Innovation Governance During Crisis:

Lessons Learned at Warp Speed During the Covid-19 Pandemic

by

Amanda Arnold

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Graduate Supervisory Committee:

Heather Ross , Co-Chair
Robert Cook-Deegan, Co-Chair
Tamara Underiner
J. Ben Hurlbut

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ABSTRACT

This work explores the dynamics in emergence, deployment, and execution of modern technoscientific initiatives in the U.S. government. I focus on the federal initiative that developed vaccine and other responses to the Covid-19 crisis. This included federal policy mechanisms used during crisis, political and financial risk in federal technoscientific solutions, and conditions for technoscientific solutions success. The focus on these dynamics during crisis response is an approach to understanding overarching governance of technoscientific initiatives in non-crisis times. The process of exploration includes a series of interviews with senior officials engaged in technoscientific initiative development. Two studies governed by the tenets of the Delphi approach were completed, one in 2020 with senior government officials engaged in Operation Warp Speed, and another in 2021 with former senior government officials involved in government-funded technoscientific initiatives including the National Nanotechnology Initiative, the National Manufacturing Initiative, and the Precision Medicine Initiative. These results were coded and then the data were triangulated and corroborated through the use of public media, follow up interviews, and fact-checking in the local Washington, D.C. policy network. This work reveals a series of theoretical, policy, and practical results. The theoretical contributions include that high profile technoscientific initiatives are undertheorized in Innovation Policy and Science and Technology Studies. This work also establishes an early typology of U.S. government technoscientific initiatives. In addition, this work suggests policy and practical

contributions regarding federal responses to emerging crises, as well as lessons from crisis-intervention policies that might be useful without crises.

DEDICATION

First and foremost, I dedicate this dissertation to my son. Wynn was a newborn when I started this odyssey. He is now almost 6 years old. I could not have balanced the demands of this degree, a full-time job, and moving three times during the pandemic without being able to just disappear into the moment with Wynn along the way. I also want to thank my mom who took expert care of Wynn so that I could travel back and forth to campus for classes, and my dad who listened to me when I was finding my footing during and after the pandemic. I also want to thank my committee members who stuck by me through the pandemic and afterwards. To my dog Biscuit, and to all of the Baristas in the Washington D.C. area, thank you for being there to give me the warmth and comfort I needed to keep going. Finally, to myself, thank you for working so hard, for never taking a day off, and for your fortitude.

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While I will continue to depend on the trusted institutional review process to protect their anonymity, I would like to thank my research subjects. This was an unusually delicate situation for data gathering. These people spoke about emerging policies and delicate political relationships in the midst of a pandemic they were desperately working to end. They prioritized supporting students and scholarly study of the pandemic moment. I am indebted to them for their courage, fortitude, and trust.

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Lisa Margonelli

Martin Perez Comisso

Nikki Stevens

Richard Krieg

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Tom Inglesby

Wendi Taylor

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1 INTRODUCTION

When I was growing up, you could be excused for watching infomercials about some technological gadget predicted to make your life better by enhancing your health or making the everyday drudgery of life faster, easier, or even tastier. Few pitchmen were better than Ron Popeil at selling dull steak knives, cumbersome roasting ovens, or personal pasta makers. In 1998, Popeil recorded a 28-minute infomercial for the Ronco Showtime Roaster Pro in which he used a tagline, "You just… 'Set it and Forget it!'(Allan Smithee, 2017). This idea of "set it and forget it" is so deliciously tantalizing. One tagline encompasses the sanguine allure of technology – that it will make your life automatically better. This is, however, not always how reality works. Just as the utility and the novelty of the Ronco Roaster wore off quickly, technology itself requires governance to be useful in society. The ambitious goal to bring effective technoscientific solutions to the forefront, responding to societal needs, is the focus of this work.

APPROACH

This work explores dynamics in the emergence, deployment, and execution of modern technoscientific initiatives in the U.S., with a focus on solution development during crisis. The objectives of this research include identifying and observing the emergence of the barriers and facilitating dynamics during the execution of technoscientific initiatives. Exploring these objectives during crisis is an approach to understanding overarching governance of innovation in non-crisis. Key questions driving this work include: What are the federal policy mechanisms utilized in the pursuit of a technoscientific solution during crisis? What role does political and financial risk play in

the federal pursuit of technoscientific solutions during crisis? What are the conditions of success for technoscientific solutions?

To undertake this work, senior officials were interviewed using the tenets of the Delphi approach. Two studies were completed, one in 2020 with senior government officials engaged in Operation Warp Speed (OWS), and another in 2021 with former senior government officials involved in government-funded technoscientific initiatives including the National Nanotechnology Initiative (NNI), the National Manufacturing Initiative (NMI), and the Precision Medicine Initiative (PMI)[1].

CONTRIBUTIONS

A series of practical, substantive results emerge from this work. These include a review of the federal policy mechanisms utilized in the pursuit of a technoscientific initiative; examples of the way political and financial risk impact response of the federal government to technoscientific initiative development; and an argument that there are two conditions for the success of a technoscientific initiative: Presidential support and existence of policy models for the solution pursued. The context for these results is the pandemic crisis and Operation Warp Speed (OWS), the government project to deliver vaccines, diagnostics, and treatments against Covid-19. This context is contrasted in this work to World War II and the Manhattan Project, the government project to develop atomic weapons. While the two crises invite different considerations, the Covid vaccine initiative was originally called Manhattan 2.0. This indicates the conceptual tie between

[1] While different in scale and scope, these four initiatives contain useful lessons, especially in relation to each other. Additional initiatives similar and different to these four are included throughout this document where appropriate.

Operation Warp Speed and the Manhattan Project for the senior officials executing OWS. The OWS context is also contrasted to the H1N1 "Swine Flu" outbreak in 2009 given links among the senior officials connected to government response in both the 2009 outbreak and the 2020 pandemic. As one of the officials I interviewed said, "It's all the same people. Right? It's all the same people that they brought back and now they're in one level up, you know?"

The theoretical contributions of this work are twofold. First, this work establishes that understanding the success of high profile technoscientific initiatives in crisis requires more theoretical work about the practice of innovation in crisis in Innovation Policy, Science and Technology Studies, and related literatures[2]. Second, this work establishes a typology of U.S. government technoscientific initiatives. More work is necessary to test and apply the provisional typology developed in this work across additional technoscience initiatives.

In addition to theoretical contributions, this work suggests policy and practical contributions regarding federal responses to emerging crises, as well as lessons from crisis-intervention policies that might be useful without crises. These are discussed in the conclusion section. The three papers included here as Chapters 4, 5, and 6 were designed to reach broad policy audiences in the aftermath of the pandemic and represent a synthesis of my theoretical and empirical work. Articles were written at the approved and recommended lengths for their respective journals to reach a broad audience, thus

[2] There are many different strands of related literatures including Innovation Economics and Sociology of Science. I demonstrated my competence in these areas, as well as recognition of the vast literature on the history of science, in my comprehensive exams.

producing a relatively condensed articulation of my research compared to a traditional dissertation or book format. This choice to package and mobilize research findings for pragmatic use by the policy community was a deliberate choice. This is consistent with the articulation of this work as use-inspired research in the spirit of Pasteur's Quadrant (Stokes, 1997) and as part of the ongoing discussion about the relationship between science and government for U.S. innovation. This choice is also in close alignment with both the ASU charter to advance research and discovery for public value (Crow, 2019) and the mission of the School for the Future of Innovation in Society to link innovation to public value (Doerfler, 2015). My hope is that this work, which captured science policy in the pandemic—a rare moment in American history—will be useful to enhance the translation from theory to practice in the areas of Innovation Policy, Science and Technology Studies, and related theory.

PLAN OF THE DOCUMENT

This document is organized in seven chapters plus an epilogue. In this Chapter 1, I outline the scholarly context for this work and discuss the objectives, aims, and research questions that comprise my approach. Chapter 1 also summarizes the contributions of this work. In Chapter 2, I review and situate the four literatures that set the stage for this work. In Chapter 3, I explain the methods I chose to pursue this work. Chapters 4, 5, and 6 are articles that present my results based on the coding and analysis of the data. Chapter 7 draws connections through the work and includes an overview of contributions and opportunities for future work. The epilogue offers retrospective commentary on the three

results chapters, two of which have been published and one of which is under review for publication at the time of the dissertation defense.

2 LITERATURE REVIEW

Four critical literatures underpin this work on the emergence and execution of technoscientific initiatives in the context of a pandemic or other major crisis. These literatures echo through the design and resulting findings of the study. The first literature section draws from political science and examines how policies emerge onto the political agenda in the U.S. context. The second, related literature focuses on the way that extraordinary interruptions, such as crises, make politics as usual no longer suitable and even ineffective. Such crises—from earthquakes to terrorist attacks to war to pandemics—can change the trajectory of policy emergence as the government is pressured to provide a solution to return society to normal times. The third literature draws on science and technology studies and communications to address the role of expertise in normal and crisis times for innovation policy. The fourth literature centers on innovation policy and narrows the policy focus in this discussion to literature on a subset of policies that include technoscientific initiatives oriented around a mission that serves the public.

ISSUE EMERGENCE

In the enduring authoritative work on political agenda setting, (Kingdon, 1984) identifies three streams – problems, policies, and politics – that intersect to contribute to the emergence of policy onto the political agenda. During "normal times," the existence of a problem that can be solved politically is insufficient for a policy solution to move onto the "action agenda." That problem must be coupled with multiple viable policy solutions that gradually accumulate, which Kingdon characterizes as the policy stream.

Such policy solutions to a problem may emerge for active consideration through the policy stream and move into the "politics" stream for implementation. That transition from policy solutions to political action can gain momentum when coupled with dynamic coupling mechanisms including government support, interest group action, or the national mood; or as here, in response to crisis. These coupling mechanisms change over time.

Players in Washington D.C. impact issue emergence and the transition to policy action. In the multiple streams framework, the U.S. President is a powerful node, while additional levers are pulled by Presidential appointees and congressional members (Levine, 1985). Recent work on the streams framework argues that interest groups play an increasingly intricate role in issue emergence by impacting all three streams of the multiple streams framework (Rozbicka & Spohr, 2016).

Focusing events can be a major influence on the framing of the problem that drives the shift from the policy stream to the action agenda. A recent paper applying Kingdon's multiple streams framework to the Ebola crisis (this outbreak in Guinea) found that national-level policies manifested during this crisis disproportionately focused on epidemic preparedness and response for Ebola. The window of opportunity for policy made during this focusing event was unique, myopic, and short-lived as public attention to the event inevitably dissipates (Kolie et al., 2019).

In the Ebola outbreak in Guinea, the perception of the problem drove a political action agenda on preparedness policies to prevent another Ebola outbreak but fell short of providing major health infrastructure enhancements that could prevent a series of major viral outbreaks. The perception of the problem can drive its agenda status as well as the

resulting policy executed. The media plays a critical role in manufacturing and shaping public perceptions and the resulting demand for a policy response to a pressing societal problem. This is not a new phenomenon; literature dating back to the 1920s identified the media's reinforcement of the vision of a democratic ideal as the driver of public support for World War I (Lippmann, 2004). Social media played dual roles in public perceptions during the Covid pandemic, on one hand creating hesitancy about protective measures (e.g., use of masks, lock-downs, and getting vaccinated) that likely cost lives (Altheide, 2020) and on the other hand as tools for the distribution of critical safety measure directives that saved lives (Klasche, 2021).

IMPACT OF MAJOR CRISES ON POLITICAL AGENDA-SETTING

In "normal" times, the policy agenda is characterized by long periods of stability, which are punctuated with short periods of change (Jones & Baumgartner, 2005). These short periods of change are often precipitated by "focusing events" (T. A. Birkland, 1998), (T. Birkland & DeYoung, 2012),(Cobb & Elder, 1971). Focusing events can include major disasters such as earthquakes, hurricanes, oil spills, nuclear power meltdowns (T. A. Birkland, 1998), and major terrorist attacks (T. A. Birkland, 2019) that cause a crisis. A crisis is "a serious threat to the basic structures or the fundamental values and norms of a social system" (Rosenthal & Kouzmin, 1997). The "crisis" term is consciously defined broadly in the literature so as to be inclusive of "focusing events" (Jones & Baumgartner, 2005; (Boin, 2008).

When a crisis occurs, the government may be perceived as the only plausible provider of help and solutions (Perry et al., 2001). Perhaps as a result of this pressure,

major moments of crisis open windows of opportunity in U.S. government policy in which novel policy approaches emerge as possibilities on the agenda (Kingdon, 1984). Otherwise unattainable resources are freed, and normal procedures may be accelerated and sometimes streamlined or suspended as the government rushes to pursue potential technoscientific solutions (Jones & Baumgartner, 2005).

Graham Allison's (1969) canonical discussion of crisis policymaking explores explanatory models in his study on the Bay of Pigs invasion including the bureaucratic politics model. In Allison's bureaucratic politics model, the government's response is not identified by a unified group but emerges as the output of bargaining games among leaders of the government's crisis response organizations. These bargaining games involve several components such as the role of personality and like-mindedness among U.S. political leaders; the necessity for leaders to remain close to the President as well as within the jurisdiction of the federal agency they lead; and the recognition that the "next best move" is likely not defined during crisis by a group of analysts crunching real-time data, but rather by the deadlines and events that force leaders to make decisions (Kapucu, 2009).

Kingdon, Allison, and Jones & Baumgartner's models still do not fully explain the kind of pressure that results in the emergence of technoscientific initiatives such as the Manhattan Project and more recently Operation Warp Speed. Both iconic government-driven technoscientific initiatives were operated under temporary extra-government structures. This suggests that existing governance structures in normal times cannot scale to the needs of government solutions in extraordinary times.

EXPERTISE AND POLICY EMERGENCE

In the literature on boundary work, the definition of expertise itself is examined in context as scholars probe the boundaries of what does and does not count as expertise (Gieryn, 1983). In the U.S. government, scientists meet a certain pedigree defined in the hiring process that helps inform their relative power, jurisdiction, and access to agency leadership and in the White House (Hoffman & Evans, 2021). External scientists, mostly in academia and medical health centers but also some in corporate roles, contribute to federal agency work as well through expert advisory opportunities (Hilgartner 2000, Jasanoff 1990, Guston 2001). These vectors in turn shape the nature of policies that emerge from the federal agencies. For our purposes, the Nanotechnology Initiative, which was shaped and modeled by the government scientists and policy leaders at the National Science Foundation for decades (Gallo, 2009) as well as shaped by the academicians who engaged it.[3]

During crisis, however, the definition of expertise can be expanded or changed. Based on my data, in the context of this pandemic, the White House initially prioritized feedback from CEOs. While initially consulted as CEO's of companies, many of the individuals had personally relevant expertise developed in formal or information context.[4] The STS literature values such forms of practical expertise as is evident in the

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[3] For example, the NNI funding was the source of support for the ASU Center for Nanotechnology in Society.

[4] This is the case with Moncef Slaoui, former head of GlaxoSmithKline Vaccines, who lead Operation Warp Speed. He was one of the few CEO's who also had scientific expertise and who was therefore doubly valuable. In particular, his experience heading the vaccine division at GSK during the development and

case studies of conservation biologists in St. Brieuc Bay who ignored local expertise and created an adverse result (Callon, 1984); the AIDS activists who fought government scientists to expand access to potentially risky treatments (Epstein, 1996); and the Cumbrian sheep farmers whose livelihoods were damaged by poor science communication in the aftermath of the Chernobyl disaster (Wynne, 1992).

Recognizing the value of practical expertise is also important in understanding the role that public perception plays in the emergence of technoscientific initiatives. This became especially obvious in the United States during the Covid pandemic (Bellolio, 2022). During the global covid pandemic, the value of effective science communication became clear as misinformation, including conspiracy theories, led to vaccine hesitancy and deaths. Recommendations to "prebunk" such theories and desensitize the public to fake news may become part of the future of pandemic preparedness response efforts (Bavel et al., 2020). In addition, sources of expertise in government must be perceived as credible and non-partisan to effectively invalidate conspiracy theories and fake news (Igwebuike & Chimuanya, 2021).

MISSION-ORIENTED TECHNOSCIENTIFIC INITIATIVES

Mission-oriented innovation is the contemporary manifestation of the Manhattan Project and the post-World War II innovation system imagined by Vannever Bush in *Science—The Endless Frontier*.[5] Contemporary technoscientific initiatives under this

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deployment of the H1N1 vaccine gave him experience working with the government on a high-speed project.

[5] For more reading on this blueprint for the demilitarization of wartime science for civilian use, and the resulting process of innovation investment by the U.S. government (Mazzucato, 2015)Mowery and Rosenberg 1982, Edquist 2012, Mowery and Rosenberg 1993, (Mowery & Rosenberg, 1989)Pursuit 1989,

moniker are oriented around grand challenges (Hekkert et al., 2020), wicked problems (Turnbull & Hoppe, 2019), and moonshots (Kattel & Mazzucato, 2018).[6]

Preliminary Typology of Technoscientific Initiatives in the U.S. These modern mission-oriented technoscientific initiatives fall into two categories,[7] rather than responding to current existential threats. The first category is based on arguments for investment in a preemptive approach to address threats to America's global economic supremacy. An example of an initiative in this category is the National Manufacturing Initiative (NMI) of the 2010s, which addressed the perceived threat based on the loss of domestic manufacturing throughout the 1990s by creating a series of advanced manufacturing institutes across the country to ignite a manufacturing revolution in the U.S. (*Is a Manufacturing Revolution on the Horizon?*, 2013). The second category of modern mission-oriented initiatives is investment in the untapped promise of current knowledge that may increase the quality of life for all Americans. An example of an initiative in this category is the Clinton Administration's 2001 National Nanotechnology Initiative (NNI), the momentum for which was the promise of nanotechnology for U.S. economic security and the future of computing just as the internet was coming online for public use.[8]

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and Mowery 2010). Schumpeter covers related work on the role of innovation for the country's economic wealth (Schumpeter, 1942).

[6] Aspects of contemporary mission-oriented initiatives are embedded in science, technology, and innovation policies in the U.S. over the last 100 years (Shipp, 2013).

[7] The Apollo Program is another kind of initiative for which the motivation differs from the two futurist motivations. The existential solutions sought as a basis for the Manhattan Project and Operation Warp Speed. The Apollo Program developed from a third category of motivation: the ability basically exists and so we should do it. Nationalism may be a motivating thread that can be identified in most technoscientific solutions identified under the mission-innovation theme. Indeed, the role of nationalism in the development of high profile technoscientific initiatives is of interest for future work.

[8] The White House was the driving force for the NNI. For instance, President Clinton launched the NNI at CalTech with the well-known line "Just imagine … shrinking all the information at the Library of Congress into a device the size of a sugar cube" (Clinton, 2000). Key White House advocate Neal Lane testified to

Similarly, the Precision Medicine Initiative, launched in 2014, built on the perceived value of the NNI (Collins & Varmus, 2015) to unlock lessons learned to revolutionize medicine (Shukla et al., 2015). These categories are considered a preliminary typology, a categorization, of technoscientific initiatives in the U.S. to include 1) a response to existential national crisis, 2) a future-focused category emphasizing a preemptive approach to address threats to America's global economic supremacy, and 3) an investment in the untapped promise of current knowledge that may increase the quality of life for all Americans.

Contemporary theorists in mission-oriented innovation and evolutionary economics led by Mariana Mazzucato seek to recoup the value of innovation for taxpayers by first pointing to a flaw in the innovation system and then pointing to a novel approach. The flaw in the innovation system is that the public is not receiving the full benefit of the U.S. innovation system. In fact, the public is being charged twice, initially as taxpayers for the innovation investment by the government and then as customers purchasing the products (the results of the innovation ecosystem) for full price on the free market. Mazzucato uses the example of the iPhone to illustrate this flaw. Mazzucato points to how Apple compiles the technology developed over decades of federal investment in the research and development (R&D) system and then sells the resulting product for full price to the American public that funded those innovations (Mazzucato, 2015).

Congress in 1998, "If I were asked for an area…that will most likely produce the breakthroughs of tomorrow, I would point to nanoscale science and engineering" (Lane & Kalil, 2005).

The new approach proposed by Mazzucato is that the government should act to the full extent of its potential as an entrepreneurial funder of first resort. In this way the federal government impacts the direction of innovation towards the country's, and even humanity's, most pressing needs. The resulting mission-oriented initiatives allow governments to utilize industrial and innovation policies to grow effective technoscientific initiatives that increasingly benefit the public (Mazzucato et al., 2020).[9]

Technoscientific initiatives during crisis. National crises serve as an extraordinary clarifying mechanism for mission-oriented technoscientific initiatives, exemplified by the Manhattan Project and Operation Warp Speed. Both federal initiatives were designed to address a technoscientific solution of last resort to solve an existential crisis for the country, the former being the atom bomb to end the second World War and the latter being the Covid vaccine to end (or at least control) the global pandemic. Despite crisis being a catalyzing moment for technoscientific initiative development, the role of innovation policy during crisis is undertheorized in the fields of Innovation Policy and Science and Technology Studies.

Implicit in the linear model argument that underpins U.S. innovation investment is that decades of investment in basic research produces the basic science tools necessary to manifest solutions needed in the future, including during crisis (Lalani et al., 2023). However, we have little theory about the actual production of technoscientific solutions

[9] Those well-defined missions must also be couched within a context of global R&D investment and innovation policy that recognizes and prepares for economic crisis across multiple contexts including novel public-private partnership models; incubators to support translation of triple helix relationship between industry, academia, and government; and prioritizing criteria for technoscientific innovation project funding (Sharif, 2012).

during crisis. The theoretical gap that exists around the particular moment of crisis innovation, the actual production of a technoscientific solution, is where this work principally contributes through three articles written for the science policy community. The first of article argued that existing standard operating procedures for both the scientific and administrative states were insufficient and even suspended during the pandemic crisis (Chapter 4). The features included a lack of government transparency and the subordination of scientific consensus mechanisms during crisis. The second article argued that the U.S. government was partially prepared for innovation in crisis through the Emergency Use Authorization mechanism, but that mechanism was subject to political pressures that undermined safety and the previous high level of legitimacy of the American system for food and drug approval (Chapter 5). The third article developed a theory of the conditions under which technoscientific initiatives to solve crises can be successful during crisis (Chapter 6).

CONCLUSION

Four distinct literatures support the work of this project, including processes of policy emergence and political agenda setting in the U.S. context within political science literatures; the impact of crisis on the agenda setting process within the emergency management literatures; mission-oriented innovation as a focused subset of innovation policy literatures; and the role of expertise and science communication from Science and Technology Studies and Science Communications literatures.

Based on this review, two conclusions emerge. First, crisis is a catalyst for technoscientific initiatives to emerge onto the policy agenda. Second, technoscience

experts have a role in molding these initiatives in crisis conditions. Yet there is very little theory about the practice of innovation policy in crisis, and especially about the production and execution of technoscience initiatives. To contribute to the multidisciplinary literatures identified here, contributions from this work will address this gap by exploring the policy mechanisms utilized, the role of political and financial risk, and the conditions of success for technoscientific solutions during crisis.

3 APPROACH AND METHODS

In Chapter 2, I outlined the literature relevant to this research about technoscientific initiatives. These initiatives are funded through federal R&D dollars and address a challenge or wicked problem presented by threats such as climate change or health. In this chapter, I offer an overview of the methods I used to undertake my original research. I review the research questions. I discuss the choice of the Delphi method, and why the Delphi is well suited to develop a typology to inform future initiatives. I review the limitations to Delphi approaches and the role of the pandemic in my research.

RESEARCH AIMS, OBJECTIVES, AND QUESTIONS

This research aims to explore the dynamics at play in the emergence and execution of modern technoscientific initiatives. The objectives of this research: to observe the barriers and facilitating dynamics during the execution of technoscientific initiatives. Key questions driving this work included: What are the federal policy mechanisms utilized in the pursuit of a technoscientific solution during crisis? What role does political and financial risk play in the federal manifestation of technoscientific solutions during crisis? What are the conditions of success for technoscientific solutions?

CHOOSING THE METHOD: THE DELPHI

A consensus-seeking method was preferred in the planning and development of this study. I did not seek consensus on events or outcomes, but used the Delphi process to identify common themes, and to discern underlying patterns. The family of consensus-seeking methods for qualitative research includes Nominal Group Technique; Focus Groups; Group Interviews; and a Delphi Study (Day & Bobeva, 2005a). The Delphi

method is uniquely designed for consensus development with experts, a critical need as this research depends on the experience of senior policy officials (Helmer, 1967).

I chose the Delphi Approach within the consensus family of qualitative methods for three reasons[10]. *First*, I chose the approach to enable the triangulation of views to identify a consensus among experts. Again, the Delphi method can be adapted to seek consensus on what is important and underlying themes, without forcing consensus on outcomes. Its original use was for technology forecasting using iterative consultation with an expert panel; it has been adapted to policy questions to identify general agreement on features that are important or salient, but without forcing agreement on normative questions or political outcomes. Following the work by Lincoln & Guba (1986) and Denzin (1978), a consistent component of the Delphi method is the meta-analysis that builds as each layer of the Delphi is conducted so that each round informs the next and together lead to new findings. This iterative aspect of the Delphi approach is important when working with policy experts as they are developing major policy; it allows the researcher to capture context that may be impacting the policy expert's opinion. *Second*, I chose the approach given the importance of anonymity of those whom I interviewed. Anonymity ensures that the researcher and the participant have a

[10] The Delphi was designed to identify areas of consensus through iteration. Discussion of the implementation of this study in a following section will include a shift from consensus searching to data triangulation of different perspectives on themes that emerged and were captured in the data codebook for this study. Given the enforced limitation of a single round with public officials only following the change in Presidential administration, the key aspects of the Delphi that led me to choose it for this study, including iteration and anonymity, still made the Delphi the most appropriate method augmented with a data triangulation method to include broader field materials to compliment the results of the Delphi by obtaining the most completely and maximally justified answers (Dzwigol, 2018).

relationship of trust which elicits more robust data from participants and allows the researcher to get to what the respondent thinks rather than just accepted political messaging. Third and finally, I chose the approach given the established role of the Delphi process in Washington with senior policy experts, the category of subjects interviewed in my research. The Delphi Method is included as a rich methodological approach in the most recent Handbook of Military and Defense Operations Research (*Handbook of Military and Defense Operations Research*, 2021). Due to the history and popularity of the method among think tanks in Washington (Helmer-Hirschberg, 1967), many senior policy experts in Washington are familiar with the approach. This comfort with the method accelerates consent protocols and puts the respondents at ease with a familiar method.

Delphi Method Guidelines. The largest Delphi ever undertaken included 1000 participants (H.A. Linstone, 1978). Seven is the minimum number recommended for a Delphi study (Mullen, 2003). Suitable results can be gained from 10-15 experts (Adler & Ziglio, 1996). The number of rounds of a Delphi can vary between two and ten (Erffmeyer et al., 1986). Day & Bobeva (2005b) recommend one month per round to provide sufficient time to deploy and aggregate the results of each round. In addition, the five stages of all Delphi studies (Linstone & Turoff, 1975) include the development of a toolkit to enhance the rigor of the data collection. For the purposes of this approach, a toolkit would include an *a priori* codebook and an Attributes Matrix to be discussed in My Approach below.

Choosing the Delphi Variant for Policy. There is a schema of Delphi structures and related methodological direction based on study needs (Strasser, 2017). The *focus* of the Policy Delphi Method Variant for my research was to define and differentiate ideas or views, which was useful in a highly politicized context. This ideas-focus differs from the traditional Delphi, which focuses on the elicitation of facts and perceptions from experts without expectation of agreement about outcomes or political views among the experts. On *panel participants,* the Policy Delphi variant includes informed advocates and referees as participants rather than a homogenous group of experts as in the traditional Delphi method. As to the *nature of participation*, both the Policy Delphi Method Variant and the Traditional Delphi method include anonymous responses. Additional prescribed approaches for the Delphi Policy Variant include that the participants are experts, in either the narrow or broad sense, and the issues to be explored should be developed from a literature review[11].

The Delphi Method in Theory Building. The Delphi method is an appropriate tool for developing quality typologies as well as vetting a typology (Silzle, 2006) (Nickerson et al., 2013). According to Doty and Glick, typologies are an accepted approach to theory building. The development of typologies has been criticized as oversimplification of complex phenomena (Dear & Scott, 1981). If crafted correctly, a typology can be testable as a theoretical construct (Doty & Glick, 1994). This research uses Bloom's taxonomy as

[11] In this way, it is similar to modified grounded theory, an iterative process that draws from the literature (Glaser & Strauss, 1967) and is a methodology frequently employed in STS (Clarke & Star, 2008).

a guide (Bloom, 1956).[12] Two prescriptive rules apply: categories formed must be inclusive of the phenomena observed (Bailey, 1994) and there can be no overlap of cases across categories (Kipnis, 1997). Aim 1 of the Delphi study allowed me to create a preliminary typology of initiatives in general (see Chapter 2). The larger theoretical contribution is a two-dimensional framework illustrating a typology to predict success of technoscience initiatives. This typology framework is included in Figure 1 and further discussed in Chapter 6.

Figure 1: Two-Dimensional Framework for Policy Success (Typology)

Presidential Support			
	High	Quadrant I: High Presidential Support/ No Existing Policy Norms	Quadrant II: High Presidential Support/ Robust Existing Policy Norms
	Tacit		
		Quadrant III: Low Presidential Support/ No existing Policy Norms	Quadrant IV: Low Presidential Support/ Robust existing policy norms
	Low		

[12] The use of the term taxonomy is generally used in relation to biology whereas the term typology is used in relation to social science.

None *Robust*

Existing Policy Norms

RESEARCH APPROACH

This research design includes four rounds or aims. A summary of the Four-Aim Delphi Design is included as Table 1. Each round is described in this section. A flow diagram mapping the process is included in Figure 2.

Table 1: *Four-Aim Delphi Design*

Delphi Aim 1	Elicit the initial set of issues to be tested or explored through the Delphi rounds
Tactic 1	Develop Literature Review and Build Attributes Matrix
Delphi Aim 2	Pilot the Toolkit on an Initiative
Tactic 2	Execute an exploratory study with policy experts from Operation Warp Speed in 2020 to further develop the toolkit to include an a priori codebook
Delphi Aim 3	Pilot the Toolkit to Learn more about the emergence and dynamics of initiatives
Tactic 3	Execute a study with experts on a Series of Grand Challenge Initiatives including the National Nanotechnology Initiative, Advanced Manufacturing Initiative, and the Precision Medicine Initiative
Delphi Aim 4	Triangulate the Results of Previous studies according to the goals of the iterative Delphi Method to develop a Typology
Tactic 4	Deploy Delphi Method techniques to build a typology to describe the emergence and dynamics of these initiatives.

Aim 1: Eliciting the Initial Set of Issues. According to the recommended schema for the Policy Delphi Method Variant, I designed a four-aim Delphi process. Aim 1 was

accomplished in the literature review in the previous chapter on major initiatives in the past including the National Nanotechnology Initiative, Advanced Manufacturing, and the Precision Medicine Initiative. To elicit a set of data to be tested, or explored, in my research, I extracted key themes from the literature to develop a framework for analysis of the interviews according to Linstone and Turnoff (1975). These themes are listed in an Attributes Matrix.

In the Toolkit: Attributes Matrix. In the Attributes Matrix, included below as Table 2. I built a bimodal profile matrix comparing cases, high-profile technoscientific initiatives, and attributes that emerged in the Aim 2 study based on Verdinelli's work on data display in qualitative research (Verdinelli & Scagnoli, 2013). The attributes include the role of crisis, military leadership, political party control, the role of presidential elections, White House staff, input from industry leadership, and the perceived reasoning for the technoscientific initiative. I used this tool in the next two aims, the study rounds, and also in my analysis.

Table 2: Attributes Matrix

Attributes	Option	Option
Did the high-profile technoscientific initiatives develop in response to an acute crisis?	Yes	No
Is military presence built into the leadership structure of the high-profile technoscientific initiatives?	Yes	No
Which Party is in control of the White House?	Republican	Democrat
Which Party is in control of the House?	Republican	Democrat
Which Party is in control of the Senate?	Republican	Democrat

Did the high-profile technoscientific initiatives emerge within one year of an upcoming presidential election?	Yes	No
Was there a greater balance of former or current industry CEOs or persons with backgrounds in a technical field engaged in the formulation of the high-profile technoscientific initiatives?	Industry leaders	scientists
Is the reasoning for the high-profile technoscientific initiatives more about social need (like war on cancer) or scientific opportunity (like Apollo)?	social need	scientific opportunity

Aim 2: Piloting the Toolkit. By design this was an inductive, exploratory study focused on Operation Warp Speed (OWS), the U.S. government's vaccine development response to the coronavirus pandemic. I undertook a series of interviews with key officials and experts associated with the U.S. Covid-19 pandemic response. I analyzed these data using open coding in which I used the text from the interviews to develop categories from which concepts emerged (Strauss, 1987).

Regarding participant recruitment, I used the theoretical sampling approach and chose a distinct group of experts most able to provide the robust data for the purposes of this study. That is, I was directly familiar with the pandemic response from my job responsibilities in Washington, DC. I followed the story in my work and was aware of major figures involved in the policy decisions. I asked those I interviewed whom else to include for interviews, incorporating iterative snowball sampling. My criteria were elite policy experts in federal pandemic preparedness and response to the Covid pandemic. Specific criteria for each participant included at least one of a series of categories including: were serving or had served as a presidential appointee; partisan staff in a

presidential administration; an advisor on a presidential transition team; or were otherwise engaged as a policy expert by presidential candidates.

For the purposes of data collection, I interviewed 12 subjects for an average of one hour virtually by Zoom. All interviews were audio recorded using the Zoom recording feature and those recordings and resulting transcripts constituted the data collection for this exploratory study. Interview questions were semi-structured with an interview guide containing open-ended questions. The Aim 2 semi-structured interview guide is included as Appendix A.

During these interviews, I employed an approach of analytical induction based in grounded theory (Strauss, 1987). I had to account for how my professional work in science and technology policy in Washington D.C. over the last 15 years might skew my design choices and data results. In order to adjust for this, I rejected the bracketing approach (that is, to put aside preconceptions), in favor for thinking naturalistically, (or trying to figure out what is going on based on your own experiences) (Storkerson, 2010) (Bogdan & Biklen, 1992). This allowed me to use my own career experience as an additional tool to aid my ability to deepen data gathering and analysis.

I used the constant comparison method to analyze the data while still conducting interviews, a process that included collecting the data; writing memos about the data to expose the ideas therein; analyzing the data in rounds of coding; adjusting the questions for future interviews; formulating theories or explanations, and then testing them through new interviews and review of existing interviews (Krathwohl, 1998) (Gladwin, 1989).

In the Toolkit: A Priori Codebook. I extracted key code families from the codebook developed during the analysis in Aim 2, the piloting process. Included in Table 3, this series of codes developed as the A Priori Codebook during Aim 2 informed analysis in Aim 3. Based on this data from Aim 2 aspects that may impact the emergence and manifestation of a technoscientific initiative include: 1) Political Context, meaning political party affiliation, dynamics, elections, and Presidential leadership; 2) Political Authority, meaning the role of the President, the White House, Presidential appointees, and congressional members; and 3) Scientific Expertise, meaning the role of scientific advisors and government scientists. Both the Attributes Matrix developed in Aim 1 and the a priori codebook developed in Aim 2 informed both the approach and the analysis in Aim 3.

Table 3: A Priori Codebook

Parent Code: Political Context
Child Code: Relevant Partisan Political Stances in Congress
Child Code: President
Sub Child Code: The President as a Driver for a Major high-profile technoscientific initiative
Sub Child Code: The Role of Political Ideology in the President's Efforts
Parent Code: Authority
Child Code: White House and Appointees Abide by Presidential Narrative
Child Code: Executive Branch Funding Through Contracting Not the Appropriations Process
Parent Code: Expertise
Child Code: Trusted Interlocutors Used to Access Expertise
Child Code: Scientific Consensus as a Liability, Similar to Bureaucracy

THE DELPHI ROUNDS: AIM 3, THE STRUCTURED STUDY

Like my approach in the Aim 2 study, I used the theoretical sampling approach according to Strauss to choose a distinct group able to provide the most robust data for the purposes of this study. Selection was nonprobability and nonrandom with preference for policy expertise in one or more of three initiatives mentioned in the introduction including the National Nanotechnology Initiative, National Manufacturing Initiative, and Precision Medicine Initiative (Strauss, 1987). I interviewed 15 respondents for at least 45 minutes each. The interviews were conducted virtually using Zoom and Microsoft dictation. I used the *a priori* codebook as the basis for analysis of the data gathered in this study. I utilized both the semi-structured interview questionnaire included as Appendix B as well as the Attributes Matrix. I analyzed the data gathered in these structured interviews with methods I used in the Aim 2 study.

THE DELPHI ROUNDS: AIM 4 AND CORROBORATION

The results of Aim 3 study reinforced a subset of the data from the Aim 2 study. The data I gathered in real time during Operation Warp Speed emerged as a highly significant thread and overtook my original plan. In response to emerging findings, rather than performing the survey approach of the traditional Delphi with the participants in Aim 3, I set out to reconnect with the participants engaged in Aim 2 of the study. However, many participants from Aim 2 were no longer available. Many people I interviewed were Trump administration appointees and could no longer be reached after President Biden's inauguration. For instance, many of the ".gov" email addresses I used to communicate with participants no longer worked. Those who were still in government

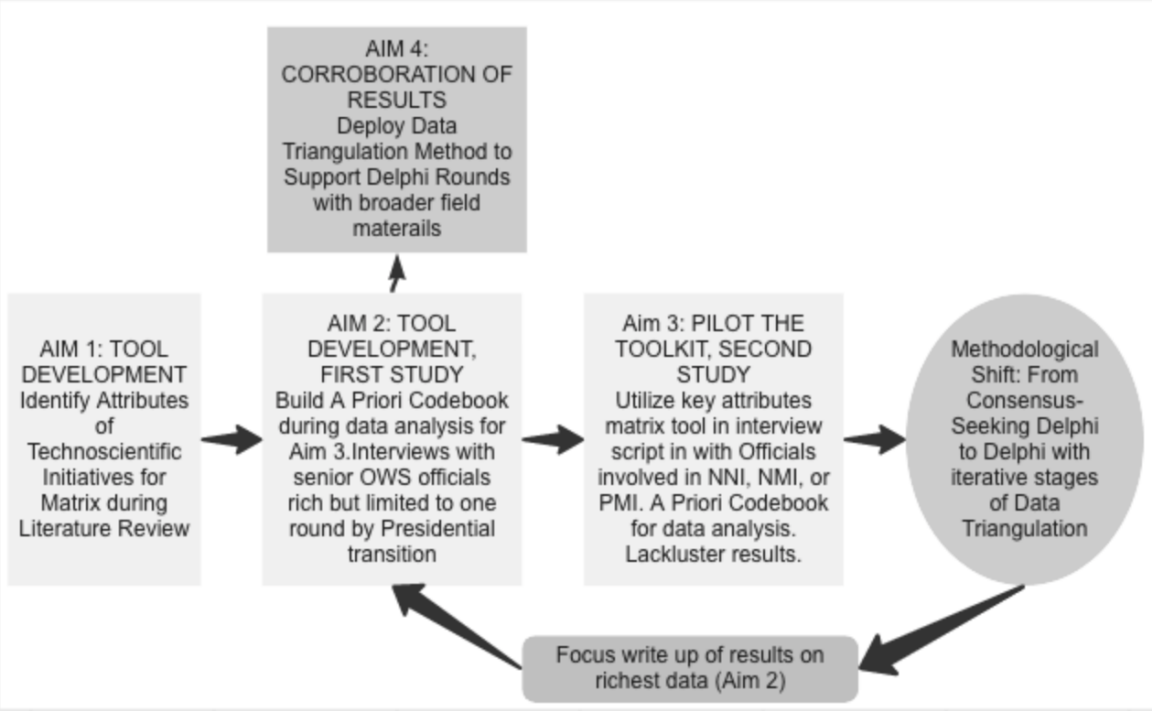
no longer felt free to communicate about the previous Administration under a new President. The policy divergence between Administrations was further exacerbated by the polarization that was illustrated by and worsened after the insurrection in the U.S. Capitol on January 6, 2021.

As a result, I modified the Delphi approach to remove further rounds of the Aim 3 interviews. Instead of focusing on the emergence of technoscientific initiatives in the abstract, I (in close consultation with the chair and co-chair of the PhD committee) instead focused on Operation Warp Speed as the central feature of my research. This was because we collectively agreed I already had significant findings from the research, and it became apparent that addressing how the pandemic response shifted from pre-crisis to crisis, and from the Trump Administration to the Biden Administration was a rich case study in policymaking. I shifted to additional rounds of data gathering based on the Delphi Aim 2 results using a secondary method of data triangulation with independent sources to complement the Delphi method. This augmented approach honored the strengths of the Delphi method, including (1) elaborating the underlying ideas in a politicized context, (2) retaining anonymity in data gathering, and (3) preserving the richness of an iterative method (Dzwigol, 2018).

Using a secondary method of data triangulation with independent sources, I corroborated my data to strengthen the basis for my analysis in the following ways. 1) I used substantial statements available to the public in reports and news articles, 2) I conducted additional interviews with staffers I was able to track who witnessed many of the moments the senior leaders communicated to me during the Aim 2 interviews, 3) I

conducted observation of original participants by personally attending events in Washington D.C. throughout 2022 in which they were speaking about lessons learned during the pandemic. Figure 2 maps the flow of the four aims including this corroboration component.

Figure 2: 4 Aims in Research Flow Diagram



Notes This diagram maps the flow of the research through the four aims.

Toward a Typology. One goal of this work was to build a decision-making tool to better understand technoscientific initiatives. The development of decision-making tools, including tools such as taxonomies and typologies, has been criticized as oversimplification of complex phenomena. The critique is that these tools can

shortchange an understanding of the complex causal processes that determine outcomes (Dear & Scott, 1981). Doty and Glick (1994) argue that, if crafted correctly, a typology can be testable as a theoretical construct. To overcome this critique in my typology building, I used the multi-aim process described to develop the typology using the Attributes Matrix. I extracted dynamics observed in the emergence of technoscientific initiatives as part of Aim 1 and then explored them against multiple expert experiences in both the Aim 2 and Aim 3 studies.

Limitations and Opportunities. As explained above, the original plan evolved in response to emerging events and conditions. Despite the Presidential election and the nature of the pandemic, I was able to capitalize on the unexpected richness of the study on Operation Warp Speed. I executed this study by modifying the Delphi process that was underway, while retaining the iterative aspects that drew me to choose the Delphi method in the first place. These strengths included iterative consensus-building around ideas, while preserving anonymity. I built consensus around themes emerging from the interviews and maintained anonymity of my subjects through the triangulation and corroboration of my data by closely following policies related to OWS in news media, government reports, additional interviews, consultation with those in my professional policy network, and direct participant observation of public events in Washington, D.C.

One weakness in my research was my inability to include a senior policy official from the Centers for Disease Control and Prevention (CDC). I did not contact CDC leaders at the time because the role of CDC leadership was not clear at the outset. Moreover, it was clear that CDC's role had been superseded by creation of the Covid

Task Force led by Vice President Pence. The impact of the loss of these inputs, especially in relation to the role of containment and mitigation, was attenuated by corroboration of the senior leaders whom I did interview, augmented by timely public statements by CDC leaders and follow-on conversations as I triangulated results with staff about the role of the CDC. As one senior respondent predicted presciently in 2020, “I'm quite sure that CDC will get the short end of the stick in this.”

Another potential weakness is the lack of follow up with the individual participants themselves. I believe, however, that I was able to compensate for this weakness, and the data triangulation and follow-up through alternative sources improved the quality of the analysis.

One real strength of my research was access to officials and experts who were making major decisions in real time on the nation’s foremost policy challenge: addressing the Covid pandemic through Operation Warp Speed. Senior government officials took time during the pandemic response for these interviews. My experience in the R&D policy sector in Washington D.C. over the last 15 years meant I was able to recruit a network of highly placed senior officials, and I was able to capture the reality as it was happening. Even if it had been possible to return to these officials for another round of direct interviews, the ideas captured would not have been the those that were salient and communicated at the height of the pandemic and before Operation Warp Speed delivered the Covid vaccines.

Additional strengths included the policy network of which I was a part: the diverse corroborating sources used to reinforce the interview data. There were numerous

meetings in Washington, and this provided a rich set of corroborating (and contrasting) perspectives. This work was aided with the richness of media articles and new government report releases following the excitement around the success of the Covid vaccines and the potential end of the pandemic.

CONCLUDING SUMMARY

In this chapter, I reviewed the research questions; discussed the four-aim Delphi design, as well as why the Delphi was an appropriate choice for this work; and also addressed limitations of the Delphi approach. I outlined the development of my Delphi study stages offering additional details about the necessary adjustments due to the pandemic, and the unique opportunity to study policy change as Administrations changed and the pandemic shifted from an existential threat overwhelming hospitals and killing over a million US residents to a still major but less existential threat. Operation Warp Speed, and particularly the development of the mRNA vaccines, was a central feature in reducing the threat level. The policies and politics surrounding OWS thus became the central focus of my research. Finally, I introduced the Delphi method as a typology building tool for the purposes of my typology development process. In the next three chapters I will present and discuss the study findings based on this approach.

4 SUSPENSION OF NORMAL OPERATING MODES

This chapter was originally published in the Spring 2022 volume of ISSUES IN SCIENCE AND TECHNOLOGY (Arnold, 2022a). ISSUES is published by the National Academies of Science, Engineering, and Medicine and Arizona State University. This quarterly journal provides a unique forum for researchers, government officials, and business leaders on issues of public policy related to advances in science and technology. This journal reaches a broad readership including the general public and policymakers. This journal is also open access (OA). Publishing with this journal fulfilled a key goal of this dissertation, which is to translate research and theory for practical use.

RULES FOR OPERATING AT WARP SPEED

On December 11, 2020, the U.S. Food and Drug Administration (FDA) authorized the first COVID-19 vaccine dose for people 16 and older (Food and Drug Administration, 2020b). Obtaining an effective vaccine less than a year after the COVID-19 pandemic began was an unprecedented achievement. The vaccine development effort, called Operation Warp Speed (OWS), was co-led by Moncef Slaoui, former head of vaccines at GlaxoSmithKline and Gustave Perna, a retired four-star general (C-SPAN, 2020) Since the authorization, OWS has been viewed as a stunning success both inside and outside government.

Making such rapid progress on the COVID vaccine during an extensive public health crisis required deviation from the federal government's usual modes of operation: in particular, it required temporarily suspending or ignoring some of the usual administrative and scientific guardrails. For instance, accelerated contracting processes

replaced the usual federal contracting process (Lupkin, 2020a). And while OWS accessed federal government biomedical and preparedness expertise, it did so in ways that deviated from existing policy processes of scientific consensus authorized via advisory committees, systematic merit review, and other established practices (Slaoui & Hepburn, 2020).

The justification for suspending these guardrails was speed. The government needed to quickly develop novel modes of detection, treatment, and prevention in response to the public health emergency caused by SARS-CoV-2. The rapid tests, monoclonal therapies, drugs, and mRNA vaccines developed or commercialized have saved lives, prevented suffering, and reduced further economic and other damage from the virus.

OWS will likely become the template for rapid government response to future crises. Whether it is used in public health emergencies, climate threats, or other disruptions, how this model handles funding accountability and scientific expertise requires more attention than it has gotten from policymakers. On the one hand, it contains cautionary lessons: If OWS-type programs become a "new normal" for government—either because they are perceived as an effective way to get results in a crisis, or because the government finds itself responding to crisis after crisis—over time important attributes of transparency and deliberation in government may be deemed to be disposable. But the lessons could also be inspirational, because more flexible spending mechanisms that can be deployed quickly either in crisis or normal times are critical to ensuring appropriate use of taxpayers' funds. Likewise, more nimble, expeditious

mechanisms for scientific consensus could help government function more efficiently both in crisis and in normal times. The key to gleaning these various lessons comes with understanding better how OWS functioned.

SUSPENSION OF THE ADMINISTRATIVE STATE

OWS was an exceptionally large expenditure. In less than a year, its financial cost was $18 billion dollars (Shulkin, 2021) – on par with the Manhattan Project, which manifested the atomic bomb at a cost of $23 billion (adjusting for inflation) over 5 years. Spending $18 billion dollars in 11 months meant that the normal guardrails for funding transparency, including Congressional oversight of appropriations and contract reporting mechanisms, were not in place (Stine, 2009). Instead, by July 2021, according to the Government Accountability Office (GAO), $12.5 billion were obligated by the Departments of Defense (DOD), Health and Human Services (HHS), and Homeland Security (DHS) through flexible contracting mechanisms known as Other Transaction Authority (OTA) (GAO, 2021).

OTA is legally binding funding agreement with the government, but it is much more flexible than a standard federal contract, grant, or cooperative agreement. Because it originally was created by DOD to support funding for research and technology prototypes, OTA (Bold & Roth, 2020a), including and the Defense Acquisition Regulations System (DFARS) (Department of Defense, 2023). In fact, the proverbial guidebook for OTA is only 53 pages long—incredibly brief in comparison to the FAR, a whopping 1,988 pages, (Bold & Roth, 2020a) and the Defense Federal Acquisition Supplement, which comes in at 1,338 pages (Bold & Roth, 2020b).

In 2020 and 2021, I interviewed senior officials at DOD, FDA, the White House, and internationally focused non-government organizations involved in the COVID vaccine development effort as research for my dissertation. These officials, who spoke confidentially—as required by the institutional review board for my dissertation—corroborated the predominant use of OTA-type contracting vehicles during OWS.

In general, the routine use of OTA avoids the government procedures meant to ensure fairness and accountability of federal funding and can permit murky federal funding processes—as has been reported by DOD's Inspector General in the past. The widespread use of OTA during the pandemic enabled limited transparency about how money was spent on OWS, particularly when third parties acted as contractors (Lupkin, 2020b).

Despite questions about accountability and transparency in relation to the use of the OTA mechanism for allocating federal funding, OTA has been proposed as the sort of "flexible contracting" tool the government could employ even in non-crisis settings (Bonvillian, 2021). While OTA was likely an appropriate choice during OWS, given the need for speed and for public-private partnering during the pandemic, its replacement of standard procurement contracts under normal circumstances has been criticized as a "black box" that can potentially subvert the important administrative mechanisms that govern proper allocation of federal funding (Maucione, 2018).

SUSPENSION OF THE SCIENTIFIC STATE: SCIENTIFIC CONSENSUS

Just as the speed required for OWS to be successful entailed moving operations outside the usual contracting mechanisms, the normal bureaucratic processes for federal

scientific advice also shifted. The government's normal operating consensus mode for science advice contrasted starkly with the mode used by OWS during the pandemic crisis.

One official I spoke with—a senior leader from DOD, who served through several administrations before, during, and after OWS—juxtaposed the two approaches. This official explained procedures during a previous administration, when normal channels were used for scientific advice: "It's group. It's consensus. It's you make policy by making sure everybody agrees with something and then with that agreement then you get some sort of approval." The official then outlined the H1N1 pre-pandemic response in the Obama administration, which followed this model and was led by health and medical experts within the government, including the CDC and the Biomedical Advanced Research and Development Authority (BARDA), an office located within HHS.

More recently, this official had clearly come to favor the OWS effort, which was characterized by top-down, rapid decision making. During OWS, government action occurred concurrently with direct engagement with industrial partners and a strong logistical focus. According to this official, the key was bringing in Slaoui, a former industry executive in R&D, and General Perna, whose expertise was in logistics, in place of the leadership of health experts. "We think that was the magic combination because it wasn't the health experts in here… decisions would be made very quickly, and we would have strategic direction and we would just know." This embedded criticism that scientific consensus is a liability in crisis was echoed by another official I spoke with – a senior leader from HHS, who served through several administrations before and during OWS – "There's ample opportunity for the scientific debate and back and forth, but in light of a

crisis, as we witness in the Trump Administration, the idea of this scientific debate is not well tolerated nor appreciated." Officials I spoke with suggested that the federal response to the COVID pandemic temporarily rewrote decades of preparedness norms in favor of crisis-driven improvisation. And while many federal scientific advisory committees continued meeting, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the congressionally mandated coordinating body for federal response to biological threats, remained un-convened throughout the pandemic. A 2021 report from a National Academies of Sciences, Engineering, and Medicine (NASEM) committee tasked with reviewing the public health emergency countermeasures enterprise stated, "During meetings with the committee, government leaders involved in OWS did not refer to PHEMCE. As the committee understands it, OWS became the de facto all-of-government MCM [medical counter measures] preparedness and response effort for COVID-19" (*Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, 2021).

On the other hand, at least one official I spoke with – a senior leader from HHS, who served through several administrations before OWS – argued that the resistance to established systems for scientific consensus during the pandemic, which was fueled by the acceleration narrative in OWS, *was* a failure in and of itself in the government response. "The leadership failure and countermeasure development overall for COVID has just been so stunning that it just makes me want to throw up. I mean if the PHEMCE had been functioning, we would not be in the shape we are in, we would not have needed

this warp speed contortion, and we would have had products. Okay? And if I'd had my way, I would have had a research network setup. I mean, this is insane."

A final question is whether the OWS template is likely to be readily applicable to other public health emergencies. Here it is important to recognize that OWS did not have to do the science from scratch: the work of the scientific state had, over decades, already created the tools and platforms—such as the pioneering work on mRNA—needed to develop the vaccine. According to OWS leader Moncef Slaoui and Biden vaccine leader Matt Hepburn, OWS did not need to do fundamental research to support vaccine development (Slaoui & Hepburn, 2020). Instead, the strategy was to select existing vaccine candidates and move them rapidly through the pipeline of clinical trials, approval, and commercialization. The fact that the right scientific knowledge and promising new technologies converged with urgent public purpose, may have been, in a sense, a lucky break. In another crisis. where the science is not sitting at the ready waiting to be moved through the regulatory pipeline, the OWS approach could disappoint.

ADAPTING GOVERNANCE FOR CRISIS AS WELL AS NORMAL TIMES

Despite concerns about the transparency and replicability of OWS, the effort made clear that slow, complex systems for awarding federal contracts, monitoring spending, and supporting cross-agency scientific consensus are incompatible with the speed and scale required for major crisis response. What is more, current conventional procedures may sometimes be incompatible with what would be ideal for normal government operations as well. Transforming our systems to support solutions to urgent

problems – be it responding to a pandemic, addressing climate change, or curing cancer – as well as everyday challenges must be something we do actively, and it will require a two-fold mission to replicate the speed and efficiency of OWS while reinforcing the scientific-administrative state as a partner rather than an obstacle.

Despite its success in delivering a vaccine, OWS exposed that the standbys that cut government contracting time and paperwork, such as OTA, do not support a robust system of accountability for spending. If crises become more frequent, this problem will only worsen. To address it, federal procurement policies should be revisited with specific attention to governance so that funding accountability and transparency is balanced with the need for expeditious government action. While a 53-page guide may not be up to the task, the contractor guidebooks that run to more than a thousand pages deserves examination.

Future crises will also require faster mechanisms, both internal and external to government, for providing scientific expertise and advice. As with government procurement and contracting, these mechanisms must be consistent across times of both crises and non-crises. In normal times, a major pathway for scientific advice in support of federal government policy is the Federal Advisory Committee structure. The Federal Advisory Committee Act (FACA), which became law in 1972, provides opportunity for advice and recommendations on agency operations and activities from experts inside and outside of government (U.S. Federal Advisory Committee Management, 2018). This legislation should be amended to enable processes for rapid scientific response in crisis. The marshalling of FACA committees to rapidly produce socially useful scientific

recommendations in crisis would be a major accomplishment and valuable tool for resilience.

In addition to FACA, another tool for external expertise engagement -- the rapid-response committees developed by NASEM – made important strides during the pandemic. At NASEM, preexisting lengthy timelines for consensus-report development were significantly reduced to support the need for expert-based guidance in real time. These rapid response committees could serve both as their own source of expertise and as a model for how cross-agency advisory groups comprised of government scientists and experts, such as PHEMCE, could best work in crisis (*Rapid Expert Consultations on the COVID-19 Pandemic*, 2020).

Looking to a future in which regular crises become part of the new normal, we must evaluate the trade-offs that these oscillations from crisis-to-non-crisis require rather than simply accept the ways that crises change our innovation system in Washington. Innovations like OWS should be explored, and their costs and benefits weighed out, to allow a deliberate approach to positively transforming the innovation system to serve the public good. Put simply, American innovation policy during crisis must evolve to honor the robust systems of transparency and expertise that exist between crises… because COVID will not be the last shock to the system.

5 PANDEMIC CRISIS INFRASTRUCTURE

This chapter was originally published in the Journal of Critical Infrastructure Policy (JCIP) (Arnold, 2022b). JCIP is an emerging, peer-reviewed, open access (OA) journal and a publication of the Policy Studies Organization in Washington D.C. The stated aspiration of the publication includes an impact on policy development to address serious challenges to infrastructure on which communities depend (Policy Studies Organization, 2023). Publication in this journal accomplished three goals. First, the practical policy mission of this journal makes it both unique and an appropriate venue to accomplish a key objective of this dissertation: to translate research to practice and link innovation to public value. Second, at the time of publication, health infrastructure resilience became a major policy topic in Washington policy circles in relation to President Biden's Build Back Better Infrastructure Plan (European Observatory on Health Systems and Policies et al., 2021) The timing of this article meant that this piece was in conversation with the actual politics of the moment in Washington D.C. Third, working with JCIP provided a unique opportunity for me to work directly with the Editor of the journal, Richard Krieg who is a visiting professor at Texas State University and former Health Commissioner for the City of Chicago.

ATLAS FOR A WARP SPEED FUTURE

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 operational modes of operation (Arnold, 2022a). This included suspension of rules that normally govern transparent and robust federal contracting and relaxing standards for

scientific consensus-building and expertise across government. It 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 to identify the key pandemic modes of action contributing to the success of OWS. The article 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 supplanted by crisis modes of action. Three features emerged: Speed, Scale, and Scope.

Speeding Contracting Using Other Transactional Authority. 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). This is because the OTA mechanism sweeps away standard government procedures usually valued as part of contracting rulebooks including the Federal Acquisition Regulations (FAR) (General Services Administration, 2019) and the Defense Federal Acquisition Regulation Supplement (DFARS) (Department of Defense, 2023).

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. Significant implications emerging from the extensive use of OTA during the pandemic include questions about the legal protections afforded by Bayh-Dole Regulations for technology transfer and commercialization (Ardizzone & Love, 2020). These legal protections are closely tied to normal modes of federal contracting. The lack of transparency in OTA contracting could even have been used to block government use rights or what is sometimes called the government's march-in authority (Douglass, 2021).

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 (Inspector, 2021). Further analysis is needed to support crisis funding mechanisms that have the same robust standards of transparency and evidentiary 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).

Scaling Conditional Drug Approval 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 (Walker, 2021b). The FDA was able to scale to this approval frequency by utilizing a critical crisis legal authority called Emergency Use Authorization (EUA) (Food and Drug Administration, 2005). 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 (Walker, 2021a). 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)(Food and Drug Administration, 2005).

EUA is a relatively new regulatory tool at FDA only codified in the Project Bioshield legislation of 2004 (108th, 2004). The first EUA was approved for an Anthrax vaccine in 2005 (Food and Drug Administration, 2005). Expanded as part of the Public Readiness and Emergency Preparedness Act (PREP Act) of 2005, the EUA was used sparingly until the swine flu pandemic of 2009 when 22 EUAs were approved (Walker, 2021a). Several pre-emptive EUAs were also issued for Ebola, Zika, and MERS, though no effective treatments or cures were identified (Bobrowski et al., 2020). 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 action in which scaling and speeding the normal federal approval process required the EUA mechanism.

The EUA mechanism expires with the emergency declaration(s) that authorized its use. There is much to debate about whether FDA is too conservative or too aggressive in its trial design and non-crisis approval mechanisms (Isakov et al., 2019). 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 (Food and Drug Administration, 2018). 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.

According to congressional testimony, HHS leadership requested a Nationwide Expanded Access IND protocol for hydroxychloroquine and chloroquine, which would have allowed unsupervised patient access to the drugs via local pharmacies. FDA struck a compromised approving the drugs via EUA for use in patients weighing more than 110 pounds who were hospitalized with confirmed Covid cases. In response to the limitation in the approval, HHS Assistant Secretary for Health Admiral Brett Giroir, an appointee of the President, placed a counter order stating by email, "NOPE…Needs to go to pharmacies as well. The EUA matters not…The drug is approved [and] therefore can be prescribed as per doctor's orders. That is a FINAL ASNWER." (Wamsley, 2020)

The EUA approval was revoked in June (Food and Drug Administration, 2020a). 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, the President's statements on their supposed effectiveness, and the pressure to deliver the drugs more

widely than the EUA approval guidelines, damaged the reputation of the FDA approval process (Piller, 2020).

This concern about the political pressure on FDA via the use of EUA was corroborated in my own interviews with senior OWS leadership in relation to the Administration's drive for other silver bullet treatments, such as convalescent plasma (McGinley et al., 2020) As one official states, "And so they set up this big expanded access program and so that's where all of these people got convalescing class, but there was no scientific evidence…Convalescent plasma collection [increased] 10 to 20 times so there was a lot collected, you know, like a blood donation. I mean it's non-trivial…That was the problem I had with it. It was like placating the political side that wanted this done."

EXPANDING SCOPE TO PRODUCT DEVELOPMENT

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 and services.

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 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 vaccines emerged from moving selected candidates through phase 2-3 clinical trials, approval, and commercialization in parallel rather than serial processes (Slaoui & Hepburn, 2020).

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). 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

The National Academies of Science, Engineering, and Medicine 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." (*Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, 2021). 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.

ELASTIC, ACCOUNTABLE, TRANSPARENT FUNDING INFRASTRUCTURES

Other Transaction Authority (OTA) will likely continue as an elastic contracting mechanism to expand medical product development funding. However, while OTA proved essential for rapid test, drug, and vaccine development during the pandemic, it also subverted 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

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 (Cohen, 2020). 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, and damaging FDA's credibility. 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

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 (Lo & Siah, 2021). There is opportunity for new approaches that leverage government investment and endorsement to actually create and increase value in markets that otherwise may not be attractive to industry (Laplane & Mazzucato, 2020). 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 government investments by leveraging the likelihood of successful investments. Just as during Covid, when many vaccine candidates failed, the ones that succeeded more than compensated for the failures. 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 (Vu et al., 2022) (Fagnan et al., 2013) (Lo & Siah, 2021). 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).

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 approaches we just experienced.

6 POLICYMAKING IN CRISIS

The following chapter was submitted to the Journal of Health Security (JHS), which is sponsored by the Center for Health Security at Johns Hopkins University. The readership of this journal includes scientific, medical, and policy experts in Washington D.C., and globally, who are focused on outbreak and disaster preparedness.

This article is to be included in a special issue on "Threat Agnostic Approaches to Biodefense and Public Health" (Security, 2023). My submission is accepted with the caveat that I add a section specific to the special issue at the editor's request. This section will elaborate on the cost, both in terms of human life as well as political economic costs, of the slow transition from containment to mitigation during the Covid pandemic. This additional section is due to the editors within two weeks following the dissertation defense. Publication of this special issue is anticipated this summer.

Publication in this journal supports the dissemination of these research results among the experts currently discussing lessons learned following the pandemic crisis. JHS is a peer reviewed journal. While it is not an open access (OA) journal, authors do have the opportunity to purchase OA for their article.

NOVEL POLICY STANDARDS FOR CRISIS RESPONSE

The Covid pandemic emerged as a public crisis in the U.S. in March 2020 and continued through 2021 and 2022, officially ending in May 2023. During this time, novel policy actions deployed by the government included the parallel execution of complementary policies. The clearest example of this is the choice made by leadership of Operation Warp Speed, the policy project that brought the Covid vaccines to the public,

to establish manufacturing lines and distribution networks while multiple vaccine targets were still in development. In addition to other elements, including the availability of mRNA vaccines and industry development prior to the pandemic, the execution of complementary policies in parallel played a key role in making it possible to reach a publicly available vaccine in just nine months.

While this parallel mode is financially risky, the crisis opened the window of opportunity for this approach. One example where this parallel mode could have been effective was in approach taken by the U.S. government to first contain and then mitigate the outbreak. The question is why this parallel policy mode was adopted for manufacturing and development during Operation Warp Speed while it was not adopted for similarly complementary policies of containment and mitigation (e.g., production and use of masks, personal protective gear, and other mitigation measures) during the Covid pandemic. The data collected to answer this question reflects interviews with 13 senior officials involved in the U.S. government response to the pandemic. I conducted these interviews from October 2020 through January 2021. My findings were corroborated using primary sources such as official records and news reports, as well as follow up conversations with staffers close to these leaders during the pandemic response. What became clear in my analysis was that during a crisis, key aspects such as Presidential preference and existing policy norms together defined whether parallel execution of complementary policies was possible.

GOVERNANCE IN CRISIS, FROM SERIAL TO PARALLEL MODES

Serial processes are the status quo in government. This is the order in which laws, regulations, executive orders, and other components of the federal system are conducted in normal times. When no impending crisis poses an existential threat, government operates on historical paths. In times of crisis, in contrast, political will is galvanized, resources are freed, and normal procedures may be accelerated and sometimes streamlined or suspended (Jones & Baumgartner, 2005).

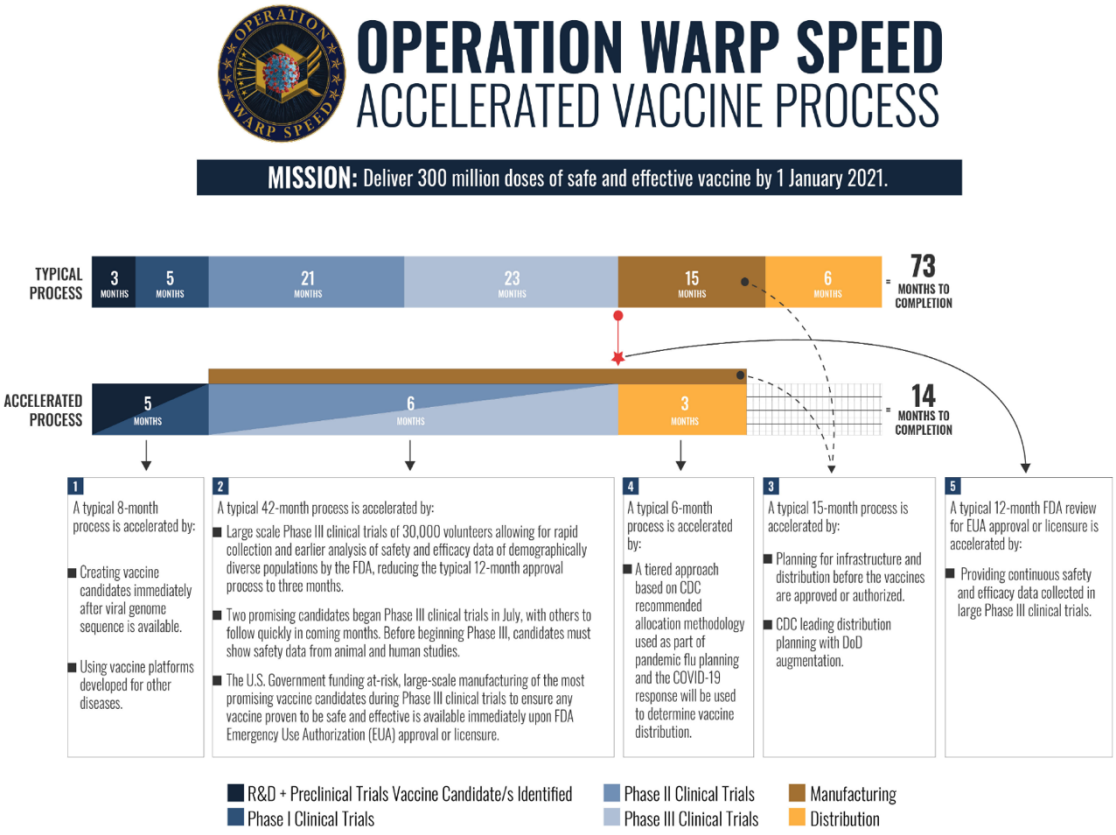
The crisis itself may make parallel modes possible. The actual transition to execution from serial to parallel modes in crisis requires two conditions. First, established policy models must provide a historical map for execution of the policy action. One example of a policy that provided a map for a parallel mode during the pandemic is the Manhattan Project during World War II. Second, presidential support, or lack of clear opposition through tacit approval, is another necessary condition for parallel action on complementary policies in crisis. One example of complementary policies that did not manifest into action during the Covid pandemic include the policies of containment and mitigation. The following two subsections explore these cases further.

MANUFACTURING VACCINES AT RISK

OWS accelerated vaccine development from the average of 73 months to 14 (U.S. Department of Defense, 2022). The effectiveness of OWS was supported by several policy actions early in the process. Relevant to this work, the government conducted large scale clinical trials on multiple vaccine targets in parallel with large-scale manufacturing preparations starting in month 6. This parallel approach in OWS was risky

and expensive. This approach is enduring following the end of OWS. It has been referred to as a pandemic paradigm (11) and a successful tool for accelerated development of medical countermeasures during extreme crisis (Slaoui & Hepburn, 2020) (Collins et al., 2020) (ShulkinDavid, 2021). The comparison of the OWS approach to the typical vaccine development process is included in Figure 3 (@NavyMedicine, 2020).

Figure 3: Vaccine Development Process in Operation Warp Speed



Note This is the comparison of the accelerated vaccine development process under Operation Warp Speed compared to the typical vaccine development process.

OWS was supported by a massive US government investment of $12.4 billion. This is a sizable investment, just over half of the cost of the Manhattan Project when adjusted for inflation (ShulkinDavid, 2021). This number does not include the decadal development funding of mRNA technology supported by the National Institutes of Health and the Department of Defense. Established technologies served as the platform for the modified mRNA Covid vaccines (Lalani et al., 2022). Preclinical development on multiple Covid vaccine candidates started in February and March 2020 (U.S. Department of Defense, 2022). Contracts for development of the vaccines and other medical countermeasures supported six companies with viable late-stage products including Pfizer-BioNTech, Johnson & Johnson, Moderna, AstraZeneca-Oxford, Novavax, and Sanofi-GlaxoSmithKline. Meanwhile, investments in manufacturing began in July 2020. The parallel policy execution in OWS meant U.S. government contracts with these companies supported clinical trials while also building new manufacturing facilities (Barone, 2020) The government pre-purchased over 900 million doses of these potentially viable vaccines, at risk. The bet paid off. The first two of three effective Covid vaccines were approved via Emergency Use Authorization and distributed before the end of 2020 (U.S. Department of Defense, 2022).

THE ROLE OF ESTABLISHED POLICY NORMS

The parallel mode exhibited in OWS, in which manufacturing and clinical development happened at the same time during the Covid pandemic, was modelled on previous experiences. The Covid pandemic was not the first time a crisis prompted the government to take a risky parallel policy mode that paid off. The Manhattan Project, the

government effort to build the atomic bomb before the axis powers in World War II, was the model for Operation Warp Speed, which my respondents repeatedly referenced. The Manhattan project explored uranium and plutonium devices, pursued purification of the active fissile materials by various methods in parallel, and built manufacturing capacity even before a prototype bomb was available (Rhodes, 1986). The Manhattan Project established a policy playbook for OWS leaders (Hall, 2022). This playbook included existing policy norms that share characteristics with OWS in which the military financed industry partners to address an existential threat to the U.S.

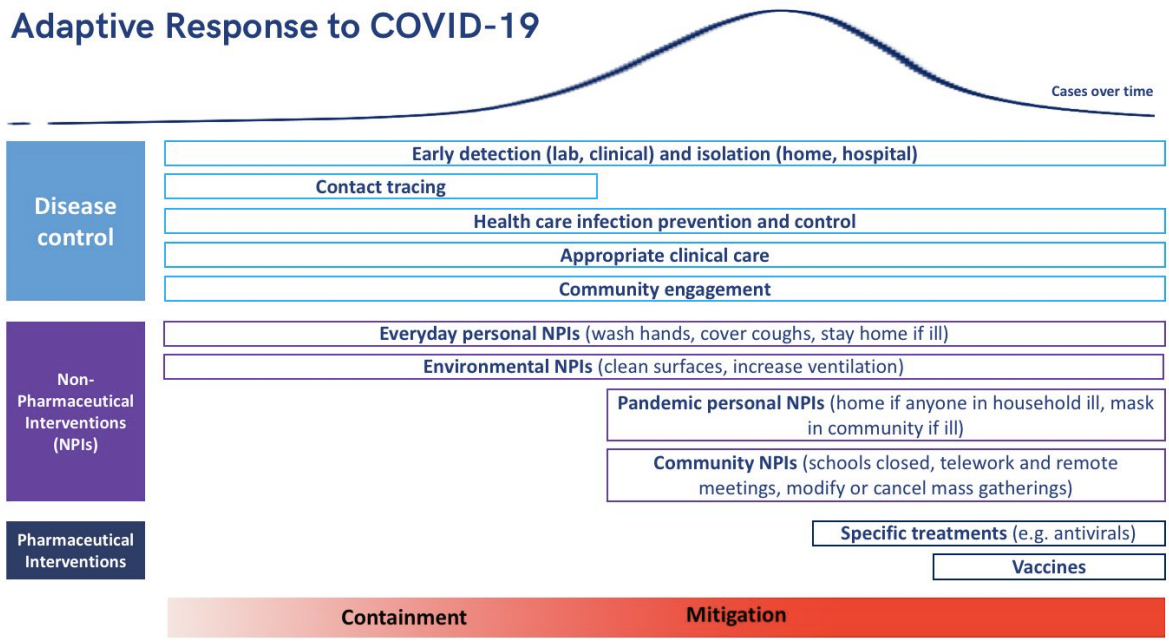
As part of the years-long effort to develop the bomb before Germany, Albert Einstein and a series of prominent physicists approached President Roosevelt to gain his support for action (Rhodes, 1986). Convinced of the promise of a fission bomb, President Roosevelt limited scientific engagement to a small Top Policy Group in 1942 (Rhodes, 1986). The leaders of the Manhattan Project adopted a parallel policy mode. According to this policy, called the "principle of parallel development", all scientific, infrastructure, and military development efforts to create the bomb would be executed concurrently. Senior technology industry leaders at Bell Laboratories and Dupont were engaged. By 1944, the Los Alamos lab was established. The Fat Man, the first fission bomb successfully tested was completed in 1945 (Rhodes, 1986). The use of the bomb effectively ended the second world war with the American atomic attack on Japan that August. The Manhattan Project cost more than the entire DOD budget at the time and the project shaped post-war perceptions about the role of science and technology for humanity (Mowery & Rosenberg, 1989).

In addition to the policy map provided by the Manhattan Project, the Covid pandemic was not the first time that this parallel policy mode emerged in response to an outbreak. One of the perceived failures of the U.S. response to the H1N1 "swine flu" outbreak in 2009 was the stalled production timeline of the vaccine following development. While the H1N1 vaccine was developed rapidly based on already developed flu-based vaccine technology, there was not a sufficient number of manufactures to deliver the finished vaccines at scale. This lack of foresight resulted in a vaccine that arrived after the H1N1 seasons had both ended in the northern and southern hemispheres (Broadbent & Subbarao, 2011). The execution of complementary policies in parallel during OWS was likely influenced by this experience. The H1N1 proved a counterexample, illuminating the necessity for this parallel mode in clinical development and manufacturing. This is likely since the scientific leader of OWS, Moncef Slaoui, was also the vaccine chief at GlaxoSmithKline during H1N1 when the government cancelled a large portion of the pre-orders after pushing heavily for GSK to develop the vaccine (Boseley & editor, 2010). This parallel execution of complementary policies did not prevail in other areas of pandemic response including the policies of containment and mitigation.

Containment, Mitigation, and Presidential Opposition. Considering containment and mitigation in tandem during an outbreak was an established best practice in the U.S. government prior to the Covid pandemic (U.S. Department of Homeland Security, 2020),(Collins et al., 2020), (Ljungberg & Isaguliants, 2020), (Kalichman et al., 2022), (U.S. Centers for Disease Prevention and Control, 2018). Containment strategies included

a coordinated national approach with an emphasis on extensive daily testing, quick contract tracing, and appropriate quarantine. The Covid response in South Korea was an effective example of containment where there were only 53 cases of Covid (Schwak, 2022). Containment and mitigation measures can be separate and distinct but also intersect in areas including early detection, health care infection and control, community engagement, and appropriate clinical care. Disease control measures, non-pharmaceutical interventions, and pharmaceutical interventions that span across containment and mitigation categories are included in Figure 4 ("Adaptive Response to COVID-19," 2020).

Figure 4: Containment and Mitigation Measures Throughout Crisis



Note As depicted in this figure, the containment and mitigation measures are distinct but do overlap across disease control efforts, non-pharmaceutical interventions, and pharmaceutical interventions. The Source of this figure is PreventPandemics.org ("Adaptive Response to COVID-19," 2020)

Mitigation strategies are a complementary policy package to containment. Mitigation strategies aim to slow the spread of the disease; reduce the number of patients to avoid surges that overwhelm hospitals; minimize the severity of the infection if possible; expand information access including the ability to easily test for the virus; and direct appropriate quarantine policies (Parodi & Liu, 2020). Similar to containment, effective mitigation measures take place on a national scale (Walensky & del Rio, 2020).

Political Interference in the Covid Response. Full containment measures and most mitigation measures lagged in the U.S. pandemic response (Parodi & Liu, 2020). The lag in planning, slow adoption of full containment and mitigation measures, and the lack of a parallel approach to both strategies in the U.S. was due in part to political interference. President Trump, the White House, and administration appointees politicized and publicly minimized the seriousness of the Covid threat (Parker & Stern, 2022), (Woolhandler et al., 2021), (Stasavage, 2020).

The Covid threat was recognized internally in the U.S. government in November 2019 in reports released by the U.S. military's National Center for Medical Intelligence (Kahana, 2021). On January 31, 2020, immediately following the World Health Organization's declaration of a Global Health Emergency, the U.S. Department of Health and Human Services declared a national emergency. President Trump responded on

February 2, 2020, by issuing a travel ban for non-U.S. citizens traveling to the U.S. from China. American citizens could still travel between the U.S. and China (Braun et al., 2020).

President Trump and the White House continually suppressed agency activity that would recognize the Covid threat. One former HHS official I interviewed stated, “I don't think there's much to say about the Trump Administration's response. I mean, I feel pretty strongly that the views of the scientific community were largely dismissed by the administration to the great detriment of the country.” Not only was the science ignored but the pandemic was political. When Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response (ASPR), led the repatriation effort for American passengers marooned on a cruise ship quarantined in Japan’s Yokohama Port, he was almost fired by President Trump. The President’s concern was that allowing the infected U.S. passengers to enter would almost double of the number of infected Americans on U.S. soil (*Banding Together*, 2022). In another instance, a seasoned CDC leader, Nancy Messonier, was re-assigned after President Trump heard a CDC podcast that both confirmed the likelihood of an imminent American outbreak and outlined likely containment and mitigation measures based on a 2017 influenza preparedness plan (Coates, 2021; Knauer, 2022; “Transcript for the CDC Telebriefing Update on COVID-19,” 2020). Immediately following Messonier’s reassignment, Vice President Pence was named chair of the White House Coronavirus Task Force (Diamond & Cancryn, 2020). That same month on February 26, 2020, Health and Human Services (HHS) Secretary Azar testified in

Congress stating that “the immediate risk to the American public remains low” (Taylor, 2020).

Despite the President declaring the Covid-19 national emergency on March 13, 2020, Vice President Pence publicly stated on April 7, 2020 that “the threat of serious illness for most Americans is relatively low” (*Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Brieng*, 2020). The President continued to minimize the threat to the point of denial by halting funding to the World Health Organization (April 14), making plans to Open America Up Again (April 16), arguing job losses were temporary, and suggesting “the problem will go away” and that many “don’t know they have it [COVID]” (May 15) (Wolfe & Dale, 2020).

Mitigation measures such as masks were not supported by the Administration and became politicized symbols (Kenworthy et al., 2021). Mitigation efforts by HHS were thwarted by the White House. The following example was relayed to me directly by a senior official in the Trump Administration and later included in publication. The Assistant Secretary for Preparedness and Response (ASPR) funded and manufactured five masks for every American household. Distribution was halted by the White House Coronavirus Task Force when the head of the task force, Vice President Pence, refused to meet with the ASPR in May of 2020 in order to give the Ok on the effort. Reasons for the White House refusal to endorse the project included the unfashionable look of the masks as well as the mode of distribution via the U.S. Post Office. Distributing the masks through the postal system could reinforce the utility of the postal agency at a time when

the President was framing the mail-in ballot effort as faulty during his Presidential re-election bid (Reichmann & Izaguirre, 2020) The idea of mask-wearing was not supported by President Trump for a majority of the pandemic, even following his own hospitalization for Covid (Mackey, 2020). The CDC director publicly endorsed mask wearing for the first time in congressional testimony well into the pandemic in September of 2020 (Diamond & Cancryn, 2020).

The Role of Presidential Support. The U.S. President is a powerful figure who can singlehandedly set agendas like no other actor in the U.S. system. Promising policy solutions that might otherwise be moved to the decision agenda can be stymied if they meet Presidential opposition. By extension, the President's appointees are both powerful and pre-conditioned to bend toward the President's will (Kingdon, 1984).

The U.S. response to Covid, shaped by President Trump, echoed the government response to the Spanish Flu Outbreak of 1918 where authorities denied the outbreak eventually losing both credibility and the opportunity to save lives (Barry, 2009). As one senior official who served during the pandemic relayed, "The next phase is the non-pharmaceutical intervention to contain the virus. That was an issue that was largely dependent on CDC and their belief, wrongly, that contact tracing and isolation and quarantine could be a means to contain the disease. And there was ample evidence, and I'll send this to you Amanda, evidence by mid-February [2020] that that was fallacious if not false. However, the containment strategy fit the President's and the political dimension context."

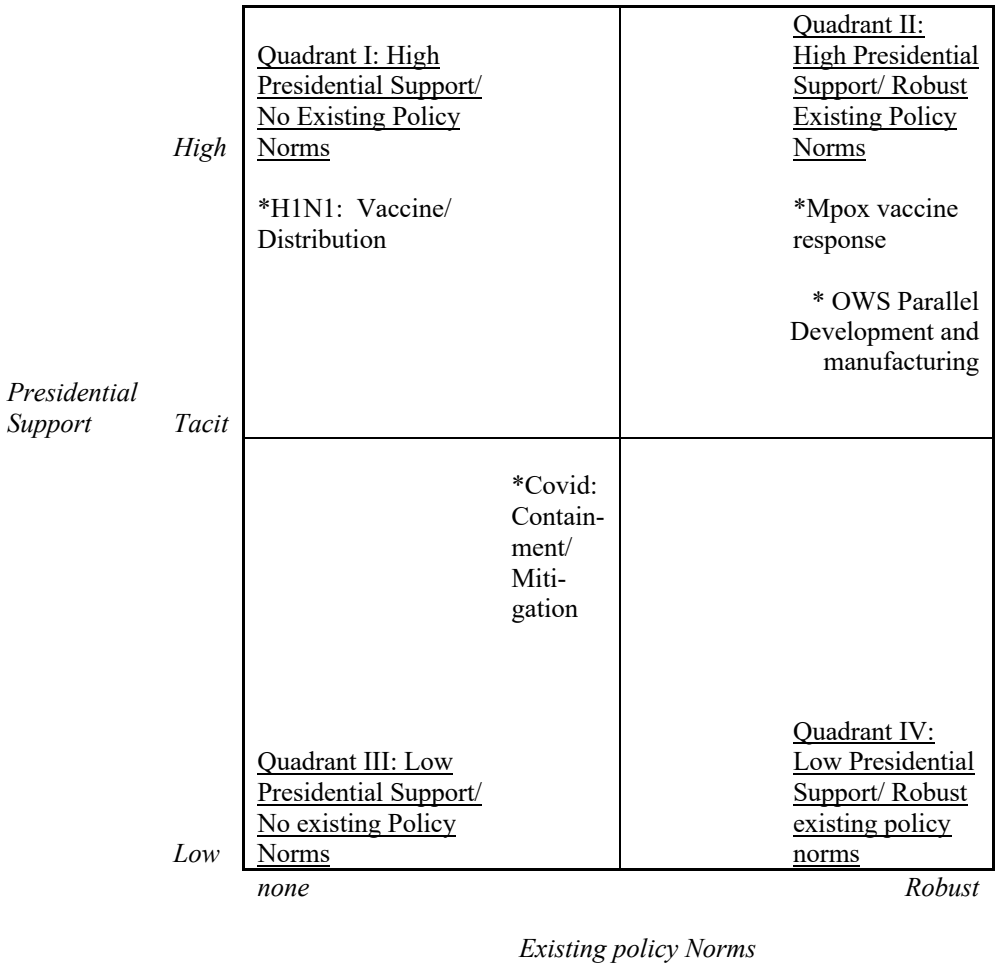
Until OWS, the Trump Administration's handling of the Covid virus was judged a dramatic failure (Guharoy & Krenzelok, 2021). The lack of a coordinated parallel approach to both containment and mitigation strategies was due to opposition by the President. This politicization prevented the parallel approach to containment and mitigation strategies and the cost was American lives. At least one study suggests the number of additional lives lost due to this poor approach to pandemic response in the U.S. was more than the human toll of World War I (University of Oxford, 2020). Moving through containment and mitigation policies in parallel mode would have enhanced pandemic response ensuring the nation's faster progression from reaction to recovery (U.S. Department of Homeland Security, 2020).

DEVELOPING A FRAMEWORK FOR ACTION DURING CRISIS

Crises, or focusing events, open a window of opportunity for parallel modes to emerge onto the policy agenda. However, action on the policy agenda requires a secondary set of conditions. First, the President must not be in opposition to either policy. Second, policy norms must exist as a map for action. When these two conditions are met, it is possible to execute complementary policies in parallel.

For further analysis, these two conditions – Presidential support and existing policy norms – are mapped onto a 2x2 matrix in Figure 5 along with outbreaks that fit the characteristics.

Figure 5 :Two-Dimensional Framework for Policy Success (Typology) in Context of Decision Support for Parallel Deployment of Complementary Policies in Crisis



Note Vaccines developed or deployed in response to crisis are mapped on a 2x2 matrix according to factors including Presidential support or lack of support, and existing policy norms from none to robust.

Parallel development and manufacturing during OWS fall into Quadrant II: High Presidential Support/ Robust Existing Policy Norms. The program enjoyed at least tacit support from the President who appointed General Perna to oversee the project and interviewed and invited Moncef Slaoui to serve as the scientific lead for the project. The program also depended on a previous model of technology development, the Manhattan

Project that developed the atomic bomb in World War II. Quadrant II is the most likely quadrant for action to execute complementary policies in parallel.

The containment and mitigation responses to the Covid pandemic fall into Quadrant III: Low Presidential Support/ No existing Policy Norms. The President was not fully opposed to containment policies. Evidence suggests the President supported ex-U.S. containment, by barring Chinese citizens from entering the U.S., more than internal U.S. containment of the contagion. The President actively opposed mitigation measures such as masking. Regarding policy norms, there were few existing policy norms for such an unprecedented outbreak in the U.S. This is despite best practices, preparedness policies, and experience in major outbreaks in other countries. Quadrant III is the least likely combination of these two conditions to result in successful execution of complementary policies in parallel.

Additional cases such as the Mpox, formerly monkeypox (Mermin, 2022), vaccine response and the H1N1 vaccine development and response perform a validating assumption for this four-quadrant framework. In the case of the Mpox outbreak, the government quickly applied the existing smallpox vaccine to protect against Mpox, manufactured the vaccines and made the vaccines available to the public (Kozlov, 2022). This parallel execution of complementary policies was done expediently. The President was in full support and there were existing policy norms to follow including the OWS experience, which provided a robust policy roadmap for action.

In the case of the H1N1 response, a vaccine became available, but the crisis ended before the vaccines could be delivered and government contracts for the final product

were cut significantly. The government cuts to previous contracts made with manufacturers for H1N1 left industry partners hesitant to engage again with the U.S. government on vaccine manufacturing in crisis. The President fully supported vaccine development. Regarding existing policy norms, it is possible that the H1N1 experience provided an explicit counter example that enabled an existing policy norm, a policy map to follow in the future. Policymakers could map a better route in OWS and Mpox in contrast to the failure of conventional policy norms related to manufacturing and development engaged in H1N1.

TECHNSCIENTIFIC INITIATIVES, CRISES, AND FUTURE RESEARCH

These cases described above indicate an important finding: that the parallel execution of complementary policies is both critical and preferable to achieve a successful, accelerated government response in pandemic crisis. These cases also lead to a framework that implies two factors are necessary for the successful execution of the execution of complementary policies in crisis, or the parallel mode. These factors include Presidential support and existing policy models. The main conclusions of this work include that technoscientific initiatives can generate a vision for the government to organize around if the conditions are correct. Achieving and benefiting from such a solution will depend on executing complementary policies in parallel along the way. Political interference, especially if led by Presidential opposition, will inhibit, or extinguish adoption of the extraordinary expense and effort needed to effect parallel crisis modes of operation. The existence of policy norms, such as those that now exist following the vaccine development experiences in H1N1 and OWS regarding the parallel

execution of clinical development and manufacturing, are also critical in the success of the parallel mode.

This theory for action on the parallel execution of complementary policies in crisis may not apply in all instances where a focusing event opens a window of opportunity for action based on Presidential support and existing policy norms. There are at least two scope conditions, or conditions within which this theory is expected to hold. First, this theory was developed to explain the parallel policy mode in action during public health crises of pandemic potential. Whether this theory may apply to focusing events such as natural disasters or extreme terrorist attacks is promising ground for future study. If this theory is expanded to include executive support instead of Presidential support, the theory could also be applied more broadly to global crises such as famine.

Second, this theory is based not just in public policy but within the tenets of innovation policy. A key aspect of this theory is the presence of a technoscientific initiative that provides a solution to a long-term existential crisis where current strategies, technologies, and existing preparedness falls short. Future work building on this theory within innovation policy could examine the role of scientific authority on the perceived value of technoscientific initiatives envisioned.

7 CONCLUSIONS

This research explored the dynamics at play in the emergence and execution of modern technoscientific initiatives. The objectives of this research were to observe the barriers and facilitating dynamics during the execution of technoscientific initiatives. Key questions driving this work included: What are the federal policy mechanisms utilized in the pursuit of a technoscientific solution during crisis? What role does political and financial risk play in the federal manifestation of technoscientific solutions during crisis? What are the conditions of success for technoscientific solutions?

During the course of this research, the pandemic enabled a focus on the role of crisis as pivotal for the creation of technoscientific initiatives funded by the U.S. government. Discussion of the dynamics and barriers at play in the emergence and execution of modern technoscientific initiatives are included in Chapters 4, 5, 6. The benefit of hindsight allows additional reflection in this conclusion on the three published pieces included in this dissertation. An overview of contributions is also included in this chapter.

In review of these chapters in hindsight, Chapter 4, Rules for Operating at Warp Speed, focused on several critical federal policy mechanisms utilized in the pursuit of a technoscientific solution during crisis. These include Other Transactional Authority as a funding structure and a narrowed approach to scientific consensus. This document was published at a time that Operation Warp Speed was unquestionably lauded as a major success and becoming the basis for multiple future operations for disaster preparedness in the federal government. This article was distilled somewhat by the length required for

publication for the target audience of policymakers, but this does not diminish the important role this piece played in exposing data that countered the pervasive idea that OWS was a successful blueprint for crisis response and should be duplicated in preparation for future crises. In the future, this piece could be expanded for a more theory-interested audience and the connections between this piece and the other articles could be further explored. An area for future study based on this work is the perception of bureaucracy and the impact of that perception on how scientific consensus is developed and received in crisis.

Chapter 5, Atlas for a Warp Speed Future, focused on the role of political and financial risk in the federal pursuit of technoscientific solutions during crisis and normal ties. This chapter is a discussion of the study data as it applies to an updated schema for the national innovation infrastructure critical to future pandemic preparedness again with a target audience of policy practitioners. As a result, discussion of theory was distilled for relevance to the journal, which led to an emphasis on policy in practice rather than an expanded theory development.

This journal was the appropriate venue for the relevant policy recommendations that emerged including lowering the financial and political risk of federally funded vaccine development through a vaccine portfolio megafund. This megafund approach would enhance national pandemic preparedness. Two benefits are highlighted here: first, by shedding the limiting idea that the government must choose or prioritize among emerging infectious disease targets, and second by removing the hesitance of the federal government to fund late-stage development. The benefits of this policy approach would

be experienced both in crisis and "normal" times; the government would not be caught flat-footed when a contagion emerged from the non-prioritized threat list, and the political and financial cost of failure of any given federally supported target would be softened by the successful medical countermeasures that would statistically emerge.

Chapter 6, Novel Policy Standards for Crisis Response, discusses particular conditions of success for technoscientific solutions. Opportunities for the parallel execution of complementary policies are explored. A comparison is made between the parallel approach to manufacturing and development in Operation Warp Speed and the (missed) opportunity to pursue containment and mitigation in parallel at the outset of the U.S. pandemic.

At the time the data was gathered in 2020, the approaches to containment and mitigation were not front of mind as the effort to develop Operation Warp Speed was still underway. Despite outreach efforts to CDC Director Robert Redfield, no senior members of the CDC were interviewed during the data gathering process. Senior officials interviewed during data collection did discuss the role of mitigation and containment during the pandemic and corroborating documents utilized to write this chapter include discussion of the role of the CDC in containment and mitigation during 2020. These corroborating documents included the politicized treatment of CDC officials who did attempt to expedite the adoption of both mitigation and containment policies such as Nancy Messonnier, Director of the National Center for Immunization and Respiratory Diseases at CDC.

A promising opportunity for future research building on this work would be to rigorously test the typology depicted in the two-dimensional framework for crisis policy success in this chapter. The typology is an expression of the argument that two factors – Presidential support and historic policy models – are jointly necessary for the success of technoscientific initiatives during extreme crisis. This framework was inductively derived and it was motivated by Pasteur's Quadrant of use-inspired research. Additional cases including the vaccine development process for the H1N1 and Mpox crises were included for comparison in the analysis. However, this framework should be tested in a study on a case different than the one from which it was derived.

These three articles included as chapters 4,5,6 are in conversation with each other. Each article builds out a different aspect of this snapshot based on the data gathered during the pandemic. Each piece does this in a way that feeds either the needs of policymakers or theorists focused on innovation practice and policy in the U.S. government in both crisis and normal times.

The main theoretical findings in this dissertation are two-fold: (1) innovation in crisis is undertheorized in Innovation Policy and Science and Technology Studies and (2) two conditions enable technoscientific initiatives to emerge onto the policy agenda and successfully deliver major solutions to society in times of crisis including presidential support and precedent policy models.

First, despite the critical role of crisis in the creation of technoscientific initiatives, there is a significant lack of theoretical insight from Innovation Policy and Science Technology Studies on how technoscientific initiatives emerge and are executed in

relation to crisis. In order to begin to address thig gap, Chapter 6 presents an argument for a two-dimensional framework for crisis policy success from the data that outlines conditions for success for a technoscientific initiative during crisis. Further research is necessary on the conditions of success for technoscientific initiatives during crisis: Once these initiatives are created, how are they managed, deployed, and what does success look like if viewed in terms of delivering value to the public based on taxpayer-driven innovation investment?

Second, this work includes a preliminary typology, a categorization, of technoscientific initiatives in the U.S. These categories include 1) a response to existential national crisis, such as the Covid pandemic, 2) a future-focused category emphasizing a preemptive approach to address threats to America's global economic supremacy as was the basis for the National Nanotechnology Initiative and the National Manufacturing Initiative, and 3) an investment in the untapped promise of current knowledge that may increase the quality of life for all Americans as was the basis for the Precision Medicine Initiative. These three categories – from existential crisis response to future-focused approaches – provide an early typology of technoscientific initiatives funded by the federal government. Additional work to expand and test this typology would provide practical context to policy makers, especially in the White House, who are in a key position to develop and execute high profile technoscientific initiatives.

Policy contributions of this work emerge in three areas. First, there is a need for elastic, accountable, transparent funding infrastructures for federally funded product development that can be activated during crisis to preserve the standards for use of

federal funds in normal times. Second, the accountability of federal agencies should be maintained during crisis response. For instance, the EUA mechanism, and the FDA, needs to be insulated from politicization by political leaders during crisis. And accountability for use of public funds cannot be sacrificed to expediency even in crisis. Third, the current federal effort to prioritize threat targets for development of medical countermeasures in normal times is insufficient to meet future pandemic preparedness and response needs. The federal government should embrace late-stage development through an innovation megafund in partnership with private and academic partners that will decrease both the financial and political risk of federally funded late-stage countermeasure development.

Together, each of the contributions in this work contributes to both the post pandemic lessons learned literature, as well as the literature gap to understand the dynamics and barriers in the production and execution of technoscientific initiatives. The substantive and practical contributions of this work include a series of details about OWS that were previously not available or not compiled in a narrative about how the U.S. innovation system responds during crisis. It is my hope that this research contributes to a future in which the number of crises yet to come are limited not only by the speed of response but also by the early deployment of technoscientific initiatives that lead to effective, life-saving solutions.

EPILOGUE

I am taking the opportunity in this epilogue to capture some concepts and observations that may not have otherwise found a place in this dissertation. These observations emerged while studying a very specific group of people inhabiting a very special place and time in history – that is, senior U.S. officials involved in Operation Warp Speed executing the largest technoscientific initiative since World War II.

Three areas of reflection include the assumptions taken for granted by myself or my subjects in this work; the "black boxes" in the tradition of Bruno Latour that are inherent in this work that merit additional exploration; and my own expectations for whether or how any of this work may actually impact policy in Washington.

To begin, there are several assumptions to expose in my conversations with the senior officials during the Covid pandemic from October of 2020 through February 2021. These include the crisis/ non-crisis dichotomy I depend on in my analysis, as well as the way Operation Warp Speed gained political ground principally based on many officials' explicit historical analogy to the Manhattan Project.

Regarding assumptions in this work, I begin with the crisis/ non-crisis dichotomy I depend on in my analysis. As noted by Kingdon (Kingdon, 1984), there is a problem component to all policy that emerges onto the action agenda. It is not possible to promote a policy without constructing a problem to be solved. I define three problems constructed in my preliminary typology of technoscientific initiatives in chapter two. These categories include defending against international threats to the U.S. economy, especially those posed by China; capturing the untapped promise of existing technologies for health

and quality of life; and developing solutions for existential threats to the nation for which the federal government is seen as the only possible hope for a solution.

In this dissertation, I move from a non-crisis, problematization mode in normal times to a crisis construction when the U.S. is facing existential threat. However, defining this crisis/ non-crisis construction is worth more explanation. For instance, I define crisis by using emergency bureaucratic responses that are triggered at a state and national scale that indicate an existential threat to the nation. Examples of bureaucratic triggers in the pandemic included the U.S. Department of Health and Human Services declaring a public health emergency on January 31, 2020. This declaration automatically expanded agency authorities including the use of Emergency Use Authorization by the Food and Drug Administration for accelerated approval of medical countermeasures. Other examples included the March 13, 2020, Presidential declaration that the Covid 19 outbreak was a national emergency; Presidential approval of the disaster declaration by Wyoming on April 11, 2020, that marked the first time in American history that a major disaster declaration was issued in all 50 U.S. states; and the President's signature on April 10, 2023, of H.J. Res 7 which officially ended the national emergency associated with the Covid 19 pandemic (U.S. Department of Defense, 2022).

Using the triggering of emergency bureaucratic responses to classify the pandemic as a crisis is a satisfactory but perhaps imperfect approach to parsing a crisis/non-crisis dichotomy. It is tautological in the sense that the bureaucracy invoked authorities that are supposed to be used only in times of crisis. In the end, the definition

rests on reaching sufficient consensus in the political system to extend executive authority, with tacit consent of Congress and the judiciary.

Of note, a relevant observation that emerged in my research is that bureaucratic crisis construction in the U.S. may be swayed more by disastrous economic impact than by the toll of human lives. I would be interested in looking at other instances in which the loss of human life is significant, but the economic impact is muted, and so a national crisis is not declared. For instance, an argument could be made that current bureaucratic standards for national crisis construction in the U.S. fail certain populations because if their marginalization in the economic system. One such population is children. One might argue that the current school shootings epidemic is a crisis but does not meet the threshold of an economic crisis and so may not elicit bureaucratic declarations of crisis.

Regarding additional assumptions in this work, Operation Warp Speed was labeled a success, at least in developing vaccines, the component that was most often directly compared to the Manhattan Project. I explore that association in this section. Operation Warp Speed captured imagination across the U.S. government based in part on analogy to the WWII era Manhattan Project. Operation Warp Speed was initially called Manhattan 2.0, implying extreme urgency. This analogy assisted in the removal of obstacles that may constrain the heavy expenditures aimed at developing a "technical fix" to the existential threat presented by the pandemic. In World War II, U.S. government alone had the wherewithal to develop a nuclear bomb; during the Covid pandemic, the enormous U.S. capacity for biomedical innovation was pressed to develop vaccines.

In WWII, the Office of Scientific Research and Development (OSRD), under the leadership of MIT's Vannevar Bush, funded war time advancements in radar, penicillin, the proximity fuse, malaria treatment, and most notably the Atom Bomb as result of the Manhattan Project. Bush went on to translate the work of the OSRD for civilian use as enshrined in the report he wrote, Science—The Endless Frontier citation. Bush's proposal for a National Research Foundation contributed to the creation of the National Science Foundation in 1950 and argued for federal support of science controlled by scientists, sketching a linear model of innovation that still influences the organization of the $656 billion U.S. R&D innovation enterprise (National Science Foundation, 2022).

One lens I considered using to further explore the work that the Manhattan Project analogy did during the pandemic, and specifically in relation to Operation Warp Speed, is the sociotechnical imaginary in science and technology studies. Sociotechnical imaginaries are defined as the ideas about public good and our collective future that are inherent in visions of scientific and technological progress (Jasanoff & Kim, 2015).

The Manhattan Project imaginary describes a series of beliefs about scientific and technological progress in the U.S. in crisis and seems potentially useful in exploring the similarities in the genesis of the Manhattan Project and Operation Warp Speed. One belief inherent in the Manhattan Project imaginary is the role of technocrats and the technocracy, or the structure of scientific and technological experts empowered to envision these initiatives to completion. As described in this dissertation, technocrats envisioned Operation Warp Speed as a Manhattan Project 2.0. The idea had to be adopted and championed by the White House, similar to the effort to bring forward an Atom

Bomb during WWII. However, in the case of Operation Warp Speed, the technocrats were disempowered by the White House. The Trump White House did not hold the first order trust in scientists and technicians that those same groups enjoyed during WWII.

For example, at the point of acceptance by the White House, it was former Republican Congressman and other ideological partners from the business community trusted by the White House, not scientists, who identified and vetted the scientific leadership for Operation Warp Speed. In this process, a former Republican congressman interviewed a short list of scientific and technical leaders, only vetting the short list with technocrats and industry advocates after identifying potential leaders. In my research, it became clear that Moncef Slaoui was the exact leader needed in the moment given his industry prowess that satisfied the White House and his scientific expertise and experience that enabled him to effectively lead the medical countermeasures development process. That being said, the process for choosing the scientific leader of Operation Warp Speed seemed overly political to me and it bothered me that the White House empowered the military to lead Operation Warp Speed with Slaoui appointed as an advisor to the President and paid just $1.

This rift in technocratic leadership exposed in the genesis stories of the Manhattan Project and Operation Warp Speed expose a larger distrust by an expanding percentage of the American public in the power of knowledge and the role of expertise in leadership. This rift will be playing out and affecting the U.S. innovation system over coming decades. The next crisis may provide clarity on the impact of this fracture on the actual ideas that underpin the U.S. innovation system and the technocracy that depends on it.

Having reflected on assumptions inherent in this work, I now turn to the "black boxes" in the tradition of Bruno Latour that are inherent in this work that merit additional exploration. In the sociology of science, black boxing is a reference to those who study both the inputs and outputs of science, but who neglect to study how that science is produced. Latour, Whitley, and Winner all speak to this idea, which is a critique of the Mertonian view of science (Pinch, 1992). Getting inside these so-called black boxes or understanding how science and even individual technological efforts actually create outputs, is an important contribution of the sociology of science.

A modern technological example of opening such a black box (though not at all related to the subject of this dissertation) is the way that automatic water taps sense skin color, the problem being that the technology was tested on beige hands and does not recognize darker hues (Ren et al., 2022). This is an example of how understanding the technology can expose social and equity issues inherent in the use of that technology. As illustrated in this example of the automatic water tap, and as I recall describing in my comprehensive exams, technologies have a gravity and a weight that reflect and determine important features of how individual citizens experience society. Additional examples of the ways that the function of technologies can impact individual citizens include the role of domestic technology that reinforces damaging gender roles as explored in Ruth Schwartz Cowan's "More Work for Mother: The Ironies of Household Technology from the Open Hearth to the Microwave", and the strength of marketing that resulted in less efficient technology becoming an American standard in the piece by Donald MacKenzie and Judy Wajcman called "Social Shaping of Technology: How the

Refrigerator Got Its Hum", both pieces I carry with me since completing my master's degree in science and technology policy at the Science Policy Research Unit (SPRU) at the University of Sussex.

In the context of the work in this dissertation on Operation Warp Speed, black boxes include the implications of the abridged contracting structures; the streamlined hierarchical organization of the initiative that removed the need for consensus mechanisms; and the tacit rules that governed access to the Commander and Chief and therefore approval to take government action during the pandemic.

Regarding the funding innovation that sped contracting and therefore the development of the Covid-19 vaccine, this funding innovation was encompassed in contracting mechanisms and specifically the use of Other Transactional Authorities (OTA) that by the very definition mimic industry funding structures. These OTA structures target acceleration of contracting with little attention to democratic values such as accountability and transparency that are inherent in far more intricate established federal funding structures.

Another black box still left to investigate in my mind is the structure of the bureaucratic relations inside the reporting layers in Operation Warp Speed. For instance, the data collected suggested that government technocrats working on Operation Warp Speed, across many agencies, communicated up through one program manager stationed within the Department of Defense who then communicated to the head of the scientific and technological approaches in Operation Warp Speed and the DOD appointed leader of the Operation. This hierarchical organization was designed, and perhaps appropriately so

during the pandemic, to speed decision making. However, this small cadre of crucial decision makers, mostly centered in DOD, circumvented potential for consensus among disparate government representatives.

Among others, this approach carries implications for the jurisdictional roles of the federal agencies during crisis. These jurisdictional issues among different U.S. government institutions are now being exposed in post-pandemic policy reviews underway in Congress. An area I find especially interesting for future exploration are the policy efforts by the agencies that were sublimated during the pandemic including the Administration for Strategic Preparedness and Response (ASPR). This includes an effort to try and duplicate within the Department of Health and Human Services the logistics capacity of the DOD as exposed during the pandemic (Stolberg & Weiland, 2022).

The last black box that I mention here as part of this reflections exercise is brief and concerned with the tacit rules that governed access to the Commander and Chief and therefore approval to take government action during the pandemic continue to trouble me.

For instance, a consistent theme in the interviews indicated that the way a person looked and dressed affected their ability to gain the approval of the President during the pandemic. For instance, subjects relayed to me that men from New York City wearing expensive, sharp suits and women with salon-styled, long hair wearing tight suits with very high heels were perceived to have more success in communications with the President.

In one example, a mid-level technocrat working on real-time military modelling data that impacted decisions about life-saving hospital supply shipments moving across the nation during the pandemic was tasked with regularly briefing the President. In order to ensure continued approval of this work by the President, she identified and regularly briefed and scripted a staffer fitting the description of those likely to be heard by the President in order to deliver the necessary information and gain approval from the President to proceed.

This emphasis on the physical appearance on staffers close to the President bothers me. While this was not a topic for this dissertation, I wonder if this requirement lowered access to the Commander and Chief at critical moments, limited the effectiveness of experts engaged in pandemic actions, and perhaps even exacerbated the pandemic tragedy.

Having reflected on the black boxes inherent in this work, I now turn to my own expectations for whether or how any of this work may actually impact policy in Washington. First, I discuss the role of policy champions and the potential home for my policy recommendations in Washington D.C. Second, I discuss the temporal aspect of crisis response policy, which appears to limit the amount of structural policy adjustments that can be made outside of the direct crisis response window.

Washington actors spend a lot of time looking for "policy champions." If an agenda item has a champion, then it will develop as policy, increasing the likelihood of moving from the policy stream to the action stream in Kingdon's framework.

For example, Senator Richard Burr (R-NC) championed the U.S. threat posture for biodefense preparedness for 20 years before his recent retirement. The staffers who moved through his office in Washington continue to work on these issues as they transition to other government service and the private sector. In this way, one member of Congress can influence a policy domain for decades. Other champions can be technical experts in the federal agencies. The ASPR, for example, is considered a policy leader in biodefense policy broadly and is often consulted while an appointee and after leaving office on a broad spectrum of biodefense policies. Still other champions can come from outside the government.

The contributions of this dissertation include policy recommendations. To have impact, these recommendations must be translated into the agenda of a champion or an organization active in Washington. I am not aware of any single organization that has compiled this unique list of policy recommendations in response to the pandemic. It may be worth my effort to seek grant funding through a think tank or another organization to establish this unique list of policy recommendations as part of a larger political agenda. Such a political agenda may be appropriate for an existing group to pursue such as the Bipartisan Commission on Biodefense, which was developed to provide regular assessments of U.S. biodefense efforts and planning.

However, gaining access to a policy champion or organization to bring the policy recommendations in this document to fruition is not sufficient. It also appears from my analysis that the window of opportunity for pandemic and outbreak related policy closes in normal times. This may be because the scope of what is financially and politically

possible during crisis changes between crisis and normal times. For instance, during crisis, the policy agenda turns to short term considerations with funding and political risk diminishing in importance. During crisis, longer term considerations do not appear on the agenda, because there is not time to have the necessary debate. This means that policy that may affect the larger government system, beyond the crisis, does not have support to on the action agenda during crisis.

This assertion about the scope and nature of crisis policy is captured in my data and in the work of others who have studied the policy response to outbreak crises. This point is encapsulated in a case study on the Ebola outbreak in Guinea, which captures a critical moment that seems to appear again and again across political systems in which crisis policy focuses acutely on response to the immediate crisis. In this case study, more therapeutics and PPE to prevent the speed of Ebola transmission were the policy focus during and after the outbreak. There was no political momentum to address underlying issues related to a stronger preparedness stance, such as strengthening suboptimal national public health systems (Kolie et al., 2019).

In my own experience on Capitol Hill, the public emergency is officially winding down and Covid is a bad word. No one wants to hear about the last crisis anymore. Everyone wants to move on. This portends poorly for building resources to address the next pandemic—and there will be one.

In brief summary of the reflections offering in this epilogue, first, the assumptions inherent in the world that the subjects inhabited in this work include a delineated, clear crisis-non crisis construction. This construction, or dichotomy, plays a significant role in

the conclusions of this dissertation and is worth questioning. I define "crisis" based on bureaucratic proclamations, or formal political actions that signal deviation from normal times. This is only one way to approach this and the questions about whether the crisis/non-crisis construction is theoretically sound for further generalization to other crises is worth further thought. The additional assumption in this work includes what may be understood as sociotechnical imaginaries. The Manhattan Project precedent was often invoked to justify the speed, parallel pursuit of diverse technical options despite extra cost and high risk, relaxation of measures for ensuring accountability for government spending, and lavish expenditures in Operation Warp Speed.

Second, using the lens of black boxing, I identify several systems that do important work and therefore warrant additional exploration. These include abridged contracting systems that circumvented democratic values such as accountability and transparency, a narrow funnel of decision-making Operation Warp Speed that reduced the ability to use consensus mechanisms and tap expertise across federal agencies, and the tacit rules that governed access to the Commander and Chief and therefore approval to take government action during the pandemic.

Third and finally, translating this research into practice is a real question for which the answer will require policy champions and the recognition of the temporal aspect of crisis response policymaking, which may limit acceptance of any truly effective policy agenda.

In addition to the theoretical, policy and other substantive contributions in this dissertation, these additional ideas may be worth further exploration. I offer this epilogue

as cathartic reflection based on this dissertation. These may serve as fodder for future work, or simply as a process of exorcising these thoughts and giving my own mind some peace. Hopefully this is useful to myself in the future as I am recalling of what I have just completed and the moment in history that I was able to capture in this work.

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APPENDIX A

AIM 2 INTERVIEW GUIDE

Aim 2 Interview Guide

EXPLORATORY STUDY: SEMI-STRUCTURED INTERVIEW GUIDE

1) Tell me about a high-profile science initiative in which you were involved.

2) What was the scientific genesis of the initiative?

3) Who were the champions of this initiative? What motivated that champion?

4) Were there political and scientific champions?

5) Is there a new pandemic initiative developing in relation to the global pandemic?

APPENDIX B

AIM 3 INTERVIEW GUIDE

Aim 3 Interview Guide

SEMI-STRUCTURED INTERVIEW GUIDE

1) What was the genesis of this initiative? Specifically, what was the accepted reasoning for the need for the initiative?

1a). Follow up: What sources lent credibility to this approach as needed and promising? i.e., particular people, books, reports, events?

2) What kind of support did the initiative receive at the beginning from particular Congresspeople, the White House, agency leaders and how did that support change and evolve?

3) How was the initiative funded? What was the balance between congressional direction and agency contracting? Was there philanthropic or industry funding?

4) Was there a preceding national or political event that opened a window for this effort?

5) Was there a policy failure associated with this effort? This can be large or small.

APPENDIX C

ARTICLE: ISSUES IN SCIENCE AND TECHNOLOGY MAGAZINE (reprinted here with permission)

VOL. XXXVIII, NO. 3, SPRING 2022 PERSPECTIVES

Rules for Operating at Warp Speed

BY AMANDA ARNOLD

On December 11, 2020, the US Food and Drug Administration (FDA) authorized the first COVID-19 vaccine dose for people aged 16 and older. Obtaining an effective vaccine less than a year after the COVID-19 pandemic began was an unprecedented achievement. The vaccine development effort, called Operation Warp Speed (OWS), was co-led by Moncef Slaoui, former head of vaccines at GlaxoSmithKline, and Gustave Perna, a retired four-star general. Since the authorization, OWS has been viewed as a stunning success both inside and outside government.

Making such rapid progress on the COVID-19 vaccine during a public health crisis required deviation from the federal government's usual modes of operation: in particular, temporarily suspending or ignoring some of the usual administrative and scientific guardrails. For instance, accelerated contracting processes replaced the

usual federal contracting procedures. And although OWS accessed federal biomedical and preparedness expertise, it did so in ways that deviated from existing policy processes of scientific consensus authorized via advisory committees, systematic merit review, and other established practices.

The justification for suspending these guardrails was speed. The government needed to quickly develop novel modes of detection, treatment, and prevention in response to the public health emergency caused by SARS-CoV-2. The rapid tests, monoclonal therapies, and mRNA vaccines that companies have developed or commercialized have saved lives, prevented suffering, and reduced further economic and other damage from the virus.

OWS could become the template for rapid government response to future crises. Whether it's used in public health emergencies, climate threats, or other disruptions, how this model handles funding accountability and scientific expertise warrants more attention than it has received from policymakers. It clearly contains cautionary lessons: if OWS-type programs become a norm for government—either because they are perceived as an effective way to get results in a crisis or because the government finds itself responding to crisis after crisis—over time important attributes of transparency and deliberation in government may be deemed disposable. But the lessons could also be instructive, because more flexible spending mechanisms that can be deployed quickly in either crisis or normal times are critical to ensuring appropriate use of taxpayers' funds. Likewise, more nimble, expeditious mechanisms for scientific consensus could help the government function more efficiently overall. The key to gleaning these various lessons lies with better understanding how OWS functioned.

SUSPENSION OF THE ADMINISTRATIVE STATE

OWS was an exceptionally large expenditure. In less than a year, its financial cost was $18 billion dollars—on par with the Manhattan Project, which developed the atomic bomb at a cost of $23 billion (adjusting for inflation) over five years.

Whether it's used in public health emergencies, climate threats, or other

disruptions, how this model handles funding accountability and scientific expertise warrants more attention than it has received from policymakers.

Spending $18 billion dollars in less than a year meant that the normal guardrails for funding transparency, including congressional oversight of appropriations and contract reporting mechanisms, were not in place. Instead, by March 2021, according to the Government Accountability Office (GAO), $12.5 billion was obligated by the Departments of Defense (DOD), Health and Human Services (HHS), and Homeland Security through flexible contracting mechanisms known as Other Transaction Authority (OTA).

OTA includes mechanisms for legally binding funding agreements with the government that are much more flexible than a standard federal contract, grant, or cooperative agreement. OTA was first used by NASA, then by DOD to support funding for research and technology prototypes. These agreements are not subject to many regulations that generally govern federal procurement, including the Federal Acquisition Regulations (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS). In fact, 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.

In 2020 and 2021, I interviewed senior officials at DOD, FDA, the White House, and internationally focused nongovernmental organizations involved in the COVID vaccine development effort as research for my dissertation. These officials, who spoke confidentially—as required by the institutional review board for my dissertation—corroborated the predominant use of OTA-type contracting vehicles during OWS.

In general, the routine use of OTA avoids the government procedures meant to ensure fairness and accountability of federal funding and can permit murky federal funding processes—as has been reported by DOD's inspector general in the past. The widespread use of OTA during the pandemic renewed persistent complaints to the GAO about the limited remedies for procurement disputes when OTA is used. It also provided limited transparency about how money was spent on OWS, particularly

when third parties acted as contractors.

Spending $18 billion dollars in less than a year meant that the normal guardrails for funding transparency, including congressional oversight of appropriations and contract reporting mechanisms, were not in place.

Despite questions about accountability and transparency in relation to the use of the OTA mechanism for allocating federal funding, OTA has been proposed as the sort of "flexible contracting" tool that the government could employ even in noncrisis settings. Although OTA was likely an appropriate choice during OWS, given the need for speed and for public-private partnering during the pandemic, its replacement of standard procurement contracts under normal circumstances has been criticized as a "black box" that can potentially subvert the important administrative mechanisms that govern proper allocation of federal funding.

SUSPENSION OF THE SCIENTIFIC STATE

Just as the speed required for OWS to be successful entailed moving operations outside the usual contracting mechanisms, the normal bureaucratic processes for federal scientific advice also shifted. As a result, the government's normal consensus mode for science advice contrasted starkly with the mode used by OWS during the pandemic crisis.

One official I spoke with—a senior leader from DOD, who served through several administrations before, during, and after OWS—juxtaposed the two approaches. This official explained procedures when normal channels are used for scientific advice: "It's group. It's consensus. It's you make policy by making sure everybody agrees with something and then with that agreement then you get some sort of approval." The official outlined the H1N1 prepandemic response in the Obama administration, which followed this model and was led by health and medical experts within the government, including the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority, an office located within

HHS.

More recently, this official had clearly come to favor the OWS effort, which was characterized by rapid, top-down decision making. During OWS, government action happened concurrently with direct engagement with industrial partners and a strong logistical focus. According to this official, the key was bringing in Slaoui, a former industry executive in research and development, and Perna, a logistician, in place of the leadership of health experts. "We think that was the magic combination because it wasn't the health experts in here … those decisions would be made very quickly, and we would have strategic direction and we would just know."

During OWS, government action happened concurrently with direct engagement with industrial partners and a strong logistical focus.

Officials I spoke with suggested that OWS temporarily rewrote decades of preparedness norms in favor of crisis-driven improvisation. And although many federal scientific advisory committees continued meeting, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the congressionally mandated coordinating body for federal response to biological threats, was not formally involved in OWS. A 2021 consensus study report from a National Academies of Sciences, Engineering, and Medicine (NASEM) committee tasked with rapidly reviewing the public health emergency countermeasures enterprise stated, "During meetings with the committee, government leaders involved in OWS did not refer to PHEMCE. As the committee understands it, OWS became the de facto all-of-government MCM [medical countermeasures] preparedness and response effort for COVID-19." (I was a science writer for the committee's report.)

A final question is whether the OWS template is likely to be applicable to other public health emergencies. Here it's important to recognize that OWS didn't have to do the science from scratch: the work of the scientific state had, over decades, already created the tools and platforms—such as the pioneering work on mRNA, lipid nanoparticles, spike protein stabilization, and rapid sequencing of the virus—needed to develop the vaccine. According to Slaoui and OWS vaccine lead Matt

Hepburn, OWS did not need to do fundamental research to support vaccine development. Instead, the strategy was to select existing vaccine candidates and compress the sequence of vaccine development, testing, regulatory approval, production, and deployment. The fact that the right scientific knowledge and promising new technologies converged with urgent public purpose may have been, in a sense, a lucky break. In another crisis, where the science isn't ready and waiting, the OWS approach could disappoint.

ADAPTING GOVERNANCE FOR CRISIS AS WELL AS NORMAL TIMES

Despite concerns about the transparency and replicability of OWS, the effort made clear that slow, complex systems for awarding federal contracts, monitoring spending, and supporting cross-agency scientific consensus are incompatible with the speed and scale required for major crisis response. What's more, these procedures may sometimes be incompatible with what would be ideal for normal government operations as well. Transforming systems to support solutions to urgent problems—be it responding to a pandemic, addressing climate change, or curing cancer—will require a two-fold mission to replicate the speed and efficiency of OWS while reinforcing the scientific-administrative state as a partner rather than an obstacle.

Despite its success in delivering a vaccine, OWS revealed that the standbys that cut government contracting time and paperwork, such as OTA, do not support a robust system of accountability for spending. As crises become more frequent, this problem will only worsen. To address it, federal procurement policies should be revisited with specific attention to governance so that funding accountability and transparency is balanced with the need for expeditious government action. While a 53-page guide is clearly not up to the task, the necessity of contractor guidebooks that run to more than a thousand pages deserves examination.

Federal procurement policies should be revisited with specific attention to governance so that funding accountability and transparency is balanced

with the need for expeditious government action.

Future crises will also require faster mechanisms, both internal and external to government, for providing scientific expertise and advice. As with government procurement and contracting, these mechanisms must be consistent across times of both crisis and noncrisis. In normal times, a major pathway for scientific advice in support of federal government policy is the Federal Advisory Committee structure. The Federal Advisory Committee Act (FACA), which became law in 1972, provides opportunity for advice and recommendations on agency operations and activities from experts inside and outside of government. This legislation should be amended to enable processes for rapid scientific response in crisis. The marshalling of FACA committees to quickly produce socially useful scientific recommendations in crisis would be a major accomplishment and a valuable tool for resilience.

In addition to FACA, another tool for external expertise engagement—the rapid response committees developed by NASEM—made important strides during the pandemic. At NASEM, preexisting lengthy timelines for consensus report development were significantly reduced to support the need for expert-based guidance in real time. These rapid response committees could serve both as their own source of expertise and as a model for how cross-agency advisory groups comprised of government scientists and experts, such as PHEMCE, could best work in a crisis.

Looking to a future in which regular crises become part of the new normal, we must evaluate the trade-offs that these oscillations from crisis to noncrisis require rather than simply accept the ways that crises change the innovation system in Washington. Innovations such as OWS should be explored, and their costs and benefits weighed out, to allow a deliberate approach to positively transforming the innovation system to serve the public good. Put simply, American innovation governance during crisis must evolve to honor the robust systems of transparency and expertise that exist between crises—because COVID-19 will not be the last shock to the system.

Amanda Arnold *is a doctoral student in the School for the Future of Innovation in Society at*

Arizona State University. She is a practitioner who has worked in the federal government, academia, and industry, including in the vaccine development sector.

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Arnold, Amanda. "Rules for Operating at Warp Speed." *Issues in Science and Technology* 38, no. 3 (Spring 2022): 17–19.

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IN FOCUS

COVID-19

The essays here deliver fresh insights on the social, political, and scientific aspects of the pandemic, which can help you more fully understand and respond to the complex and difficult events that are now unfolding.

APPENDIX D

ARTICLE: JOURNAL OF CRITICAL INFRASTRUCTURE POLICY (reprinted here with permission)

Journal of Critical Infrastructure Policy • Volume 3, Number 1 • Spring / Summer 2022

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.

APPENDIX E

ARTICLE: JOURNAL OF HEALTH SECURITY ARTICLE IN DRAFT FOR PEER REVIEW (reprinted here with permission)

Health Security
formerly Biosecurity and Bioterrorism

Novel Policy Standards for Crisis Response

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Execution of Complimentary Policies in Parallel:

Novel Policy Standard for Crisis Response

ABSTRACT

Novel policy approaches emerged in the U.S. pandemic experience. The parallel execution of complementary policies of manufacturing and development was key to the success of Operation Warp Speed, the government effort to get a Covid vaccine. This successful example of the parallel policy mode exhibited in OWS is juxtaposed to the slow linear transition from containment to mitigation policies, a failed opportunity to execute complementary policies in parallel during the Covid pandemic. The relevant literature focuses on the window of opportunity that opens for new policies to emerge onto the agenda. The focus of this work is on the conditions for action for these parallel modes that emerge onto the national policy agenda. In this work, the dynamics that led to the differences in these pandemic response policies are explained using the nexus of Presidential support and existing policy norms. Understanding the favorable conditions for this parallel policy mode during crisis has the potential to increase the public value of technocratic solutions to existential threats such as a global pandemic.

Introduction

The Covid pandemic manifested as a public crisis in the U.S. in March of 2020 and continued through 2021. During this time, novel policy actions deployed by the government included the parallel execution of complementary policies. The clearest example of this is the choice made by leadership of Operation Warp Speed, the policy project that brought the Covid vaccines to the public, to establish manufacturing lines and distribution networks while multiple vaccine targets were still in development. In addition to other elements, including the availability of mRNA vaccines and industry development prior to the pandemic, the execution of

complementary policies in parallel played a key role in making it possible to reach a publicly available vaccine in just nine months.

While this parallel mode is financially risky, the crisis opened the window of opportunity for this approach. One example where this parallel mode could have been effective was in approach taken by the U.S. government to first contain and then mitigate the outbreak. The question is why this parallel policy mode was adopted for manufacturing and development during Operation Warp Speed while it was not adopted for similarly complementary policies of containment and mitigation during the Covid pandemic. The data collected to answer this question reflects interviews with 13 senior officials involved in the U.S. government response to the pandemic. I conducted these interviews from October 2020 through January 2021. My findings are corroborated using primary sources such as official records and news reports, as well as follow up conversations with staffers close to these leaders during the pandemic response. What becomes clear in my analysis is that during a crisis, key aspects such as Presidential preference and existing policy norms together define whether parallel execution of complementary policies is possible.

Crisis Opens Windows of Opportunity for Novel Approaches

The policy agenda is normally characterized by long periods of stability, which are punctuated with short periods of change (1). These short periods of change can be precipitated by "focusing events". Focusing events include major manmade and natural disasters such as earthquakes, hurricanes, oil spills, nuclear power disasters (2) (3), and major terrorist attacks (4). The focusing event literature considers attacks, disasters, and other dramatic and critical events broadly with the goal of keeping the notion of "crisis" as vague as possible to be inclusive of any event (5) (6).

Mary Ann Liebert, Inc., 140 Huguenot Street, New Rochelle, NY 10801

For the purposes of public policy, the definition of crisis is "a serious threat to the basic structures or the fundamental values and norms of a social system"(7). When a crisis occurs, the government is perceived as the only plausible provider of help and solutions(8). Major moments of crisis open windows of opportunity in U.S. policy in which novel policy approaches emerge as possibilities on the policy agenda.

Through the adaptation of Kingdon's (9) multiple streams framework to the Covid crisis, this work explains how the window of opportunity to execute novel policy options opened but there is a gap in understanding exactly why action took place, or did not, during the crisis. Key conditions for the parallel execution of complementary policies in crisis, also referred to here as the parallel policy mode, include Presidential support and existing policy norms. Parallel action on complementary policies may be possible given a window of opportunity that opens during a crisis but in order to be executed, the policies must have Presidential support, or tacit approval. Tacit approval is an acceptable intermediate value between Presidential support and opposition. The execution of policies in parallel also depends on established policymaking norms, a policy map that has already worked on those policies, or similar, in the past.

Governance in Crisis, from Serial to Parallel Modes

Serial processes are the status quo in government. This is the order in which laws, regulations, executive orders, and other components of the federal system are conducted in normal times. When no impending crisis poses an existential threat, government operates on historical paths. In times of crisis, in contrast, political will is galvanized, resources are freed, and normal procedures may be accelerated and sometimes streamlined or suspended (1).

The crisis itself may make parallel modes possible. The actual transition to execution from serial to parallel modes in crisis requires two conditions. First, established policy modes

must provide a historical map for execution of the policy action. One example of a policy that provided a map for a parallel mode during the pandemic is the Manhattan Project. Second, presidential support, or lack of clear opposition through tacit approval, is another necessary condition for parallel action on complementary policies in crisis. One example of complementary policies that did not manifest into action during the Covid pandemic include the policies of containment and mitigation. The following two subsections explore these cases further.

Manufacturing Vaccines at Risk, and the Role of Existing Policy Norms

OWS accelerated vaccine development from the average of 73 months to 14 (10). The effectiveness of OWS was supported by several policy actions early on in the process. Relevant to this work, the government conducted large scale clinical trials on multiple vaccine targets in parallel with large-scale manufacturing preparations starting in month 6. This parallel approach in OWS was risky and expensive. This approach is enduring following the end of OWS. It has been referred to as a pandemic paradigm (11). and a successful tool for expedient development of medical countermeasures during extreme crisis (11) (12) (13). The comparison of the OWS approach to the typical vaccine development process is included in Exhibit 1 at the end of this work(14).

OWS was supported by a massive US government investment of $12.4 billion. This is a sizable investment, just over half of the cost of the Manhattan Project when adjusted for inflation(13). This number does not include the decadal development funding of mRNA technology supported by the National Institutes of Health and the Department of Defense. This technology served as the platform for the modified mRNA Covid vaccine (15). Preclinical development on multiple Covid vaccine candidates started in February and March 2020 (16). Contracts for development of the vaccines and other medical countermeasures supported six

companies with viable late-stage products including Pfizer-BioNTech, Johnson & Johnson, Moderna, AstraZeneca-Oxford, Novavax, and Sanofi-GlaxoSmithKline. Meanwhile, investments in manufacturing began in July 2020. The parallel policy execution in OWS meant U.S. government contracts with these companies supported clinical trials while also building new manufacturing facilities(17). The government pre-purchased over 900 million doses of these potentially viable vaccines, at risk. The bet paid off. The first of three sufficiently effective Covid vaccines were approved via Emergency Use Authorization and distributed before the end of 2020 (16).

The Role of Established Policy Norms in the Parallel Execution of Complementary Policies during OWS

The parallel mode exhibited in OWS in which manufacturing and clinical development happened at the same time during the Covid pandemic was modelled on previous experiences. The Covid pandemic was not the first time a crisis prompted the government to take a risky parallel policy mode that paid off. The Manhattan Project, the government effort to build the atomic bomb before the axis powers in World War II, was the model for Operation Warp Speed, which my respondents repeatedly referenced. The Manhattan Project established a policy playbook for OWS leaders (18). This playbook includes a series of existing policy norms that share characteristics with OWS in which the military finances industry partners to manifest a technological solution to an existential threat to America.

As part of the decades-long effort to develop the bomb before Germany, Albert Einstein and a series of prominent physicists approached President Roosevelt to gain his support for action (19). Convinced of the promise of a fission bomb, President Roosevelt limited scientific engagement to a small Top Policy Group in 1942 (19). The leaders of the Manhattan Project

adopted a parallel policy mode. According to this policy, called the "principle of parallel development", all scientific and infrastructure efforts to create the bomb would be executed concurrently. The principal of parallel development, in which the military would approach as many pathways to the bomb as possible, was enacted. Senior technology industry leaders at Bell Laboratories and Dupont were engaged. By 1944, the Los Alamos lab was established. The Fat Man, the first fission bomb successfully tested was completed in 1945(19). The use of the bomb effectively ended the second world war with the American atomic attack on Japan later that year. The Manhattan Project cost more than the entire DOD budget at the time and the project shaped post-war perceptions about the role of science and technology for humanity (20).

In addition to the policy map provided by the Manhattan Project, the Covid pandemic was not the first time that this parallel policy mode emerged as a preferred approach for outbreak response. One of the perceived failures of the U.S. response to the H1N1 "swine flu" outbreak in 2009 was the stalled production timeline of the vaccine following development. While the H1N1 vaccine was developed rapidly based on already developed flu-based vaccine technology, there was not a sufficient number of manufactures to deliver the finished vaccines at scale. This lack of foresight resulted in a vaccine that arrived after the H1N1 seasons had both ended in the northern and southern hemispheres (21). The execution of complementary policies in parallel during OWS was likely influenced by this experience. The H1N1 proved a counterexample, illuminating the necessity for this parallel mode in clinical development and manufacturing. This is likely since the scientific leader of OWS, Moncef Slaoui, was also the vaccine chief at GlaxoSmithKline during H1N1 when the government cancelled a large portion of the pre-orders after pushing heavily for GSK to develop the vaccine (22).

This parallel execution of complementary policies did not manifest in other areas of pandemic response including the policies of containment and mitigation.

Containment and Mitigation and the Role of Presidential Opposition

Considering containment and mitigation in tandem during an outbreak was an established best practice in the U.S. government prior to the Covid pandemic (23),(12),(24),(25),(26). Containment strategies include a coordinated national approach with an emphasis on extensive daily testing, quick contract tracing, and appropriate quarantine. The Covid response in South Korea is an effective example of containment where there were only 53 cases of Covid. Containment and mitigation measures can be separate and distinct but also intersect in areas including early detection, health care infection and control, community engagement, and appropriate clinical care. Disease control measures, non-pharmaceutical interventions, and pharmaceutical interventions that span across containment and mitigation categories are included in Exhibit 2(27).

Mitigation strategies are a complementary policy package to containment. Mitigation strategies aim to slow the spread of the disease; reduce the number of patients to avoid surges that overwhelm hospitals; minimize the severity of the infection if possible; expand information access including the ability to easily test for the virus; and direct appropriate quarantine policies(28). Similar to containment, effective mitigation measures take place on a national scale(29).

Political Interference in the Covid Response

Full containment measures and most mitigation measures lagged in the U.S. pandemic response (28). The lag in planning, slow adoption of full containment and mitigation measures, and the lack of a parallel approach to both strategies in the U.S. was due in part to political

interference. President Trump, the White House, and administration appointees politicized and publicly minimized the seriousness of the Covid threat.(30),(31), (32).

The Covid threat was recognized internally in the U.S. government in November 2019 in reports released by the U.S. military's National Center for Medical Intelligence(33). On January 31, 2020, immediately following the World Health Organization's declaration of a Global Health Emergency, the U.S. Department of Health and Human Services declared a national emergency. President Trump responded on February 2, 2020 by issuing a travel ban for non-U.S. citizens traveling to the U.S. from China. American citizens could still travel between the U.S. and China(34).

President Trump and the White House continually suppressed agency activity that would recognize the Covid threat. When Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response (ASPR), led the repatriation effort for American passengers marooned on a cruise ship quarantined in Japan's Yokohama Port, he was almost fired by President Trump. The President's concern was the almost doubling of the number of infected Americans on U.S. soil with the addition of infected American passengers (35). In another instance, a seasoned CDC leader, Nancy Messonier, was re-assigned after President Trump heard a CDC podcast that both confirmed the likelihood of an imminent American outbreak and outlined likely containment and mitigation measures based on a 2017 influenza preparedness plan(36)(37)(38). Immediately following Messonier's reassignment, Vice President Pence was named chair of the White House Coronavirus Task Force (39). That same month on February 26, 2020, Health and Human Services (HHS) Secretary Azar testified in Congress stating that "the immediate risk to the American public remains low."(40)

Despite the President declaring the Covid-19 national emergency on March 13, 2020, Vice President Pence publicly stated on April 7, 2020 that "the threat of serious illness for most Americans is relatively low"(41). The President continued to minimize the threat to the point of denial by halting funding to the World Health Organization (April 14), making plans to Open America Up Again (April 16), arguing job losses were temporary, and suggesting "the problem will go away" and that many "don't know they have it [COVID]" (May 15)(42).

Mitigation measures such as masks were not supported by the Administration and became politicized symbols(43). Mitigation efforts by HHS were thwarted by the White House. ASPR funded and manufactured five masks for every American household. Distribution was halted by the White House Coronavirus Task Force when the head of the task force, Vice President Pence, refused to meet with the ASPR in May of 2020 in order to give the Ok on the effort. Reasons for the White House refusal to endorse the project included the unfashionable look of the masks as well as the mode of distribution via the U.S. Post Office. Distributing the masks through the postal system could reinforce the utility of the postal agency at a time when the President was framing the mail-in ballot effort as faulty during his Presidential re-election bid.(44) The idea of mask wearing was not supported by President Trump for a majority of the pandemic, even following his own hospitalization for Covid (45). The CDC director publicly endorsed mask wearing for the first time in congressional testimony well into the pandemic in September of 2020.(39)

The Role of Presidential Support

The U.S. President is a powerful figure that can singlehandedly set agendas like no other actor in the U.S. system. (Agendas 23) Promising policy solutions that might otherwise be moved to the decision agenda can be stymied if they meet Presidential opposition. (Agendas

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175) By extension, the President's appointees are both powerful and pre-conditioned to bend toward the President's will (25) (Agendas 29 INCORRECT). As recently as 2020, decisions by the Supreme Court and actions taken by President Trump in relation to immigration orders indicate that the powers of the US president are expanding (4).

The U.S. response to Covid, shaped by President Trump, echoed the government response to the Spanish Flu Outbreak of 1918 where authorities denied the outbreak eventually losing both credibility and the opportunity to save lives (47). Until OWS, the Trump Administration's handling of the Covid virus was judged a dramatic failure.(48) The lack of a coordinated parallel approach to both containment and mitigation strategies was due to opposition and politization these strategies as promoted by the President. This politicization prevented the parallel approach to containment and mitigation strategies and the cost was American lives. At least one study suggests the number of additional lives lost due to this poor approach to pandemic response in the U.S. was more than the lives lost in World War I(49). Moving through containment and mitigation policies in parallel mode would have enhanced pandemic response ensuring the nation's faster progression from reaction to recovery.(23)

Developing a Framework for Action During Crisis

Crises, or focusing events, open a window of opportunity for parallel modes to emerge onto the policy agenda. However, action on the policy agenda requires a secondary set of conditions. First, the President must not be in opposition of either policy. Second, policy norms must exist as a map for action. When these two conditions are met, it is possible to execute complementary policies in parallel.

For further analysis, these two conditions – Presidential support and existing policy norms – are mapped onto a 2x2 matrix in Exhibit 3. Parallel development and manufacturing

during OWS fall into Quadrant II: High Presidential Support/ Robust Existing Policy Norms. The program enjoyed at least tacit support from the President who appointed General Perna to oversee the project and interviewed and invited Moncef Slaoui to serve as the scientific lead for the project. The program also depended on a previous model of technology development, the Manhattan Project that developed the atomic bomb in World War II. Quadrant II is the most likely quadrant for action to execute complementary policies in parallel.

The containment and mitigation responses to the Covid pandemic fall into Quadrant III: Low Presidential Support/ No existing Policy Norms. The President was not fully opposed to containment policies. Evidence suggests the President supported ex-U.S. containment, by barring Chinese citizens from entering the U.S., more than internal U.S. containment of the contagion. The President actively opposed mitigation measures such as masking. Regarding policy norms, there were few existing policy norms for such an unprecedented outbreak in the U.S. This is despite best practices, preparedness policies, and experience in major outbreaks in other countries. Quadrant III is the least likely combination of these two conditions to result in successful execution of complementary policies in parallel.

Additional cases such as the Mpox, formerly monkeypox(50), vaccine response and the H1N1 vaccine development and response perform a validating assumption for this four-quadrant framework. In the case of the Mpox outbreak, the government quickly applied the existing smallpox vaccine to protect against Mpox, manufactured the vaccines and made the vaccines available to the public (51). This parallel execution of complementary policies was done expediently. The President was in full support and there were existing policy norms to follow including the OWS experience, which provided a robust policy roadmap for action.

In the case of the H1N1 response, a vaccine became available, but the crisis ended before the vaccines could be delivered and government contracts for the final product were cut significantly. The government cuts to previous contracts made with manufacturers for H1N1 left industry partners hesitant to engage again with the U.S. government on vaccine manufacturing in crisis. The President fully supported vaccine development. Regarding existing policy norms, it is possible that the H1N1 experience provided an explicit counter example that enabled an existing policy norm, a policy map to follow in the future. Policymakers could map a better route in OWS and Mpox based on the lack of existing policy norms engaged in H1N1.

Technocratic Solutions, Crises, and Future Research

These cases described above indicate an important finding: that the parallel execution of complementary policies is both critical and preferable to achieve a successful, accelerated government response in pandemic crisis. These cases also lead to a framework that implies two factors are necessary for the successful execution of the execution of complementary policies in crisis, or the parallel mode. These factors include Presidential support and existing policy norms. The main conclusions of this work include that technocratic solutions will perform a vision for the government to organize around if the conditions are correct. Achieving and benefiting from such a technocratic solution will depend on executing complementary policies in parallel along the way. Political interference, especially if led by Presidential opposition, will negatively impact the public value of the eventual technocratic solution. The existence of policy norms, such as those that now exist following the vaccine development experiences in H1N1 and OWS regarding the parallel execution of clinical development and manufacturing, are also critical in the success of the parallel mode.

This theory for action on the parallel execution of complementary policies in crisis may not apply in all instances where a focusing event opens a window of opportunity for action based on Presidential support and existing policy norms. There are at least two scope conditions, or conditions within which this theory is expected to hold. First, this theory was developed to explain the parallel policy mode in action during public health crises of pandemic potential. Whether this theory may apply to focusing events such as natural disasters or extreme terrorist attacks is promising ground for future study. If this theory is expanded to included executive support instead of Presidential support, the theory could also be considered more broadly to global crises such as famine.

Second, this theory is based not just in public policy but within the tenets of innovation policy. A key aspect of this theory is the presence of a technocratic solution to a seemingly long-term existential crisis where current strategies, solutions, technologies, and existing preparedness falls short. Future work building on this theory within innovation policy could examine the role of scientific authority on the perceived value of technoscience solutions envisioned.

EXHIBIT 1
Vaccine Development Process in Operation Warp Speed
This is the comparison of the accelerated vaccine development process under Operation Warp Speed compared to the typical vaccine development process.
https://twitter.com/NavyMedicine/status/1334622519412797441

EXHIBIT 2
Containment and Mitigation Measures Over Time
The containment and mitigation measures are both distinct and overlap spanning disease control efforts, non-pharmaceutical interventions, and pharmaceutical interventions.
Adaptive Response to COVID-19 [Internet]. Prevent Epidemics. [cited 2023 Jan 31]. Available from: https://preventepidemics.org/covid19/science/insights/adaptive-response-to-covid-19/

EXHIBIT 3
Matrix for Decision Support of Parallel Deployment of Complementary Policies
Vaccines developed or deployed in response to crisis are mapped on a 2x2 matrix according to factors including Presidential support or lack of support, and existing policy norms from none to robust.

EXHIBIT 1
Vaccine Development Process in Operation Warp Speed

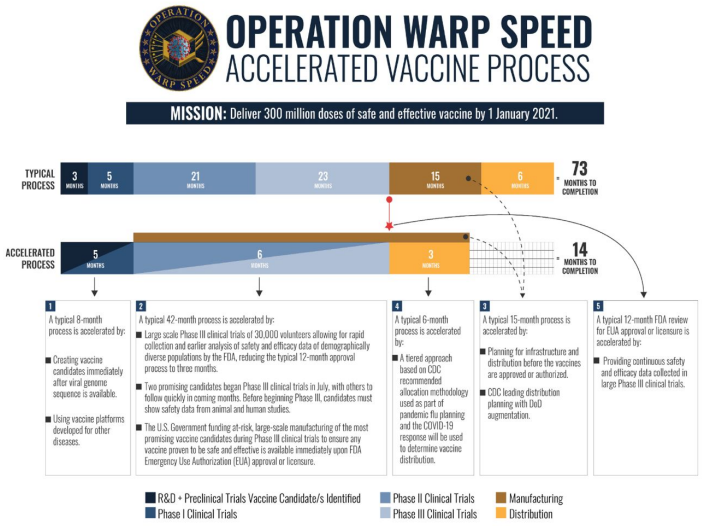


EXHIBIT 2
Containment and Mitigation Measures Over Time

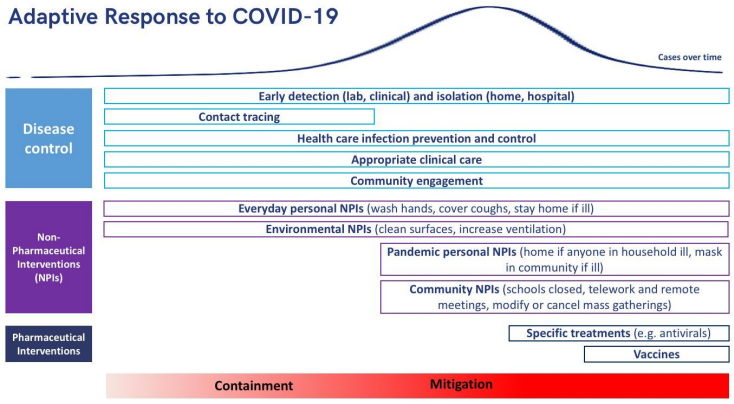
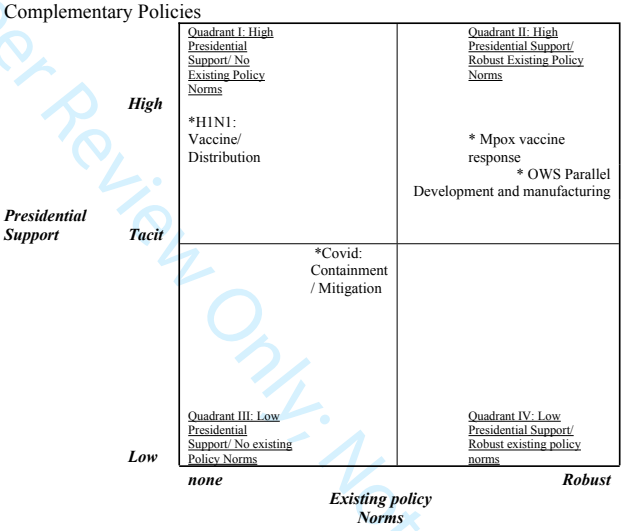


EXHIBIT 3
Matrix for Decision Support of Parallel Deployment of Complementary Policies

Figure 1Matrix for Decision Support of Parallel Deployment of Complementary Policies



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