or no animal data for safety and efficacy, but these might not be realistic precedents to set.

Deployment and uptake would also be mission critical as the Hepatitis C population is vaccine hesitant and often faces barriers to accessing care. This would provide an opportunity for the Pandemic Prevention Task Force to exercise its public health messaging across federal and local agencies as well as partnerships with community health organizations to ensure that the most at-risk Hepatitis C populations, such as the homeless and intravenous drug users, would be able to easily access a potential vaccine.

VII. Alzheimer's Counterexample

The growing burden of Alzheimer's Disease and lack of a promising cure has prompted many to call for an OWS-style effort. According to the Global Burden of Disease, Alzheimer's Disease was the fifth leading cause of death in the United States in 2019.³⁴ Across high-income countries, Alzheimer's Disease is projected to be the first or second leading cause of years of life lost in 2040 (Foreman et al. 2018). These metrics have implications for increasing demand as well as cost for care. With the economic costs of caregiving responsibilities and increased projected life expectancies, an OWS-style effort for Alzheimer's Disease might be considered, however as this challenge does not satisfy most of the OWS criteria, only specific OWS programmatic features are generalizable.

Currently, Alzheimer's Disease is largely still in the discovery phase with work being done to elucidate the underlying disease mechanisms. As this is still an R&D challenge, there is no clear product goal yet. Additionally, Alzheimer's Disease is not the same type of emergency as the pandemic and would need less of an emphasis on programmatic execution, speed, or close

cooperation with industry. There is no need for the U.S. government to spend prodigiously to scale up manufacturing and map out deployment, nor would a direct line to the West Wing or a whole-of-government response be warranted. Once promising candidates have been identified, regulation could be streamlined by incorporating innovative trial design given the target population. However, this would not require a full OWS approach.

Two OWS features the U.S. government might consider using to address Alzheimer's Disease, include incentivizing multiple shots on goal and the use of push and pull funding. While the commercial market would drive a single successful Alzheimer's Disease therapeutic, government intervention could be used to ensure independent bets on different promising technologies to increase the probability of a range of successful therapeutics. Moreover, with both the growing burden of neurodegenerative diseases and persistent research challenges, there would be considerable positive value from investment in failed technologies. Push and pull funding could be used to foster public-private partnerships and derisk different technological therapies.

VIII. Conclusion

In this paper, we identified a series of Operation Warp Speed (OWS) features contributing to its success. To develop vaccines for the novel coronavirus that could be rolled out to a significant portion of the U.S. population as quickly as possible, it dedicated resources not seen for innovation program since the Manhattan Project and Apollo Mission. OWS prioritized speed and scale over minimizing waste, fraud, and abuse. It funded multiple candidates including some long shots such as mRNA vaccines, a platform that had as yet never produced an approved vaccine. To reduce the typical lag between approval and manufacturing scale up, it funded at-risk capacity expansion in advance of approval even though this investment might be “wasted” if the funded candidate failed to be approved. Rather than deciding between push funding (funding inputs into innovating firms’ R&D and manufacturing) or pull funding (advance contracts paying for successful products), OWS did both. The FDA focused the agency’s resources on shrinking the process from a year to mere weeks. OWS leadership coordinating multiple government agencies and along with the FDA adopted a cooperative posture with industry.

The common theme behind the elements of OWS is that in a crisis, the tradeoff tips away from minimizing waste, fraud, and abuse toward maximizing the probability of successful

innovation and production. To do so, the program should spend prodigiously, leaving no stone unturned, and spend effectively, cutting red tape.

Table 2: Social problems meeting criteria for full OWS treatment

Social problem	Scale required	Time frame for innovation	Spillovers involved
<u>War</u>	<u>National</u>	<u>Month</u>	<u>National defense</u>
<u>Pandemic</u>	<u>National</u>	<u>Month</u>	<u>Infectious</u>
<u>Global warming</u>	<u>National</u>	<u>Year</u>	<u>Environmental</u>
Natural disaster	Regional	<u>Week</u>	<u>Economic system</u>
Cancer	<u>National</u>	Decade	Payment system
Alzheimer's	<u>National</u>	Decade	Payment system
Seasonal flu	<u>National</u>	Year	<u>Infectious</u>

Notes: Highlighted entries in last three columns indicate that box is checked by the social problem. Highlighted entries in first column indicate that all three boxes checked for it, suggesting it is a plausible candidate for full OWS treatment.

For which other social problems would the tradeoff similarly tip and call for prodigious spending and streamlining of bureaucracy rather than more traditional policy? We argue that the tradeoff is most obvious for social problems exhibiting three characteristics: scale, speed, and spillovers. Table 2 provides some examples that fit all of these criteria and some social problems that fit some but not all.

If the problem is small, one agency may be able to address the challenge through ordinary budget appropriation or slight reallocation and not require a substantial program. Thus, it is only large-scale social problems that might call for a substantial, special program. If the problem is large such as cancer or Alzheimer's but speed is less of the essence because only a limited cohort contracts the disease and it is not infectious, so its spread does not result in the shutdown of the economy and school, again, traditional programs may suffice. Even if large resources need to be dedicated to the problem, ordinary legislative and regulatory processes can be used because short lags are less damaging. Supply chains need not be commandeered. With these hugely damaging but non-infectious diseases, there are no large externalities that would prevent the free functioning of markets to provide adequate innovation incentives. Perhaps there are externalities in one person's illness is funded by private or government insurance, but this may not destroy commercial

incentives. The cases that seem to check all three boxes making the best case for an OWS-type approach are wars, pandemics, and climate change.

Federal OWS-successor efforts have sought to institutionalize some of the flexibility that allowed OWS to cut through red tape and take big bets. HHS has made congressional requests to more readily cutting through red tape, including expanded contracting authorities to more flexibly partner with firms and to increasing regulatory agility by increasing personnel and creating a program focused on emerging pathogens. In terms of successor-programs, HHS has institutionalized OWS logistical and deployment capabilities and created a short-term initiative to de-risk investments in next-generation medical countermeasures.

This paper proposes pandemic prevention as a challenge ripe for an institutionalized OWS approach as it fits well within the scale, speed, and spillovers paradigm. Additionally, uncertainty around what agent might cause the next pandemic, the economic benefits of prevention, the positive spillover from prevention efforts on other infectious diseases efforts, the need for a clear command and control structure, sustained investment, and routinely exercise prevention capacity contribute to the need for an OWS approach. To compliment the recently created command and control structure of the White House Office of Pandemic Preparedness and Response Policy, this paper proposes two efforts that would incorporate six OWS features critical to both cutting through red tape and leaving no stone unturned.

The combination of an OWS-style Pandemic Prevention Task Force and an office within ARPA-H would address key outstanding challenges in pandemic prevention by keeping critical capabilities and infrastructure warm. The Pandemic Prevention Tasks Force would ensure existing prevention capacity did not atrophy by routinely exercising or conducting sprints and could piggyback off existing public health challenges such as Hepatitis C to exercise such muscles. The Task Force would also coordinate across government, and when needed with firms, to address identified gaps in pandemic prevention, preparedness, and response. A dedicated ARPA-H Office with the mission to disarm all infectious diseases could take ambitious technological bets and ensure smooth capability transition and procurement.

OWS appeared to accelerate the widespread availability of vaccines in the United States faster than in many other countries. The rollout of vaccines appeared to avoid some of the hiccups experienced by therapeutics and diagnostics.

Still, we do not claim that OWS was a perfect program. Some experts argued that the program was being too conservative in applying its own principles. In their op-ed, Athey et al. (2020) called for spending not \$18 billion on six candidates but \$70 billion on 15 to 20. Systematic analysis by Snyder et al. (2020) and Ahuja et al. (2021) reinforced the optimality of greater expenditures. OWS was focused on the nation, not the world at large. There is a danger of a single country monopolizing emergency supplies for its own citizens to the detriment of the globe, especially low-income countries which may not be able to afford a spot up in the contract queue. Done properly, advance investment in R&D and capacity by a world leader such as the United States can provide public goods for the rest of the world by being careful to honor contracts and avoid export controls. But international coordination is easier to achieve if the framework is worked out in advance by setting principles, treaties, and financing programs.

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