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COVID-19 Response in an Alternative America: Legal Tools that the US Government Failed to Invoke

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COVID-19 Response in an Alternative America: Legal Tools that the U.S. Government Failed to Invoke

Neil Davey*

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I. INTRODUCTION

On December 2, 2021, with the Omicron variant spreading like wildfire throughout the United States, the Biden Administration announced a plan to increase access to COVID-19 antigen tests by expanding distribution through community sites and rural clinics.¹ This would involve spending \$1 billion for delivery and another \$2 billion on the pharmaceutical sector to increase its testing capacity.² Importantly, throughout the COVID-19 pandemic, testing had been hailed by many health experts as a prerequisite to curbing the spread of the disease.³ Unfortunately, during the rapid rise of the Omicron variant in the 2021–22 winter, many Americans were unable to access PCR tests due to shortages and were unable to access rapid at-home antigen tests due to high costs.⁴ For example, Abbott was charging nearly \$24 for a two-pack of its BinaxNOW tests after an agreement with the White House to sell the kits at cost expired.⁵ Though the Biden plan would require insurance companies to cover such at-home tests beginning January 15, 2022, many Americans could not freely access these tests during the peak of the Omicron spike in late December and early

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1. Press Release, White House, President Biden Announces New Actions to Protect Americans Against the Delta and Omicron Variants as We Battle COVID-19 this Winter (Dec. 2, 2021).

2. *Id.*

3. See Mark Kessel, *Opinion: What COVID-19 Has Taught Us About the Importance of Testing*, THE SCIENTIST (Feb. 1, 2022), <https://www.the-scientist.com/critic-at-large/what-covid-19-has-taught-us-about-the-importance-of-testing-69585>.

4. See Sophie Mellor, *Omicron Testing Shortages and Delays are Making Results Useless—And Deepening COVID Inequality*, FORTUNE (Jan. 10, 2022, 3:55 PM), <https://fortune.com/2022/01/10/omicron-testing-shortages-delays-covid-inequality/>.

5. Nathaniel Meyersohn, *COVID Rapid Test Prices are Going Up*, CNN (Jan. 4, 2022, 6:20 PM), <https://www.cnn.com/2022/01/04/business/rapid-test-binaxnow-walmart-kroger/index.html>.

January.⁶ Thus, while President Biden's plan was a well-intentioned move to increase access to free rapid tests, which were already being distributed freely for months in peer countries like the UK, it was probably too little too late.⁷

Beyond the unaffordability and delays associated with testing, this dilemma also presents a serious fairness problem. Namely, billions were spent by the federal government in the first instance to develop and expand testing,⁸ and now the federal government is paying again (at least \$3 billion) to get the tests into the hands of American consumers.⁹ This "paying-twice" by the government—and hence by American taxpayers—is a common concern, not only for the COVID-19 pandemic.¹⁰ The worry is that despite having paid for some of the initial research and development (R&D), the federal government took no further action than to simply purchase testing kits from manufacturers and subsidize them for Americans. Critics have suggested implementing reasonable pricing clauses as contractual provisions to ameliorate this transactional unfairness and limit the rights of pharmaceutical companies when marketing federally funded medications.¹¹ However, those responding to this suggestion have forcefully argued that such critics are conflating "the separate issues of *affordability* for patients and *incentives* for developers," particularly in the COVID-19 context, where the federal government is providing vaccines to all Americans for no out-of-pocket costs.¹² They would instead argue

6. *Id.* See also *How to Get Your At-Home Over-The-Counter COVID-19 Test for Free*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/how-to-get-your-at-home-OTC-COVID-19-test-for-free> (last modified Sept. 6, 2023, 5:05 PM).

7. See David A. Simon, *The Devil Is in the Details with Biden's Free COVID Testing Plan*, PETRIE-FLOM CTR. HARV. L. SCH.: BILL OF HEALTH (Dec. 3, 2021), <https://blog.petrieflom.law.harvard.edu/2021/12/03/biden-free-covid-tests/>; Mellor, *supra* note 4.

8. See Press Release, US Dep't. Health & Hum. Serv., Biden Administration to Invest More Than \$12 Billion to Expand COVID-19 Testing (Mar. 17, 2021) (announcing \$10 billion in funding for testing in schools and \$2.25 billion to scale up testing for underserved populations).

9. Press Release, White House, *supra* note 1.

10. Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177, 177–78 (2019).

11. *Id.* at 179.

12. Jacob 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>.

that pharmaceutical profits and public health are not incompatible.¹³

This article hopes to explore such debates and demonstrate that while the “paying-twice” critique has been common beyond just testing (e.g., initial government funding for Gilead’s remdesivir treatment), one legal tool may not be the best fit for every technology type. The testing case study above is a microcosm of some of the major stumbling blocks in America’s response to the COVID-19 pandemic. Beyond testing, the government faced a severe shortage in the antiviral drug remdesivir and found itself struggling with rapid vaccine distribution. Admittedly, the regulatory landscape differs significantly between diagnostics, therapeutics, and vaccines. But similar issues—such as resistance to bypassing intellectual property rights or leveraging government buying power to creatively contract with the biomedical industry—are a consistent theme throughout. This article hopes to shed light on which legal mechanisms could be used for the next pandemic, realizing that not every tool is equally effective for every technology.

This article begins with a description of the regulatory and patent landscape for various COVID-19 technology types, including testing (diagnostics), drugs (therapeutics), and vaccines. It then describes the COVID-19 crisis response in the United States from the Trump to Biden Administrations. Next, this article details how the government might have invoked other legal tools during this emergency. These include (1) bypassing patent rights in the pharmaceutical industry, (2) leveraging the government’s central authority to contract creatively and drive know-how transfer, and (3) invoking executive authority to commandeer part of the pharmaceutical sector. Unfortunately, the federal government failed to employ any of these three legal tools to increase access to COVID-19 testing, drugs, and vaccines. Understanding the nuances that may exist for different technology types, this article concludes with tailored solutions on what *could* have been used to end the pandemic more quickly and effectively. Ultimately, some of the core concerns around innovation incentives that exist for one technology type (e.g., compulsory licensing for complex vaccines) may not exist for

13. See Daniel Hemel & Lisa L. Ouellette, *Pharmaceutical Profits and Public Health are Not Incompatible*, N.Y. TIMES (Apr. 8, 2020), <https://www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html>.

another, given different market characteristics due to varying regulatory and patent landscapes. Thus, there is ripe ground for greater government intervention during future crises, without undermining needed innovation.

II. REGULATORY, PATENT, AND MARKET LANDSCAPE BY TECHNOLOGY TYPE

The regulatory and patent landscape is quite different for diagnostics, therapeutics, and vaccines. These differences greatly inform cost structures and market strategies by pharmaceutical players and are important considerations when tailoring various legal solutions to increase access. While not aiming to lay out all the regulatory differences, this Part of the article will provide the relevant background on these three technology types in the COVID-19 context. Scholars have argued that the Food and Drug Administration (FDA) is not only a consumer protection agency, but one that aims to promote innovation and thereby force the disclosure of costly information developed by manufacturers, such as information developed during clinical trials.¹⁴ On this view, FDA regulatory policy and intellectual property are deeply interlinked, and thus both inform what the right solution may be to balance access and innovation. Experts have noted that the fact that the FDA regulates market exclusivities for pediatric and orphan drugs, thought to be in the province of the United States Patent and Trademark Office, is a strange phenomenon, but nonetheless represents how interwoven the two institutions are.¹⁵ Thus, the variation in FDA regulatory and IP background will inform the best legal tools by technology.

A. DIAGNOSTIC TESTING

This article focuses on point-of-care RT-PCR and rapid antigen testing that inform a user whether they *currently* have COVID-19, as opposed to antibody-based tests which may tell a user of a past infection status.¹⁶ In some ways, the acute

14. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 345–48 (2007).

15. See generally Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 29 (2018) (comparing the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act's regulatory regimes).

16. Nicholson Price et al., *How is Regulatory Policy Influencing the Development and Marketing of Antibody Testing for COVID-19?*, WRITTEN

problems faced resulting from the shortage of COVID-19 testing and fewer innovation concerns in the diagnostics market make this technology type most suitable for the use of novel legal tools to increase access. Most health experts agree that the United States' problems with testing exacerbated the pandemic, and that widespread testing should be immediately available if we were to face a similar crisis.¹⁷ Additionally, since "diagnostics are comparatively easy to develop and cheap to bring to market" relative to vaccines and drugs, companies do not require the same incentives as for drugs and vaccines.¹⁸ Therefore, more aggressive solutions from the government to lower the aforementioned price of such diagnostics are likely warranted. While diagnostics are often not patentable due to recent Supreme Court decisions that have made patentability requirements more stringent,¹⁹ solutions such as advance purchase agreements with stricter pricing conditions could encourage sufficient innovation by guaranteeing some profits while preventing a serious hinderance to access through very high prices.

Beyond incentive issues, the FDA has a significant role in increasing access to such testing through its approval process. For example, former Health and Human Services (HHS) Secretary Alex Azar issued guidance that COVID-19 diagnostics could receive Emergency Use Authorization (EUA) on February 4, 2020, intending to speed up the process by reducing the regulatory hurdles in the regular approval process.²⁰ Unfortunately, the attempt backfired as it required laboratory developed tests (LDTs), which typically do not face regulatory requirements as they are developed and employed in a single

DESCRIPTION (May 4, 2020), <https://writtendescription.blogspot.com/2020/05/how-is-regulatory-policy-influencing.html>.

17. Lisa L. Ouellette et al., *How Can Innovation and Regulatory Policy Accomplish Robust COVID-19 Testing?*, WRITTEN DESCRIPTION (Apr. 15, 2020), <https://writtendescription.blogspot.com/2020/04/how-can-innovation-and-regulatory.html> ("It's now clear that expansive, population-wide testing is part-and-parcel of every successful COVID-19 containment strategy.").

18. *Id.*

19. Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 256–57 (2015) (citing Supreme Court decisions holding that diagnostic applications are ineligible for patents).

20. DEP'T OF HEALTH & HUM. SERV., DETERMINATION OF A PUBLIC HEALTH EMERGENCY AND DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564(B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360BBB-3 (Feb. 4, 2020).

facility, to go through the EUA process as well.²¹ While the FDA ultimately realized its mistake and modified its position to permit testing while EUA approval was ongoing, commentators have noted that this policy resulted in a “lost month [as] new tests sat unused at labs around the country.”²² Ultimately, the FDA reversed course entirely and issued a statement in August 2020 that it would not regulate LDTs at all.²³ Some health experts were concerned that while this may increase the number of tests on the market, they could be highly inaccurate or unreliable.²⁴ Further, the Centers for Disease Control and Prevention (CDC) contributed to the testing shortage by halting authorized use on safety grounds for a few weeks, as did the Centers for Medicare and Medicaid Services, which blocked many labs from testing, alleging improper certification.²⁵ Interagency coordination problems are thus important to consider in ensuring a robust manufacturing capacity and distribution network of nationwide testing, as well as for other COVID-19 technologies.

B. VACCINES

The regulatory and patent landscape for vaccines is most complicated, particularly for the complex mRNA vaccines that exist for COVID-19. For one, vaccines are far more expensive than diagnostics and therapeutics, and are typically less profitable than repeat-use treatments, given public health and political implications.²⁶ As a result, the federal government must be particularly careful in developing appropriate innovation policy to remedy this market failure.²⁷ The Trump

21. Ouellette et al., *supra* note 17.

22. Michael D. Shear et al., *The Lost Month: How a Failure to Test Blinded the U.S. to COVID-19*, N.Y. TIMES (Oct. 1, 2021), <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html>.

23. Lisa L. Ouellette et al., *Why Is HHS Blocking FDA from Regulating some Diagnostics, and How Will This Affect COVID-19 Testing?*, WRITTEN DESCRIPTION (Aug. 25, 2020), <https://writtendescription.blogspot.com/2020/08/why-is-hhs-blocking-fda-from-regulating.html>.

24. *Id.*

25. Ouellette et al., *supra* note 17.

26. Qiwei Claire Xue & Lisa L. Ouellette, *Innovation Policy and the Market for Vaccines*, J. L. & BIOSCIENCES 1, 20 (2020).

27. 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>.

Administration accordingly poured billions of dollars into a program known as Operation Warp Speed to incentivize vaccine development in the private sector.²⁸ While some contend that this funding justifies reasonable pricing clauses to cap final prices, or enacting compulsory licenses to circumvent vaccine patents,²⁹ such policies *may* undermine the program to encourage under-incentivized vaccine research in the first place.³⁰

Beyond innovation-related concerns, vaccines are distinctive from testing and drugs because they are extremely complex biologics that are difficult to reverse-engineer.³¹ Thus, replicating the COVID-19 mRNA vaccines would likely require cooperation from companies like Moderna and Pfizer, which is why compulsory licensing of these products alone may not achieve the desired ends of increasing access. Licensing may antagonize the companies, and without proper access to underlying vaccine manufacturing know-how, it would be difficult to develop the technology independently. As innovation policy experts note, “[w]hatever merits compulsory licensing offers for some basic pharmaceuticals, vaccines are quite different.”³² In the view of these scholars, the tradeoff between access and innovation incentives in the vaccine context need not be antagonistic.³³ Furthermore, unlike many diagnostics and drugs, complex vaccines are often covered by multiple patents, which adds to the challenge.³⁴ Nonetheless, this article addresses some possibilities that the United States government could explore to overcome these hurdles, including mandating

28. Press Release, U.S. Dep’t of Def., Trump Administration Announces Framework and Leadership for ‘Operation Warp Speed’ (May 15, 2020); see *infra* Part III.

29. Elisabeth Rosenthal, *How a COVID-19 Vaccine Could Cost Americans Dearly*, N.Y. TIMES (July 6, 2020), <https://www.nytimes.com/2020/07/06/opinion/coronavirus-vaccine-cost.html>.

30. See *supra* Part I.

31. Interview by Sharon Driscoll with Lisa L. Ouellette (May 4, 2021), <https://law.stanford.edu/2021/05/04/stanfords-lisa-ouellette-on-waiving-covid-19-vaccine-patents/>.

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. Daniel J. Hemel & Lisa L. Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 593 (2019).

34. Ana S. Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J. L. & POL’Y 167, 177 (2021).

the sharing of know-how.³⁵ Such strategies, while antagonistic to the pharmaceutical industry, may ultimately be justified on one-off occasions such as the COVID-19 pandemic, where companies may still not be deterred from innovating in the future given the immense market potential from such global emergencies. Regardless, “the particular facts underlying the development of new vaccines [might] counsel in favor of solutions to this problem that differ” from solutions for other COVID-19 technologies.³⁶

C. THERAPEUTIC DRUGS

Gilead’s antiviral drug remdesivir (sold as Veklury) was the first COVID-19 therapeutic approved in October 2020, and several other therapies (including Pfizer’s Paxlovid) have been given Emergency Use Authorization since.³⁷ Remdesivir’s story is illuminating because it reveals important regulatory and intellectual property considerations when defining innovation policy for such drugs. Unfortunately, the drug experienced extreme shortages given an inadequate supply from Gilead, requiring rationing.³⁸ This was likely “exacerbated by Gilead Sciences’ refusal to license its patents more broadly” in the United States.³⁹ Additionally, after spending around \$37.5 million in funding remdesivir’s development and contributing to fundamental research, government researchers were not listed on the key patents for the drug.⁴⁰ The case of remdesivir shows missed opportunities by the federal government in invoking its ability to circumvent critical patents and leverage its prior funding to increase the supply of the much-needed drug.

Further, the innovation story for such drugs is sufficiently different from diagnostics and vaccines to fully explore patent-related solutions to increase access. Unlike for diagnostics, patents play a substantial role in covering drugs. Similarly, unlike complex vaccines, there is not substantial know-how (that may be covered by trade secret) required to develop such an anti-

35. *See infra* Part IV.

36. Sachs et al., *supra* note 27.

37. *Know Your Treatment Options for COVID-19*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19> (last modified June 28, 2023).

38. Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 57, 85 (2022).

39. *Id.* at 86.

40. *Id.* at 82–83.

viral drug. Accordingly, patent-related solutions through compulsory licensing may be best suited for this technology type.⁴¹

III. THE REALITY: COVID-19 RESPONSE IN THE U.S.

As of March 11, 2023—more than three years since the start of the pandemic—the United States has seen approximately 104 million cases of COVID-19 and over one million COVID-19 deaths.⁴² Beyond an immense toll on human health and life, the pandemic has also had a severe impact on the national economy, resulting in increased unemployment and GDP contraction.⁴³ The United States fared worse in the COVID-19 crisis than many peer countries.⁴⁴ Factors causing poorer response in the United States include political decisions, such as downplaying the danger of the disease and ignoring scientific experts at the early stages, as well as structural issues, such as a decentralized health system that could not adequately ramp up testing and conduct robust contact tracing.⁴⁵ On the political side, many experts have blamed President Trump for cutting public health budgets, generally repudiating and politicizing science during his first few years in office, and failing to act early and aggressively against COVID-19.⁴⁶ For example, the federal Strategic National Stockpile was inadequately stocked prior to the pandemic, and thus protective gear such as masks were quickly depleted by April 2020.⁴⁷ Experts have also criticized our fragmented healthcare system that makes it difficult to

41. See *infra* Part IV.

42. *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. TIMES, <https://www.nytimes.com/interactive/2023/us/covid-cases.html> (last modified Dec. 6, 2023). The CDC stopped reporting case data on March 11, 2023. *Id.*

43. Jiangzhuo Chen et al., *Epidemiological and Economic Impact of COVID-19 in the US*, NATURE (Oct. 14, 2021), <https://www.nature.com/articles/s41598-021-99712-z>.

44. See generally Tanya Lewis, *How the U.S. Pandemic Response Went Wrong—and What Went Right—During a Year of COVID*, SCI. AM. (Mar. 11, 2021), <https://www.scientificamerican.com/article/how-the-u-s-pandemic-response-went-wrong-and-what-went-right-during-a-year-of-covid/>.

45. *Id.*

46. Steffie Woolhandler et al., *Public Policy and Health in the Trump Era*, 397 LANCET COMM'NS 705, 705–08 (2021).

47. Nick Miroff, *Protective Gear in National Stockpile is Nearly Depleted, DHS Officials Say*, WASH. POST (Apr. 1, 2020), https://www.washingtonpost.com/national/coronavirus-protective-gear-stockpile-depleted/2020/04/01/44d6592a-741f-11ea-ae50-7148009252e3_story.html.

affordably centralize testing and distribute essential medicines at scale.⁴⁸ Both the political and structural dimensions are likely contributing reasons for America's slow response to COVID-19 and the astounding number of deaths. As one health policy expert noted, partisan pandemic response in combination with the federal government only able to play a "back-up" role contributed to America's "failure" to prevent the ongoing spread of COVID-19.⁴⁹

A. EARLY LEGISLATIVE ENACTMENTS DURING TRUMP'S PRESIDENCY

Given the limited amount of funding for healthcare in the pre-COVID Trump era, Congress acted quickly to provide emergency supplemental appropriations when the pandemic took full force in March 2020. On March 5, 2020, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which provided \$8.3 billion to combat the spread of COVID-19.⁵⁰ Among other provisions, the appropriations included \$3.4 billion for the development and "purchase of vaccines, therapeutics, diagnostics" as well as \$1.9 billion to the CDC to "prevent, prepare for, and respond to coronavirus, domestically or internationally" (of which \$950 million was allocated to state and local response).⁵¹ Soon after, Congress passed the Families First Coronavirus Response Act (FFCRA) on March 18, 2020, which provided emergency paid sick and family medical leave, additional funding for food stamps, and free COVID-19 testing to be paid for by *all* public and private insurance plans.⁵² Though *at-home* testing was not abundant at the time of the statute's passage, legal experts interpreted the relevant provision of the Act as indistinguishable

48. See Arush Lal et al., *Fragmented Health Systems in COVID-19: Rectifying the Misalignment Between Global Health Security and Universal Health Coverage*, 397 LANCET COMM'NS 61, 62 (2021).

49. Drew Altman, *Understanding the U.S. Failure on Coronavirus*, BMJ (Sept. 14, 2020), <https://www.bmj.com/content/370/bmj.m3417>.

50. Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116–123, 134 Stat. 146 (2020).

51. *Id.* See also Stephanie Oum et. al., *The U.S. Response to Coronavirus: Summary of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, KAISER FAM. FOUND. (Mar. 11, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-u-s-response-to-coronavirus-summary-of-the-coronavirus-preparedness-and-response-supplemental-appropriations-act-2020/#> (providing summary of appropriations).

52. Families First Coronavirus Response Act, Pub. L. 116–127, 134 Stat. 178 (2020).

“between at-home and provider-administered tests in terms of reimbursement availability.”⁵³ However, much confusion ensued as to whom would be covering such non-provider tests.⁵⁴ The Biden Administration only officially stated that eight rapid at-home COVID-19 tests per month would be reimbursed beginning January 15, 2022.⁵⁵ This left Americans without free at-home testing for nearly two years since the passage of the FFCRA, and particularly during the Omicron spike in December 2021.

On March 27, 2020, Congress acted even more aggressively by passing a \$2.2 trillion stimulus bill called the Coronavirus Aid, Relief, and Economic Security Act (hereinafter CARES Act).⁵⁶ While much of the statute focused on economic recovery (including \$300 billion in one-time payments to individuals, \$260 billion in unemployment benefits, \$500 billion to corporations, \$350 billion to small businesses, and \$340 billion to state or local governments),⁵⁷ approximately \$250 billion was provided for health-related activities.⁵⁸ Of this, \$1 billion was allocated to enforce the Defense Production Act for personal protective equipment (PPE) and other medical equipment,⁵⁹ \$5 billion for further R&D efforts around vaccines and diagnostics, and more than \$100 billion to the HHS to reimburse overwhelmed hospital systems and healthcare workers responding to the pandemic.⁶⁰

53. Nicholson Price et al., *How Can Policymakers Encourage the Expansion of At-Home Diagnostic Testing for COVID-19?*, WRITTEN DESCRIPTION (June 3, 2020), <https://writtendescription.blogspot.com/2020/06/how-can-policymakers-encourage.html>.

54. Jacob S. Sherkow et al., *How Can the Government Improve Access to COVID-19 Preventatives and Treatments for Low-Income Americans?*, WRITTEN DESCRIPTION (June 18, 2020), <https://writtendescription.blogspot.com/2020/06/how-can-government-improve-access-to.html>.

55. Lindsey Dawson et al., *How Are Private Insurers Covering At-Home Rapid COVID Tests?*, KAISER FAM. FOUND. (Jan. 20, 2022), <https://www.kff.org/policy-watch/how-are-private-insurers-covering-at-home-rapid-covid-tests/>.

56. CARES Act, Pub L. 116–136, 134 Stat. 281 (2020).

57. Kelsey Snell, *What's Inside The Senate's \$2 Trillion Coronavirus Aid Package*, NPR (Mar. 26, 2020, 5:34 PM), <https://www.npr.org/2020/03/26/821457551/whats-inside-the-senate-s-2-trillion-coronavirus-aid-package>.

58. Kellie Moss et al., *The Coronavirus Aid, Relief, and Economic Security Act: Summary of Key Health Provisions*, KAISER FAM. FOUND. (Apr. 9, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-coronavirus-aid-relief-and-economic-security-act-summary-of-key-health-provisions/>.

59. See *infra* Part VI for greater detail.

60. Moss et al., *supra* note 58.

Additionally, the CARES Act included provisions to stock the Strategic National Stockpile with various medical supplies to address ongoing supply shortages of critical medical equipment, allowed the FDA to prioritize reviews of COVID-19 drug applications, and increased the accessibility of telehealth services. Critics argued that the CARES Act did not do enough in terms of health coverage and access to medicines that would eventually be approved.⁶¹

Finally, Congress passed the Consolidated Appropriations Act on December 27, 2020, which was a \$2.3 trillion stimulus package in response to the COVID-19 pandemic.⁶² In terms of COVID-19 relief, the statute again focused primarily on economic relief through direct checks for individuals, greater unemployment benefits, forgivable loans for small business, aid to state and local governments, financing for schools and universities, and additional food and rental subsidies.⁶³ On the healthcare front, around \$85 billion was appropriated: \$30 billion for the Strategic National Stockpile, \$22 billion for testing facilities, \$9 billion for healthcare providers, and \$4.5 billion for mental health.⁶⁴ Funds were distributed not just for R&D efforts around vaccines, therapeutics, and diagnostics, but also for their delivery and distribution.

These statutes are important not only for context on the American response but to understand whether Congress implicitly approved the President's ability to commandeer the pharmaceutical industry, or otherwise precluded it. Further, these legislative spending approvals, in combination with Operation Warp Speed, demonstrate the federal government's critical role in spurring COVID-19 R&D and bolster the argument that the government should potentially use this leverage to increase access to care.

Beyond Congress, the Trump and Biden Administrations also played pivotal roles in jumpstarting development in the context of testing, drugs, and vaccines for COVID-19.

61. See SHARON PARROTT ET AL., CARES ACT INCLUDES ESSENTIAL MEASURES TO RESPOND TO PUBLIC HEALTH, ECONOMIC CRISES, BUT MORE WILL BE NEEDED 7 (Ctr. on Budget & Pol'y Priorities ed., 2020).

62. See Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182 (2020).

63. *Highlights of \$900 Billion COVID-19 Relief, Wrapup Bills*, ASSOCIATED PRESS (Dec. 21, 2020, 3:16 PM), <https://apnews.com/article/health-care-reform-health-legislation-coronavirus-pandemic-762f84e4da11d350d8b5be5680ab01c4>.

64. *Id.*

B. OPERATION WARP SPEED, FDA APPROVALS, AND DISTRIBUTION ISSUES

In May 2020, the Trump Administration created a federal public-private partnership through the Department of Defense—known as Operation Warp Speed (OWS)—to accelerate drug, vaccine, and diagnostic development and manufacturing efforts, using close to \$10 billion originally allocated to hospitals from the CARES Act.⁶⁵ Under the program, the United States government made deals with Johnson & Johnson, Moderna, Sanofi-GlaxoSmithKline, and Pfizer-BioNTech to purchase 100 million doses of each company's vaccine.⁶⁶ The primary goal of OWS was to help quickly develop safe and effective vaccines while promoting competition between various biotechnology companies who were attempting to use different vaccine platforms.⁶⁷ Notably, though not officially part of OWS, the federal government also awarded nearly \$250 million to seven biomedical technology companies in early August 2020 for point-of-care testing through the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx) program.⁶⁸ The RADx initiative, a \$1.5 billion award program for at-home testing, has a unique funding structure that resembles an accelerator and provides both *ex ante* grants and *ex post* prizes.⁶⁹ Regardless of the incentive mechanism, which differs greatly between vaccines and diagnostic tests, such

65. See Press Release, U.S. Dep't of Def., *supra* note 28; Rachel Cohrs, *The Trump Administration Quietly Spent Billions in Hospital Funds on Operation Warp Speed*, STAT NEWS (Mar. 2, 2021), <https://www.statnews.com/2021/03/02/trump-administration-quietly-spent-billions-in-hospital-funds-on-operation-warp-speed/>.

66. Noah Higgins-Dunn, *The U.S. Has Already Invested Billions in Potential Coronavirus Vaccines. Here's Where the Deals Stand*, CNBC (Aug. 14, 2020, 6:30 AM), <https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html>.

67. Moncef Slaoui & Matthew Hepburn, *Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach*, 383 NEW ENG. J. MED. 1701, 1702 (2020), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2027405?articleTools=true>.

68. Francis Collins, *Charting a Rapid Course Toward Better COVID-19 Tests and Treatments*, NIH DIRECTOR'S BLOG (Aug. 6, 2020), <https://directorsblog.nih.gov/2020/08/06/charting-a-rapid-course-toward-better-covid-19-tests-and-treatments/>.

69. Rachel Sachs et al., *How Is the NIH Seeking to Encourage Investment in Diagnostic Testing for COVID-19?*, WRITTEN DESCRIPTION (Aug. 13, 2020), <https://writtendescription.blogspot.com/2020/08/how-is-nih-seeking-to-encourage.html>.

programs illustrate the critical role by the federal government in funding early R&D for COVID-19 technologies.

While the OWS program did not ultimately reach its goal of *administering* 20 million doses before January 2021 due to distribution issues,⁷⁰ OWS was largely successful in fast-tracking the industry to *develop* effective therapeutics, vaccines, and diagnostics. In October 2020, the FDA approved remdesivir as the first and only treatment for COVID-19.⁷¹ In December 2020, the FDA gave Emergency Use Authorization for the first two COVID-19 vaccines by Moderna and Pfizer-BioNTech.⁷² Only two months later in February 2021, the FDA approved a third COVID-19 vaccine by Johnson & Johnson (Janssen) under the same emergency use pathway.⁷³ In the testing sphere, the FDA has approved close to twenty at-home (mostly antigen-based) tests as well as numerous molecular diagnostic tests that largely use PCR-based DNA amplification technology.⁷⁴ As previously discussed, the FDA's inconsistent regulation of COVID-19 diagnostics (e.g., for LDTs) ultimately defined their slow ramp-up.⁷⁵

Nonetheless, criticism remained about the CARES Act and OWS not doing enough to address structural barriers that would prevent effective *delivery* of vaccines.⁷⁶ The twenty-two

70. See Andrew Dunn & Aria Bendix, *Only 2.8 Million Americans Have Received COVID-19 Vaccines, Far Short of the Trump Administration's Goal to Reach 20 Million by Year's End*, BUS. INSIDER (Dec. 31, 2020, 8:47 AM), <https://www.businessinsider.com/challenges-with-us-coronavirus-vaccine-distribution-warp-speed-goal-2020-12>.

71. See Press Release, Food & Drug Admin., FDA Approves First Treatment for COVID-19 (Oct. 22, 2020).

72. See Press Release, 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); see also Press Release, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020).

73. See Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021).

74. See *generally At-Home OTC COVID-19 Diagnostic Tests*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests> (last modified Nov. 1, 2023); *In Vitro Diagnostics EUAs – Molecular Diagnostic Tests for SARS-CoV-2*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2> (last modified Nov. 16, 2023).

75. Ouellette et al., *supra* note 17.

76. See Sarah Krouse et al., *Behind America's Botched Vaccination Rollout: Fragmented Communication, Misallocated Supply*, WALL ST. J. (Feb. 18, 2021,

billion dollars allocated to HHS through the CARES Act did not specify how eventually approved vaccines would be *distributed*, with much of this “operational responsibility” falling on state and local governments.⁷⁷ Accordingly, the initial rollout of the approved vaccines was rather slow and varied drastically by state.⁷⁸ Beyond varying policies around which populations in each state would get the vaccine first, numerous resource-constrained states had lower levels of healthcare infrastructure that led to several logistical hurdles. With little top-down federal guidance and a lack of transparent communication from the White House, various states lacked the necessary centralization to effectively distribute vaccines rapidly. Public health expert Ashish Jha noted that local health officials and hospitals, rather than federal officials, were required to organize “the hardest part of the vaccination — which is actually getting the vaccines administered into people’s arms.”⁷⁹ He concluded that “[u]ltimately, the buck seems to stop with no one.”⁸⁰

C. COVID-19 UNDER THE BIDEN ADMINISTRATION

While some of the major vaccine distribution problems were resolved in the first few months of 2021, President Biden still did not deliver on all COVID-19 promises in his first year. On one hand, in his first 100 days, President Biden managed to distribute nearly 220 million doses of the COVID-19 vaccine, far outpacing his original target of 100 million doses.⁸¹ The President also increased the federal government’s role in pandemic response by providing greater guidance to local vaccine administration sites, deploying Federal Emergency Management Agency (FEMA) to assist states in vaccine

10:43 AM), https://www.wsj.com/articles/behind-americas-botched-vaccination-rollout-fragmented-communication-misallocated-supply-11613663012?mod=searchresults_pos19&page=1.

77. Hemi Tewarson et al., *State Strategies for Addressing Barriers During the Early U.S. COVID-19 Vaccination Campaign*, 11 AM. J. PUB. HEALTH 1073, 1073 (2021).

78. See Rebecca Robbins et al., *Here’s Why Distribution of the Vaccine Is Taking Longer Than Expected*, N.Y. TIMES (Jan. 11, 2021), <https://www.nytimes.com/2020/12/31/health/vaccine-distribution-delays.html>.

79. *Id.*

80. *Id.*

81. Maegan Vazquez et al., *Biden’s First 100 Days: What He’s Gotten Done*, CNN (Apr. 28, 2021, 5:14 PM), <https://www.cnn.com/2021/04/28/politics/president-biden-first-100-days/index.html>; *President Biden’s First 100 Days as President Fact-Checked*, BBC (Apr. 29, 2021), <https://www.bbc.com/news/56901183>.

distribution, and generally improving communication lines with state and local governments.⁸² Despite these improvements, however, Biden failed to establish a “predictable and robust” system of centralized testing—highlighted during the Omicron variant spike, which resulted in severe testing shortages.⁸³ Additionally, while vaccine rollout was broadly successful, many rural populations remain unvaccinated.⁸⁴

Though some of these issues were not predictable and are political in nature, there were legal tools the President could have invoked to overcome persisting structural barriers in the healthcare system and increase access to care during the crisis. These include circumventing patents on essential COVID-19 medicines and technologies, contracting creatively with the pharmaceutical sector to encourage sharing of know-how, and possibly commandeering a portion of the industry during the national emergency.

IV. CIRCUMVENTING PHARMACEUTICAL PATENTS VIA STATUTORY AUTHORITY

Patents in the pharmaceutical industry represent a tradeoff between incentivizing innovation and providing sufficient access to care. The debate has been ongoing for decades, and many access-to-medicines activists argue that a historically pro-patent view in the United States has been harmful—even in non-pandemic times—by restricting access to lifesaving medicines, especially in lower-income populations.⁸⁵ Patent rights effectively create temporary monopolies, wherein patent holders

82. Stephanie Armour & Sabrina Siddiqui, *Biden's First Month of Covid-19 Response Marked by Larger Federal Role*, WALL ST. J. (Mar. 2, 2021, 10:56 AM), https://www.wsj.com/articles/bidens-first-month-of-covid-19-response-marked-by-larger-federal-role-11613840400?mod=searchresults_pos1&page=1.

83. Dan Diamond, *A Year Ago, Biden Unveiled a 200-Page Plan to Defeat Covid. He Has Struggled to Deliver on Some Key Promises*, WASH. POST (Jan. 18, 2022, 11:25 AM), <https://www.washingtonpost.com/health/2022/01/18/biden-covid-response-assessment/>.

84. See generally Lily Datz, *Why COVID-19 Vaccination Rates Are Lower in Rural Areas of the U.S.*, SYRACUSE U. NEWS (Oct. 4, 2021), <https://news.syr.edu/blog/2021/10/04/why-covid-19-vaccination-rates-are-lower-in-rural-areas-of-the-u-s/> (noting that Trump vote share is the single largest contributor to county-level variation in COVID-19 vaccination rates).

85. See generally Robin C. Feldman et al., *Negative Innovation: When Patents Are Bad for Patients*, 39 NATURE BIOTECHNOLOGY 914 (2021) (describing negative innovation, which is when patent law drives innovation into spaces that are affirmatively harmful to patients).

have unrestricted ability to set prices for a fixed amount of time.⁸⁶ The pharmaceutical industry has maintained that due to high R&D costs for cutting-edge technologies, such exclusive patents and correspondingly high prices are necessary to recoup expenditures.⁸⁷ Critics have shown that pharmaceutical companies still enjoy substantial profit margins relative to other companies.⁸⁸ A number of patent-related abuses also exist in the pharmaceutical sector—from “evergreening” to extend patent life by making immaterial tweaks on existing molecules,⁸⁹ to the creation of “me-too” drugs which are awarded new patents despite only minor improvements over existing products for common lifestyle conditions.⁹⁰ Additionally, studies have shown many cases of “pay-for-delay” tactics, or reverse payment patent settlements, wherein branded manufacturers encourage generic companies to stay off the market by sharing some of their monopoly profits.⁹¹

The patent landscape differs between diagnostic tests, therapeutic drugs, and vaccines.⁹² Much analysis has been done on drugs such as remdesivir, and thus this Part focuses on patent-related solutions in that context. Similar patent strategies could apply for diagnostics, which require far lower R&D costs and therefore present fewer innovation-related concerns. However, as noted above, many diagnostics are not

86. S. Vincent Rajkumar, *The High Cost of Prescription Drugs: Causes and Solutions*, 10 BLOOD CANCER J. 2 (2020).

87. See Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844 (2020) (estimating R&D costs upwards of \$1 billion for each successful drug). See also Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, <https://www.cbo.gov/publication/57126> (“The expected cost to develop a new drug ... has been estimated to range from less than \$1 billion to more than \$2 billion”).

88. See Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 JAMA 834 (2020).

89. See Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 320–22 (2015); Robin Feldman, *May Your Drug Price be Evergreen*, 5 J. L. BIOSCIENCES 590, 596–97 (2018).

90. GRAHAM DUTFIELD, *THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY, 1880–2020* at 449 (2020).

91. Robin Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249 (2019); Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive>.

92. See *supra* Part II.

patent-protected, given that the underlying mechanisms are not novel, and the Supreme Court has restricted patentability on naturally occurring correlations.⁹³ Vaccines present the opposite issue; they require immense R&D costs and are often covered by multiple patents (while manufacturing know-how is often under trade secret).⁹⁴ Further, there are fewer robust regulatory pathways that exist for generic vaccine production (known as biosimilars), as opposed to generic small molecule production.⁹⁵ And as noted earlier, unlike for drugs, public health pressures limit the possibility of exorbitant pricing, so governments must be careful to balance incentives with access. However, due to the patent abuses that have been documented for drugs, the clear shortage of products like remdesivir, and very high pricing, statutory tools to circumvent patents could have been used to increase access to COVID-19 therapeutics. Ultimately, given the lack of a centralized purchasing model in the U.S., such patent abuses often permit pharmaceutical companies to price patients out of survival on life-saving therapies.⁹⁶ These concerns are undoubtedly heightened during a global pandemic where rapid access to medicines can substantially lower the rate of virus spread, hospitalization, and death.

Importantly, the United States government *does* have legally viable means through which it could circumvent these patents in times of national emergency: government patent use and government march-in rights.⁹⁷ While these were not employed during the COVID-19 pandemic (and historically have never been used in the pharmaceutical context), they represent critical tools that the government should invoke during crises to increase access to essential medicines.

93. Eisenberg, *supra* note 19.

94. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1046–47 (2016).

95. Jacob S. Sherkow et al., *Are Patents the Cause of—or Solution to—COVID-19 Vaccine Innovation Problems? (No!)*, WRITTEN DESCRIPTION (Mar. 4, 2021), <https://writtendescription.blogspot.com/2021/03/are-patents-cause-of-or-solution-tocovid.html>.

96. Michelle Chen, *Patents Against People: How Drug Companies Price Patients Out of Survival*, 60 DISSENT 71 (2013).

97. Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 279–80 (2016).

A. GOVERNMENT PATENT USE

28 U.S.C. § 1498 is a statute that explicitly permits the federal government to use or manufacture a patented invention in exchange for reasonable compensation.⁹⁸ This statute has been analogized to eminent domain as an “outworking of the organization of courts and the logic of sovereign immunity.”⁹⁹ While government patent use has been used frequently in the defense context, it has never been employed for pharmaceuticals alone. For example, the Department of Defense invoked the statute to obtain generic medicines in the 1960s–70s, and the government also threatened to invoke Section 1498 to procure antibiotics after the 2001 anthrax attacks.¹⁰⁰

Nonetheless, since the Act was envisioned specifically to “avoid situations where private rightsholders can hold up the public for more than reasonable compensation,” it would be appropriate to use the statute for pharmaceuticals with exorbitant prices that the public cannot afford, particularly during a pandemic.¹⁰¹ Professor Amy Kapczynski has previously pushed for invoking Section 1498 to increase access to direct-acting antiviral treatments for Hepatitis C.¹⁰² Similarly, government patent use could be employed to increase the supply of Gilead’s COVID-19 drug remdesivir. As previously noted, though Gilead was given substantial public funding for research and clinical development of the drug, the United States government has no ownership rights over the final product.¹⁰³ And since Gilead has enforced its patent rights against others who hoped to manufacture the compound, there has been overpricing as well as serious supply shortages of the drug in

98. 28 U.S.C. § 1498(a) (2018) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”).

99. Amy Kapczynski, *Realizing Public Rights Through Government Patent Use*, 49 J.L. MED. & ETHICS 34, 36 (2021).

100. Brennan et al., *supra* note 97, at 280.

101. Kapczynski, *supra* note 99, at 36.

102. Amy Kapczynski & Aaron S. Kesselheim, *Government Patent Use: A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFF. 791, 792 (2016).

103. Kapczynski, *supra* note 99, at 35 (“Gilead alone appears to hold the patents, which give it a general entitlement to prevent all other companies from making, using, selling, or importing the compound into the United States.”).

America.¹⁰⁴ Accordingly, proponents of Section 1498 have noted its speed, flexibility, and possibility for an ex post remedy by an impartial adjudicator as advantages of using the statute to remedy remdesivir shortages.¹⁰⁵ While any product created by the government after invocation of Section 1498 would still need to be approved by the FDA,¹⁰⁶ expedited approval can be given either to: (a) generic versions of the drug through the Abbreviated New Drug Application pathway, or (b) slight variations of the drug through Section 505(b)(2).¹⁰⁷ Thus, the remdesivir shortage is a prime example of a missed opportunity by the federal government to invoke compulsory licensing through Section 1498.

Some counter that intellectual property has little to do with the remdesivir shortage, instead noting that the federal government is ultimately responsible for controlling the drug's distribution after the Emergency Use Authorization (EUA), and therefore the crisis was unrelated to Gilead's patent.¹⁰⁸ Certainly, supply chain issues during the pandemic were serious and contributed to the shortages.¹⁰⁹ However, examples from other countries show that patents are nevertheless playing some role in restricting access. Indeed, Gilead *did* engage in voluntary licensing of remdesivir to generic manufacturers in countries such as Pakistan (in return for a royalty), which greatly reduced shortage problems there.¹¹⁰ And other successful voluntary licensing schemes—such as of Gilead's Hepatitis C drug Sovaldi in India—demonstrate that patents are at least part of the problem when it comes to expensive therapeutics and reduced

104. *Id.* (noting that thirty-eight hospitals across twelve states have experienced remdesivir shortages).

105. See Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 50 (2020).

106. Michael Liu et al., *March-In Rights and Compulsory Licensing—Safety Nets for Access to a COVID-19 Vaccine*, HEALTH AFFS. (May 6, 2020), <https://www.healthaffairs.org/doi/10.1377/forefront.20200501.798711/full/>.

107. Brennan et al., *supra* note 97, at 341–45.

108. See Jacob S. Sherkow et al., *Remdesivir Part II: Allocating Access*, WRITTEN DESCRIPTION (May 19, 2020), <https://writtendescription.blogspot.com/2020/05/remdesivir-part-ii-allocating-access.html> (noting that in remdesivir's EUA, the FDA stated that drug distribution would be controlled by the federal government).

109. Lisa L. Ouellette et al., *How Can the U.S. Address Coronavirus Drug Shortages?*, WRITTEN DESCRIPTION (Apr. 7, 2020), <https://writtendescription.blogspot.com/2020/04/how-can-us-address-coronavirus-drug.html>.

110. Kumar, *supra* note 38, at 87.

access.¹¹¹ Professor Jacob S. Sherkow and other critics of patent-related solutions acknowledge that “expanding generic manufacturing worked for driving down the price of easy-to-copy HIV/AIDS drugs, but is unlikely to be effective for more complex biologic medicines like vaccines.”¹¹² As a small molecule, remdesivir itself is no more complex than drugs used to treat HIV/AIDS or Hepatitis C, and a number of COVID-19 drugs in the pipeline have similarly simple mechanisms, which could benefit from compulsory licenses.¹¹³ Remdesivir is far from the complex biologics that comprise COVID-19 mRNA vaccines and is arguably simpler to replicate through generic production than combination HIV/AIDS therapies.

B. MARCH-IN RIGHTS

March-in rights through the Bayh-Dole Act are a specialized use of Section 1498 in cases where the federal government has financially contributed to the development of the invention.¹¹⁴ The Bayh-Dole Act is a microcosm of the innovation versus access debate when it comes to patenting medicines. On one hand, the statute has been applauded for spurring biotechnology innovation by allowing federally funded research to be patented (i.e., research conducted by universities and academic medical centers).¹¹⁵ On the other hand, Congress recognized the problems that could arise from patent holders exerting unilateral control over federally funded products. Thus, the Bayh-Dole Act incorporates an escape hatch known as the march-in rights provision, which permits the federal funding agency to require the patent holder to “grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the

111. Press Release, Gilead Scis., Inc., Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries (Sept. 15, 2014, 6:31 AM), <https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>.

112. Sherkow et al., *supra* note 12.

113. See *Coronavirus (COVID-19) Drugs*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2022), <https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs> (listing approved drugs to treat COVID-19).

114. 35 U.S.C. § 200–215 (1980).

115. Gabrielle Athanasia, *The Legacy of Bayh-Dole’s Success on U.S. Global Competitiveness Today*, CTR. FOR STRATEGIC & INT’L STUD. (Jan. 12, 2022), <https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-oles-success-us-global-competitiveness-today>.

circumstances,” including when such an action is “necessary to alleviate health or safety needs which are not reasonably satisfied” by the patent holder.¹¹⁶

March-in rights differ from Section 1498 in two primary ways. First, they are broader than Section 1498 because compulsory licenses can be used by any party, not just the federal government. This creates opportunities to greatly ramp up production of a medicine in short supply by assigning a license to a third-party manufacturer. Second, march-in rights are far more restrictive than Section 1498 because several statutory and regulatory criteria must be met before they can be invoked.¹¹⁷ Most importantly, the government must have monetarily contributed to the invention, defined in the statute as “conceived or first actually reduced to practice in the performance of work under a funding agreement.”¹¹⁸ As other scholars have noted, this does not cover many key contributions from the government, such as expending money to identify disease biomarkers for the industry.¹¹⁹

Further, it seems that agencies such as the Biomedical Advanced Research and Development Authority (BARDA) have instead “used contracts that seem to eliminate even these limited [march-in] obligations for recipients of its funding” during the COVID-19 pandemic to encourage additional innovation.¹²⁰ This appears to be the wrong balance between innovation and access; rather than invoke these statutorily authorized rights in the name of access, the government has contracted them away to the pharmaceutical industry under the pretense of innovation. This is incomprehensible, particularly when the federal government has in fact spent billions on R&D for COVID-19 products and would otherwise meet the statutory criteria, at least in the context of pandemic technologies. Even before the pandemic, though the government had been petitioned six times to use Bayh-Dole march-in rights in the pharmaceutical sector, the National Institutes of Health (NIH) had rejected all petitions and has *never* used these rights for

116. 35 U.S.C. § 203(a) (1980).

117. 35 U.S.C. § 203(a)(2) (1980); Morten & Duan, *supra* note 105, at 51 n.228.

118. 35 U.S.C. § 201(e) (1980).

119. Kapczynski, *supra* note 99, at 35.

120. *Id.*

medicines.¹²¹ If not invoke this escape provision during a global emergency to overcome patent barriers and increase access to medicines, then when?

Beyond crisis contexts like COVID-19 or HIV/AIDS, Bayh-Dole march-in rights could also be invoked when the pharmaceutical industry is reluctant to budge on pricing despite significant public pressure, creating a chronic shortage of an essential drug. For example, there have been repeated calls to invoke the provision to lower the price of Xtandi, a lifesaving prostate cancer drug, though these requests have been denied by the federal government.¹²² Some health experts have argued that march-in rights would actually improve public-private partnerships in the long run by better aligning private incentives with the public interest.¹²³

Certainly, the pharmaceutical and biotechnology industries are strongly against march-in rights as alleged impediments to innovation, but these concerns seem overstated considering the dire circumstances.¹²⁴ An important counterpoint is that patents under the Bayh-Dole Act result in the “internalization” of international benefits; namely, that “patents on publicly supported inventions allow the nation-state that sponsors the research to capture a larger share of the global benefits generated by its efforts, with potentially positive effects on the overall level of public R&D funding.”¹²⁵ While avoiding march-in rights may generally be justified on this ground, the negative externalities resulting from patents restricting access

121. JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 1 (2016).

122. Liza Vertinsky, *Exercising March-In Rights Would Make Biomedical Public-Private Partnerships Stronger*, HEALTH AFFS. (Apr. 4, 2022), <https://www.healthaffairs.org/content/forefront/exercising-march-in-rights-would-make-biomedical-public-private-partnerships-stronger>.

123. *Id.* (noting a need for “public actors to meaningfully participate in choices made along the R&D project lifecycle and providing them with reasonable opportunities to protect public rights of affordable access to the results”).

124. See generally PHRMA, HOW THE BAYH-DOLE ACT PROPELLED U.S. GLOBAL LEADERSHIP IN LIFE SCIENCES 16 (2015), <https://dokumen.tips/documents/how-the-bayh-dole-act-propelled-us-global-transfer-from-universities-and.html?page=1> (explaining the positive economic impact of the Bayh-Dole Act); Stephen Ezell, *The Bayh-Dole Act’s Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOVATION FOUND., Mar. 2019, at 4 (explaining the major actors in the life sciences ecosystem and Bayh-Dole’s positive effect).

125. Daniel J. Hemel & Lisa L. Ouellette, *Bayh-Dole Beyond Borders*, 4 J. L. & BIOSCIENCES 282, 285 (2017).

domestically and the desire not to internalize global benefits during a global pandemic militate against hyper-formalistic application of Bayh-Dole during such crises. Not only would the march-in rights solely be used given the nature of the crisis, march-in rights are likely more justified and externally palatable than Section 1498 because they can only be used when the government actually funded the invention in question, as was the case for many COVID-19 products currently in short supply.¹²⁶ Ultimately, however, the empirical effects of breaking such patents on pharmaceutical innovation are inconclusive, and thus weigh against being so patent-protective during national crises.¹²⁷ As a first step, Congress could amend the statutory language to loosen the restrictions on when march-in rights can be used, or the responsible agency—the National Institute of Standards and Technology (NIST)—could otherwise clarify the relevant regulations and promulgate a rule lowering the bar for when the government could march in.¹²⁸

V. CREATIVE CONTRACTING TO INCREASE ACCESS TO CARE

Though Section 1498 and by extension Bayh-Dole Act march-in rights represent a first step towards increasing access, critics are right to note that patents are not the only barrier to ameliorating inequities caused by the pandemic. Activists such as James Love have pointed out that for complex biotechnologies like the COVID-19 mRNA vaccine, fundamental *know-how* around manufacturing the product is equally as valuable as the patented molecule.¹²⁹ This know-how is oftentimes not covered by patents, but rather by trade secrets that cannot be circumvented through Section 1498 and the Bayh-Dole Act. Given the immense amount of federal support that the pharmaceutical industry received in creating testing kits, drugs,

126. See Christopher Rowland, *Trump Administration Makes it Easier for Drugmakers to Profit from Publicly Funded Coronavirus Drugs, Advocates Say*, WASH. POST (July 1, 2020, 4:43 PM), <https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/>.

127. See Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from Health Care Markets*, 16 INNOVATION POL'Y & ECON. 53, 57 (2016).

128. 37 C.F.R. § 401.6 (2023); 37 C.F.R. § 401.14(j) (1987).

129. James Love, *Buying Know-How to Scale Vaccine Manufacturing*, MEDIUM (Mar. 20, 2021), <https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36>.

and vaccines, this problem can be overcome by creative contracting strategies between the public and private sectors. Unlike patent-related tools, contracting solutions could effectively be used across technology types, though may be best applicable for testing and therapeutics, as opposed to vaccines, for which innovation is already under-incentivized due to high R&D costs in combination with low pricing constraints.

A. LEVERAGING CENTRALIZATION TO LOWER PRICES

Unlike the United Kingdom, which has a single body known as the National Institute for Health and Care Excellence within its National Health Service that effectively negotiates drug prices for the entire country, the United States does not have a central, advance purchaser.¹³⁰ However, the federal government should recognize its critical role in funding pharmaceutical technologies, and accordingly use this leverage to manage the pharmaceutical pricing dilemma that afflicts this country. Based on analysis of underlying patents, empirical studies have demonstrated an immense amount of public funding for the research and development of drugs in government and academic labs, which are eventually licensed out to the pharmaceutical industry.¹³¹ Further, the government contributes to nearly 50% of basic research funding for pharmaceuticals and biotechnologies,¹³² and to almost half of the academic publications underlying final FDA approval for various medicines.¹³³ Despite these contributions, the federal government usually loses control on the final product after it is licensed out, as demonstrated by the low number of public-sector patents.¹³⁴

130. DUTFIELD, *supra* note 90, at 447.

131. Bhaven Sampat & Frank Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFFS. 332, 335–36 (2011) (noting the presence of indirect government funding for almost half of all drugs approved and for nearly two-thirds of priority-review drugs).

132. Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCI. (Mar. 9, 2017), <https://www.science.org/content/article/data-check-us-government-share-basic-research-funding-falls-below-50>.

133. Ekaterina G. Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PNAS 2329, 2332 (2018).

134. Sampat & Lichtenberg, *supra* note 131, at 335 (indicating that only 9% of all drugs received public-sector patents).

This is incredibly unfair, as billions of dollars of taxpayer money contribute to various medicines that are eventually controlled exclusively by private companies, who then charge high prices and restrict access to those very same American taxpayers. The remdesivir case study is a perfect example of this: “[d]espite the substantial investment made by taxpayers [to Gilead] . . . , the public exerts no direct control over the price or supply of the medicine.”¹³⁵ Moderna’s COVID-19 vaccine also illustrates this problem. Though the company received substantial assistance from government scientists to develop its mRNA technology, the biotechnology company did not name federal researchers as co-inventors on the patent.¹³⁶ As a result, the federal government has not been able to control any manufacturing or distribution of the vaccine, and “the Biden administration has expressed frustration that Moderna has not done more to provide its vaccine to poorer nations even as it racks up huge profits.”¹³⁷ And as Jacob Sherkow notes, patents are “just one piece of an otherwise very large jigsaw puzzle . . . [t]he patent license does not build factories, it doesn’t source raw materials, it doesn’t train workers.”¹³⁸ To overcome the industry’s control over both patents and underlying know-how in trade secrets, the government must engage in creative contracting.

To begin, the government should not *remove* restrictions on pharmaceutical players (as BARDA did with march-in rights for various COVID-19 products), but rather *add additional* requirements before agreeing to fund a certain technology for a pharmaceutical company or before licensing out a technology to the private sector. For example, the federal government could require Moderna—which received at least \$1 billion in research aid and another \$1.5 billion in a deal with the government to deliver additional doses¹³⁹—to provide its product for free to

135. Kapczynski, *supra* note 99, at 35.

136. Sheryl Gay Stolberg & Rebecca Robbins, *The N.I.H. Says It Isn’t Giving Up in Its Patent Fight with Moderna*, N.Y. TIMES (Nov. 10, 2021), <https://www.nytimes.com/2021/11/10/us/politics/moderna-vaccine-patent-nih.html>.

137. Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 11, 2021), <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>.

138. *Id.*

139. Eric Sagonowsky, *After Nearly \$1B in Research Funding, Moderna Takes \$1.5B Coronavirus Vaccine Order from U.S.*, FIERCE PHARMA (Aug. 12,

Medicaid populations. Explicitly, the government could require Moderna to cover the cost of vaccine doses for these lower-income patients (or otherwise provide them at a heavily subsidized rate) such that the government does not have to pay. Recent estimates suggest the federal government gave Moderna nearly \$10 billion of taxpayer money total for R&D as well as advance purchases.¹⁴⁰ Despite this vast amount of funding, the federal government failed to use any leverage to require vaccine distribution to lower-income populations in the United States at reduced prices. A similar approach could have been used to increase access to COVID-19 testing kits, which the government had a comparably large role in funding at an early stage.¹⁴¹ Attaching additional strings to contracts with the private sector *upstream* of approval could prevent major access issues in the future.

Admittedly, this process is difficult for complex products that require multiple technology components under various contracts. Namely, the barrier that numerous patents place on effectively invoking Section 1498 and march-in rights on mRNA vaccines could similarly cause issues on the contracting front. From an administrability standpoint, the government might only attach conditions on a subset of components that go into a final product. Such implementation issues are difficult and would need to be worked out through greater interagency coordination.¹⁴² For example, HHS may need to establish uniform standards by which technologies of a certain type (e.g., sub-components of vaccines) are given similar conditions; thus, there is some consistency no matter if the product is being developed in collaboration with the NIH, FDA, or BARDA. Alternatively, the HHS Secretary could promulgate a rule stating that the subpart that is most encumbered (e.g., has the most restrictions) is controlling for the entire product. Ultimately, there are serious implementation problems that would need to be worked out in this model, but it is otherwise straightforward at least for simpler technologies with fewer components, like diagnostics and drugs.

2020, 9:18 AM), <https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s>.

140. Carrie Teicher, *What Moderna Owes the World*, STAT NEWS (Nov. 4, 2021), <https://www.statnews.com/2021/11/04/what-moderna-owes-the-world/>.

141. See, e.g., News Release, Nat'l Inst. of Health, NIH RADx Initiative Expands COVID-19 Testing Innovation for Additional Types of Rapid Tests (Oct. 14, 2021).

142. Ouellette et al., *supra* note 17.

An alternative to attaching conditions to contracts when out-licensing could be that the pharmaceutical companies who in-license certain federally funded technologies (e.g., from government labs or federally funded academic centers) are charged higher prices by the government. This increased revenue can then be earmarked towards subsidizing medicines for poorer populations. Again, this would require fairly sophisticated coordination between agencies, as funds from public R&D partners like the NIH would need to be transferred to Centers for Medicare and Medicaid Services for the purposes of reimbursement. Finally, when out-licensing, the government could simply require the pharmaceutical company to set a certain price or set a cap based on the amount of federal funding received (or the cost of clinical development). Though the political feasibility of this approach is questionable, a bipartisan Congress has recently been more receptive to the notion that Medicare should negotiate drug prices with manufacturers.¹⁴³ But regardless of the specific contracting restrictions applied, the basic point is the same—as a significant funder of the private sector’s pharmaceutical R&D, the government should attach conditions to its funds to ensure sufficient access later, particularly during pressing crises. Such creative contracting would reduce surplus to the pharmaceutical sector and improve general societal welfare.

B. FACILITATING KNOW-HOW TRANSFER

Creative contracting could similarly be used to ameliorate the aforementioned know-how problem. Namely, government contracts with pharmaceutical companies for funding or licensing complex biotechnologies should include provisions requiring future know-how transfer. For example, such conditions could require that any clinical trade secrets be shared back with the government, or to any other manufacturer (domestic or global), when there are supply shortages. This approach could overcome some of the deeper contractual and infrastructural problems at play beyond just the patent

143. Juliette Cubanski et al., *What’s the Latest on Medicare Drug Price Negotiations?*, KAISER FAM. FOUND. (July 23, 2021), <https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/>.

problem.¹⁴⁴ While the White House has stated it cannot *compel* know-how transfer,¹⁴⁵ the federal government can certainly require future know-how transfer in its early *contracts* with pharmaceutical companies. For context, “at least some U.S. government contracts [with Moderna] build in provisions for technology transfer in the event of the firm’s decision to terminate production.”¹⁴⁶ But the provisions should go even further and add more stringent requirements. For example, the government could require that each company it contracts with shares knowledge across all the firms with which it has contracted.¹⁴⁷ To conclude, the federal government could use its bargaining power—through its position as a significant early-stage funder of biopharmaceuticals—to draft contracts that increase access to essential medicines.

An alternative solution to the know-how problem is for the government to keep early-stage R&D “in house” for as long as possible before licensing technologies to the private sector. Namely, encouraging government and federally funded academic labs to conduct further clinical development would allow for some of the manufacturing trade secrets to originate within the government itself. In addition to enhancing the bargaining position of the federal government when out-licensing patents, by being further along in the clinical process, this approach also encourages the public sector to build up its own knowledge base, which could be deployed if pharmaceutical players are later restricting access to their technologies. Importantly, government and academic labs have been credited as being worse than the pharmaceutical industry at translational work, and brilliant discoveries often fail to become marketable products by not traversing the so-called “valley of death” between preclinical and clinical spheres.¹⁴⁸ However, the federal

144. Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, PETRIE-FLOM CTR. HARV. L. SCH.: BILL OF HEALTH (May 5, 2021),

<https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/>.

145. Jen Psaki, Press Secretary, Press Briefing at the White House (Oct. 18, 2021) (“[M]y understanding is also that the U.S. government does not have the ability to compel Moderna to take certain actions.”); *see also infra* Part VI.

146. W. Nicholson Price II et al., *Knowledge Transfer for Large-scale Vaccine Manufacturing*, 369 SCI. 912, 913 (2020).

147. *Id.* at 914.

148. Attila A. Seyhan, *Lost in Translation: The Valley of Death Across Preclinical and Clinical Divide – Identification of Problems and Overcoming Obstacles*, 4 TRANSLATIONAL MED. COMMC’NS 1 (2019).

government can counteract this problem by investing more upfront in the clinical capacity of these labs to reduce reliance on the pharmaceutical sector. For this to work effectively, Congress must subsidize government and government-affiliated labs—on the condition that they increase their clinical capacity—and openly encourage taking preclinical products into the clinical phase. Greater funding could incentivize researchers from re-orienting their laser focus on academic publications to also developing clinical stage products that will eventually reach patients.

Subsidizing early-stage researchers in this way has several advantages. First, since much fundamental R&D occurs in government and funded university labs to begin with,¹⁴⁹ this approach allows credit to be given where it is due—to the true innovators as opposed to the manufacturers and distributors. This does not just mean credit in the sense of recognition; rather, current preclinical assets are often undervalued given the high failure rate in drug development.¹⁵⁰ Thus, allowing early-stage researchers to reach *clinical* inflection points could allow them to receive additional value when eventually licensing out their technologies, thereby also reducing the surplus enjoyed by the pharmaceutical industry. As an aside, it is important not to confuse the ideas of incentives and affordability.¹⁵¹ Namely, reducing the surplus that belongs to the pharmaceutical sector and placing it in the hands of early-stage researchers at government and university labs will not alone increase access to medications. Substantial coordination efforts are required within the government to effectively out-license these technologies (at higher prices) to the pharmaceutical sector, which will work towards final product approval and eventual marketing/distribution. On the incentives side, especially for lower-price products like vaccines (as opposed to drugs) where higher prices cannot justify the increased licensing costs, the government can use innovation policy levers such as advance purchase agreements to keep pharmaceutical companies motivated.¹⁵² Finally, on the access front, the newly developed in-house manufacturing capacity and know-how within

149. See generally Sampat & Lichtenberg, *supra* note 131.

150. Tohru Takebe et al., *The Current Status of Drug Discovery and Development as Originated in United States Academia*, 11 CLIN. & TRANSLATIONAL SCI. 597, 598 (2018).

151. See generally Sherkow et al., *supra* note 12; Sachs et al., *supra* note 27.

152. Price et al., *supra* note 32.

government labs should serve as a sufficient threat to the industry and deter unaffordable pricing.

Further, this approach would respond to the recent criticisms that the Federal Trade Commission (FTC) has received for its “prior approval” process, which aims to block consolidation in the pharmaceutical industry through a more restrictive merger policy.¹⁵³ While critics have been vocal about the potential negative impact the FTC’s seemingly anti-merger policy may have on innovation in the biopharmaceutical industry—since government labs and small biotechnology companies without clinical capacity rely on acquisitions from larger pharmaceutical companies—the government’s subsidization of clinical development in these smaller organizations would reduce their reliance on the pharmaceutical sector, pushing back the mergers to a later time. Thus, the subsidies could allow for the pro-competitive effects of the FTC policy without having any deleterious impact on innovation. Moreover, as noted above, encouraging clinical development in government funded labs will permit more manufacturing-related trade secrets to remain with the government before the technologies are handed over to the private sector. As a general matter, the federal government ought to increase its control over the pharmaceutical sector, and it currently possesses the requisite legal capacity to do so, despite the fact that there are some implementation hurdles to be worked out. This solution could be utilized across technology types, though may be most effective in the testing and therapeutic arenas wherein incentives to innovate are not already suppressed.

VI. COMMANDEERING THE PHARMACEUTICAL INDUSTRY

While circumventing patents may be helpful mostly for therapeutics and otherwise for select diagnostics, creative contracting strategies could be used for diagnostics, therapeutics, and vaccines alike. However, given the unique cost and market structure for vaccines, ex ante solutions could serve

153. See Jamie E. France & JeanAnn Tabbaa, *Prior Approval Provisions in FTC Merger Consent Orders*, GIBSON DUNN (Apr. 28, 2022), <https://www.gibsondunn.com/prior-approval-provisions-in-ftc-merger-consent-orders/>; Zachary Brennan, *Pharma in the Crosshairs: How the FTC is Expanding its Antitrust Powers Under its New Chair*, ENDPOINTS NEWS (July 2, 2021, 9:52 AM), <https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/>.

as a deterrent to innovation on much-needed prophylactics. Further, companies like Pfizer ultimately did not take public money during Operation Warp Speed,¹⁵⁴ so government control on their vaccine was likely not possible through contracting strategies. Thus, a third and more aggressive ex-post approach—beyond circumventing patents or contracting creatively with the pharmaceutical sector to increase access to COVID-19 medicines—would involve temporarily commandeering the pharmaceutical industry, or at least a segment of the larger industry. This strategy would be effective across technology types, but possibly most necessary for vaccines wherein the underlying manufacturing know-how is protected by trade secret and otherwise difficult to discover. Just as the United States government has been deeply involved with the private military sector through the extensive use of contractors, similar involvement is legally viable with the pharmaceutical industry, at least during times of crisis. In fiscal year 2009, the Department of Defense (DOD) spent nearly \$316 billion on defense contracts;¹⁵⁵ by contrast, such extensive outsourcing does not exist for biopharmaceuticals. However, there are potential legal pathways through which the United States can take more control of the sector, especially during national emergencies. This Part will first describe a statutory scheme—the Defense Production Act—which has been invoked in a limited capacity, and then assert that a constitutional mechanism exists for the President to commandeer certain industries (or parts of them) in times of crisis.

A. USE OF THE DEFENSE PRODUCTION ACT

In 1950, Congress passed the Defense Production Act (DPA) after the start of the Korean War to establish the infrastructure to quickly mobilize production for defense.¹⁵⁶ In particular, the Act authorizes the President to compel the private sector to provide essential material goods for national defense in times of

154. *Was Pfizer's Work on a Coronavirus Vaccine Aided Through Operation Warp Speed?*, CNN FACTS FIRST, https://www.cnn.com/factsfirst/politics/factcheck_565aa63a-4c46-4eea-9586-093253d1bdf3 (last visited Nov. 20, 2023).

155. Peter W. Singer, *The Regulation of New Warfare*, BROOKINGS INST. (Feb. 27, 2010), <https://www.brookings.edu/opinions/the-regulation-of-new-warfare/>.

156. See ALEXANDRA G. NEENAN & LUKE A. NICASTRO, CONG. RSCH. SERV., R43767, *THE DEFENSE PRODUCT ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS 2* (2023).

emergency.¹⁵⁷ Over the years, Congress has expanded the term “national defense” beyond United States military capabilities to include domestic preparedness, response, and recovery from natural hazards, terrorist attacks, and other national emergencies.¹⁵⁸ Specifically, the stated Congressional policy underlying the DPA is to “supply materials and services for the national defense and to prepare for and respond to military conflicts, *natural* or man-caused disasters, or acts of terrorism within the United States.”¹⁵⁹ The statute explicitly notes that “national defense” includes “emergency preparedness activities”¹⁶⁰ per Title VI of the Stafford Act, which includes all activities designed to “prepare for or minimize the effects of a hazard upon the civilian population [and] to deal with the immediate emergency conditions which would be created by the hazard.”¹⁶¹ Thus, responding to the COVID-19 pandemic fits comfortably within the DPA’s broad scope, and both Presidents Trump and Biden recognized COVID-19 as a DPA-triggering hazard.

Three authorities of the DPA are still in force today. First, the President may require businesses to prioritize and accept contracts for certain “critical and strategic” materials or services for national defense, codified in Title I.¹⁶² Second, the President can “provide appropriate incentives to develop, maintain, modernize, restore, and expand the productive capacities” for critical goods, codified in Title III.¹⁶³ Third, the President can reorganize and make “voluntary agreements” with the private industry in Title VII.¹⁶⁴ Titles I and III are most relevant to the COVID-19 context. Critically, under Title I, the President can restrict hoarding and price gouging of designated scarce materials.¹⁶⁵

157. *Id.*

158. *Id.* at 4.

159. 50 U.S.C. § 4502(a)(1) (emphasis added).

160. 50 U.S.C. § 4552(14).

161. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5195a(a)(3).

162. 50 U.S.C. § 4511(b).

163. 50 U.S.C. § 4517(a).

164. 50 U.S.C. § 4558(e).

165. 50 U.S.C. § 4512; JAY B. SYKES, CONG. RSCH. SERV., LSB10472, ANTITRUST ENFORCEMENT DURING THE COVID-19 PANDEMIC: FREQUENTLY ASKED QUESTIONS 2 (2020).

1. Title I Authority

On March 18, 2020, President Trump gave the Secretary of Health and Human Services (HHS) authority under Title I to restrict hoarding of personal protective equipment (PPE) and critical medical equipment.¹⁶⁶ HHS responded by designating N95 respirators, portable ventilators, and disinfecting devices as “scarce or threatened.”¹⁶⁷ Further, the Secretary compelled various companies—including General Motors, Phillips, and General Electric—to prioritize contracts for over 187,000 ventilators, totaling nearly \$3 billion.¹⁶⁸ 3M was also later ordered to produce approximately 165 million N95 ventilators under Title I.¹⁶⁹

2. Title III Authority

Despite the overall success of Title I, Title III was largely underutilized. Both Presidents Trump and Biden could have invoked the DPA more broadly to create a robust supply chain of testing and nasal swabs, beyond ventilators and masks.¹⁷⁰ In late March 2020, President Trump did delegate Title III authority to the HHS and Department of Homeland Security Secretaries to respond to the crisis through incentives including loans, direct purchases, and purchase commitments.¹⁷¹ The DOD also invoked its Title III authority twice to scale up nasal swab

166. Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19, 85 Fed. Reg. 16,227,16,228 (Mar. 18, 2020); Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID-19, 85 Fed. Reg. 17001 (Mar. 23, 2020); Aidan Lawson & June Rhee, *Usage of the Defense Production Act Throughout History and To Combat COVID-19*, YALE SCH. MGMT. PROGRAM ON FIN. STABILITY (June 3, 2020), <https://som.yale.edu/blog/usage-of-the-defense-production-act-throughout-history-and-to-combat-covid-19>.

167. Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures, 85 Fed. Reg. 17,592 (Mar. 25, 2020).

168. Lawson & Rhee, *supra* note 166.

169. Anshu Siripurapu, *What is the Defense Production Act?*, COUNCIL ON FOREIGN RELS. (Dec. 22, 2021, 3:40 PM), <https://www.cfr.org/in-brief/what-defense-production-act>.

170. See Aishvarya Kavi, *Virus Surge Brings Calls for Trump to Invoke Defense Production Act*, N.Y. TIMES (July 22, 2020), <https://www.nytimes.com/2020/07/22/us/politics/coronavirus-defense-production-act.html>.

171. Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID-19, 85 Fed. Reg. 17001 (Mar. 23, 2020).

and N95 mask production, in contracts totaling \$208 million.¹⁷² Nevertheless, there has been criticism that the Trump Administration used the DPA too little, too late. Several Congressmembers wrote a letter to the President urging him to fully use Title III to increase production of *all* critical COVID-related medical supplies,¹⁷³ and a bill was even proposed accordingly in the Senate to “federalize the entire medical supply chain.”¹⁷⁴ Therefore, while Title I was invoked numerous times, many decried President Trump’s limited “use” of Title III (i.e., only to issue direct loans or loan guarantees) to promote the production of medical supplies as “totally inadequate.”¹⁷⁵ And neither Title was used much for the production of diagnostics, vaccine supplies, or therapeutics.

By August 2020, the Trump Administration had allegedly invoked the DPA eighteen times through Operation Warp Speed to curb the pandemic, but there was limited transparency around which specific Titles were invoked.¹⁷⁶ There is no requirement that the Executive Branch publish DPA actions, and therefore “no centralized repository” exists that collects such actions.¹⁷⁷ Importantly, the administration’s DPA implementation pattern was deemed “sporadic and relatively narrow.”¹⁷⁸ In November 2020, the Government Accountability Office found retrospectively in a study that the Trump Administration did in fact invoke Title III a few more times between April and August 2020, but ultimately argued that there is a lack of robust centralized reporting and “opportunities

172. Press Release, Dept. of Def., DOD Details \$75 Million Defense Production Act Title 3 Puritan Contract (Apr. 29, 2020); Press Release, Dept. of Def., DOD Details \$133 Million Defense Production Act Title 3 COVID-19 Project (Apr. 21, 2020).

173. Letter from 59 Members of Congress, Andy Levin et al., to President Trump about the DPA (Mar. 13, 2020) (found at <https://sherrill.house.gov/media/press-releases/sherrill-joins-colleagues-in-urgent-letter-to-the-president-to-invoke-defense-production-act-authority-and-increase-availability-of-vital-medical-supplies>).

174. Lawson & Rhee, *supra* note 166.

175. Letter from 9 Senators, Chris Van Hollen et al., to President Trump about Title III (May 6, 2020) (found at [https://www.vanhollen.senate.gov/imo/media/doc/2020%2005%2006%20POTUS%20re%20DPA%20Title%20III\[1\].pdf](https://www.vanhollen.senate.gov/imo/media/doc/2020%2005%2006%20POTUS%20re%20DPA%20Title%20III[1].pdf)).

176. Press Release, White House, Statement from the Press Secretary (Dec. 29, 2020).

177. Michael H Cecire & Heidi M. Peters, CONG. RSCH. SERV., IN11470, DEFENSE PRODUCTION ACT (DPA): RECENT DEVELOPMENT IN RESPONSE TO COVID-19 2 (2020).

178. *Id.* at 3.

exist to increase transparency and identify future [DPA] actions to mitigate medical supply chain issues.”¹⁷⁹

More recently, though President Biden signed various executive orders suggesting a comprehensive framework to build up coronavirus supplies and develop a permanent public health supply chain, the new administration has also been reluctant to invoke the DPA’s full authority.¹⁸⁰ In March 2021, the Biden administration invoked the DPA to equip Merck facilities to manufacture the Johnson & Johnson vaccine, forging a collaboration between two of the largest American pharmaceutical companies.¹⁸¹ The DPA itself was not asserted to coerce the companies to work together; rather BARDA provided a \$105 million investment to require Merck to convert and upgrade its facilities.¹⁸² Many argue that the deal was ultimately made possible in the backdrop of the DPA’s authority.¹⁸³ Nonetheless, numerous health experts have advocated for still fuller use of the DPA to end the pandemic, noting that the DPA can be used to drastically scale up global vaccine production.¹⁸⁴ Further, the DPA could have been used to massively scale up production of at-home rapid tests in light of the Omicron variant.¹⁸⁵ Full invocation of the DPA to scale up

179. U.S. GOV’T ACCOUNTABILITY OFF., GAO-21-108, DEFENSE PRODUCTION ACT: OPPORTUNITIES EXIST TO INCREASE TRANSPARENCY AND IDENTIFY FUTURE ACTIONS TO MITIGATE MEDICAL SUPPLY CHAIN ISSUES 1 (2020).

180. Cf. Shayan Karbassi, *Understanding Biden’s Invocation of the Defense Production Act*, LAWFARE (Mar. 4, 2021), <https://www.lawfareblog.com/understanding-bidens-invocation-defense-production-act> (explaining that Biden’s initial actions are indicative of a more hands-on approach).

181. Press Release, Dep’t Health & Hum. Servs., Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines (Mar. 2, 2021).

182. *Id.*

183. Sydney Lupkin, *Defense Production Act Speeds Up Vaccine Production*, NPR (Mar. 13, 2021, 7:00 AM), <https://www.npr.org/sections/health-shots/2021/03/13/976531488/defense-production-act-speeds-up-vaccine-production>.

184. Zain Rizvi et al., *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFFS. (Aug. 6, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/>.

185. Timi Iwayemi, *Free At-Home Tests Are a Start, But Biden Must Move Faster and Go Bigger to End Pandemic*, REVOLVING DOOR PROJECT (Dec. 22, 2021), <https://therevolvingdoorproject.org/free-at-home-tests-are-a-start-but-biden-must-move-faster-and-go-bigger-to-end-pandemic/> (“However, the administration’s efforts have been insufficient in handling the scale of tests truly needed to appropriately manage the pandemic.”).

production for the Strategic National Stockpile can also mitigate the effects of the next pandemic.¹⁸⁶

It is now clear that while *ad hoc* executive orders to prioritize ventilator production through Title I were certainly helpful, the DPA could have been more frequently and widely invoked to create a sustainable supply chain for *all* pandemic-related technologies.¹⁸⁷ The reluctance to more broadly apply the DPA stemmed from the typical concerns when it comes to the pharmaceutical industry—with fears that Title III “nationalization” and compulsory production mandates would eventually lower innovation in the sector.¹⁸⁸ This position stands in stark contrast with the defense sector, where the DOD has a standing Title III program to “mitigate critical shortfalls in domestic defense industries,” and has invoked the Title most recently in July 2019 to expand production capacity of rare earth elements.¹⁸⁹ Ultimately, the question remains: what is so different about pharmaceuticals than traditional defense products that makes the United States government so reluctant to invoke Title III? The usual response is about not deterring innovation in an industry where the cost of R&D can exceed \$1 billion for a single drug.¹⁹⁰ But this response may not hold empirically, particularly when compared to the defense sector with similarly high production costs, and especially during a global crisis and national emergency wherein access concerns are accentuated.

Overall, the lack of expansive DPA invocation during the pandemic represents the government’s general unwillingness to interfere with the highly profitable pharmaceutical sector.

186. See Dan Else, *The History of the Defense Production Act and What it Means for COVID-19*, WAR ON THE ROCKS (Apr. 13, 2020), <https://warontherocks.com/2020/04/the-history-of-the-defense-production-act-and-what-it-means-for-covid-19/>.

187. See U.S. GOV’T ACCOUNTABILITY OFF., GAO-22-105380, AGENCIES ARE TAKING STEPS TO IMPROVE FUTURE USE OF DEFENSE PRODUCTION ACT AUTHORITIES 7–9 (2021) (noting that between March 2020 and September 2021, priority-rated contracts under Title I of the DPA were invoked a total of seventy-three times, and domestic production expansion efforts—through Title III of the DPA—were invoked a total of only six times).

188. Lawson & Rhee, *supra* note 166.

189. *Defense Production Act (DPA) Title III*, DEP’T DEF. INDUS. POL’Y, (June 6, 2020), <https://web.archive.org/web/20200606071531/https://www.businessdefense.gov/Programs/DPA-Title-III/>.

190. Rajkumar, *supra* note 86, at 2.

3. The DPA for Intellectual Property

While the prior discussion was about the use of—and potential for the greater use of—the DPA as pertaining to real property, there are also questions around the possibility of invoking the DPA for *intellectual* property. In the vaccine context, some scholars have argued that Title I could be used to *coerce* pharmaceutical players to transfer their technologies.¹⁹¹ In their view, Title I of the DPA could be another means to facilitate sharing of vaccine know-how. However, as alluded to before, the current White House believes that an effort to compel pharmaceutical companies to share vaccine technology “would invariably lead to a drawn-out legal battle, which would be counterproductive.”¹⁹² Thus, the possibility of forcing technology and know-how transfer through Title I remains contested.

However, health law scholar Amy Kapczynski contends that coercing technology and know-how transfer *is* contemplated by the DPA, which defines “materials” as including “any technical information and services ancillary to the use of” products and commodities.¹⁹³ And it is the government who ultimately sets the terms of DPA contracts per regulation.¹⁹⁴ For example, in its contract with the United States government, “Pfizer agreed to transfer the know-how and production process from its partner BioNTech in Europe to the US.”¹⁹⁵ Thus, Kapczynski argues, requiring the pharmaceutical sector to accept contracts that mandate transfer of know-how (e.g., to a governmental entity like BARDA, which can share this information more broadly) is likely statutorily authorized by the DPA.¹⁹⁶ Professor Kapczynski accordingly believes that the government can set up technology transfer hubs under the DPA’s Title I authority, and as was previously noted, some of the United States government’s contracts with Moderna already reference this possibility in the event that the company decides to terminate vaccine

191. Rizvi et al., *supra* note 184.

192. Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Nov. 9, 2021), <https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html>; Psaki, *supra* note 145.

193. Amy Kapczynski & Jishian Ravinthiran, *How to Vaccinate the World, Part 2*, L. & POL. ECON. PROJECT (May 4, 2021), <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>.

194. 45 C.F.R. § 101.33 (2022).

195. Rizvi et al., *supra* note 184.

196. *Id.*

production.¹⁹⁷ These contractual provisions accordingly reinforce the view that the DPA likely permits such mandatory technology transfer in extreme cases when a manufacturer is being obstinate. Unlike for real property, forcing production or transfer of intellectual property is arguably more detrimental to innovation as once the know-how becomes public, the temporary takings effectively becomes permanent. Regardless of the statutory basis, such forced technology transfer raises two serious constitutional questions:

a. Takings Clause

The Fifth Amendment of the United States Constitution states that “private property [shall not] be taken for public use, without just compensation.”¹⁹⁸ However, as Kapczynski notes, the Fifth Amendment concern with compelling technology transfer is mitigated so long as just compensation is provided.¹⁹⁹ The constitutionality of this conduct would be no different than that under Section 1498 or the Bayh-Doles Act’s march-in rights provision; in all cases, the government would provide just compensation to satisfy the Takings Clause. Critically, invoking this option is still possibly far cheaper for the government than invoking the traditional Title I or III pathways for real property, since it would likely pay for the technology at cost, which would be considered reasonable, particularly during a global pandemic. Specifically, while Titles I and III would likely require payment at or near the fair market value, reasonable compensation under the Takings Clause could account for “the risk-adjusted value of federal subsidies, investments, and technology,” resulting in a far lower price.²⁰⁰ Thus, President Biden’s action to purchase testing kits is probably more expensive for the government because while it is likely purchasing the products at a subsidized

197. Price II et al., *supra* note 146; Moderna, Inc., Current Report (Form 8-K) (Aug. 11, 2020) (“If . . . the Company either makes a formal management decision to terminate the manufacture or sale of mRNA-1273 to the U.S. Government . . . the Company will provide the U.S. Government with certain items required for the U.S. Government to have a third party manufacture mRNA-1273 exclusively for sale to the U.S. Government, including a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government certain Moderna patent and other intellectual property rights required to manufacture mRNA-1273.”).

198. U.S. CONST. amend. V.

199. Rizvi et al., *supra* note 184.

200. *Id.*

rate, it is not as inexpensive as circumventing the patent altogether or mandating technology transfer for “just compensation,” as could be defined liberally by the government based on its prior federal funding of the company.²⁰¹ One wrinkle with employing the DPA to transfer *know-how* within trade secrets rather than patents is that valuation of just compensation is more difficult, but that is a question for the parties or ultimately the adjudicator assessing damages.

b. Compelled Speech under the First Amendment

Another possible concern about coercing companies to share intellectual property is whether this amounts to a First Amendment violation, namely compelling speech.²⁰² Of course, this problem does not arise with Section 1498 or march-in rights since pharmaceutical patents are publicly registered with the United States Patent and Trademark Office. But what about trade secrets underlying the technology? Can the government require a company to hand over certain documents, or if the manufacturing know-how is rather in the mind of one engineer at a pharmaceutical company, can the government require them to share the information in the name of national defense? One way to get around the challenge is to characterize technology transfer not as speech but rather conduct. And so long as the conduct is not expressive like political speech,²⁰³ the First Amendment does not apply. However, this is likely a difficult argument to make.

Importantly, while commercial speech *is* protected by the First Amendment, it typically gets less protection than traditional political speech.²⁰⁴ In *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*,²⁰⁵ the Supreme Court held that commercial speech typically gets an

201. See generally *Knick v. Twp. of Scott*, PA, 139 S. Ct. 2162, 2170 (2019) (discussing just compensation in relation to the time of the taking).

202. See, e.g., *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943) (holding that students cannot be forced to salute the American flag or say the pledge of allegiance in public schools).

203. See generally *United States v. O'Brien*, 391 U.S. 367 (1968) (holding that burning a draft card is expressive speech protected under the First Amendment and therefore statutes prohibiting such conduct are subject to heightened scrutiny).

204. VICTORIA L. KILLION, CONG. RSCH. SERV., 7-5700, THE FIRST AMENDMENT: CATEGORIES OF SPEECH (2019).

205. *Central Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

intermediate (rather than a strict) level of scrutiny, requiring a substantial government interest and means by the government that are not broader than necessary to achieve that interest. It is very likely that during a pandemic—when the government hopes to curb the spread of disease and protect its citizenry from a deadly contagion—a court would find that the federal government meets the substantial government interest prong when attempting to coerce the transfer of know-how that underlies a vaccine, drug, or diagnostic in order to increase access to that technology. The “reasonable fit” inquiry would be more fact specific. In particular, the government would need to not ask for more intellectual property than is required to address whatever crisis is present. As an example, the government could show that due to the Omicron variant’s rapid spread and the shortage of testing nationwide, Abbott must transfer know-how of its BinaxNOW test to increase needed access to diagnostic care. However, the government likely cannot mandate that Abbott share know-how underlying other non-COVID technologies. Finally, in cases of purely factual disclosure of uncontroversial information, the Supreme Court has applied a standard even less stringent than intermediate scrutiny, which would make the government’s case even easier if it can make the adequate showing.²⁰⁶

In conclusion, the government will likely succeed on First Amendment grounds—so long as it makes reasonably narrow requests—during a national emergency given the government interest at stake.

B. THE CONSTITUTIONALITY OF COMMANDEERING THE PHARMACEUTICAL INDUSTRY

Taking the analogy between the defense and biopharmaceutical industries to its logical extreme, there may be a possibility for the entire industry to be taken over during a national emergency. Namely, beyond invoking statutorily authorized provisions of the Defense Production Act, some have argued that the President may be able to commandeer the pharmaceutical industry in times of crisis merely through her inherent Article II powers.²⁰⁷ In the seminal case *Youngstown*

206. See *Zauderer v. Off. of Disciplinary Couns. of Supreme Court of Ohio*, 471 U.S. 626 (1985).

207. See Jeannie Suk Gersen, *Who’s In Charge of the Response to the Coronavirus?*, NEW YORKER (Apr. 19, 2020),

Sheet & Tube Co. v. Sawyer,²⁰⁸ the Supreme Court held that President Truman did not have the authority to seize private production steel mills during the Korean War in the absence of statutory authority conferred by Congress or by the explicit text of Article II. To avoid a labor strike resulting from the steel industry's rejection of wage increases, Truman seized the facilities to prevent shortages that would cripple the production of defense materials for the war. Critically, the administration chose to simply seize the mills rather than constrain the unions through the Taft-Hartley Act because the President saw the industry, and not the unions, as responsible for the problem. Though the seizure was deemed unlawful, Justice Jackson in his concurrence laid out a tripartite framework for permissible Presidential action, considering background Congressional authority.²⁰⁹ This framework is highly influential today and presents an opportunity for the President to similarly take over the pharmaceutical industry in a national crisis like the COVID-19 pandemic.

Justice Jackson divided Presidential authority into three categories with descending levels of legitimacy: (1) When the President is legitimately acting with express (or implied) authority from Congress; (2) When the President is acting with independent powers in shared areas of authority, where Congress has thus far been silent, known as the "zone of twilight"; and (3) When the President is clearly defying the orders of Congress.²¹⁰ In *Youngstown* itself, Justice Jackson argued that the seizure of steel mills fell into the third category, where Presidential power is at its "lowest ebb," since Congress explicitly rejected an amendment to the Taft-Hartley Act wherein such seizures would have been allowed to resolve labor disputes.²¹¹ Further, he found that the President's actions were not in the second category because Congress had passed statutes giving the President power in the general arena—including the Selective Service Act, the Defense Production Act, and the Labor

<https://www.newyorker.com/news/our-columnists/whos-in-charge-of-the-response-to-the-coronavirus>.

208. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

209. *Id.* at 635–38 (Jackson, J., concurring).

210. *Id.*

211. *Id.* Reliance on such legislative history, and particularly the rejection of a proposed amendment, is a highly disfavored judicial practice today. Thus, in addition to the recent logic from *Dames & Moore*, it is more likely that a Court today would have placed President Truman's actions in Category 2, not Category 3.

Management Relations Act—but had not granted him the specific authority to seize private property during times of war.²¹²

Interestingly, many constitutional scholars argue that the seizure of steel mills should have actually fallen within Category 2, since Congress legislated in the general field, even though the President did not specifically invoke either of the three statutes mentioned. For example, in a later case, the Supreme Court found that President Reagan’s suspension of all legal claims against Iran filed in United States courts fell within the second *Youngstown* category, given the breadth of the Hostage Act.²¹³ Namely, even though Congress never directly authorized the President to cancel US-Iran legal claims in this manner, the Court implied Congressional intent for this action from the statute legislating in the generally relevant neighborhood.²¹⁴

Analogously, given the Defense Production Act and its reauthorizations over the years, which have expanded the definition of national defense and thereby broadened the President’s authority during emergencies, there is a strong argument that seizure of the pharmaceutical industry during crises would fall within the second of the *Youngstown* categories. Importantly, the DPA itself demonstrates the President has shared powers with Congress in directing the pharmaceutical sector (or any relevant sector) in the name of national defense. Additionally, Congressional spending through the Coronavirus Preparedness and Response Supplemental Appropriations Act,²¹⁵ Families First Coronavirus Response Act,²¹⁶ and Coronavirus Aid, Relief, and Economic Security (CARES) Act²¹⁷—all which gave the Executive Branch significant discretion in using appropriations and which broadly involved spurring development of vaccines, therapeutics, and diagnostics

212. *Id.* at 653.

213. *Dames & Moore v. Donald T. Regan*, 453 U.S. 654 (1981).

214. *Id.* at 678 (“Although we have declined to conclude that the IEEPA or the Hostage Act directly authorizes the President’s suspension of claims for the reasons noted, we cannot ignore the general tenor of Congress’ legislation in this area in trying to determine whether the President is acting alone, or at least with the acceptance of Congress.”).

215. Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146 (2020).

216. Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020).

217. Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).

as well as increasing access to care—demonstrates that the President’s seizure of the pharmaceutical industry would not be incompatible with Congressional intent. One might counter that because Congress did not explicitly authorize commandeering, it precluded this possibility. This is a valid concern, and one that will be worked out by the courts when the President’s actions are challenged, particularly since the scope of Article II authority has not been fully fleshed out. However, the similarity to *Dames & Moore* in terms of a broad statute authorizing Presidential actions in the general neighborhood would make a strong case. Namely, the CARES Act in particular committed billions of dollars of funding to the discretion of the President, including \$1 billion to enforce the DPA.²¹⁸ Ultimately, if a crisis is dire enough that the President needs to commandeer a portion of the industry, she has a good faith defense based on the various statutory enactments and precedent since *Youngstown*.

Though the holding in *Youngstown* alone would suggest otherwise, *Dames & Moore* has indicated that the tripartite framework is now governing law, and the decision has demonstrated the Court’s expansive view of Article II powers over the last few decades.²¹⁹ When operating within this second category, Justice Jackson noted: “[A]ny actual test of power is likely to depend on the imperatives of events and contemporary imponderables, rather than on abstract theories of law.”²²⁰ Like in *Youngstown*, wherein President Truman chose seizure over statutory pathways such as the Taft-Hartley Act, seizure may have been more appropriate at the height of the COVID-19 pandemic rather than merely invoking the Defense Production Act, given the pharmaceutical industry’s clear profit motive.²²¹ Jackson’s pragmatic approach would likely find a temporary takeover of the pharmaceutical sector by the President acceptable in light of the extenuating circumstances and clearly

218. Moss et al., *supra* note 58. *See supra* Part III.

219. *Dames & Moore v. Donald T. Regan*, 453 U.S. 654, 659 (1981).

220. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637 (1952) (Jackson, J., concurring).

221. Just as President Truman justified the seizure of the steel mills rather than invocation of the Taft-Hartley Act given that he blamed not the unions but rather the industry, the President could argue that the pharmaceutical industry here is similarly responsible for the problems associated with access to COVID-19 technology; thus, taking over the sector rather than making DPA payments—which might manifest as the government (and thereby the taxpaying public) paying twice for the technology—would be pragmatic.

misaligned incentives between the industry and the taxpaying public.

Assuming the constitutionality of seizure during a global pandemic, the President has discretion as to when and which segments of the pharmaceutical industry should be commandeered. The testing market during the height of the Omicron variant in November 2021 through January 2022 would have been a good target. Rather than take control of this critical market segment during the spread of the variant, President Biden spent nearly \$1 billion to send rapid antigen tests to 500 million households, and another \$2 billion for the pharmaceutical sector to increase testing capacity.²²² Given that testing has been shown to be a vital prerequisite to curbing COVID-19 spread, hospitalizations, and death, it was a grave mistake to act on the variant so late—especially when the federal government (i.e., American taxpayers) contributed to initial R&D funding of these tests.²²³ With pharmaceutical companies like Abbott charging \$24 for a two-pack of BinaxNOW tests—and PCR tests being in short supply—many Americans simply could not access testing during the peak of the Omicron variant, more than two years into the global pandemic.²²⁴ A one or two-month seizure of select facilities to expand production of PCR and antigen tests as well as testing sites could have resulted in reduced prices and dramatic increases in access for Americans. Unlike for more complex vaccines, circumventing patents or commandeering the industry for fairly simple tests also presents fewer of the common concerns associated with deterring expensive biomedical innovation. However, even for the COVID-19 vaccine, if supplies were exceedingly low and the federal government were unable to replicate the complex technologies, commandeering mRNA manufacturing facilities and mandating transfer of know-how for a limited time may have been the appropriate response from the President. While some may consider this a radical idea, the seizure would be temporary, and the pandemic was, and still is, an unprecedented time for our country, requiring novel solutions.

222. Press Release, The White House, *supra* note 1.

223. Kessel, *supra* note 3; Press Release, U.S. Dep't Health & Hum. Serv., *supra* note 8; News Release, Nat'l Inst. of Health, *supra* note 141.

224. Simon, *supra* note 7.

VII. CONCLUSION

Ultimately, the United States fell short of its potential in responding to the COVID-19 pandemic. Political hurdles aside, Congress has provided adequate authority to the President to overcome structural healthcare barriers in times of crisis. These include circumventing patents through Section 1498 or the Bayh-Dole Act's march-in rights provision, and the Defense Production Act to require manufacturers to prioritize certain contracts or ramp up production. In combination with the three COVID-19 response statutes enacted in March 2020, the Defense Production Act also likely demonstrates sufficient Congressional intent to provide the President the discretion to commandeer the pharmaceutical industry during national emergencies, acting within *Youngstown* Category 2. Finally, the federal government could have just used its leverage to employ creative contracting techniques in lowering prices and requiring know-how transfer. While questions around whether the government can compel technology transfer under the DPA remain uncertain, the massive amount the government spent on the private sector to develop diagnostics, therapeutics, and vaccines during the pandemic should at least militate towards the federal government having greater control over the technologies and thereby their accessibility.

Ultimately, however, the legal solution must be tailored to the technology type and broader political context. Patent-based solutions are likely optimal for therapeutics given the cost structure in the vaccine industry and IP hurdles for diagnostics.²²⁵ Section 1498 and march-in rights are likely to face political barriers as well, but have gained momentum even outside the COVID-19 context for certain lifesaving drugs.²²⁶ Creative contracting solutions can be employed across technology types but will present interagency coordination problems, especially for complex technologies like the mRNA vaccine. However, such implementation issues can be worked out with practice, and such schemes are likely administrable for simpler testing technologies even today. Finally, a commandeering approach is the final solution when all else fails. For physical products, both the Trump and Biden

225. Xue & Ouellette, *supra* note 26.

226. Press Release, Sen. Elizabeth Warren, Warren, King, Doggett Urge HHS to Exercise March-in Rights for Life-Saving Cancer Drug Xtandi to Dramatically Lower its Price for Millions of Americans (Feb. 18, 2022).

Administrations employed the DPA to ramp up production, and this approach has been supported on a bipartisan basis. The question is less clear for intellectual property such as trade secrets, but the President likely can act within constitutional bounds. The arsenal of tools presented in this paper should inform the next pandemic, allowing the government to respond more rapidly to increase access to essential technologies and curb the spread of disease.
