

Innovation Law and COVID-19

Promoting Incentives and Access for New Health Care Technologies

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I INTRODUCTION

As the devastating COVID-19 pandemic first swept the globe, it posed a crucial test of biomedical innovation institutions. Containing the virus required developing new technologies including diagnostics, pharmaceuticals, and vaccines; manufacturing them at enormous scale; and rapidly distributing them globally. This, in turn, required mobilizing and coordinating scientists, industry, and government at levels not seen since World War II. Underlying the successes and failures of these efforts was the complex legal architecture of biomedical innovation and access.

This chapter considers how this legal architecture both encouraged and impeded the development and allocation of new technologies in the fight against COVID-19 – and provides lessons about how it might be better deployed for future pandemics. This chapter focuses on three key areas of innovation law: biopharmaceutical regulation; health care reimbursement; and government subsidies for research and development (R&D). The first part of this chapter discusses the need to coordinate government agencies in a public health emergency, especially pertaining to developing, validating, and distributing diagnostic tests. The second part counsels agencies to ensure that early access to therapies in a public health crisis does not obviate developers' ability (or incentive) to generate robust information about such therapies' safety and efficacy. The third relays lessons about the successes of incentives for COVID-19 vaccine development – and their failures for vaccine distribution. Addressing the flaws in US biomedical innovation institutions that have been highlighted by COVID-19 will help avoid repeating these failures during the next pandemic.

II COORDINATING AGENCIES IN A PUBLIC HEALTH EMERGENCY

Fostering interagency coordination at the federal level is a key element of innovation policy, driving both incentives to develop new products and allocation mechanisms

to disseminate them.¹ Early in the COVID-19 pandemic, however, federal agencies failed to collaborate and coordinate in the development and rollout of diagnostic testing. As a result, public health officials were unable to identify where the virus was spreading, hindering their ability to contain it. This lack of interagency coordination resulted in unnecessary delays in the dissemination and scale-up of accurate tests for COVID-19.

*A Delayed COVID-19 Diagnostics Due to a Lack
of Interagency Coordination*

The delayed development and rollout of diagnostic testing for COVID-19 illustrates problems that can arise when interagency relationships are not carefully considered in the innovation process. Three federal agencies – the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS) – should have worked together from the beginning of the pandemic to facilitate the creation of more robust testing capacity. Instead, the actions of each agency independently slowed the development and scale-up of diagnostic testing.

In January 2020, as concern regarding the virus that would later be named SARS-CoV-2 began to emerge in the United States, the CDC developed a diagnostic test for the disease and obtained the FDA's permission to share the kit with state public health laboratories. However, the CDC quickly discovered a problem with the kits' negative controls and instructed states to stop using them.² The CDC was unable to solve this problem for more than a month. Although the agency finally announced, on February 28, that states could restart testing using the CDC kits, many states would not begin doing so until March. Although there was certainly communication between the CDC and its fellow health agencies – the FDA had granted emergency authorization for the test in early February – there were also periods of miscommunication. Perhaps most notably, the CDC temporarily blocked an FDA official from visiting the agency to help address the testing issues, reportedly due to “a scheduling misunderstanding.”³ Acting separately, the FDA likely also inadvertently slowed the emergence of nationwide testing capacity. Under an emergency declaration from Health and Human Services (HHS) Secretary Alex Azar, the FDA used its emergency use authorization (EUA) powers to permit test manufacturers to enter the market with fewer pre-market review requirements than usual. But even these more limited evidentiary requirements slowed products' entry into the market,

¹ Rachel E. Sachs, *Administering Health Innovation*, 39 *Cardozo L. Rev.* 1991 (2018); Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 *Harv. L. Rev.* 1131 (2012).

² James Bandler et al., *Inside the Fall of the CDC*, *ProPublica* (Oct. 15, 2020), www.propublica.org/article/inside-the-fall-of-the-cdc.

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

particularly given both the FDA and companies were dealing with a novel pathogen. Companies spent weeks working with the agency before receiving their EUAs, during which the virus was spreading largely unseen. For laboratory-developed tests, such as those developed by academic medical centers (as contrasted with firms who make kits for others' use), the FDA's EUA requirements represented an *increase* over their usual level of review,⁴ further slowing dissemination. There are, of course, important reasons for the FDA to maintain evidentiary standards during a pandemic, as later demonstrated by the FDA's overly permissive authorizations for antibody tests.⁵ But the FDA's heightened scrutiny for diagnostics at the beginning of the pandemic meant that other laboratories could not readily fill the space left by the CDC's delays.

At the same time, laboratory certification requirements imposed by the CMS likely also limited the number of labs even eligible to obtain FDA authorization for their own tests. The CMS independently regulates clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Many academic laboratories with the technical ability to perform COVID-19 diagnostic tests could not do so legally because they lacked CLIA certification and found it challenging to work with labs possessing such certification.⁶ Stronger coordination between these three agencies could have helped address these delays. As head of the parent agency for the CDC, the FDA, and the CMS, HHS Secretary Azar could have worked to mediate disputes and identify where agency policies were delaying the diagnostic rollout. Reporting suggests that the CDC and the FDA waited weeks for Secretary Azar to even approve fallback plans for diagnostic testing.⁷ More actively, Secretary Azar could have directed the CDC and the FDA to move forward collaboratively to adapt and authorize the public testing protocol developed by the World Health Organization (WHO), which was in use in many other countries.⁸ White House officials could also have taken a stronger hand in coordinating issues that arose.

However, it is possible that these officials were not sufficiently aware of the different legal issues at play – FDA Commissioner Stephen Hahn and CMS Administrator Seema Verma were not even added to the COVID-19 Task Force until well after these testing failures were known.

⁴ Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-19 Testing Debacle*, 130 *Yale L. J. F.* 78, 88 (2020).

⁵ See Jeffrey Shuren & Timothy Stenzel, *The FDA's Experience with COVID-19 Antibody Tests*, 384 *New Eng. J. Med.* 592 (2021).

⁶ Amy Maxmen, *Thousands of Coronavirus Tests Are Going Unused in US Labs*, *Nature* (Apr. 9, 2020), www.nature.com/articles/d41586-020-01068-3.

⁷ Dan Diamond & Adam Canercyn, *Azar in the Crosshairs for Delays in Virus Tests*, *Politico* (Mar. 2, 2020), www.politico.com/news/2020/03/02/azar-crosshairs-delays-coronavirus-tests-118796.

⁸ David Willman, *The CDC's Failed Race Against COVID-19: A Threat Underestimated and a Test Overcomplicated*, *Wash. Post* (Dec. 26, 2020), www.washingtonpost.com/investigations/cdc-covid/2020/12/25/c2b418ae-4206-11eb-8db8-395dedaa036_story.html.

B Encouraging Interagency Cooperation Going Forward

Establishing strong norms of interagency coordination can help avoid harms like these and others that have arisen during the pandemic (such as those related to shortages of N95 respirators).⁹ Additionally, such coordination can be used to accomplish more affirmative innovation policy goals. Different policymakers have different tools for encouraging interagency coordination, and different strategies may be useful depending on the situation and the goal to be achieved.

Congress can encourage interagency collaboration either by requiring it or just by signaling that collaboration is an important policy goal. For instance, Congress requires the National Institutes of Health (NIH) to report annually on its activities “involving collaboration with other agencies” within HHS.¹⁰ Some of these activities – of which there are several hundred – are congressionally mandated, such as the Interagency Pain Research Coordinating Committee.¹¹ But most of the NIH’s interagency collaborations are not legally required. Instead, Congress has emphasized the importance of interagency collaboration while leaving the areas and form of such collaboration largely to the expert agencies.

Administrative solutions might differ depending on whether structural barriers, personnel, or political considerations are the primary impediments to coordination. Where structural barriers exist, options might involve forcing interagency collaboration either through HHS (as the parent agency for many relevant agencies) or the White House (where a whole-of-government response is needed).¹² A White House-led initiative has been effective at driving innovation in some areas of technology where there is sufficient political will, such as with the focus of Operation Warp Speed on vaccine development, discussed further in Section IV.

Generally, it will be easier to foster novel interagency collaborations if there is already a culture of cooperation within each agency. The more existing collaborations there are, the more potential channels there may be for communicating potential interagency challenges going forward.

III DEVELOPING NEW EVIDENCE WHILE ALLOWING EXPERIMENTAL USE

The FDA balances the goal of making new health care technologies quickly available to the public with the need for sufficient evidence that those technologies are

⁹ Lisa Larrimore Ouellette et al., *Regulatory Responses to N95 Respirator Shortages*, Written Description (Apr. 21, 2020), <https://writtendescription.blogspot.com/2020/04/regulatory-responses-to-n95-respirator.html>.

¹⁰ 42 U.S.C. § 283a(a).

¹¹ 42 U.S.C. § 284q(b).

¹² Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 *Geo. Wash. L. Rev.* 1 (2008).

safe and effective – evidence which is costly and time-consuming to gather. Striking this balance is contentious and has been the subject of substantial scholarship. The pandemic placed greater demands on the agency to make decisions on the basis of very little evidence, sometimes in ways that jeopardized the development of further evidence on the topic. In particular, the agency allowed access to COVID-19-targeted therapeutics using both its Expanded Access (EA) and EUA pathways, each of which requires much lower evidentiary standards than traditional approval or clearance.¹³ These cases illustrate the importance, even when prioritizing speed, of ensuring that high-quality data will continue to be collected and evaluated once technologies are available.

A Quick Authorizations and Limited Evidence for COVID-19 Therapeutics

The FDA granted EUAs for several COVID-19 treatments, most notably hydroxychloroquine, remdesivir, and convalescent plasma. The standard for granting an EUA is low; under 21 USC § 360bbb-3, the FDA must determine, based on the “totality of the scientific evidence” available, that it is “reasonable to believe” that the drug “may be effective” in treating the disease and that the known and potential benefits outweigh the known and potential risks.

This evidence may – or may not – include randomized controlled clinical trials, which are key elements of the typical FDA approval standard.

After the FDA issued an EUA for hydroxychloroquine to treat COVID-19 on March 28, 2020, prescriptions soared.¹⁴ The EUA came after President Trump repeatedly touted its benefits based on relatively little evidence, leading to it being asked whether there had been political pressure on the FDA. Nevertheless, when the FDA issued the EUA, multiple clinical studies of hydroxychloroquine were ongoing, presenting the agency with another opportunity to look at the drug’s safety and efficacy, and potentially revise its decision. Once those studies finished, the evidence was strong that hydroxychloroquine does *not* work to treat COVID-19; indeed, it is affirmatively harmful in some instances.¹⁵ On June 15, 2020, the FDA revoked the EUA on the basis of these data.

Convalescent plasma presents an even more troubling story. On April 3, 2020, the FDA permitted the use of convalescent plasma in clinical trials as an Investigational New Drug and immediately launched a nationwide EA program. Under the program, patients anywhere in the United States could receive convalescent plasma

¹³ Jacob S. Sherkow, *Regulatory Sandboxes and the Public Health*, 2022 *U. Ill. L. Rev.* 357.

¹⁴ Lara Bull-Ottersen et al., *Hydroxychloroquine and Chloroquine Prescribing Patterns by Provider Specialty Following Initial Reports of Potential Benefit for COVID-19 Treatment—United States, January–June 2020*, 69 *Morbidity & Mortality Wkly. Rep.* 1210 (2020).

¹⁵ Caleb P. Skipper et al., *Hydroxychloroquine in Nonhospitalized Adults with Early COVID-19: A Randomized Trial*, 173 *Ann. Intern. Med.* 623 (2020); The RECOVERY Collaborative Grp., *Effect of Hydroxychloroquine in Hospitalized Patients with COVID-19*, 383 *New Eng. J. Med.* 2030 (2020).

through the Mayo Clinic without participating in clinical trials.¹⁶ Unsurprisingly, faced with the choice between participating in a clinical trial – and running the risk of receiving a placebo – or definitely receiving convalescent plasma, patients overwhelmingly participated in the EA program. Accordingly, randomized controlled trials floundered as they were unable to enroll enough patients, and the efficacy of convalescent plasma remained unvalidated for months.¹⁷ Despite this, in August 2020, on the basis of weak observational evidence – and under substantial pressure from President Trump – the FDA issued an EUA for convalescent plasma.¹⁸ Evidence remains minimal and mixed; several studies found no significant benefit from plasma,¹⁹ though one study published in January 2021 found positive effects for plasma when it was administered very early in the course of infection.²⁰ In February 2021, the FDA narrowed the EUA for convalescent plasma based on evidence that it was useful only in limited circumstances.²¹

B *Planning for Adequate Data Collection After Approval or Authorization*

The tension between speed and evidence in FDA approvals is not new.²² For some time now, the needle-threading solution has been to pair various forms of faster access with commitments to generate information after access has already begun.²³ The COVID-19 pandemic and its stumbles along this path cast this strategy into a harsher light. In emergency contexts, policymakers should ensure that the FDA is considering the impact of its access decisions – whether an EUA, an EA program, or something else – on the ability to generate high-quality clinical trial data to confirm or reject preliminary evidence of safety and efficacy. Although some emergencies may end before such high-quality data are ever generated – witness the short-lived Middle East Respiratory Syndrome outbreak of 2012 – policymakers should not assume such a flameout.

¹⁶ Coronavirus (COVID-19) Update: FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19, Food & Drug Admin. (Apr. 3, 2020), www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19.

¹⁷ Katie Thomas & Noah Weiland, As Trump Praises Plasma, Researchers Struggle to Finish Critical Studies, NY Times (Aug. 4, 2020), www.nytimes.com/2020/08/04/health/trump-plasma.html.

¹⁸ Rachel E. Sachs, Understanding the FDA's Controversial Convalescent Plasma Authorization, Health Affs. Blog (Aug. 27, 2020), www.healthaffairs.org/doi/10.1377/hblog20200827.190308/full/.

¹⁹ Louis M. Katz, (A Little) Clarity on Convalescent Plasma for COVID-19, 384 *New Eng. J. Med.* 666 (2021).

²⁰ Romina Libster et al., Early High-Titer Plasma Therapy to Prevent Severe COVID-19 in Older Adults, 348 *New Eng. J. Med.* 610 (2021).

²¹ FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data, Food & Drug Admin. (Feb. 4, 2021), www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data.

²² FDA in the Twenty-First Century, pt. IV (Holly Fernandez Lynch & I. Glenn Cohen, eds. 2015).

²³ W. Nicholson Price II, Drug Approval in a Learning Health System, 102 *Minn. L. Rev.* 2413 (2018).

Problematic incentives hamper both the generation and the use of post-market information generally. For traditional biopharmaceutical products made by a single manufacturer charging supra-competitive prices, incentives to generate costly information on safety and effectiveness are sharply lowered once the product can be sold. Additional positive information on safety or efficacy in subpopulations is realistically unlikely to lead to greater sales. Negative information, meanwhile, could lead to problems, lawsuits, or even withdrawal from the market. These structural problems loom larger in emergencies where products are allowed on the market with less evidence in the first place.

On the use side, the FDA has historically faced difficulty acting on negative post-market information.²⁴ Patient groups exert substantial pressure against withdrawing drugs from the market. And in the case of EUAs for a second use of an existing product, such as hydroxychloroquine, withdrawing an EUA does not even remove the product from the market. Doctors remain free to prescribe the product off-label.

At least two potential avenues exist to improve the generation of post-market information, especially in emergencies. The first, and most straightforward, is a simple mandate. The agency should release clear statements about what circumstances will lead EUAs to be expanded, revoked, or modified. Such statements should include not only triggers for what evidence will lead to what result (e.g., certain efficacy signals leading to expansion, or certain safety signals leading to revocation), but also how much evidence must be generated.²⁵

Unfortunately, such mandates work much better for products with a single, identified manufacturer. The Moderna and BioNTech-Pfizer vaccines fit neatly into this category; the companies have incentives to ensure that the vaccines remain on the market and are actually approved rather than just authorized, with the difference impacting reimbursement and potentially vaccination mandates. For products made by many entities, such as hydroxychloroquine (generic manufacturers) or convalescent plasma (hospitals), incentives are diffuse and a mandate would not have a clear focus. It is hard to see whose behavior would change had the FDA made the convalescent plasma EA program or EUA conditional on the timely generation of high-quality clinical trial data. Data on convalescent plasma were limited by the lack of interested research participants (as several clinical trials closed due to inadequate enrollment), not a lack of clarity or incentive regarding the scope of their EUAs.

Second, government investment could make information generation less costly so that incentives to generate information do not need to be as strong. Research grants can support the costs of pandemic-focused clinical trials, for instance – a

²⁴ US Gov't Accountability Off., *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 5 (2006).

²⁵ Sherkow, *supra* note 13, at 40–41.

non-excludable knowledge good when conducted on already marketed products or generic drugs.²⁶ But, as noted, trials must also be able to enroll sufficient patients, something that can be aided with government coordination.²⁷ Reducing the costs of generating higher-quality observational data could also help. Although observational data are typically less dispositive than randomized controlled trial data, learning health systems that systematically collect large amounts of data can help fill evidentiary gaps, particularly in pandemic emergencies when controlled studies must compete for finite patients over short time horizons. Infrastructure for the ongoing collection of such data could help reduce the information problem of rapidly authorized therapeutics. Finally, policymakers could facilitate the use of intermediate protocols that are less costly than patient-level randomization but generate better data than observational studies, such as randomization at the hospital or county level.

Sometimes, though, the tension between the need for high-quality data and the need for broad, early access to novel therapeutics may be irreconcilable. Indeed, for COVID-19 vaccines, the FDA seems to have reached exactly this conclusion, announcing EUA standards in the summer of 2020 that foreclosed the possibility of early access based on the typical relaxed EUA data standard. While policymakers can improve the generation of post-market data, sometimes the best answer is to do it right the first time.

IV REWARDING VACCINES FOR DISEASES WITH PANDEMIC POTENTIAL

Vaccine development in the United States is rife with both political and market failures.²⁸ But in the COVID-19 context, the record-breaking speed of vaccine development has been the biggest success story. Most notably, policymakers aggressively implemented several reward structures to advance the development and dissemination of new vaccines. Unfortunately, SARS-CoV-2 will not be the last devastating infectious disease, so it is worth considering how the approaches used in this context can be applied more broadly.

²⁶ Lisa Larrimore Ouellette et al., Nonexcludable Innovations and COVID-19, Written Description (May 27, 2020), <https://writtendescription.blogspot.com/2020/05/nonexcludable-innovations-and-covid-19.html>; Amy Kapczynski & Talha Syed, The Continuum of Excludability and the Limits of Patents, 122 *Yale L. J.* 1900 (2013).

²⁷ Michelle N. Meyer et al., An Ethics Framework for Consolidating and Prioritizing COVID-19 Clinical Trials, 18 *Clinical Trials* 226 (2021).

²⁸ Daniel J. Hemel & Lisa Larrimore Ouellette, Valuing Medical Innovation, 75 *Stan. L. Rev.* 517 (2023); Michael Kremer & Christopher M. Snyder, Preventatives Versus Treatments, 130 *Q. J. Econ.* 1167 (2015); Ana Santos Rutschman, The Vaccine Race in the 21st Century, 61 *Ariz. L. Rev.* 729 (2019); Q. Claire Xue & Lisa Larrimore Ouellette, Innovation Policy and the Market for Vaccines, 7 *J. L. Biosciences* (2020).

A COVID-19 Vaccines at Warp Speed

Effective COVID-19 vaccines reached the public with record-breaking speed. Less than a year after China announced that an outbreak in Wuhan was caused by a novel coronavirus in January 2020, the FDA issued EUAs for the first two vaccines, from BioNTech-Pfizer (on December 11) and Moderna (on December 18). By contrast, the development of most vaccines takes over a decade, while the prior record was four years (for mumps).

How were COVID-19 vaccines developed so quickly? Part of the story is getting lucky with science: researchers were able to build on years of work on the novel mRNA platform that supported both the BioNTech-Pfizer and Moderna vaccines. Part of the story is effective FDA regulation: clinical trials were allowed to proceed more quickly than usual, and the agency set clear approval standards in advance so that companies had certainty about what would be required for authorization.²⁹ But perhaps the most important part of the story is that governments committed substantial public resources to the effort.

In a reverse of typical funding patterns, public funding of COVID-19 vaccines focused more on covering the final stages of development and manufacturing costs, building on substantial private investments in early-stage research.³⁰ Both Massachusetts-based Moderna and German-based BioNTech did receive some government and non-profit funding for developing their mRNA platforms pre-pandemic, but from 2017 through 2019, grants constituted less than 4 percent of Moderna's \$1.4 billion in R&D expenses and less than 2 percent of the €450 million spent by BioNTech. By the end of 2019, each firm had been working on mRNA technology for about a decade and had incurred net losses every year, with accumulated losses of \$1.5 billion for Moderna and €425 million for BioNTech. But because of these investments, both startups could quickly pivot to applying their platform to COVID-19.

In Moderna's case, a key partner was the NIH, which launched the first human clinical trial on March 16. The following day, BioNTech announced a collaboration with pharmaceutical giant Pfizer, and they launched their own human trial on April 23. In April, Moderna received \$483 million from the Defense Department's Biological Advanced Research and Development Authority to support clinical trials and manufacturing; this was later increased to a maximum of \$955 million. In May, the firm raised \$1.3 billion in private equity to help contract with additional manufacturers. BioNTech funded development through both Pfizer's large cash reserves and a €375 million grant from the German government. The primary goal of this funding

²⁹ Rachel Sachs et al., *How Will the FDA's New COVID-19 Vaccine Guidance Affect Development Efforts?*, Written Description (July 10, 2020), <https://writtendescription.blogspot.com/2020/07/how-will-fdas-new-covid-19-vaccine.html>.

³⁰ Moderna, Inc., Annual Report (Form 10-K) (Feb. 27, 2020), www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm; BioNTech SE, Annual Report (Form 20-F) (Mar. 31, 2020), <https://investors.biontech.de/node/7381/html>.

was to reduce developers' risks so that steps that usually would depend on the success of earlier stages – such as building manufacturing capacity – could proceed in parallel.

Another critical source of funding for COVID-19 vaccine development was from governments committing to purchase vaccines before clinical trials were completed. In the United States, this effort was coordinated through Operation Warp Speed (OWS), a multi-agency effort primarily run through HHS and the Department of Defense. By mid-August, OWS had already committed to purchasing 800 million doses from six developers if those vaccines ultimately proved effective, including 100 million doses from Moderna (for milestone payments up to \$1.5 billion), and 100 million doses from BioNTech-Pfizer (for \$1.95 billion).³¹ These pre-commitments were both an effective spur to innovation and a form of “vaccine nationalism” that secured early US access to the resulting products, at the expense of other nations.³² The Biden Administration continued to increase its purchases of vaccines from both BioNTech-Pfizer and Moderna even after the vaccines' authorization, including hundreds of millions of doses for both domestic boosters and global distribution.

Advance vaccine purchases were not completely novel: a 2007 \$1.5 billion advance market commitment for pneumococcal disease vaccine doses had been used to spur development and dissemination, resulting in the immunization of over 150 million children in low-income countries.³³ And guaranteeing or increasing reimbursement through health insurance functions as a similar pull incentive for innovation.³⁴ Indeed, the first empirical study showing that policies to expand health care use can increase R&D was in the vaccine context.³⁵ But as a whole-of-government push for vaccine development and dissemination, OWS was relatively novel.

Although OWS largely succeeded in getting vaccines through FDA authorization in record-breaking time, vaccines are not vaccinations, and the initial US rollout of the vaccines was tragically slow. Vaccine distribution initially received insufficient attention from the federal government, either in terms of resources or coordination.³⁶

³¹ Jacob S. Sherkow et al., Multi-Agency Funding for COVID-19 Vaccine Development, Written Description (Aug. 19, 2020), <https://writtendescription.blogspot.com/2020/08/multi-agency-funding-for-covid-19.html>.

³² 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>.

³³ Michael Kremer et al., Advance Market Commitments: Insights from Theory and Experience, 110 *AEA Papers & Proc.* 269 (2020); Daniel Hemel & Lisa Larrimore Ouellette, Want a Coronavirus Vaccine, Fast? Here's a Solution, *Time* (Mar. 4, 2020), <https://time.com/5795013/coronavirus-vaccine-prize-challenge>.

³⁴ Rachel E. Sachs, Prizing Insurance: Prescription Drug Insurance as Innovation Incentive, 30 *Harv. J. L. Tech.* 153 (2016); Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, The Medicare Innovation Subsidy, 95 *N.Y.U. L. Rev.* 75 (2020).

³⁵ Amy Finkelstein, Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry, 119 *Q. J. Econ.* 527 (2004).

³⁶ Lisa Larrimore Ouellette et al., What Can Policymakers Learn from the Disastrously Slow COVID-19 Vaccine Rollout?, Written Description (Jan. 12, 2021), <https://writtendescription.blogspot.com/2021/01/what-can-policymakers-learn-from.html>.

Even after COVID-19 vaccines became widely available in the United States, vaccine hesitancy limited uptake domestically. And internationally, vaccine inequity remains a global tragedy: one year after vaccines became available, less than 1 percent of doses had been administered in low-income countries.

B Vaccines for the Next Pandemic

Part of the reason the COVID-19 pandemic wrought as much devastation as it did was inadequate preparation, including “insufficient R&D investment and planning for innovative vaccine development and manufacture.”³⁷ Properly rewarding vaccine developers and distributors during the COVID-19 pandemic is important not only for controlling this pandemic, but also for being better prepared for the next one.

Most importantly, policymakers should work to increase public funding for vaccine R&D and to increase incentives for private funding. Research on vaccines for diseases with pandemic potential has enormous social value; ideally, R&D investments should be made up to the point that the marginal social benefit equals the marginal cost. But the vaccine sector has been beset by both political and market failures. Market incentives are insufficient because vaccines are preventatives and because individual prices do not account for societal benefits, such as herd immunity; political incentives are insufficient because payoffs from these investments span electoral cycles, and voters do not pay much attention to problems that were successfully averted.³⁸

Even with the mobilization of public funding during COVID-19, the all-in prices paid by the United States to Moderna and to BioNTech-Pfizer are only a small fraction of a low-end estimate of their vaccines’ social value.³⁹ But hopefully these rewards for the firms’ private investments and the salience of the costs of an unchecked pandemic will help spur greater private and public investment going forward.

Additionally, we hope that academics, patient advocates, and politicians can use the COVID-19 experience to broaden conventional understandings of the policy playbook for promoting access to medicines. The importance of widespread access to COVID-19 vaccines led some commentators to argue for limits on profits and patent rights for vaccine developers; for example, both Moderna and BioNTech-Pfizer were criticized for rejecting calls to sell their vaccines for no profit. But out-of-pocket costs paid by patients represent an entirely separate question from financial

³⁷ Global Preparedness Monitoring Bd., *A World at Risk: Annual Report on Global Preparedness for Health Emergencies* 6, 28 (2019), www.gpmb.org/annual-reports/annual-report-2019.

³⁸ Hemel & Ouellette, *supra* note 28.

³⁹ Carsten Fink, *Calculating Private and Social Returns to COVID-19 Vaccine Innovation* (WIPO Economic Research Working Paper No. 68, 2022), www.wipo.int/publications/en/details.jsp?id=4595.

rewards for developers.⁴⁰ Vaccines can be free to patients even if developers receive enormous financial rewards, and access-to-medicines advocates should look for policies that reduce patient costs while still aligning profits with social value.

Even if policymakers recognize that social value is the right lodestar for R&D spending, numerous questions remain about optimal innovation policy design. How should rewards be divided between competing vaccine developers? Between developers and distributors? Who should estimate value? Could more vaccine development or distribution be conducted in-house by the federal government? Many of these questions parallel ones that legal scholars have long grappled with in the patent law context. But for vaccines, rewards are substantially shaped by government decisions on issues such as direct R&D funding, coverage requirements, and market subsidies, requiring these questions to be considered anew.

The critical role of government health agencies in vaccine innovation is a challenge, but it is also an opportunity. COVID-19 has led to an outpouring of scholarship on how to improve vaccine incentives.⁴¹ Now the United States needs the political will to make it happen.

V CONCLUSION

The triumphs and sorrows of the COVID-19 pandemic in the United States ultimately have significant roots in innovation policy. A lack of agency coordination and cooperation regarding diagnostics delayed the country's ability to identify where the virus was spreading. A rush to questionable therapeutics – by enthusiasm, by demand, by political pressure – without developing robust information about their safety and efficacy hampered providers' ability to treat patients. And even while the creation of COVID-19 vaccines was a success story – thanks to advances in science, market incentives, and luck – the failure to rapidly deploy them when the virus was at its peak was a tragedy.

The COVID-19 pandemic has been a truly exceptional event: a rapidly spreading, deadly disease plagued by the failures of political administration and exacerbated by a diminishing trust in science. But pandemics and social failures have long been part of the fabric of history, from the Plague of Athens following the Peloponnesian War to now. New pandemics will emerge, and in less than ideal political circumstances. Innovation policymakers should take lessons from this crisis to guard against history repeating itself.

⁴⁰ Daniel J. Hemel & Lisa Larrimore Ouellette, Innovation Policy Pluralism, 128 *Yale L. J.* 544 (2019); Daniel Hemel & Lisa Larrimore Ouellette, Pharmaceutical Profits and Public Health Are Not Incompatible, *NY Times* (Apr. 8, 2020), www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html.

⁴¹ Amrita Ahuja et al., Preparing for a Pandemic: Accelerating Vaccine Availability, 111 *AEA Papers & Proc.* 331 (2021); Matthew Goodkin-Gold et al., Optimal Vaccine Subsidies for Endemic Diseases, 84 *Int'l J. Indus. Org.* 102840 (2022).