ARTICLE

# ENCOURAGING INTERAGENCY COLLABORATION: LEARNING FROM COVID-19

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*In the health innovation context, federal regulatory authority is sharply fragmented among different agencies. The National Institutes of Health, Food and Drug Administration, Centers for Medicare and Medicaid Services, and other agencies all share responsibilities in the development and dissemination of new healthcare technologies. Scholars have previously written about the importance of interagency collaboration both in the healthcare area and more generally, and about strategies for encouraging collaborative efforts to promote various policy goals. Under these accounts, a failure to collaborate between federal agencies may be unfortunate, but it does not typically result in or exacerbate a crisis. In the COVID-19 context, however, failures of federal interagency coordination may have had much more severe negative consequences for the spread of the pandemic in the United States. This Article first spotlights two examples of healthcare innovation for COVID-19—diagnostic tests and vaccines—and details both the ways in which agency failures of collaboration created serious problems for our COVID-19 response and the ways in which interagency collaborations have successfully driven innovation and access to these new technologies. The Article goes on to consider what lessons can be learned from the successes and failures of these innovative efforts about best—and worst—practices in interagency collaboration going forward.*

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## INTRODUCTION

> *"What we needed was a coordinated response that involved contributions from multiple agencies… That didn't happen on testing, or on a whole lot of other things."*.
>
> – Former FDA Commissioner Dr. Scott Gottlieb[1]

The COVID-19 pandemic has severely tested the United States' health care institutions. The pandemic has exacerbated the racial inequities already present in our health care system,[2] stressed our hollowed-out public health infrastructure,[3] and reduced many people's trust in their public officials.[4] It has sickened and killed far too many people, both in the United States and abroad.[5]

The pandemic has also served as a stress test of our innovation institutions. Typically, a wide range of public and private sector actors must

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[1] Michael D. Shear et al., *Trump's Focus as the Pandemic Raged: What Would It Mean for Him?*, N.Y. TIMES (Dec. 31, 2020), https://www.nytimes.com/2020/12/31/us/politics/trump-coronavirus.html.

[2] Samantha Artiga et al., *Racial Disparities in COVID-19: Key Findings from Available Data and Analysis*, KAISER FAM. FOUND. (Aug. 17, 2020), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-covid-19-key-findings-available-data-analysis/.

[3] Lauren Weber et al., *Hollowed Out Public Health System Faces More Cuts Amid Virus*, ASSOCIATED PRESS (July 1, 2020), https://apnews.com/article/b4c4bb2731da9611e6da5b6f9a52717a; *see generally* MATT MCKILLOP & VINU ILAKKUVAN, TRUST FOR AMERICA'S HEALTH, THE IMPACT OF CHRONIC UNDERFUNDING ON AMERICA'S PUBLIC HEALTH SYSTEM: TRENDS, RISKS, AND RECOMMENDATIONS (2019) (describing how a lack of CDC program funding presents obstacles to public health interventions).

[4] Liz Hamel et al., *KFF Health Tracking Poll—September 2020*, KAISER FAM. FOUND. (Sept. 10, 2020), https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/ ("[T]he share of adults who trust the CDC to provide reliable information has decreased by 16 percentage points since April.").

[5] Hamdi Alkhshali, *Global Coronavirus Death Toll Surpasses 2.5 Million*, CNN (Feb. 25, 2021, 1:10 PM), https://www.cnn.com/world/live-news/coronavirus-pandemic-vaccine-updates-02-25-21/h_0894eab9f6fb1ab71c8b5a579c478ab6.

all play a part in bringing a new health technology product to market. Perhaps the National Institutes of Health (NIH) funds a university laboratory's basic research project, which is then licensed to a pharmaceutical company for further development. That pharmaceutical company must traverse the complex Food and Drug Administration (FDA) approval process before receiving approval, after which the company would hope to obtain insurance reimbursement for its product, including from the Centers for Medicare and Medicaid Services (CMS). Physicians and (often) retail pharmacies[6] must be made aware of the new drug, and ultimately patients may begin to receive it. This is a long, complex process, often taking more than a decade from start to finish[7] and requiring hundreds of millions or billions of dollars in investment.[8]

In a public health crisis of the magnitude of COVID-19, our innovation institutions could not—and did not—allow innovation to proceed along these normal time frames and channels. The FDA compressed its usual ten-month agency review period into just three weeks,[9] companies built enormous amounts of at-risk vaccine manufacturing capacity (often with federal support),[10] and our innovation ecosystem successfully brought to market two safe, effective COVID-19 vaccines in less than a year—shattering the previous record of four years.[11] But there were failures as well—failures of

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[6] Although many drugs are provided through retail pharmacies, others are administered in physicians' offices or hospital settings. *See* MEDICARE PAYMENT ADVISORY COMM'N, MEDICARE PAYMENT STRATEGIES TO IMPROVE PRICE COMPETITION AND VALUE FOR PART B DRUGS, *in* REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 55 (June 2019) ("Medicare Part B covers drugs and biologics that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs).").

[7] Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 719 (2014).

[8] *See, e.g.*, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) (estimating pre-approval costs to be $2.558 billion); JORGE MESTRE-FERRANDIZ ET AL., THE R&D COST OF A NEW MEDICINE 3 (2012), https://www.ohe.org/publications/rd-cost-new-medicine# (estimating costs at $1.5 billion); Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 426, 448–57 (2014).

[9] Noah Weiland & Katie Thomas, *Pfizer Applies for Emergency FDA Approval for COVID-19 Vaccine*, N.Y. TIMES (Nov. 20, 2020), https://www.nytimes.com/2020/11/20/health/pfizer-covid-vaccine.html; U.S. FOOD & DRUG ADMIN., *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[10] *See infra* text accompanying notes 54–59.

[11] Nsikan Akpan, *Why a Coronavirus Vaccine Could Take Way Longer than a Year*, NAT'L GEOGRAPHIC (Apr. 10, 2020), https://www.nationalgeographic.com/science/2020/04/why-coronavirus-vaccine-could-take-way-longer-than-a-year/ (noting that the mumps vaccine was developed in approximately four years).

diagnostic testing which enabled the unseen spread of the pandemic near its beginning in early 2020, and failures of vaccine administration which delayed our capacity to end the pandemic.

Many of these failures were traceable to a lack of interagency collaboration. Federal agencies failed to work together to solve identified problems until the problems became far larger than they otherwise might have. Although interagency collaboration is often desirable, its absence may sometimes be difficult to detect, particularly in the innovation context. It is hard to "see" the innovative health care technology that *could have been* discovered if federal agencies had worked together, or to see how the regulatory pathways *could have been* abbreviated in such a circumstance, precisely because those collaborative efforts did not occur. But the COVID-19 pandemic made those failures of interagency collaboration all too visible.

Interagency collaboration has been a recent topic of discussion in the legal literature, with experts referring to the issue as "one of the central challenges of modern governance."[12] Scholars have focused on problems involving legislative delegations of power that are fragmented and overlapping,[13] problems of intra-agency coordination,[14] and ways the executive can "pool" resources delegated to different agencies,[15] among other topics.[16] The COVID-19 pandemic provides the opportunity to examine some of the hypotheses put forth in the literature, as well as to consider new questions regarding executive-created interagency collaborations and collaborations created under emergency conditions.

This Article examines two innovation case studies from the pandemic, including their successes as well as their failures, to consider what lessons might be learned from the COVID-19 pandemic for interagency collaboration going forward. Part I considers the development of diagnostic testing for the SARS-CoV-2 virus. Failures of interagency collaboration early on in the pandemic led to catastrophic delays in the development of testing capacity in the United States, allowing the virus to spread. Months later, though, agencies

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[12] Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1134 (2012).

[13] *Id.* at 1138; *see also* Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 203 (2006); Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 1993 (2018).

[14] Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421, 427 (2015).

[15] Daphna Renan, *Pooling Powers*, 115 COLUM. L. REV. 211, 213 (2015).

[16] *See also, e.g.*, David A. Hyman & William E. Kovacic, *Why Who Does What Matters: Governmental Design and Agency Performance*, 82 GEO. WASH. L. REV. 1446, 1451 (2014); Jason Marisam, *Interagency Administration*, 45 ARIZ. ST. L.J. 183, 183 (2013); Bijal Shah, *Uncovering Coordinated Interagency Adjudication*, 128 HARV. L. REV. 805, 806–07 (2015); Jacob S. Sherkow, *Administering Patent Litigation*, 90 WASH. L. REV. 205, 208 (2015). For a detailed example outside the legal literature see EUGENE BARDACH, GETTING AGENCIES TO WORK TOGETHER: THE PRACTICE AND THEORY OF MANAGERIAL CRAFTSMANSHIP (1998).

began working together to develop innovative new diagnostic technologies—a collaboration that is now bearing fruit.

Part II examines Operation Warp Speed (OWS), which drove the development of vaccines to prevent COVID-19. OWS was successful in its goal of supporting the development of safe, effective vaccines faster than had ever been done before—but it failed in its earliest promises to administer them to patients. Although there are many contributing factors to this failure, at least some of the problems are due to failures of interagency collaboration.

Part III considers three lessons that can be learned from these two examples, and how those lessons might not only inform future policymakers (and future pandemics) but also how they might bear on existing scholarly debates. The role of agenda-setting power, the importance of organizational structure, and the creation of cultures of collaboration are all important factors in the success and failure of innovation efforts both during the COVID-19 pandemic and beyond. To be sure, we should be careful not to overlearn lessons drawn from a singular, crisis event—or a singular individual. It will be important to look to other examples of interagency collaboration, especially those that took place under less critical circumstances, to support or refute these arguments, as Part III does. At the same time, it might be the case that the scale of the COVID-19 pandemic provides opportunities to learn about whole-of-government efforts that are not present in much smaller-scale examples of interagency collaboration.

## I. DIAGNOSTIC DELAYS AND INNOVATION

A robust diagnostic testing system for COVID-19 is essential to identify where the SARS-CoV-2 virus is spreading and to enable public health officials to determine and implement appropriate mitigation efforts. However, particularly early in the pandemic, federal agencies—especially the Centers for Disease Control (CDC), FDA, and CMS—did not collaborate in the development or distribution of diagnostic testing for the SARS-CoV-2 virus. Their failure to do so has been analyzed very publicly, with a range of media and scholarly reports explaining how a lack of interagency coordination resulted in avoidable delays in the development and dissemination of accurate diagnostic tests for COVID-19.

This Part will first describe the ways in which the actions of individual federal agencies slowed the development of COVID-19 diagnostics, before explaining how stronger interagency coordination could have sped the rollout of accurate diagnostics. This Part closes by considering a more positive example of interagency collaboration in the diagnostics space, in which a collaborative interagency group is aiming to drive the development and distribution of testing technology going forward.

In January 2020, as public health agencies began to learn more about the SARS-CoV-2 virus and its potential spread into the United States, the CDC developed its own diagnostic test for the virus and began to share testing kits with state public health laboratories. Unfortunately, soon after distribution a problem with the kits was discovered,[17] causing the CDC to tell states to stop using the test kits.[18] For many weeks, as the virus spread largely undetected in the United States, the CDC was unable to solve the problem with its test.[19] Meanwhile, other countries were able to implement their own testing programs by using the protocol that had been developed and publicly shared by the World Health Organization (WHO) (a protocol the CDC declined to adopt).[20] Finally, on February 28, the agency announced that states could begin retesting using a modified version of the CDC kits.[21]

The FDA itself took actions which also likely delayed the development of testing capacity in the United States. Health and Human Services (HHS) Secretary Alex Azar had made an emergency declaration which unlocked the FDA's ability to grant emergency use authorizations (EUAs),[22] enabling test manufacturers to enter the market with less premarket review than would typically be required for companies producing and shipping testing kits.[23] Yet particularly given the novel pathogen involved, products were still slow to meet even these more limited evidentiary requirements,[24] and companies reported spending weeks working with the agency before obtaining EUAs for their products.[25] Laboratories aiming to develop their own in-house diagnostics (as compared with companies that planned to ship diagnostic kits around the country) have largely been exempt from FDA review, and for these products even the limited EUA requirements represented *more* onerous regulation than they have come to anticipate, contributing to delays in

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[17] Michael D. Shear et al., *The Lost Month: How a Failure to Test Blinded the U.S. to COVID-19*, N.Y. TIMES (March 28, 2020), https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html.

[18] *Id.*

[19] *Id.*

[20] David Willman, *The CDC's Failed Race Against COVID-19: A Threat Underestimated and a Test Overcomplicated*, WASH. POST (Dec. 26, 2020), https://www.washingtonpost.com/investigations/cdc-covid/2020/12/25/c2b418ae-4206-11eb-8db8-395dedaaa036_story.html.

[21] *Id.*; CTRS. FOR DISEASE CONTROL, *Transcript for the CDC Telebriefing Update on COVID-19* (Feb. 28, 2020), https://www.cdc.gov/media/releases/2020/t0228-COVID-19-update.html.

[22] Declaration by Alex M. Azar II, U.S. Dep't Health & Hum. Servs., Determination of a Public Health Emergency (Feb. 4, 2020), https://www.fda.gov/media/135010/download.

[23] 21 U.S.C. § 360bbb-3(c)(2) (2012).

[24] *See* Shear, *supra* note 17.

[25] *Id.*

authorization.[26] Although the FDA's actions were motivated by the need to maintain its evidentiary standards, despite—or even especially because of—the pandemic,[27] its EUA requirements slowed the ability of other laboratories to fill the void left by the CDC's absence.

To be clear, there was sufficient communication between the CDC and the FDA to enable the FDA to grant the CDC's test an emergency authorization in early February (even after the agency's testing problems became evident).[28] But in other situations, the agencies appeared to be at odds with each other. At one point, the CDC even blocked an FDA official (though temporarily) from entering the CDC to help address the ongoing testing problems.[29]

Independent laboratory certification requirements overseen by CMS under its authority provided by the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[30] likely also limited the set of labs eligible to perform COVID-19 diagnostic testing. Many academic laboratories, in particular, had the technical ability to perform COVID-19 tests, but they did not possess CLIA certification.[31] Some were able to partner with CLIA-certified labs to offer COVID-19 testing, but many were not able to overcome the administrative barriers to doing so.[32]

Interagency coordination between CDC, FDA, and CMS could have avoided or at least mitigated these delays, particularly those attributable to the problems with the CDC's own test. Even if these agencies did not work together on their own initiative, the three agencies all share a parent agency in HHS. But rather than working to identify conflicts between the agencies and help accelerate the diagnostic development and dissemination process,[33]

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[26] Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE L. J. F. 78, 88 (2020).

[27] Nicholson Price et al., *How Is Regulatory Policy Influencing the Development and Marketing of Antibody Testing for COVID-19?*, WRITTEN DESCRIPTION (May 4, 2020, 3:56 PM), https://writtendescription.blogspot.com/2020/05/how-is-regulatory-policy-influencing.html; *see also* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 10–11 (2010) (presenting the agency's regulatory power as deriving in part from its reputation for consumer protection).

[28] Willman, *supra* note 20.

[29] Dan Diamond, *CDC Blocked FDA Official from Premises*, POLITICO (Mar. 3, 2020), https://www.politico.com/news/2020/03/03/cdc-blocked-fda-official-premises-119684.

[30] Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, § 353, 102 Stat. 2903, 2903-04 (codified as amended at 42 U.S.C. § 263a (2018)); CTRS. FOR MEDICARE & MEDICAID SERVS., *Clinical Laboratory Improvement Amendments (CLIA)* (2020), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA.

[31] Amy Maxmen, *Thousands of Coronavirus Tests Are Going Unused in US Labs*, NATURE (April 9, 2020), https://www.nature.com/articles/d41586-020-01068-3.

[32] *Id.*

[33] Dan Diamond & Adam Cancryn, *Azar in the Crosshairs for Delays in Virus Tests*,

HHS Secretary Azar reportedly "blocked efforts" to allow private laboratories to obtain testing approval in the CDC's absence[34] and waited to take action to address testing issues until the very end of February, only after National Institute of Allergy and Infectious Disease Director Dr. Tony Fauci encouraged Azar's chief of staff to act.[35] Administration officials have referred to Secretary Azar's conduct as "a management failure," noting that "CDC and FDA should have been working hand in hand."[36]

The public might also have expected White House officials to take stronger roles here as well and aim to solve these types of problems. One problem, as discussed below in Part III.A, may have been that there were signals coming from President Trump to deprioritize testing, partly in an effort to downplay the number of cases.[37] As a result, the COVID-19 Task Force (itself an interagency coalition) may have felt pressure to focus on other areas of the government's response. At the same time, it is possible that the relevant government officials did not understand which agencies needed to be represented in the decision-making process. For instance, FDA Commissioner Stephen Hahn and CMS Administrator Seema Verma did not even become part of the COVID-19 Task Force until March, after the government's initial testing issues had been resolved.[38]

These initial testing failures were certainly catastrophic for the government's ability to detect and respond to the COVID-19 pandemic in the early months of 2020. But since then, there have also been more positive examples of interagency coordination in the COVID-19 diagnostics area. Most notably, the National Institutes of Health (NIH) is leading the Rapid Acceleration of Diagnostics (RADx) Initiative, aiming to "speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing."[39] Through RADx, the NIH has sought to work together with the CDC, FDA, Biomedical Advanced Research and Development Agency (BARDA), and Defense Advanced Research Projects

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POLITICO (March 2, 2020), https://www.politico.com/news/2020/03/02/azar-crosshairs-delays-coronavirus-tests-118796.

[34] Rebecca Ballhaus & Stephanie Armour, *Health Chief's Early Missteps Set Back Coronavirus Response*, WALL ST. J. (Apr. 22, 2020), https://www.wsj.com/articles/health-chiefs-early-missteps-set-back-coronavirus-response-11587570514.

[35] *See* Shear, *supra* note 17; Willman, *supra* note 20.

[36] Diamond & Cancryn, *supra* note 33.

[37] *See infra* Part III.A.

[38] Press Release, The White House, Vice President Pence and Secretary Azar Add Key Administration Officials to the Coronavirus Task Force (Mar. 2, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/vice-president-pence-secretary-azar-add-key-administration-officials-coronavirus-task-force-3.

[39] NAT'L INST. HEALTH, *Rapid Acceleration of Diagnostics (RADx)*, https://www.nih.gov/research-training/medical-research-initiatives/radx (last visited May 8, 2021).

Agency (DARPA) to encourage each of these goals.[40]

The $1.5 billion RADx Initiative aimed to use a "shark tank"-type[41] approach to bring to market at-home and point-of-care tests for COVID-19, with the initial goal of making "millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020, and even more in time for the flu season."[42] Although the Initiative may not have quite met this initial goal,[43] it has certainly sped the development of a range of new diagnostic options for COVID-19.[44] One grantee, Ginkgo Bioworks,[45] is innovating in pooled testing in an effort to provide surveillance capabilities for K-12 schools around the country.[46] Another grantee, Ellume,[47] received the very first FDA authorization for a rapid at-home test that is available over-the-counter.[48]

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[40] *Id.*

[41] NAT'L INST. HEALTH, *RADx Programs*, https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs (last updated Dec. 23, 2020); ABC, *About Shark Tank*, https://abc.com/shows/shark-tank/about-the-show (last visited May 8, 2021).

[42] NAT'L INST. HEALTH, *NIH Mobilizes National Innovation Initiative for COVID-19 Diagnostics* (Apr. 29, 2020), https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics.

[43] As the NIH noted, "RADx Tech and RADx-ATP contracts are expected to increase test capacity by 2.7 million tests per day by the end of 2020." NAT'L INST. HEALTH, *NIH RADx Initiative Advances Six New COVID-19 Testing Technologies* (Oct. 6, 2020), https://www.nih.gov/news-events/news-releases/nih-radx-initiative-advances-six-new-covid-19-testing-technologies. However, many fewer tests were being conducted by the end of 2020, with testing delays being widely reported. Ken Alltucker, *The Demand for COVID-19 Testing is Up, Stressing Labs and Delaying Results*, USA TODAY (Nov. 26, 2020), https://www.usatoday.com/story/news/health/2020/11/26/covid-19-testing-delays-record-demand-thanksgiving/6417506002/.

[44] RADx has also created additional grant programs with related goals. For instance, the "RADx Radical" program supports "non-traditional viral screening approaches" to combat the pandemic. NAT'L INST. HEALTH, *NIH to Support Radical Approaches to Nationwide COVID-19 Testing and Surveillance* (Dec. 21, 2020), https://www.nih.gov/news-events/news-releases/nih-support-radical-approaches-nationwide-covid-19-testing-surveillance. For instance, RADx Radical grantees include those developing airborne detectors for continuous surveillance of large spaces as well as development of wastewater technologies for estimating community infection levels. *Id.*

[45] NAT'L INST. HEALTH, *NIH Delivering New COVID-19 Testing Technologies to Meet U.S. Demand* (July 31, 2020), https://www.nih.gov/news-events/news-releases/nih-delivering-new-covid-19-testing-technologies-meet-us-demand.

[46] Ginkgo Bioworks, *Ginkgo Bioworks Launches COVID-19 Pooled Classroom Testing Pilot for K-12 Schools*, CISION PR NEWSWIRE (Dec. 23, 2020), https://www.prnewswire.com/news-releases/ginkgo-bioworks-launches-covid-19-pooled-classroom-testing-pilot-for-k-12-schools-301198122.html.

[47] NAT'L INST. HEALTH, *supra* note 43.

[48] NAT'L INST. HEALTH, *NIH-Funded COVID-19 Home Test is First to Receive Over-the-Counter Authorization from FDA* (Dec. 15, 2020), https://www.nih.gov/news-events/news-releases/nih-funded-covid-19-home-test-first-receive-over-counter-

The steps involved in developing and disseminating this wide range of tests illustrates the importance of the interagency collaboration involved in RADx. These companies must not only address any scientific challenges in the development of these tests, but they must also obtain FDA authorization for their new technologies and provide broad access to them. Particularly for smaller start-ups with little or no prior experience dealing with regulatory agencies, these challenges may prove overwhelming. The involvement in RADx of FDA, CDC, and other agencies is designed to help surmount these difficulties. The FDA is working with RADx not only "to provide general advice on test validation" but is also "prioritizing the review of emergency use authorization (EUA) for tests supported by RADx."[49] More purposeful use of interagency collaborations like these early in the pandemic may have been able to avoid or at least minimize some of the initial testing failures involved.

## II. PRIORITIZING VACCINE DEVELOPMENT, RATHER THAN DISTRIBUTION

The development and broad distribution of vaccines that are effective at preventing COVID-19 is critical to enabling the world to move beyond the COVID-19 pandemic. Unlike with diagnostic testing, the Trump Administration quickly established a whole-of-government initiative—Operation Warp Speed (OWS)—with the initial goal of "deliver[ing] 300 million doses of a safe, effective vaccine for COVID-19 by January 2021."[50] Led by the Secretary of Health and Human Services and the Secretary of Defense,[51] OWS aimed to bring together officials from dozens of different

authorization-fda. More recently, the federal government has signed a procurement deal with Ellume, awarding $231.8 million to the company in exchange for 8.5 million tests. Press Release, U.S. Dep't of Defense, DoD Awards $231.8 Million Contract to Ellume USA LLC to Increase Domestic Production Capacity and Deliver COVID-19 Home Tests (Feb. 1, 2021), https://www.defense.gov/Newsroom/Releases/Release/Article/2488793/dod-awards-2318-million-contract-to-ellume-usa-llc-to-increase-domestic-product/.

[49] NAT'L INST. HEALTH, *supra* note 45.

[50] U.S. DEP'T HEALTH & HUMAN SERVS., *Fact Sheet: Explaining Operation Warp Speed*, https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html (last updated Jan. 15, 2021). Although quickly at least some of the public messaging shifted, to promise only "the initial doses" being made available by January 2021, while other public messaging still promised far greater achievements. *Id.* As one example, White House Chief of Staff Mark Meadows publicly stated in September that the goal was to have 100 million doses available by the end of October and 300 million doses by January 2021. Morgan Chalfant, *Meadows Disputes CDC Director's Vaccine Timeline*, THE HILL (Sept. 17, 2020), https://thehill.com/homenews/administration/516855-meadows-disputes-cdc-directors-vaccine-timeline.

[51] Nicholas Florko, *New Document Reveals Scope and Structure of Operation Warp*

government agencies to collaborate to accelerate the development of effective vaccines. OWS was able to meet part of its goal, as the FDA granted emergency use authorizations for COVID-19 vaccines from both Pfizer-BioNTech and Moderna in December 2020.[52] But OWS largely failed in its goal of distributing those vaccines, with 14 million vaccines distributed and just over 3 million actually administered by the end of 2020.[53] Many of these early distributional failures appear attributable to failures of interagency coordination.

This Part will first describe the successes of OWS, explaining how intense focus on interagency collaboration and public-private collaboration truly did accelerate the development and regulatory review of these new vaccines. This Part will go on to consider OWS' relative failures on distribution and administration of COVID-19 vaccines, explaining how a lack of interagency coordination caused early delays in the vaccine rollout, and how those failures could have been avoided.

OWS provided essential support in the development of the Pfizer-BioNTech and Moderna vaccines, leading to their record-breaking authorization by the FDA less than one year after the companies began to develop the vaccines.[54] The support provided by OWS to these and other vaccine manufacturers was both financial and logistical.[55] It would not have been possible to provide these types of support without the significant interagency collaboration facilitated by OWS.

OWS provided financial support to a range of potential vaccine candidates in two primary ways: encouraging at-risk manufacturing and

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*Speed and Underscores Vast Military Involvement*, STAT (Sept. 28, 2020), https://www.statnews.com/2020/09/28/operation-warp-speed-vast-military-involvement/. At the time of Operation Warp Speed's creation, Mark Esper served as the Secretary of Defense, though after President Trump fired Esper days after the November 2020 elections, Acting Defense Secretary Christopher Miller took over this role. U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 50.

[52] Carl Zimmer et al., *Coronavirus Vaccine Tracker*, N.Y. TIMES, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (last visited Jan. 26, 2021).

[53] Orion Rummler, *U.S. Set to End 2020 With Just over 3 Million Vaccine Doses Administered*, AXIOS (Dec. 31, 2020), https://www.axios.com/coronavirus-vaccines-administered-2020-9ec0cebf-58cd-4294-8b1e-9334c76363c8.html.

[54] *See, e.g.*, Zimmer et al., *supra* note 52 (examining the Pfizer and Moderna vaccines' expedited authorization timelines).

[55] U.S. DEP'T HEALTH & HUMAN SERVS., FROM THE FACTORY TO THE FRONTLINES: THE OPERATION WARP SPEED STRATEGY FOR DISTRIBUTING A COVID-19 VACCINE (2020), https://media.defense.gov/2020/Sep/16/2002498509/-1/1/1/OPERATION_WARP_SPEED_STRATEGY_FOR_DISTRIBUTING_COVID19_VACCINE.PDF (outlining a strategy for vaccine distribution, administration, monitoring, and engagement dependent on communication and cooperation at the state, tribal, and local government levels).

securing advanced purchases of the resulting vaccines.[56] Given the high cost of building the manufacturing capacity for a new vaccine, pharmaceutical companies are relatively unlikely to invest in developing such capacity while there is still a high risk that their product may fail in clinical trials, causing them to lose their investments in manufacturing.[57] But given the enormous social costs of the COVID-19 pandemic, one critical goal of OWS was to invest in at-risk manufacturing capacity for several chosen candidates. OWS invested hundreds of millions of dollars in the manufacturing efforts of each of a range of vaccine candidate sponsors,[58] expecting that some of these investments would not pan out—but knowing that the social value of the ones that did would far exceed the financial investment.

Moderna was one such company benefiting from these investments, as early as April 2020 accepting up to $483 million in funding to support the scale-up of their manufacturing efforts and the completion of their late-stage clinical trials.[59] As Moderna had never brought a product to market successfully before, they gladly partnered with the federal government to develop at-risk manufacturing capacity for their vaccine candidate. By contrast, Pfizer, already one of the world's largest pharmaceutical firms and vaccine manufacturers, did not accept this funding, although its German Partner, BioNTech, did accept €375 million from the German government for similar manufacturing and clinical trials purposes.[60] Pfizer began preparations to shift its manufacturing capacity toward a COVID-19 vaccine as early as March 2020,[61] with CEO Albert Bourla noting that "[i]f we were

[56] Bhaven N. Sampat & Kenneth C. Shadlen, *The COVID-19 Innovation System*, 40 HEALTH AFFS. 400, 402 (2021).

[57] Sarah McCammon, *NIH Director Hopes For At Least 1 Safe and Effective Vaccine by Year's End*, HOUSTON PUBLIC MEDIA (June 7, 2020, 12:37 PM), https://www.houstonpublicmedia.org/npr/2020/06/07/868833292/nih-director-hopes-for-at-least-1-safe-and-effective-vaccine-by-years-end/.

[58] U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 51 (identifying candidate vaccines and the manufacturing funding provided by OWS, including $1 billion for Johnson & Johnson and $1.6 billion for Novavax).

[59] *Id.*; *see also* MODERNA, *Moderna Announces Award from U.S. Government Agency BARDA for up to $483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus* (Apr. 16, 2020, 5:55 PM), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million (noting the award "will fund manufacturing process scale-up to enable large-scale production in 2020 for pandemic response").

[60] GLOBENEWSWIRE, *BioNTech to Receive Up To €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162* (Sept. 15, 2020), https://www.globenewswire.com/news-release/2020/09/15/2093535/0/en/BioNTech-to-Receive-up-to-375M-in-Funding-from-German-Federal-Ministry-of-Education-and-Research-to-Support-COVID-19-Vaccine-Program-BNT162.html.

[61] Jared S. Hopkins, *How Pfizer Delivered a COVID Vaccine in Record Time: Crazy*

unsuccessful, we would have to write off $2 billion."[62] For Pfizer, with $52 billion in annual revenues, Dr. Bourla emphasized, "This is painful for any corporation, but it was not going to break us."[63]

But OWS also provided billions in financial support—including to both Pfizer and Moderna—in the form of advance purchase commitments of vaccines.[64] The United States (and other countries around the world) contracted to purchase enormous quantities of vaccines well before those vaccines received marketing authorization. OWS reserved more vaccine doses (from manufacturers whose vaccine candidates made use of a diverse range of technological approaches) than necessary to vaccinate the entire American population,[65] again expecting that some vaccine candidates would be unsuccessful. The United States initially ordered 100 million doses of Pfizer-BioNTech's vaccine for $1.95 billion in July 2020,[66] and in August similarly ordered 100 million doses of Moderna's vaccine for $1.5 billion.[67] In other situations, advanced purchase commitments like these have served as effective innovation drivers, where the vaccine manufacturer cannot be sure that there is a viable market for the product in question.[68] Here, though,

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*Deadlines, a Pushy CEO*, WALL ST. J. (Dec. 11, 2020, 9:34 PM), https://www.wsj.com/articles/how-pfizer-delivered-a-covid-vaccine-in-record-time-crazy-deadlines-a-pushy-ceo-11607740483; Nathan Vardi, *The Race Is On: Why Pfizer may be the Best Bet to Deliver a Vaccine by This Fall*, FORBES (May 20, 2020, 6:30 AM), https://www.forbes.com/sites/nathanvardi/2020/05/20/the-man-betting-1-billion-that-pfizer-can-deliver-a-vaccine-by-this-fall/?sh=464b6508382e.

[62] Sharon LaFraniere et al., *Politics, Science, and the Remarkable Race for a Coronavirus Vaccine*, N.Y. TIMES (Nov. 21, 2020), https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html.

[63] *Id.* As Moderna CEO Stephan Bancel noted, "[W]e don't have a balance sheet like Pfizer." *Id.*

[64] U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 50.

[65] *Id.* (identifying the pre-ordered doses, including 300 million from AstraZeneca alone, 100 million from Johnson & Johnson, 100 million from Novavax, 100 million from GlaxoSmithKline, in addition to the vaccines from Pfizer and Moderna).

[66] PFIZER, *Pfizer and BioNTech Announce an Agreement with U.S. Government for Up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2* (July 22, 2020, 7:10 AM), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600.

[67] U.S. DEP'T HEALTH & HUMAN SERVS., *Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine* (Aug. 11, 2020), https://www.hhs.gov/about/news/2020/08/11/trump-administration-collaborates-with-moderna-produce-100-million-doses-covid-19-investigational-vaccine.html. As of this writing, the United States is planning to purchase enough vaccine from Pfizer and Moderna alone to vaccinate up to 300 million Americans. Adam Cancryn & Rachel Roubein, *Biden Administration to Buy 200 Million More Doses of COVID Vaccine*, POLITICO (Jan. 26, 2021, 4:30 PM), https://www.politico.com/news/2021/01/26/biden-covid-vaccine-purchase-462803.

[68] These commitments are a type of "pull" mechanism, in which sponsors "commit to

it is unlikely that these advanced purchases made the difference in convincing manufacturers to invest in the development of vaccines for this truly global pandemic.[69] It is more likely that they encouraged companies to increase the speed of their development process, where possible, and that they enabled (mostly wealthy) countries to reserve doses for their citizens, in a way that creates distributional concerns globally.[70]

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purchase a specified number of doses at a specified price if a vaccine meeting certain specifications were developed." Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSPS. 67, 83 (2002). This "pull" mechanism thus provides certain rewards for companies who succeed in developing such a product, while also ensuring access for countries at defined prices. Previously, GAVI's Advance Market Commitment (AMC) was the premier example of this innovation policy tool, where GAVI and other international stakeholders used the AMC to encourage the development of a vaccine for pneumococcal disease that would be particularly administered in low-income countries. GAVI's AMC has resulted in the administration of pneumococcal vaccines to hundreds of millions of children worldwide. AMC SECRETARIAT OF GAVI, ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES ANNUAL REPORT: 1 JANUARY – 31 DECEMBER 2019, at 6 (2020), https://www.gavi.org/sites/default/files/document/2020/2019-Pneumococcal-AMC-Annual-Report.pdf.

[69] *See* Nicholson Price et al., *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, An Effective Spur to Innovation, or Something in Between?*, WRITTEN DESCRIPTION (Aug. 5, 2020), https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html ("COVID-19 is truly global in scale; there is an *enormous* potential market for the vaccine. There is also less concern that the disease will dissipate before a vaccine arrives, as COVID-19 is harder to contain than other diseases for which vaccines have been researched.").

[70] There is concern that countries have engaged in "vaccine nationalism," a situation in which "countries push to get first access to a supply of vaccines and potentially hoard key inputs for vaccine production . . . ." MARCO HAFNER ET AL., COVID-19 AND THE COST OF VACCINE NATIONALISM, RAND at iii (2020), https://www.rand.org/pubs/research_reports/RRA769-1.html; *see also* Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. OF INT'L AFFAIRS (forthcoming), https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/ ("Law, policy, and geopolitics have systematically given selected countries the ability to negotiate agreements that further their interests to the detriment of public health in less developed economies."). One response to these concerns is the development of COVAX, aiming to promote global and equitable access to a COVID-19 vaccine. WORLD HEALTH ORG., *COVAX: Working for Global Equitable Access to COVID-19 Vaccines* (2021), https://www.who.int/initiatives/act-accelerator/covax. COVAX recognizes that because of the global nature of the pandemic, "no one is safe, unless everyone is safe." *Id.* Through COVAX, high- and middle-income countries can help subsidize access to COVID-19 vaccines for low-income countries, ensuring that residents of all nations have access to the resulting vaccines. Under the Trump Administration, the United States was one of just two countries globally (the other being Russia) to decline to join COVAX, due to the involvement of the WHO (and the Trump Administration's concerns about the WHO), but the Biden administration has announced that the U.S. will be joining COVAX after all. Dave Lawler, *Biden Will Bring U.S. Into COVAX Vaccine Initiative, Blinken Says*, AXIOS (Jan. 19, 2021), https://www.axios.com/us-covax-initiative-biden-tony-blinken-68181bd3-41bd-4dca-8317-e1e30b120fd5.html.

Warp Speed-funded manufacturers also received logistical and operational support. Moderna relayed two notable issues that arose during their clinical trials process:

> When Moderna discovered this summer that an air handling unit for its factory could not be delivered over a weekend because of Covid-19 limitations on interstate trucking, the major's team stepped in. Warp Speed officials arranged a law enforcement escort to accompany the massive piece of equipment from the Midwest to its Massachusetts manufacturing plant.
>
> The team again sprang into action when Moderna discovered that a specialized pump, needed to make the first batches of vaccine for the clinical trials, was marooned in a rail car and was not going to be delivered on time. Federal workers tracked down the train and rummaged through it until they found the pump.[71]

"Instrumental" interventions like these[72] ensured that Moderna was able to complete its clinical trials as quickly as possible.

The different areas of expertise involved in these areas explains why a foundation of strong interagency collaboration was critical in supporting OWS. Expert scientific agencies, including NIH and BARDA, were critical in the process of selecting a range of vaccine candidates for investment.[73] Once identified, each vaccine maker was assigned a team of "around 15 trial specialists, epidemiologists, and budget experts" aiming to assist the firm as it navigated the clinical trials process.[74] Logistical experts based in military agencies helped remove operational challenges as they arose, as Moderna's examples detail.[75] Similarly, the military has comparative expertise in the use of procurement contracts to encourage the development and supply of new technologies, something that HHS has not previously focused on (despite its use globally).[76] Any single agency or even the combination of the health-focused agencies could not have completed all of these tasks. The unison of scientific expertise and logistical support was essential to the record-breaking

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[71] LaFraniere et al., *supra* note 62.

[72] *Id.*

[73] Jon Cohen, *Operation Warp Speed's Opaque Choices of COVID-19 Vaccines Draw Senate Scrutiny*, SCI. MAG. (July 2, 2020, 7:10 PM), https://www.sciencemag.org/news/2020/07/operation-warp-speed-s-opaque-choices-covid-19-vaccines-draw-senate-scrutiny.

[74] LaFraniere et al., *supra* note 62.

[75] Florko, *supra* note 51.

[76] Sarah E. Light, *The Military-Environmental Complex*, 55 B.C. L. REV. 879, 881-82 (2014).

development of both the Pfizer-BioNTech and Moderna vaccines.

To be sure, OWS did not include representatives from every relevant agency. Perhaps most notably, the FDA was largely absent from the process.[77] In part, this was by design, due to the need to maintain FDA impartiality and independence over later decisions that would be made to permit these products to come to market or not.[78] Dr. Peter Marks, the Director of the FDA's Center for Biologics Evaluation and Research, was initially named to be part of OWS but soon withdrew to focus on the agency full-time.[79]

Even as OWS succeeded in its goal of bringing effective vaccines against COVID-19 to market rapidly, it did not have such success in meeting its stated goals around supply and distribution. Throughout the fall, OWS and other Trump Administration officials repeatedly stated that they planned to vaccinate twenty million people in December,[80] though ultimately just over three million Americans received the vaccine before the end of the year.[81] Although there are undoubtedly many contributors to the slow vaccine rollout,[82] at least some of these delays were due to failures of interagency

[77] Dr. Janet Woodcock took a leave from her role as head of the FDA's Center for Drug Evaluation and Research to lead OWS' therapeutics initiative, which was separate from its vaccine arm. Florko, *supra* note 51.

[78] *Id.*

[79] At least some news accounts suggested that political issues may have been at play in his withdrawal. Sarah Owermohle, *FDA Struggles to Remain Independent Amid Race for Virus Cure*, POLITICO (June 3, 2020, 7:55 PM), https://www.politico.com/news/2020/06/03/fda-struggles-to-remain-independent-amid-race-for-virus-cure-299127.

[80] Olivia Goldhill, *On the Ground, the Pledge to Vaccinate 20 Million Against Covid-19 in December Seems Unrealistic*, STAT (Dec. 7, 2020), https://www.statnews.com/2020/12/07/pledge-to-vaccinate-20-million-against-covid19-in-december-seems-unrealistic/.

[81] Rummler, *supra* note 53.

[82] One large contributing factor, for instance, was a failure of communication between the federal government and the states (who were ultimately responsible for vaccinating their residents), and an associated lack of support. The federal government primarily hoped to "shift responsibility for leading the fight against the pandemic . . . to the states." Michael D. Shear et al., *Inside Trump's Failure: The Rush to Abandon Leadership Role on the Virus*, N.Y. TIMES (July 18, 2020), https://www.nytimes.com/2020/07/18/us/politics/trump-coronavirus-response-failure-leadership.html. But the federal government did not provide states with the financial support they needed to do so. Trump officials even "actively lobbied Congress to deny state governments any extra funding for the COVID-19 vaccine rollout," even as states warned that they needed the additional resources. Nicholas Florko, *Trump Officials Actively Lobbied to Deny States Money for Vaccine Rollout Last Fall*, STAT (Jan. 31, 2021), https://www.statnews.com/2021/01/31/trump-officials-lobbied-to-deny-states-money-for-vaccine-rollout/. ("It's true that the states hadn't spent most of the money by October. State health departments, for their part, say there are several good reasons why. For one, they hadn't begun vaccinating anyone yet."). States often received conflicting information from the federal government about how many vaccine doses they would be receiving, making their jobs more difficult. *See, e.g.*, Ellie Kaufman et al., *States Told by*

coordination, as the example of long-term care facilities illustrates.

Perhaps the most vulnerable population during the pandemic has been residents of long-term care and other assisted living facilities. These residents are typically elderly and may have other chronic conditions, and they are typically unable to socially distance as they live in congregate care settings. As a result, nursing home residents have been hit hard by the pandemic: although just 5% of all diagnosed cases are linked to nursing homes, 34% of all deaths are, with more than 172,000 nursing home residents dying of COVID-19 as of the end of February.[83] While the case fatality rate from COVID-19 nationwide is close to 2%, that rate climbs to 10% for patients who are residents of nursing homes.[84]

Because of these vulnerabilities, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that residents of long-term care facilities should be among the first people to be offered access to any authorized vaccines against COVID-19 (as well as health care personnel).[85] On December 13, after Pfizer's vaccine had received its EUA, HHS Secretary Azar predicted that all nursing home residents could be vaccinated by Christmas.[86] But as of the end of January, tens of thousands of residents still had not received their first dose of the vaccines, with the process estimated to run into mid-February.[87] In many states, the process did not even begin

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*Federal Government They Will Receive Fewer Pfizer Vaccine Doses Next Week, Sparking Confusion*, CNN (Dec. 17, 2020), https://www.cnn.com/2020/12/17/politics/pfizer-vaccine-fewer-doses-states-confusion/index.html. ("Officials in numerous states including Iowa, Illinois, Washington, Michigan, and Oregon have said they were recently told they would receive fewer doses than originally planned for by the federal government's Operation Warp Speed.").

[83] *More Than One-Third of U.S. Coronavirus Deaths Are Linked to Nursing Homes*, N.Y. TIMES (Updated Feb. 26, 2021), https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html. In some states, these rates are far higher—in nine states, more than half of recorded deaths are linked to long-term care facilities. *Id.*

[84] *Id.*

[85] Kathleen Dooling et al., *The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine—United States, December 2020*, 69 MORBIDITY & MORTALITY WEEKLY REP'T 1657, 1657 (2021), https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w. All states have followed these recommendations, though several have added other populations to this priority group (such as first responders or other vulnerable individuals, such as psychiatric patients). Jennifer Kates et al., *The COVID-19 "Vaccination Line": An Update on State Prioritization Plans*, KAISER FAMILY FOUND. (Jan. 11, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/the-covid-19-vaccination-line-an-update-on-state-prioritization-plans/.

[86] Melissa Quinn, *Azar Says All Nursing Home Residents Could be Vaccinated by Christmas*, CBS NEWS (Dec. 13, 2020, 12:03 PM), https://www.cbsnews.com/news/covid-19-vaccine-alex-azar-face-the-nation/.

[87] Joe Mahr & Robert McCoppin, *In Illinois Nursing Homes, Tens of Thousands Still Waiting for COVID-19 Vaccinations: "This is Beyond an Emergency,"* CHI. TRIB. (Jan. 22,

until after Christmas,[88] weeks after the vaccines were authorized.

The weeks-long delays in starting the vaccination process for residents in long-term care facilities were attributable, in large part, due to failures of interagency coordination. In practice, the problem was one of informed consent. A large number of residents of long-term care facilities may have delegated their medical decision-making authority to a family member or other party, such as if the resident suffers from dementia or another illness.[89] As a result, the medical staff at the facility could not simply ask each resident whether they would like to receive an FDA-authorized (but still not formally approved) vaccine. They needed to communicate with every resident's authorized medical decisionmaker. Every facility needed to engage in dozens or even hundreds of these communication efforts,[90] as well as speaking with residents who do make their own healthcare decisions. Both types of communication efforts required lengthy educational efforts, given the novelty of the products involved. With long-term care facilities already resource-constrained, this process was expected to take weeks or months.

This process of requiring informed consent was not only foreseeable—it was foreseen. HHS officials reportedly warned OWS that this process of education and consent would take time, and that it should begin even before the FDA's authorization of either vaccine candidate.[91] In particular, they warned that there should be "high-level coordination" within the government

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2021), https://www.chicagotribune.com/coronavirus/ct-illinois-nursing-home-vaccination-delay-20210123-dz7lvyqt5vhuzh2jrzudevhlwu-story.html; Rebecca Robbins, *Frustrations Boil at Pace of Vaccinations at Long-Term Care Facilities*, N.Y. TIMES (Jan. 16, 2021), https://www.nytimes.com/2021/01/16/business/covid-vaccine-nursing-homes.html ?action=click&module=Top%20Stories&pgtype=Homepage.

[88] Miriam Marini, *Coronavirus Vaccine Distribution Begins in Michigan, Starting with Skilled Nursing Homes*, DETROIT FREE PRESS (Dec. 28, 2020), https://www.freep.com/story/ news/local/michigan/2020/12/28/coronavirus-vaccine-distribution-nursing-homes/4068134001/; Dhruv Khullar, *Why Are So Many Health-Care Workers Resisting the COVID Vaccine?*, NEW YORKER (Feb. 2, 2021), https://www.newyorker.com/science/ medical-dispatch/why-are-so-many-health-care-workers-resisting-the-covid-vaccine. ("Alex Azar . . . suggested that all nursing-home residents could have their first dose by Christmas. But, even before Azar spoke, many states had informed the C.D.C. that their programs responsible for nursing-home vaccinations wouldn't be active until at least December 28th.").

[89] Fenit Nirappil & Yasmeen Abutaleb, *Nursing Homes Face Daunting Task of Getting Consent Before They Give Coronavirus Vaccines*, WASH. POST (Dec. 20, 2020), https://www.washingtonpost.com/health/nursing-homes-covid-vaccine-consent-delays/ 2020/12/19/730ecd4a-3fd5-11eb-8bc0-ae155bee4aff_story.html.

[90] Lauren Harris Kojetin et al., *Long-Term Care Providers and Services Users in the United States 2015-2016*, CTRS. FOR DISEASE CONTROL & PREVENTION, at 7 (2019), https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf ("Nursing homes ranged in capacity from 2 to 1,389 certified beds, with an average of 106 certified beds.").

[91] Nirappil & Abutaleb, *supra* note 89.

even before the FDA considered whether to authorize Pfizer's vaccine candidate, with former FDA Commissioner Scott Gottlieb suggesting that one goal of such collaboration would be to produce a fact sheet for residents and their medical decisionmakers that could be used in the consent process.[92] Yet the process seemingly did not begin until after the vaccines received FDA authorization.[93]

If OWS wanted to begin vaccinating residents of long-term facilities sooner, it could have directed the relevant agencies to begin producing such a consent document or informational sheet even before the vaccines were authorized. Such a document would have required the participation of the FDA,[94] but the FDA could not have either instigated or completed the process on its own. As former FDA Commissioners have noted,[95] it would have required collaboration with agencies with a role in the regulation of those facilities, especially CMS, as facilities are required to comply with federal regulations (including those around resident consent)[96] to receive reimbursement under Medicare and Medicaid.[97]

## III. INTERAGENCY COLLABORATION: LEARNING FROM COVID-19 SUCCESSES AND FAILURES

Scholars and policymakers should seek to learn lessons from both the successes and failures of innovation policy during the COVID-19 pandemic. Although there are undoubtedly lessons to learn that are relevant to a wide range of policy questions, at least some of these lessons will bear on questions of interagency collaboration. The successes and failures of the diagnostic and vaccine initiatives can help inform best (and worst) practices for interagency collaboration in the innovation policy space, in at least three ways: exploring the role of agenda-setting power, appreciating the importance of organizational structure, and establishing a culture of collaboration. Importantly, we ought to be wary of overlearning lessons drawn from crises in general, but also from a singular event, especially if singular personalities

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[92] *Id.*

[93] Some officials argued that it would have been premature or even *more* problematic to formulate a fact sheet prior to authorization, particularly if the FDA's review "produced additional data and risks that were not yet known." *Id.* But nursing home staff noted that they had been receiving conflicting directions from the federal government throughout this process, as well. *Id.*

[94] *Id.*

[95] Scott Gottlieb (@ScottGottliebMD), TWITTER, (Dec. 13, 2020, 6:51 PM), https://twitter.com/ScottGottliebMD/status/1338270360769323009.

[96] 42 C.F.R. § 483.10 (2021).

[97] 42 C.F.R. § 483.1(b) (2021).

are involved. As such, this Part presents other examples of interagency collaboration drawn from more typical circumstances to support or refute these arguments. At the same time, the scale and urgency of the COVID-19 pandemic may offer opportunities to learn about whole-of-government efforts that are not present in smaller-scale examples of interagency collaboration.

### A. *The Role of Agenda-Setting Power*

This lesson is simple to state: the President and agency heads have great agenda-setting power and can direct some amount of agency capacity toward their policy priorities. Relatedly, the President and agency heads can also act (or fail to act) to signal that something is *not* a priority, such that regulators will not or cannot address the issue. Presidential or agency head activities and statements not only signal the importance of a particular issue, but are likely essential for follow-through as well. Especially where a certain instance of collaboration is likely difficult or unwanted (by lower-level agency officials), executive-level focus matters to both focus and refocus attention on the policy goal at hand. This matters particularly in encouraging interagency collaboration, where inertia (particularly in the form of organizational barriers to starting such collaborations) may be of greater concern.

In the COVID-19 context, the application of this lesson was simple: President Trump did not want the United States to develop robust diagnostic testing capacity. Testing was "overrated,"[98] he said. "If we didn't do any testing, we would have very few cases."[99] He "said to [his] people, 'slow the testing down please.'"[100] After all, "[w]hen you test, you create cases"—and testing "makes us look bad."[101]

To be clear, this belief was far from universally held, and many career scientists and agency staff understood deeply—and quite early—the potential threat the virus posed.[102] But at least some political appointees may have

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[98] Aaron Blake, *Trump's Continually Strange Comments on Possibly "Overrated" Coronavirus Testing*, WASH. POST (May 15, 2020), https://www.washingtonpost.com/politics/2020/05/15/trumps-thoroughly-strange-commentary-coronavirus-testing/.

[99] *Id.*

[100] Maegan Vazquez, *Trump Now Says He Wasn't Kidding When He Told Officials to Slow Down Coronavirus Testing, Contradicting Staff*, CNN (June 23, 2020), https://www.cnn.com/2020/06/22/politics/donald-trump-testing-slow-down-response/index.html. Although aides asserted that the comment was made as a joke, the President responded, "I don't kid . . . let me make it clear." *Id.*

[101] Sharon Begley, *Trump Said More COVID-19 Testing "Creates More Cases." We Did the Math*, STAT (July 20, 2020), https://www.statnews.com/2020/07/20/trump-said-more-covid19-testing-creates-more-cases-we-did-the-math/.

[102] Perhaps most notably, the CDC's Dr. Nancy Messonier, the Director of the agency's National Center for Immunization and Respiratory Diseases, publicly warned in February

feared taking aggressive actions that would have angered the president. For instance, the *Wall Street Journal* concluded that HHS Secretary Azar "waited for weeks to brief the president on the threat, oversold his agency's progress in the early days and didn't coordinate effectively across the health-care divisions under his purview."[103] Particularly early on, delays like these may have slowed the development of robust testing capacity and allowed the virus to spread unnoticed within the United States. Later, some political appointees even came to advocate for a "herd immunity" strategy, writing explicitly about lower-risk groups that "we want them infected."[104] News reports have documented efforts by political appointees within both the White House and HHS to interfere in the CDC's work throughout the pandemic,[105] which may have made it more difficult for the agency to coordinate with other science-focused agencies.

By contrast, President Trump wanted *very badly* for the United States to develop a vaccine as quickly as possible, and he attempted to suggest as clearly as he could—albeit without ever explicitly promising—that a vaccine would be ready by Election Day. Privately, it was reported that he appeared "fixated" on the need to "deliver a vaccine—or at least convince the public that one is very near" by Election Day, consistently "press[ing] health officials to speed up the vaccine timeline . . . ."[106] His public comments reflected this goal. In early September 2020, he stated that "[w]e're going to have a vaccine very soon, maybe even before a very special date."[107] In mid-

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2020 that the public should prepare for community spread of the virus and significant disruptions to daily life, including school closures. Erica Werner et al., *Coronavirus' Spread in U.S. is "Inevitable," CDC Warns*, WASH. POST (Feb. 28, 2020), https://www.washingtonpost.com/us-policy/2020/02/25/cdc-coronavirus-inevitable/. In response, President Trump threatened to fire Dr. Messonier, Ballhaus & Armour, *supra* note 34, and sidelined the CDC more generally from briefing the American public. Lena H. Sun, *CDC, the Top U.S. Public Health Agency, Is Sidelined During Coronavirus Pandemic*, WASH. POST (Mar. 19, 2020), https://www.washingtonpost.com/health/2020/03/19/cdc-top-us-public-health-agency-is-sidelined-during-coronavirus-pandemic/.

[103] Ballhaus & Armour, *supra* note 34.

[104] Dan Diamond, *"We Want Them Infected": Trump Appointee Demanded "Herd Immunity" Strategy, Emails Reveal*, POLITICO (Dec. 16, 2020), https://www.politico.com/news/2020/12/16/trump-appointee-demanded-herd-immunity-strategy-446408.

[105] Dan Diamond, *Trump Officials Interfered with CDC Reports on COVID-19*, POLITICO (Sept. 11, 2020), https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809; Noah Weiland, *"Like a Hand Grasping": Trump Appointees Describe the Crushing of the CDC*, N.Y. TIMES (Jan. 15, 2021), https://www.nytimes.com/2020/12/16/us/politics/cdc-trump.html.

[106] Philip Rucker et al., *Trump Fixates on the Promise of a Vaccine—Real or Not—as Key to Reelection Bid*, WASH. POST (Sept. 5, 2020), https://www.washingtonpost.com/politics/trump-vaccine-election/2020/09/05/c0da86d6-edf5-11ea-99a1-71343d03bc29_story.html.

[107] Jordyn Phelps, *Trump Makes Rosy Vaccine Timing Front and Center in Campaign,*

September, he said that "[w]e think we can start [vaccine distribution] sometime in October."[108] In late October, he said "[w]e have a vaccine that's coming, it's ready."[109]

But President Trump didn't just talk about the need to develop a vaccine in record time—he also took action to bring it about. He brought in Dr. Moncef Slaoui, formerly the Chairman of Global Vaccines at GlaxoSmithKline, as a chief advisor to lead OWS alongside General Gustave Perna.[110] More problematically, his chief of staff initially blocked the FDA's release of its revised vaccine EUA guidance, believing that the guidance's call for two months of safety follow-up data would preclude the possibility of a vaccine authorization before Election Day.[111] The President publicly suggested that these guidelines "sound[] like a political move."[112] It was clear to all staffers, political and non-political, that vaccine development was a top priority, and it is difficult to overstate the apparent public contradiction between these two positions on diagnostics and vaccines.

The general form of this insight is not novel, as the literature has already noted the importance of Presidential focus in encouraging interagency collaboration efforts.[113] In the health innovation context alone, the Human Genome Project is one example of this lesson, where President Clinton's support (financial, administrative, and otherwise) of the program over his

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*Predicting It's Possible Before Election Day*, ABC NEWS (Sept. 8, 2020), https://abcnews.go.com/Politics/trump-makes-rosy-vaccine-timing-front-center-campaign/story?id=72877119.

[108] THE WHITE HOUSE, *Remarks by President Trump in Press Briefing* (Sept. 16, 2020, 5:17 PM), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-september-16-2020/.

[109] THE COMM'N ON PRESIDENTIAL DEBATES, *Presidential Debate at Belmont University in Nashville, Tennessee* (Oct. 22, 2020), https://www.debates.org/voter-education/debate-transcripts/october-22-2020-debate-transcript.

[110] DEPT. OF DEF., *Trump Administration Announces Framework and Leadership for "Operation Warp Speed"* (May 15, 2020), https://www.defense.gov/Newsroom/Releases/Release/Article/2310750/trump-administration-announces-framework-and-leadership-for-operation-warp-speed/.

[111] Sharon LaFraniere & Noah Weiland, *White House Blocks New Coronavirus Vaccine Guidelines*, N.Y. TIMES (Oct. 5, 2020), https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html. The guidance was eventually released publicly, after the FDA was able to append the substance of the guidance to the briefing documents for an October FDA Advisory Committee meeting. Michael Mezher, *FDA Issues COVID-19 Vaccine EUA Guidance After Clash With White House*, REGUL. AFFS. PRO. SOC'Y (Oct. 6, 2020), https://www.raps.org/news-and-articles/news-articles/2020/10/fda-issues-covid-19-vaccine-eua-guidance-after-cla.

[112] Sheryl Gay Stolberg, *Trump May Reject Tougher FDA Vaccine Standards, Calling Them "Political,"* N.Y. TIMES (Sept. 23, 2020), https://www.nytimes.com/2020/09/23/us/politics/coronavirus-science.html.

[113] Freeman & Rossi, *supra* note 12, at 1197. To be sure, there has been less focus on executive interference with interagency collaboration.

eight years in office was surely important to its ultimate success.[114] But the opposing positions taken by President Trump on diagnostics and vaccines allow for a sharpening of the broader point. In the diagnostics context, at least some career officials within different federal agencies very much wanted to develop accurate testing technology. If the President had either supported this goal or had even remained absent from the discussion entirely, diagnostic development and relevant coordination toward that goal might have proceeded apace. But in a situation where the President and particular political appointees publicly (and perhaps privately) opposed this goal, career civil servants were unable to overcome this intransigence for weeks.

### B. *The Importance of Organizational Structure*

Another potential distinction to draw between the diagnostic and vaccine case studies is to consider the importance of organizational structure. . How much of the failure of the early diagnostic roll-out was due to the localization of the dispute within HHS, and how much of the initial success of OWS was due to its higher-level organization, led by the White House? To be sure, it is difficult to answer this question, and especially difficult to disentangle the organizational structure of the innovation actors from the agenda-setting powers of the individuals at the helm (as noted above). But when considering the ideal organizational structure for a particular innovation project, it is important to consider 1) the legal, regulatory, and practical tools needed to accomplish that goal and 2) the institutional structure needed to bring each of those tools to the table.

For instance, it is likely that important elements of OWS' innovation success came from its combination of scientific authority and logistical expertise, which arose only from the higher-level work to unite the leadership of HHS and DOD. OWS' incorporation of scientific and regulatory expertise from HHS and its component agencies was likely essential in the selection of a diverse range of vaccine candidates and in shepherding them through the complex regulatory system in record time. Simultaneously, the logistical expertise of the military leadership was undoubtedly key to overcoming barriers to manufacturing scale-up, as Moderna's examples[115] illustrate. As a result, OWS could not have been housed within HHS or DOD alone, but needed to be constituted at a higher level to combine resources of a broad range of agencies. In many ways, OWS was also a public-private partnership,

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[114] *See, e.g.*, NAT'L HUM. GENOME RES. INST., *NHGRI History and Timeline of Events* (2020), https://www.genome.gov/about-nhgri/Brief-History-Timeline (highlighting NHGRI's elevation within the NIH, support of legislation arising out of the project, formal White House announcements of milestones, and President Clinton's "Executive Order to prevent genetic discrimination in any federal workplace" in February 2000).

[115] *See supra* text accompanying note 71.

involving relationships with large, complex companies with high levels of regulatory sophistication.[116]

With the diagnostic roll-out, by contrast, it should have been possible to construct and scale-up a primarily HHS-led testing effort. RADx is just one example of this, bringing together NIH, CDC, and FDA to drive innovation in new diagnostic technologies for COVID-19.[117] At least in the beginning, those agencies possessed the scientific and regulatory expertise to develop these tests and provide regulatory clarity for private-sector firms seeking to develop them as well.[118] It is not necessarily clear that siting the diagnostic effort within the White House, rather than within HHS, would have been necessary for the success of the effort (and could even have been counterproductive, given the President's stated concerns about testing capacity). It may be that in this case, organizational structure may have been less important than the identity and motivations of the particular individuals in charge.

The issue of organizational structure has applications for at least two broader discussions occurring in the literature, beyond the COVID-19 context. One is the idea raised in prior scholarship regarding the creation and role of an innovation regulator with some authority to coordinate innovation goals across agencies. Professors Arti Rai and Stuart Benjamin have proposed the creation of an independent Office of Innovation Policy housed within the White House, rather than within individual component agencies (like HHS or the Environmental Protection Agency), to serve this function.[119] Giving this office the authority to propose new areas for agency action and also to respond to agency proposals (such as through the Office of Information and Regulatory Affairs review process)[120] would allow for broader input into the innovation process than currently exists. Particularly for innovation projects seeming to require a whole-of-government response, as with OWS, siting this regulator within the White House structure would appear to be most effective. But as they note, there are advantages of developing specialized knowledge in particular fields (including

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[116] A fuller explanation of the role of public-private partnerships in interagency collaboration is beyond the scope of this piece.

[117] *See* NAT'L INST. HEALTH, *supra* note 39. RADx also includes BARDA and DARPA as partners, but their inclusion is not an obstacle to housing the effort within the NIH.

[118] Shawn Boburg et al., *Inside the Coronavirus Testing Failure: Alarm and Dismay Among the Scientists Who Sought to Help*, WASH. POST (Apr. 3, 2020), https://www.washingtonpost.com/investigations/2020/04/03/coronavirus-cdc-test-kits-public-health-labs/.

[119] Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 6, 61–62 (2008).

[120] *Id.* at 64.

healthcare),[121] and in practice this might translate into the appointment of staff members with expertise in different fields.[122]

Rai and Benjamin, though, note the potential costs of such centralization, including the problem of "bad decision-making (whether due to capture or otherwise)."[123] Clearly, such problems are not unique to decisions that are centralized within the White House (as compared to those devolved to the relevant expert agencies). But it is also possible that elevating some of these issues can create political or logistical problems where they might have otherwise been avoided. The goal, instead, might be to preserve the possibility of White House-led innovation but without requiring it, allowing HHS itself to manage internal innovation disputes as they arise in the first instance.[124]

More generally, discussions around interagency coordination—particularly those that relate to HHS and its component agencies, including NIH, CDC, FDA, and CMS—implicate the ongoing policy and scholarly discussions around whether the FDA should become an independent agency. Even prior to the pandemic, multiple former FDA Commissioners (serving under presidents from different parties) argued that the FDA should be moved out of HHS and reconfigured as an independent agency.[125] The former Commissioners note the "administrative bottlenecks" that can occur given the need to obtain "multiple levels of clearance" within HHS, but also that independence would better allow the agency to "protect its integrity."[126]

That integrity has been severely tested over the last few years, but especially during the pandemic.[127] HHS has taken a number of administrative actions both within and outside the COVID-19 context to usurp the FDA's authority in a variety of areas. To name just a few: In the summer of 2020, over objections from FDA Commissioner Stephen Hahn, HHS Secretary Azar stripped the FDA of its ability to regulate a large segment of diagnostic

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[121] *Id.* at 58.

[122] Sachs, *supra* note 13, at 2043.

[123] Benjamin & Rai, *supra* note 119, at 56.

[124] Sachs, *supra* note 13, at 2044.

[125] Robert M. Califf et al., *Seven Former FDA Commissioners: The FDA Should Be An Independent Federal Agency*, 38 HEALTH AFFS. 84, 84 (2019); *see also* Helen Branswell, *Six Former Commissioners Say FDA Should Be Independent Agency*, STAT (June 25, 2016), https://www.statnews.com/2016/06/25/six-former-commissioners-say-fda-get-cabinet-status/.

[126] Califf et al., *supra* note 125, at 85.

[127] *See* Sarah Owermohle & Adam Cancryn, *FDA Fights for Independence in Trump Administration's Final Days*, POLITICO (Jan. 12, 2021), https://www.politico.com/news/2021/01/12/fda-independence-hhs-458515 (describing rising tensions between the HHS and FDA in "the latest example of Trump political appointees exerting control over scientific decisions," causing "[a]gency leaders [to] fear [that] HHS intrusion is eroding the FDA's authority and distracting from its pandemic response").

tests, including (but not limited to) those used for COVID-19.[128] In September, HHS issued a statement requiring the HHS Secretary—rather than the FDA Commissioner—to formally sign various FDA regulatory actions. The impact of this statement was to jeopardize ongoing litigation involving the agency, as well as to limit its independence.[129] And in January 2021, HHS signed a memorandum of understanding (MOU) with the United States Department of Agriculture that would strip the FDA's jurisdiction over certain genetically modified animals and give that authority to the Department of Agriculture—a move long sought by the livestock industry.[130] FDA Commissioner Hahn took the very unusual step of disagreeing with HHS' decision publicly, stating in a lengthy thread on Twitter that "FDA does not support the Memorandum of Understanding" signed by HHS.[131] He was supported by former Commissioner Scott Gottlieb, who called the agreement an "unprecedented usurping of FDA public health authority."[132] These and other actions support the Commissioners' calls for increased agency independence.[133]

At the same time, some of the Commissioners' goals for the agency—including "speed[ing] the development of biomedical innovations"[134]—will often require collaboration with other agencies which are currently under the

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[128] Adam Cancryn & Sarah Owermohle, *HHS Chief Overrode FDA Officials to Ease Testing Rules*, POLITICO (Sept. 15, 2020), https://www.politico.com/news/2020/09/15/hhs-alex-azar-overrode-fda-testing-rules-415400 ("'I've never seen such a complete political overruling of the agency,' said one former HHS official."). Although HHS officials argued that the decision was motivated by legal considerations, the legal arguments involved have been well known for many years, and it was not otherwise apparent why the administration would choose the middle of a pandemic to strip the FDA of this authority. *Id.*; Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1897 (2016) (discussing the legal challenges the FDA faces in "regulating all LDTs").

[129] *See, e.g.*, Steve Usdin, *HHS Statement Jeopardizes Litigation, Undermines FDA Independence, Agency Sources Say*, BIOCENTURY (Sept. 22, 2020), https://www.biocentury.com/article/630578/hhs-statement-jeopardizes-litigation-undermines-fda-independence-agency-sources-say. ("Former FDA Commissioner Robert Califf tweeted Saturday that the Azar memo 'is more of a problem than most people would realize on the surface.'").

[130] Adam Cancryn & Liz Crampton, *11th-Hour Deal Strips FDA Oversight of Genetically Modified Animals*, POLITICO (Jan. 19, 2021), https://www.politico.com/news/2021/01/19/fda-hhs-genertically-modified-animals-460486.

[131] Stephen M. Hahn (@SteveFDA), TWITTER, (Jan. 19, 2021, 1:45 PM), https://twitter.com/SteveFDA/status/1351616813705154562.

[132] Scott Gottlieb (@ScottGottliebMD), TWITTER, (Jan. 19, 2021, 2:08 PM), https://twitter.com/ScottGottliebMD/status/1351622618647027713.

[133] One of President Trump's former policy staffers even noted that "Alex Azar may be the last HHS secretary to have FDA underneath him." Owermohle & Cancryn, *supra* note 127.

[134] Califf et al., *supra* note 125, at 85.

auspices of HHS, including NIH, CDC, and CMS. As a result, formally moving the FDA out of HHS could possibly make innovation collaborations that are organized by HHS more difficult, and would give credence to the argument by Professors Rai and Benjamin that such coordination should be done by a White House-led entity. More specifically, it would make it more challenging for a motivated HHS Secretary to encourage interagency collaborations that involved FDA. At the same time, though, FDA has already taken many of the needed procedural steps to establish formal information-sharing relationships with other agencies,[135] which could simplify collaborations even if it were to become independent.

Existing scholarship has considered efforts to reform agencies of various types in the wake of systemic crises or failures, including the September 11 attacks, financial crisis, or Deepwater Horizon oil spill.[136] In some cases, agency responsibilities have been consolidated post-crisis,[137] and in other cases they have been split apart.[138] In some of these cases, Congressional reorganization may represent a symbolic response to a true collaboration failure. But in this case, because the arguments for removing FDA from HHS' oversight both predate and are meaningfully independent (substantively) from the pandemic itself, the case for doing so may be strengthened.

### C. *Establishing a Culture of Collaboration*

More fundamentally, these initiatives may help highlight the importance of establishing a culture of collaboration among the relevant agencies, particularly where there is no top-down pressure to coordinate.[139] A study of collaborations occurring between NIH and other HHS agencies (including the CDC and FDA) found that "[t]he most common method for initiating successful interagency collaborations was through personal connections and professional networks," with "directives from department/agency leadership" coming in a distant second place.[140] Yet agency staff also reported that not knowing who to contact or how to initiate such collaborations was a significant barrier to getting a collaboration started.[141] These findings suggest

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[135] *See infra* text accompanying notes 142-148.

[136] *See, e.g.*, CHRISTOPHER CARRIGAN, STRUCTURED TO FAIL? REGULATORY PERFORMANCE UNDER COMPETING MANDATES 5-6 (2017).

[137] *Id*. at 2, 57.

[138] *Id.* at 3-4, 92.

[139] This issue is addressed in detail in BARDACH, *supra* note 16.

[140] NAT'L INST. HEALTH, NIH-HHS COLLABORATIONS STUDY BRIEF 4 (2015), https://dpcpsi.nih.gov/sites/default/files/NIH-HHSCollaborations_Study_Summary_Final_Dec_2015_508.UPDATED.pdf (noting that 57% of respondents reported successful collaborations as initiated by staff, versus, 15% as initiated by departmental directives).

[141] *Id.* at 5 (quoting a staffer who noted, "I just don't know where to start in terms of who the people are that might care about the topic areas that my office cares about. HHS is

that once collaborative channels exist, those same career staff members may be more likely to engage in or otherwise support new collaborative efforts in the future. In short, collaboration breeds collaboration.

In some ways, the combination of these factors may explain why the early development and dissemination of diagnostic tests for COVID-19 was so challenging. Not only was there no top-down directive or infrastructure that created space for collaboration, but the relevant agency decisionmakers may not have had the required familiarity with each other. The FDA typically uses its enforcement discretion and declines to regulate large swathes of diagnostic tests,[142] meaning that it is possible they may not have the infrastructure in place to work with other agencies in this substantive area.

At the same time, though, the FDA does have established formal MOUs with other HHS agencies, including CDC[143] and CMS,[144] to allow agency officials to collaborate when needed. The MOU between FDA and CDC exists for the purpose of "provid[ing] a framework for coordination and collaborative efforts between these two agencies,"[145] noting that the two "sister agencies" both "exist and work to protect the public health but have different statutory mandates and responsibilities."[146] Under the terms of the MOU, each agency must "designate central contact points" for communication with the other agency.[147] The MOU was renewed in June of 2019,[148] and in theory should have enabled the needed communication between the two agencies. Perhaps this suggests that, in at least some cases,

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so huge, and so it's figuring out where to start [that is the biggest barrier].").

[142] The FDA has traditionally exercised its enforcement discretion and refrained from large-scale regulation of laboratory-developed tests that are designed and used within a single laboratory. U.S. FOOD & DRUG ADMIN., *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories, Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* 5–7 (Oct. 3, 2014), https://www.fda.gov/media/89841/download. Although in 2014 the agency began to propose a framework for regulating LDTs more broadly, the FDA decided not to move forward with this new regulatory undertaking in the final days of President Obama's administration. U.S. FOOD & DRUG ADMIN., *Discussion Paper on Laboratory Developed Tests (LDTs)* (Jan. 13, 2017), https://www.fda.gov/media/102367/download/. Under the Trump Administration, HHS subsequently acted to strip the FDA of its authority to regulate LDTs through the guidance process. *See supra* text accompanying note 127.

[143] U.S. FOOD & DRUG ADMIN., *Memorandum of Understanding Between the Food and Drug Administration and the Centers for Disease Control and Prevention* (June 19, 2019), https://www.fda.gov/about-fda/domestic-mous/mou-225-14-017.

[144] U.S. FOOD & DRUG ADMIN., *Memorandum of Understanding Between United States Food and Drug Administration and Centers for Medicare & Medicaid Services* (June 25, 2015), https://www.fda.gov/about-fda/domestic-mous/mou-225-10-0010.

[145] U.S. FOOD & DRUG ADMIN., *supra* note 143.

[146] *Id.*

[147] *Id.*

[148] *Id.*

directives from agency leadership may be necessary, though certainly not sufficient, to drive innovative activity forward.

Similarly, the makeup of OWS may help explain the problems encountered in vaccine administration. Reporting suggests that OWS' military leadership prioritized metrics around vaccine *distribution* rather than vaccine *administration*, preferring instead to delegate responsibility for administration to state and local officials.[149] By contrast, many health policy officials encouraged OWS to develop a "last mile" strategy for vaccine administration.[150] The CDC's Dr. Nancy Messonier noted the collaborative difficulties involved in "rapidly mashing together two cultures,"[151] and those difficulties (when combined with the other personnel and ideological approaches involved) may have diminished OWS' focus on the administration problem.

Going forward, policymakers should consider a range of ideas that would foster a culture of collaboration.[152] These ideas may take the form of encouragement, mandates, or encouraging mandates. As an example of an encouraging mandate, Congress has instructed the NIH to report annually on the "activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services."[153] Congress has required this reporting as a way of *encouraging* the NIH to "increase interagency collaboration and coordination,"[154] but most of these

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[149] Katherine Eban, *"A Huge Potential for Chaos": How the COVID-19 Vaccine Rollout Was Hobbled by Turf Wars and Magical Thinking*, VANITY FAIR (Feb. 5, 2021), https://www.vanityfair.com/news/2021/02/how-the-covid-19-vaccine-rollout-was-hobbled. This was a strategy the Trump Administration had pursued throughout the pandemic as it related to the rollout of other healthcare technologies, including Gilead Sciences' remdesivir and the antibody drugs produced by Eli Lilly and Regeneron. Both delegation strategies were also severely flawed. *See* Gina Kolata, *Haphazard Rollout of Coronavirus Drug Frustrates Doctors*, N.Y. TIMES (May 8, 2020), https://www.nytimes.com/2020/05/08/health/coronavirus-remdesivir-hospitals.html ("Doctors treating coronavirus patients say they are flummoxed by what seems to be an unpredictable distribution system."); JoNel Aleccia, *Patients Fend for Themselves to Access Highly Touted Covid Antibody Treatments*, KAISER HEALTH NEWS (Jan. 20, 2021), https://khn.org/news/article/patients-fend-for-themselves-to-access-highly-touted-covid-antibody-treatments/. ("'The bottleneck here in the funnel is administration, not availability of the product,' said Dr. Janet Woodcock, a veteran FDA official in charge of therapeutics for the federal Operation Warp Speed effort.").

[150] Eban, *supra* note 149.

[151] *Id.*

[152] BARDACH, *supra* note 16, 306-07.

[153] 42 U.S.C. § 283a(a) (2021).

[154] *Id.*

(several hundred)[155] collaborations themselves are not *mandated*.[156]

Congress might also consider amendments to the Public Health Service Act's emergency declaration powers that would encourage similar collaborative efforts. The Secretary of HHS has the authority to declare a Public Health Emergency under Section 319 of the Public Health Service Act,[157] a declaration which unlocks a broad range of emergency powers under federal law.[158] Many of these powers authorize the Secretary to access and use particular emergency funds, to grant waivers or modifications of various public health insurance programs (including Medicare and Medicaid[159]), or otherwise to work collaboratively with state and local governments to respond to the relevant emergency.[160] But very few of the Act's provisions seem to contemplate interagency coordination at the federal level, outside of quite narrow circumstances.[161]

Policymakers might consider strengthening permissive or encouraging statutes like these to become encouraging mandates. Rather than merely

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[155] NAT'L INST. HEALTH, REPORT ON NIH COLLABORATIONS WITH OTHER HHS AGENCIES FOR FISCAL YEAR 2019 (2020), https://crs.od.nih.gov/CRSPublic/default.aspx?FY=2019. ("In FY 2019, NIH reported 563 collaborations with other HHS entities . . . . Forty-six new collaborations were reported in FY 2019.").

[156] Congress does mandate collaboration in occasional circumstances. For instance, the Affordable Care Act created the Interagency Pain Research Coordinating Committee, whose purpose is to "coordinate all efforts" within HHS and other agencies relating to pain research, and whose membership must specifically include members "from agencies that conduct pain care research and treatment." 42 U.S.C. § 284q(b).

[157] 42 U.S.C. § 247d(a) (2021). For COVID-19, Secretary Azar made the relevant determination as of January 27, 2020. U.S. DEP'T HEALTH & HUMAN SERVS., *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[158] A declared emergency under Section 319 is not sufficient to enable the FDA to grant EUAs, however. The Secretary must make a separate emergency declaration under Section 564 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b), as Secretary Azar did on February 4, 2020. U.S. DEP'T HEALTH & HUMAN SERVS., Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7316 (Feb. 7, 2020).

[159] For instance, in response to the COVID-19 emergency declaration, CMS issued a waiver vastly expanding Medicare's ability to provide reimbursement for healthcare delivered by telemedicine. CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Telemedicine Health Care Provider Fact Sheet* (Mar. 17, 2020), https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

[160] U.S. DEP'T HEALTH & HUMAN SERVS., *Public Health Emergency Declaration* (Nov. 26, 2019), https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx. The Act's focus on federal-state cooperation is further emphasized by the broader structure of the statute: Section 319 is included within Part B of Title 42 of the U.S. Code: "Federal-State Cooperation." 42 U.S.C. §§ 243-247d-10 (2021).

[161] For instance, a Section 319 declaration enables the HHS Secretary to work with the Secretary of Defense "to deploy military trauma care providers providing care at high-acuity trauma centers" pursuant to a particular federal grant program. 42 U.S.C. § 300d-91 (2021).

allowing collaboration, policymakers could go a step further by requiring some form of information-sharing (even just meetings) between related agencies as a consequence of a declared public health emergency. Importantly, policymakers could stop short of requiring active collaboration itself (as with the NIH reporting requirements above). But creating a statutory or regulatory channel to force the provision of relevant information about topics of mutual interest may be important to ensure that the relevant agencies are fully informed.

## IV. CONCLUSION

This Article has examined two examples of health innovation policymaking during the COVID-19 pandemic—the development of diagnostic tests and of vaccines—and explored the ways in which they represent both successes and failures of interagency collaboration. Although we should endeavor not to put too much weight on the particulars of any one case study, the particular emergency challenges created by the pandemic provide valuable opportunities to improve innovation policymaking going forward. Lessons learned from these innovation case studies may be useful to scholars and policymakers considering problems of interagency collaboration more generally.