Atlas for a Warp Speed Future: Enhancing Usual Operating Modes of the U.S. Government

Amanda Arnold[1]

[1] School for the Future of Innovation, Arizona State University, aarnold@asu.edu

Abstract

Operation Warp Speed (OWS) delivered new and effective vaccines to the general public in just 9 months, exploding previously held ideas about the government's role in medical countermeasure (MCM) development as well as what is possible on the timescale of vaccine development. OWS has potential to become a map for action in future pandemic crises. This article examines federal modes of governance that emerged in response to the Covid-19 crisis, with special attention to how those modes differ from normal government operations. It is at the intersection of crisis modes of action and normal modes of operation that lessons emerge from OWS that may be worth applying in normal times – or not.

In "Rules for Operating at Warp Speed," I outlined how the leadership of OWS was able to accelerate operations under a suspension of the government's usual modes of operation (Arnold, 2020[1]). This included suspension of rules that normally govern transparent and robust federal contracting and relaxing standards for scientific consensus-building and expertise across government. This article draws from interviews completed in 2020 and 2021 with senior officials at the Department of Defense (DOD), Food and Drug Administration (FDA), and the White House in order to identify the key pandemic modes of action contributing to the success of OWS. It also discusses whether (and how) those modes of action might be adapted to enhance critical infrastructure preparedness in non-crisis times.

Pandemic Modes of Action

When confronting the uncertainty, death, and social disruption of the Covid-19 pandemic, the normal modes of government operation were set aside in order to make room for crisis modes of action. Three modes of action emerged: Speed, Scale, and Scope.

1 https://issues.org/rules-operation-warp-speed-arnold/

doi: 10.18278/jcip.3.1.7

*Speeding Contracting using Other Transactional Authority: Driving Vaccine Develop*ment

As of July 2021, the Department of Defense (DOD), Department of Health and Human Services (HHS), and the Department of Homeland Security (DHS) obligated $12.5 billion in response to the Covid-19 pandemic through flexible contracting mechanisms, including Other Transaction Authority (OTA). According to a Government Accountability Office (GAO) report, OTA was routinely used to allocate funds in Operation Warp Speed in the name of acceleration. The report found that extensive use of this contracting authority mechanism lacked sufficient transparency and oversight (GAO, 2021[2]). This is because the OTA mechanism sweeps away standard government procedures usually valued as part of contracting rulebooks including the Federal Acquisition Regulations (FAR[3]) and the Defense Federal Acquisition Regulation Supplement (DFARS[4]). The difference between OTA and the traditional procurement regulations are stark: "the proverbial guidebook for OTA is only 53 pages long—incredibly brief in comparison to the FAR, a whopping 1,988 pages, and the DFARS, which comes in at 1,338 pages." (Arnold, 2022[5]). Interviews completed in conjunction with my doctoral research with late Trump and early Biden Administration officials (2020-20210) corroborated both the predominant use of these types of contracting mechanisms during OWS and a lack of accountability associated with OTA.

Prior to its expansive use during OWS, OTA was viewed as a potential abrogation of important administrative mechanisms that support the principled allocation of federal funding (Ardizzone, 2020[6]). Significant implications emerging from the extensive use of OTA during the pandemic include questions about the legal protections afforded by Bayh-Dole Regulations[7] for technology transfer and commercialization. These legal protections are closely tied to normal modes of federal contracting. The lack of transparency in OTA contracting could have been used to block government use rights or march-in authority (Douglass, 2021[8]).

The routine use of OTA in non-crisis times may threaten the standards of government procedures meant to ensure fairness and accountability of federal funding (Audit, 2021[9]). Further analysis is needed to support enhancing crisis funding mechanisms having the same robust standards of transparency and evi-

2 https://www.gao.gov/assets/gao-21-501.pdf

3 https://www.acquisition.gov/sites/default/files/current/far/pdf/FAR.pdf

4 https://www.acquisition.gov/sites/default/files/current/dfars/pdf/DFARS.pdf

5 https://issues.org/rules-operation-warp-speed-arnold/

6 https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf

7 https://grants.nih.gov/grants/bayh-dole.htm

8 https://cshe.berkeley.edu/sites/default/files/publications/rops.cshe.3.2021.douglass.fedresearchbayhdolecovid.2.23.2021_1.pdf

9 https://media.defense.gov/2021/Apr/23/2002626394/-1/-1/1/DODIG-2021-077.PDF

dentiary support required in normal times. Likewise, there is a need to develop principled, novel funding mechanisms for use in normal times that can flex to accommodate crisis speeds. One avenue in seeking such approaches may be the growing interest in applying industrial policy to government modes of investment (Bonvillian, 2021[10]).

Scaling Conditional Drug: Flooding the Market Using Emergency Use Authorization

The Covid pandemic tested FDA's accelerated emergency capacity on a massive scale, with FDA issuing conditional approval for over 400 tests, vaccines, and antiviral drugs in the first 13 months of the pandemic (Parasidis, 2021[11]). The FDA was able to scale to this approval frequency by utilizing a critical crisis legal authority called Emergency Use Authorization (EUA).[12] EUA may only be deployed following emergency declaration by the President or his appointees. In 40 days of February and March 2020 Secretary of Health and Human Services Alex Azar exercised this authority making three emergency declarations.[13] This authority allows FDA to approve promising countermeasures as they show promise earlier on and works by spreading risk in clinical trial design across pre-clinical and post-market authorization. The goal is getting products to patients who would otherwise die without a medical countermeasure (MCM) (FDA, 2022[14]).

EUA is a relatively new regulatory tool at FDA only codified in the Project Bioshield legislation of 2004.[15] The first EUA was approved for an Anthrax vaccine in 2005 (Federal Register, 2005[16]). Expanded as part of the Public Readiness and Emergency Preparedness Act (PREP Act[17]) of 2005, the EUA was used sparingly until the swine flu pandemic of 2009 when 22 EUAs were approved (Iwry, 2021[18]). Several pre-emptive EUAs were also issued for Ebola, Zika, and MERS, though no effective treatments or cures were identified (Bobrowski, 2020[19]). There is much work still to be done to study the challenges associated with this massive expansion of the EUA mechanism during the Covid-19 pandemic. For the purposes of this work, the EUA reflects an important pandemic mode of

10 https://itif.org/publications/2021/10/04/emerging-industrial-policy-approaches-united-states/

11 https://www.fdli.org/2021/12/assessing-covid-19-emergency-use-authorizations/

12 https://www.law.cornell.edu/uscode/text/21/360bbb-3

13 https://blog.petrieflom.law.harvard.edu/2021/01/28/fda-emergency-use-authorization-history/

14 https://www.fda.gov/media/142749/download

15 https://www.govinfo.gov/content/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf

16 https://www.federalregister.gov/documents/2005/02/02/05-2028/authorization-of-emergency-use-of-anthrax-vaccine-adsorbed-for-prevention-of-inhalation-anthrax-by

17 https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx

18 https://www.fdli.org/2021/09/fda-emergency-use-authorization-a-brief-history-from-9-11-to-covid-19/

19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361119/

action in which scaling the normal federal approval process required additional authority.

The EUA mechanism expires with the emergency declaration(s) that authorized its use. Normal modes of operation within the FDA allow for at least four non-crisis mechanisms designed to accelerate the approval of drugs and vaccines including accelerated approval for serious conditions and expedited development.[20] While these non-crisis mechanisms cannot meet the scale of new candidates explored during the Covid pandemic, more assessment is essential to enhance the EUA mechanism. For instance, the EUA path may allow pressure by influential political leaders on conditional approval of drugs widely seen as ineffective or even dangerous. This was the case in the FDA's EUA approval of hydroxychloroquine and chloroquine for conditional use in hospitals in late May, 2020. The approval was revoked in June (FDA, 2020[21]). Despite the comparatively quick revocation of the approval, the close connection between FDA's EUA issued for the application of these malaria drugs to Covid-19 – and the President's statements on their supposed effectiveness – damaged the reputation of the FDA approval process (Science 2020[22]). This concern for the political pressure on FDA via the use of EUA was corroborated in my own interviews with senior OWS leadership.

Expanding Scope to Product Development: Beyond the Linear Model of Federal Investment

The scope of OWS expanded federal funding infrastructure beyond the normal modes of operation. Funding was pushed far in the direction of product development and steps done in parallel rather than the usual process of waiting for a prototype, then lead product, and then progressing stepwise through clinical trials. In non-crisis, according to this linear model of innovation that has governed federal R&D since WWII, the federal government normally invests heavily in discovery science and pre-clinical development of medical countermeasures through mechanisms such as R01 (investigator-initiated) grants at the National Institutes of Health. Government typically provides less support for subsequent steps in development and marketing, leaving those steps to small company formation, technology transfer between universities and industry, and R&D investment in industry to further develop and commercialize research leads into actual products.

This point is especially important in relation to OWS, which did not facilitate the *invention* of a vaccine to curb Covid but rather *developed* existing

20 https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review

21 https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or

22 https://www.science.org/content/article/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus

candidates. This point is corroborated by OWS leaders Moncef Slaoui and Matt Hepburn who wrote that the strategy for OWS was to select existing vaccine candidates held by industry that used one of four vaccine-platforms including mRNA; replication-defective live-vector; recombinant-subunit-adjuvanted protein; or attenuated replicating live-vector. Many of the efforts to make a SARS-CoV-2 vaccine emerged from moving selected candidates through phase 2-3 clinical trials, approval, and commercialization (Slaoui, 2020[23]).

The government made this investment in Covid treatments and vaccines through an expanded scope of federal investment not seen since WWII. The massive financial cost of OWS was $18 billion in just over one year, an expenditure on par with the Manhattan Project, which built the atomic bomb at a cost of $23 billion over 5 years (inflation-adjusted) (Shulkin, 2021[24]). Similar to the Manhattan Project, OWS was a development effort, not a research project.

It is clear from the experience in OWS that government investment in this final stage of development, where the science is developed over the decades preceding, does speed the movement of new vaccines and other medical countermeasures from industry labs to patients awaiting much-needed medical interventions. Given the likelihood of pandemic crisis-non-crisis oscillation, extending the scope of federal investment into the final stages of development should move more products from the lab to the market, providing more value to patients.

Adapting Pandemic Modes of Action to Critical Pandemic Preparedness Infrastructure

The National Academies of Science recently released a report on aspects of the government-wide response to the pandemic stating, "[medical countermeasure] preparedness and response requires an enterprise that manages resources efficiently in day-to-day work, without compromising on quality." (NASEM, 2021[25]) The key to enhancing medical countermeasure (MCM) development in the U.S. government is through enhancing robust, transparent, and elastic mechanisms that function in both crisis and non-crisis at the necessary speed, on the necessary scale, and with necessary scope to develop the medical products that are needed.

Accountable and transparent funding infrastructures for product development are needed that are sufficiently elastic to support the speed and flexibility required during crisis

Other Transaction Authority (OTA) will likely continue as an elastic contracting

23 https://pubmed.ncbi.nlm.nih.gov/32846056/

24 https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0001

25 https://nap.nationalacademies.org/catalog/26373/ensuring-an-effective-public-health-emergency-medical-countermeasures-enterprise

mechanism to expand medical product development funding. However, while OTA proved essential for rapid test, drug, and vaccine development during the pandemic, it also subverts important principles underlying normal contracting procedures. In the short term, the key lever should not be sole reliance on after-action reporting to ensure transparency and ethical spending. A data-based approach to capturing in real time who is being funded and under what reasoning and by whom – by way of a dynamic crisis dashboard – is critical. Such an analysis should be transmitted to the Office of the Assistant Secretary for Preparedness and Response (ASPR) as well as the Office of Management and Budget (OMB) at regular intervals during crisis. The dashboard should also be made available to the public.

The accountability of federal agencies, including the FDA, cannot be sacrificed during crisis response as scale

The EUA is an authority that enabled a scale of approvals to meet the pandemic need that would not have been otherwise been possible. However, the emergency declaration that triggered this new approval authority by FDA also contributed to delay. This is because the CDC's first approved test for Covid experienced an issue with the reagent and no other test had been created nor approved by FDA. The emergency declaration required emergency approval by FDA whereas this emergency approval by FDA would not have been required prior to the emergency declarations.

The importance of diagnostic testing at the outset of the pandemic cannot be overstated. The pandemic declarations, and the FDA authorities that ensued, did also create a bureaucratic hurdle that significantly slowed early response (Science, 2020[26]). In addition, and as outlined above, the EUA authority itself was used as a political tool by the President when FDA allowed a controversial drug, hydroxychloroquine, to be used as a therapeutic, leaving a deficit of accountability in its wake. The testing issue must be addressed for the future. The question of how to prevent the politicization of the EUA authority in future crises must also be considered.

Federal Funding for medical product development is an untapped opportunity to speed medical countermeasures to patients

The current model of development for medical countermeasures, especially related to emerging and infectious disease, will not be sufficient to meet future pandemic preparedness and response needs (Vu, 2022[27]). There is opportunity for new approaches that leverage government investment and endorsement to actually create

26 https://www.science.org/content/article/united-states-badly-bungled-coronavirus-testing-things-may-soon-improve

27 https://alomit.wpengine.com/wp-content/uploads/2020/04/P0695-1.pdf

and increase value in markets that otherwise may not be attractive to industry (Laplane, 2020[28]). The experience during OWS suggests that the traditional model of federal funding for basic and early applied research, depending on private capital for late-stage development, can rapidly meet non-crisis health needs if scope of federal funding support is expanded all the way through development with serial process collapsed into parallel processes along the way.

There is already a suggestion for how to fund this expanded scope of federal research and development infrastructure. Using the principles of financial engineering and securitization, Andrew Lo of MIT suggests the development of a fully leveraged megafund to organize and grow support across a series of medical candidates. This approach would mitigate the risk of failed investments by the government by leveraging the likelihood of successful investments. If the fund is large enough and based on models of the megafund completed to date, the returns could yield a profit of up to 8 percent for the government and industry investors (Fangnan, Yang, and Lo, 2015[29], 2013[30] and Lo, 2021[31]). An additional benefit of having a concerted government effort to expand government R&D would be the opportunity to establish evaluation practices at the outset to measure the success of such efforts through evidence-based policy (Baron, 2018[32]).

Conclusions

Normal modes of government operation associated with accountability and transparency were relaxed during the Covid pandemic crisis to allow new modes of action associated with speed, scale, and scope to emerge. As the pandemic threat continues, policy actions are needed to bring these two extremes into harmony. Several of the policy recommendations discussed here – including accountable crisis contracting mechanisms; the maintenance of principled federal agency actions; and the expansion of federal government in support of product development – would enhance the harmony between normal and crisis modes. The study of Operation Warp Speed, including what worked and what did not work, provides an important atlas to navigate a future of crisis/non-crisis oscillation in a way that will be less disruptive and more manageable than the crisis approach we just experienced.

28 https://www.sciencedirect.com/science/article/pii/S2590145120300025#bib0220

29 https://www.science.org/doi/abs/10.1126/scitranslmed.aaa2360

30 https://www.aeaweb.org/articles?id=10.1257/aer.103.3.406

31 https://jsf.pm-research.com/content/27/1/17.abstract

32 https://journals.sagepub.com/doi/abs/10.1177/0002716218763128

Author Capsule Bio

Amanda Arnold is a policy practitioner in Washington DC who has worked in the federal government, academia, and industry. This includes work in the vaccine development sector for over 15 years. A published author, she holds a master's degree in Science and Technology Policy and is a Doctoral Candidate with graduation anticipated in 2022.