Discussion paper

IP and access to publicly funded research results in health emergencies

US policy, law and practice

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WIPO

Discussion Paper on IP and Access to Publicly Funded Research Results in Health Emergencies

The discussion paper on the topic of access to publicly funded research results in health emergencies was produced as one of the activities under WIPO's COVID-19 Response Package.

This chapter of the discussion paper was prepared by Ms. Lisa Larrimore Ouellette, Deane F. Johnson Professor of Law, Stanford Law School, and Senior Fellow, Stanford Institute for Economic Policy Research. Her insights are focused on the perspectives of the United States of America.

The views and opinions expressed in the paper are of the author, and do not necessarily reflect those of WIPO or its Member States.

IP and access to publicly funded research results in health emergencies. US policy, law and practice

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Abstract:

The urgent demands posed by the COVID-19 pandemic galvanized the scientific research community, with substantial support from government funding. The results of this research have often been protected by intellectual property (IP), including patents and trade secrecy. This has led to substantial interest in the laws and policies enabling the public to benefit from publicly funded research. This discussion paper, prepared at the request of the World Intellectual Property Organization (WIPO) Patent and Technology Law Division, describes the US approach to these issues and outlines best practices to prepare for future health emergencies.

The US Government supports innovation through a pluralistic approach, mixing and matching the market exclusivity provided by IP with a host of other policy mechanisms. Most prominently, the government directly funds innovation ex ante through grants, R&D contracts, and national laboratories; supports additional ex ante R&D spending through tax incentives; and provides ex post innovation rewards ranging from government insurance like Medicare and Medicaid to procurement contracts such as for the Department of Veterans Affairs and for COVID-19 vaccines and therapeutics. Under a broad definition that includes direct or indirect benefit from any of these forms of taxpayer support, every new medical product that reaches the US public is at least partially "publicly funded," but most also depend on substantial private-sector investment. This paper examines these public funding policies, the legal framework for IP protections on publicly funded research, the implementation of these policies in contractual conditions attached to public R&D funding, and the application of these policies during the pandemic.

COVID-19 is both a global tragedy and an opportunity for structural changes. Such reforms should not focus on whether an innovation benefited from any particular type of public funding, which has little bearing on key policy decisions such as who should have access to that innovation. Instead, two goals should guide reforms of IP and innovation systems: (i) better

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aligning the rewards for new medical technologies with their social value and (ii) providing widespread access to those innovations, both in the United States and around the globe.

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1. Introduction

As the devastating COVID-19 pandemic unfurled around the globe, the public- and private-sector research communities scrambled to understand how to monitor the virus, limit its spread, and reduce the harm to those infected. These researchers were supported by an unprecedented influx of targeted government R&D funding, including around $5 billion worldwide in just the first few months of 2020.[2] The fruits of this research were often protected by intellectual property (IP), including patents and trade secrecy, leading to a reinvigoration of longstanding debates[3] about the effect of exclusive IP rights on public access to publicly funded research. These concerns have been heightened by stark health inequalities, both within and across countries, which have been exacerbated during the pandemic.

This discussion paper examines these issues from the US perspective. Section 2 begins by considering the typical role of public funding in US biomedical research. US innovation policy is pluralistic, combining IP laws with additional policy mechanisms to incentivize innovation and allocate access to new medical technologies.[4] The government directly funds R&D projects ex ante through grants, R&D contracts, and national laboratories—primarily through the National Institutes of Health (NIH)—and provides additional ex ante support through R&D tax incentives. The US Government also funds ex post rewards for successful innovations through government insurance such as Medicare and Medicaid and through procurement contracts like for the Department of Veterans Affairs and for COVID-19 vaccines and therapeutics. Under a broad definition of "publicly funded research" that includes all innovations that benefited directly or indirectly from any of these forms of taxpayer support, *every* new medical product that reaches the US public is at least partially publicly funded. Most of these innovations, however, also depend on even more substantial private-sector investment, particularly for clinical trials and other late-stage expenses. There is no consensus among academics or policymakers on when a particular innovation should be considered "publicly funded." Rather, the answer to this question depends on *why* one is examining public R&D funding. In general, the amount of public funding for a new medical product has relatively little bearing on relevant policy questions, such as how that product should be rewarded, who should have access to it, or whether information about it should be publicly disclosed.

Section 3 describes the US legal framework for IP protections on publicly funded research, under which non-IP innovation policies are typically a complement to, not a substitute for, IP. R&D tax incentives and ex post government-funded rewards do not restrict the simultaneous use of IP. Inventions based on direct ex ante federal funding may generally be patented and exclusively licensed under the Bayh-Dole and Stevenson-Wydler Acts, under the theory that

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[2] OECD (2021). "OECD Science, Technology and Innovation Outlook 2021: Times of Crisis and Opportunity." Available at: https://www.oecd.org/sti/science-technology-innovation-outlook/crisis-and-opportunity/STIO-Brochure-FINAL-UDP.pdf.

[3] Sampat B.N. (2021). "The Government and Pharmaceutical Innovation: Looking Back and Looking Ahead," *Journal of Law, Medicine & Ethics*, Vol. 49, No. 1, pp. 10-18.

[4] Hemel D.J. and Ouellette L.L. (2019). "Innovation Policy Pluralism." *Yale Law Journal*, Vol. 128, No. 3, pp. 544-614.

patents can help promote commercialization and use of these inventions. These frameworks reserve some rights for the US Government, including to address public health needs, although the government has generally declined to exercise some of these rights. The government has taken stronger steps to require access to the *information* resulting from direct federal funding, such as publication and data-sharing requirements, although there are exceptions to protect certain information as trade secrets. There are no separate legal rules governing FDA-administered regulatory exclusivity for products relying on any form of public funding.

Section 4 examines how these US policies were implemented during the COVID-19 pandemic. The US Government provided the largest global source of public funding and purchasing for COVID-19 research, primarily through its "Operation Warp Speed" manufacturing and procurement contracts. The most successful portion of this funding was spent on vaccines, but the government also invested in therapeutics and in developing public health information not tied to a particular pharmaceutical intervention. Unlike the typical practice in which late-stage development is almost entirely funded by the private sector, the US Government was involved in all stages of development of COVID-19-related products. The government often followed the standard framework for IP protections on publicly funded research, but some Operation Warp Speed contracts provided weaker government rights in IP and data. The government did ensure that all individuals residing in the United States could have free access to these medical innovations. However, rollout was often slow and inequitable, and there was little attention to residents of other countries. The results of publicly funded studies on public health information were generally quickly and freely shared, although there was limited federal coordination to improve the reliability and clarity of the results. Overall, the successes and failures of the US response to COVID-19 had little to do with IP policy; rather, they stemmed from choices about where—and where not—to invest the substantial resources of the US Government, both financial and organizational.

Finally, Section 5 considers lessons learned to prepare for future health emergencies. In reforming biomedical innovation institutions, policymakers should not focus on whether an innovation benefited from any particular form of public funding, which has little bearing on key policy decisions such as who should have access to that innovation or to information about its safety and efficacy. Instead, reforms should be guided by two goals: (i) better aligning the rewards for new medical technologies with the demonstrated social value of those innovations and (ii) providing broad access to those innovations.[5] These principles apply to both tangible innovations (like pharmaceuticals) and the information embedded in those products (like the clinical trial results showing that a particular pharmaceutical is effective against a particular disease). The goals of value-based rewards and widespread access are not incompatible, and they can be accomplished through multiple policy levers. Addressing underinvestment in pandemic-related innovation and access to healthcare systems will require substantial political

[5] Hemel D.J. and Ouellette L.L. (2023). "Valuing Medical Innovation." *Stanford Law Review*, Vol. 77, No. 3, pp. 517-599.

will and global cooperation, but the tragedy of COVID-19 may also be an opportunity for this structural change.

2. Public funding of US biomedical research

The US Government incentivizes innovation and allocates access to new medical technologies through a pluralistic policy approach beyond IP. Section 2.1 describes direct ex ante funding through grants, R&D contracts, and national laboratories; Section 2.2 describes R&D tax incentives; and Section 2.3 describes ex post rewards in the form of government insurance like Medicare or Medicaid or direct government procurement of medical technologies.

Hemel and Ouellette have emphasized two key points about this assortment of innovation policies. First, for incentivizing innovation, no single policy is uniformly optimal.[6] For example, government-set incentives such as grants can correct market failures, but they also entail a substantial informational burden on the policymakers who must "pick winners." Grants also have the advantages of ex ante incentives that do not depend on a project's success, such as reducing risk and the need to raise private capital—as well as the downsides, such as a reduced incentive for success compared with ex post rewards.

Second, how to *incentivize* innovation is a distinct policy choice from how to *allocate access* to those innovations.[7] For example, using IP as part of the innovation incentive policy mix does not mean access must be allocated through IP-based proprietary pricing; instead, IP incentives are often matched with open-access allocation through government insurance and procurement.

As explained in Section 2.4, this pluralistic approach to innovation policy makes it difficult to assess which medical technologies should be deemed "publicly funded." A broad definition that includes all direct or indirect support from any form of public funding would cover every medical product marketed in the US, but this definition would not be useful for informing any policy decisions. Instead, policymakers should focus on doing the most to save lives and improve health, regardless of whether a given innovation benefited from public funding.

2.1 Direct ex ante spending: grants, R&D contracts, and national laboratories

Federal and state governments directly fund a substantial but declining portion of R&D in the US. The best estimates of US R&D expenditures come from the National Center for Science and Engineering Statistics (NCSES) within the National Science Foundation (NSF), which conducts annual national surveys of the primary organizations responsible for US R&D.[8] As shown below in Figures 1 and 2, these data indicate that although total inflation-adjusted US

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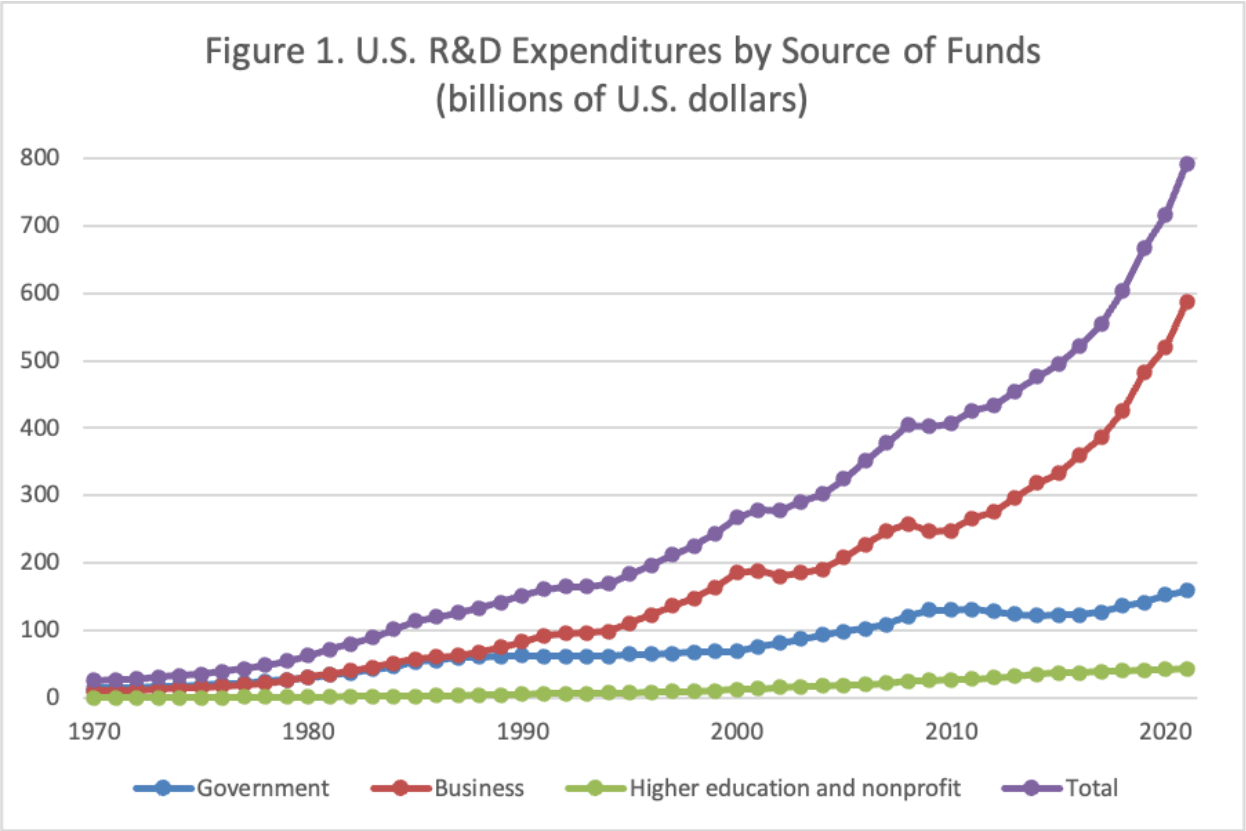
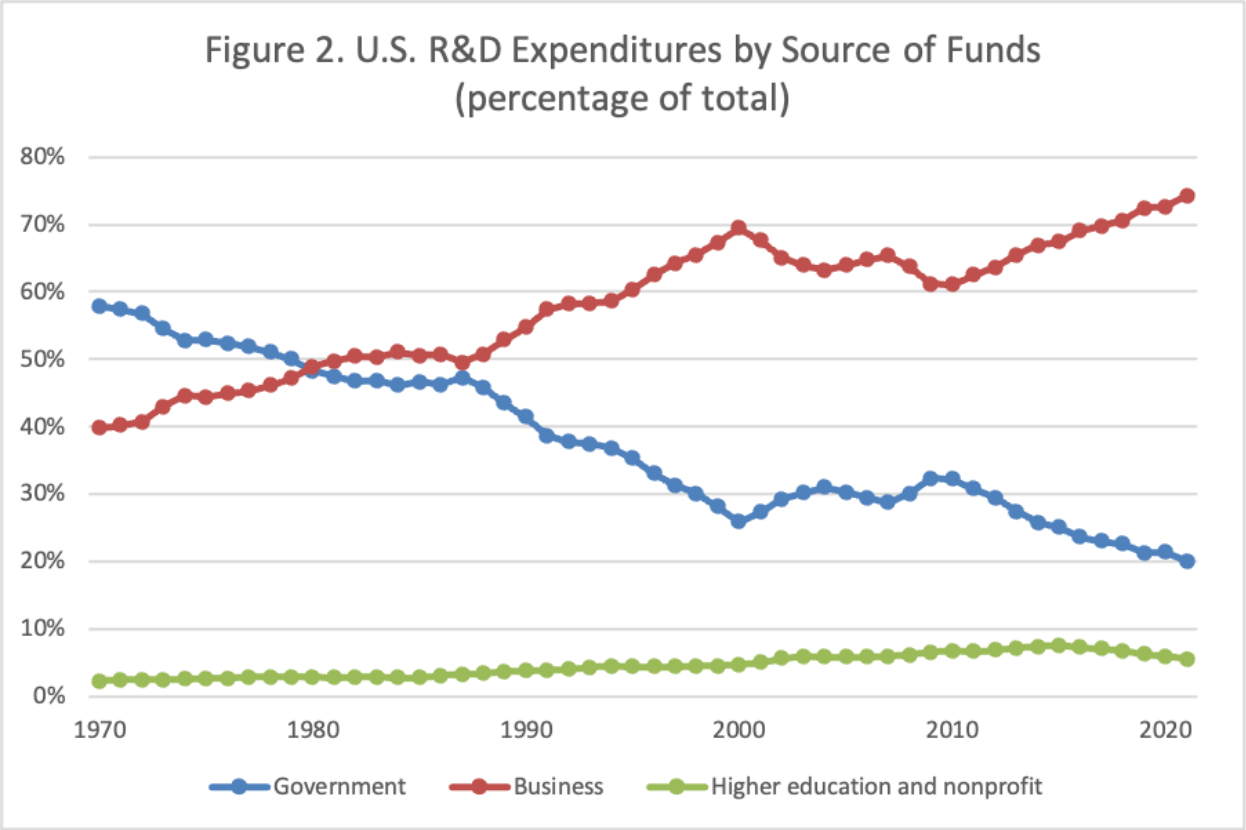
[6] Hemel D.J. and Ouellette L.L. (2013). "Beyond the Patents-Prizes Debate." *Texas Law Review*, Vol. 92, No. 2, pp. 303-382.
[7] Hemel and Ouellette. "Innovation Policy Pluralism," *supra* note 4.
[8] National Center for Science and Engineering Statistics (NCSES) (2023). "National Patterns of R&D Resources: 2020–21 Data Update." National Science Foundation, Alexandria, VA (NSF 23-321). Available at: https://ncses.nsf.gov/pubs/nsf23321.

R&D expenditures increased from around $26 billion in 1970 to $792 billion in 2021, this growth has been driven primarily by private-sector funding. Figure 2 shows that the percentage of R&D funded by federal or state governments declined from around 58 percent in 1970 to just 20 percent in 2021.





Over 95 percent of US Government funding for R&D is through the federal government, primarily through the Department of Defense (DOD), Department of Health and Human Services (HHS) (home to the NIH), Department of Energy, National Aeronautics and Space Administration, NSF, and Department of Agriculture.[9] The remaining government R&D funding is mostly from state government agencies, which spent over $1 billion in health-related R&D in 2020 and 2021.[10] This paper will focus on the legal framework for federal spending, given its dominant role.

Figuring out what portion of this federal R&D funding is relevant to health emergencies is challenging, but most would be funded by the NIH. Of the NIH's $45 billion annual budget, over 84 percent supports extramural research, mainly by researchers at universities, hospitals, and independent research institutes, and over 10 percent supports intramural research at NIH labs across its 27 distinct Institutes and Centers.[11] The NIH is the world's single largest funder of biomedical research, but this does not mean that most US biomedical research is publicly

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[9] Burke A., Okrent A., and Hale K. National Science Board (2022). "The State of US Science & Engineering 2022." National Science Foundation, Alexandria VA (NSB-2022-1). Available at: https://ncses.nsf.gov/pubs/nsb20221/u-s-and-global-research-and-development.
[10] Pece C.V. National Center for Science and Engineering Statistics (NCSES) (2022). "State Agencies' R&D Increased 1% in FY 2021; Five States Account for Nearly 60% of All State R&D." National Science Foundation, Alexandria, VA (NSF 23-301). Available at: https://ncses.nsf.gov/pubs/nsf23301.
[11] National Institutes of Health (2022). "What We Do: Budget." National Institutes of Health, Bethesda, MD. Available at: https://www.nih.gov/about-nih/what-we-do/budget.

funded. For example, private-sector R&D spending by the US pharmaceutical industry totaled around $90 billion per year in 2019[12] and 2020[13] and almost $100 billion in 2021[14] (around 17-18 percent of all industrial R&D spending). This is more than twice the NIH budget, only some of which is pharmaceutical-related. One study concludes that the share of US medical research funded by industry grew from 46% in 1994 to 58% in 2012, with industry providing the primary funding for late-phase clinical trials.[15]

How vital these different R&D inputs are for resulting biomedical innovations depends on how one counts. If one focuses narrowly on the *direct* costs of developing specific commercial products and services, these costs are paid mainly by the private sector. For example, Durvasula, Ouellette, and Williams document that, of new small-molecule drugs approved by the US Food and Drug Administration (FDA) from 1981 to 2014, less than 8 percent had even one utility patent based on public R&D, and 2 percent had exclusively public patents.[16] Similarly, Sampat and Lichtenberg report that only 9 percent of FDA-approved drugs from 1998 to 2005 had a public-sector patent—but they also show that the public sector has a much greater *indirect* influence on approved drugs, with nearly half of all drugs and two-thirds of "priority-review" drugs having a patent that *cited* a public-sector patent or publication.[17] In an even more expansive measure of this kind of indirect influence, another study found that NIH funding contributed to *every one* of the 210 new FDA-approved drugs from 2010 to 2016, with 90 percent of this funding representing basic research.[18]

More generally, over half of NIH funding is for basic science, such as understanding the biological mechanisms of disease rather than testing whether a particular drug improves clinical outcomes.[19] Public funding for basic science and other research without an obvious short-term commercial application is vital because these projects are less likely to be funded by the private

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[12] Wolfe, R.M. National Center for Science and Engineering Statistics (NCSES) (2021). "Businesses Reported an 11.8% Increase to Nearly a Half Trillion Dollars for US R&D Performance During 2019." National Science Foundation, Alexandria VA (NSF 22-303). Available at: https://ncses.nsf.gov/pubs/nsf22303.

[13] Wolfe, R.M. National Center for Science and Engineering Statistics (NCSES) (2022). "Businesses Spent Over a Half Trillion Dollars for R&D Performance in the United States During 2020, a 9.1% Increase Over 2019." National Science Foundation, Alexandria VA (NSF 22-343). Available at: https://ncses.nsf.gov/pubs/nsf22343.

[14] Britt R. National Center for Science and Engineering Statistics (NCSES) (2023). "Business R&D Performance in the United States Tops $600 Billion in 2021." National Science Foundation, Alexandria VA (NSF 23-350). Available at: https://ncses.nsf.gov/pubs/nsf23350.

[15] Moses H., III *et al.* (2015). "The Anatomy of Medical Research: US and International Comparisons." *Clinical Review & Education*, Vol. 313, No. 2, pp. 174-189.

[16] Durvasula M., Ouellette L.L., and Williams H. (2021). "Private and Public Investments in Biomedical Research." *AEA Papers and Proceedings*, Vol. 111, pp. 341-345.

[17] Sampat B. and Lichtenberg F.R. (2011). "What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?" *Health Affairs*, Vol. 30, No. 2, pp. 332-339.

[18] Cleary E.G., Beierlein J.M., Khanuja N.S., and McNamee L.M. (2018). "Contributions of NIH Funding to New Drug Approvals 2010-2016." *Proceedings of the National Academy of Sciences*, Vol. 115, No. 10, pp. 2329-2334.

[19] National Institutes of Health (2022). "Basic Research – Digital Media Kit." National Institutes of Health, Bethesda, MD. Available at: https://www.nih.gov/news-events/basic-research-digital-media-kit.

sector.[20] But while there is strong evidence that the social returns from R&D expenditures are higher than the private returns,[21] thereby providing justification for public investment, estimating the causal impact of public R&D funding is much more challenging. Indirect influence cannot always be traced through citation chains, and many studies lack a control group to determine whether public research is merely correlated with or even "crowds out" private-sector investments, as opposed to causing improvements in health technologies.

In one of the most rigorous empirical estimates of the causal impact of NIH R&D support, Azoulay, Graff Ziven, Li, and Sampat use variation around NIH funding cutoffs to document that each $10 million increase in NIH funding leads to 2.7 additional private-sector patents.[22] (To be sure, the focus on patenting as an outcome is a limitation of this study, including because some medical innovations—such as ICU hygiene checklists—are not easily excludable with patents.[23]) This kind of analysis is important as a step toward better estimating the social payoffs from public R&D investments, which can help inform how this innovation policy mechanism should be used going forward.

2.2 Tax expenditures to incentivize R&D

In addition to directly funding some R&D projects through grants, contracts, and national laboratories, the US Government also provides substantial R&D tax incentives, which reduce the cost of R&D conducted by firms subject to US taxes. Tax incentives can replicate some of the advantages of IP systems in leveraging private information about the costs and benefits of different research projects, coupled with the advantages of ex ante rewards that are provided early in the R&D process—as well as the corresponding disadvantages on both fronts.[24] The details of US tax incentives to encourage R&D are complex; in brief, the federal Internal Revenue Code has included three main provisions for incentivizing R&D under Sections 41, 174, and 45C.

First, the credit for increasing research activities under Section 41 provides a tax credit for firms that increase qualifying research expenses over a base amount determined from their past research spending (with a maximum base of 16 percent of gross receipts). In its simplest form, the credit equals 20 percent of research expenses over the base amount, but the full provision adds numerous complexities. In March 2023, the US Department of the Treasury estimated that total tax expenditures on the credit for increasing research activities would be around

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[20] Price W.N., II (2019). "Grants." *Berkeley Technology Law Review*, Vol. 34, No. 1, pp. 1-65.
[21] Lucking B., Bloom N., and Van Reenen J. (2020). "Have R&D Spillovers Declined in the 21st Century?" *Fiscal Studies*, Vol. 40, No. 4, pp. 561-590.
[22] Azoulay P., Graff Ziven J.S., Li D., and Sampat B.N. (2019). "Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules." *Review of Economic Studies*, Vol. 86, pp. 117-152.
[23] Kapczynski A. and Syed T. (2013). "The Continuum of Excludability and the Limits of Patents." *Yale Law Journal*, Vol. 122, No. 7, pp. 1900-1963.
[24] Hemel and Ouellette. "Beyond the Patents-Prizes Debate," *supra* note 6.

$23 billion in 2022 and $25 billion in 2023.[25] The portion claimed by biomedical firms would be smaller; for a rough estimate, consider that the pharmaceutical industry is responsible for around 17-18 percent of all industrial R&D spending.

Second, expensing of research and experimental expenditures under Section 174 has allowed firms to write off certain R&D costs immediately instead of amortizing them over a longer period. However, this provision unexpectedly lapsed in 2022. There is strong bipartisan support for reinstituting Section 174, but there is legislative stalemate over whether it should be paired with additional tax reform, creating uncertainty and headaches for firms relying on the benefit.[26]

Finally, the "orphan drug" tax credit under Section 45C allows firms to claim a tax credit for 25 percent of their clinical testing expenses for rare diseases (diseases that affect fewer than 200,000 people in the United States). The credit was originally 50 percent under the Orphan Drug Act of 1983, but it was halved by the federal tax reform in December 2017. Combined with the other provisions of the Orphan Drug Act (a seven-year regulatory exclusivity period for orphan drugs and additional grant funding for orphan-drug development), this provision was effective in spurring orphan drug development.[27] The Treasury Department estimates that tax expenditures on the orphan-drug tax credit will be just under $2 billion in 2022 and just over $2 billion in 2023.

Along with these federal tax incentives, firms can also benefit from state-level R&D tax credits, although in practice these state laws may mainly shift R&D from one state to another.[28] Given this evidence of firm relocation in response to tax incentives, quantifying the aggregate effects of R&D tax incentives has proven challenging.[29] R&D tax incentives are also not well tailored to address market failures in the biomedical sector.[30]

2.3 Ex post rewards: government insurance and procurement

The US Government also affects biomedical innovation by directly shaping the market for successful products. The US healthcare market is extraordinarily complicated, but the largest government insurance programs, Medicare (for Americans 65 or over, or with long-term disabilities) and Medicaid (for Americans with low incomes or disabilities), collectively cover over

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[25] US Department of the Treasury Office of Tax Analysis (2023). "Tax Expenditures." US Department of the Treasury, Washington, DC. Available at: https://home.treasury.gov/system/files/131/Tax-Expenditures-FY2024-update.pdf.
[26] Rubin R. (2023). "Small Businesses Face Big Tax Bills from Research-Deduction Change." *Wall Street Journal*, Mar. 17, 2023. Available at: https://www.wsj.com/articles/small-businesses-face-big-tax-bills-from-research-deduction-change-a189b113.
[27] Yin W. (2008). "Market Incentives and Pharmaceutical Innovation." *Journal of Health Economics*, Vol. 27, No. 4, pp. 1060-1077.
[28] Wilson D.J. (2009). "Beggar Thy Neighbor? The In-State, Out-of-State, and Aggregate Effects of R&D Tax Credit." *Review of Economics and Statistics*, Vol. 91, No. 2, pp. 431-436.
[29] Bryan K.A. and Williams H.L. (2021). "Innovation: Market Failures and Public Policies." *Handbook of Industrial Organization*, Vol. 5, pp. 281-388.
[30] Eyal-Cohen M. and Rutschman A.S. (2022). "Promoting Vaccine Innovation." *Ohio State Law Journal*, Vol. 83, No. 6, pp. 1003-1068.

40 percent of the US population and around 40 percent of US prescription drug spending.[31] The government chooses how to set reimbursement amounts for these programs, which it currently links to private-sector prices in ways that distort pharmaceutical markets.[32]

These policies were primarily created to provide *access* to medical technologies, but they also affect *incentives* to create those technologies in the first place. For example, Blume-Kohout and Sood document that the introduction of a prescription drug benefit in Medicare Part D increased research in drug classes with the largest projected market expansion.[33] Legal scholars have begun to explore how these programs might be tailored as innovation policy levers, such as by increasing Medicaid reimbursement to improve incentives for diseases affecting low-income populations,[34] recognizing that expanding Medicare access would increase current returns to innovation,[35] or replacing current reimbursement formulas with prices explicitly based on a product's demonstrated social value.[36]

Furthermore, the US Government is a substantial direct purchaser of pharmaceuticals and other medical innovations, including through the DOD, the Department of Veterans Affairs, the Indian Health Service, the Federal Bureau of Prisons, and the Department of State. In 2018, the almost $15 billion spent on pharmaceutical procurement by the DOD and the Department of Veterans Affairs accounted for almost 5 percent of US drug expenditures.[37] And as discussed in more detail in Section 4, the US Government also engaged in pharmaceutical procurement on a much larger scale by purchasing COVID-19 vaccines and therapeutics for use by the entire US public. Just as a commitment to provide high Medicare reimbursement increased incentives to develop drugs for elderly Americans, these market commitments during the pandemic likely helped spur the record-fast development of COVID-19 vaccines.

2.4 Which innovations are "publicly funded"?

The widespread mixing of public R&D funding with IP protections on medical technologies has increased interest in whether the public benefits from publicly funded research. But the binary question of whether a given technology is "publicly funded" is ill-posed. Under a broad definition

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[31] Cubanski J., Rai M., Young K., and Damico A. (2019). "How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?" Kaiser Family Foundation, May 20, 2019. Available at: https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid.
[32] Duggan M. and Scott Morton F.M. (2006). "The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing." *Quarterly Journal of Economics*, Vol. 121, No. 1, pp. 1-30.
[33] Blume-Kohout M.E. and Sood N. (2013). "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development." *Journal of Public Economics*, Vol. 97, pp. 327-336.
[34] Sachs R.E. (2016). "Prizing Insurance: Prescription Drug Insurance as Innovation Incentive." *Harvard Journal of Law and Technology*, Vol. 30, No. 1, pp. 153-208.
[35] Lemley M.A., Ouellette L.L., and Sachs R.E. (2020). "The Medicare Innovation Subsidy." *New York University Law Review*, Vol. 95, No. 1, pp. 75-129.
[36] Hemel and Ouellette. "Valuing Medical Innovation," *supra* note 5.
[37] Congressional Budget Office (2021). "A Comparison of Brand-Name Drug Prices Among Selected Federal Programs." Congressional Budget Office, Washington, DC. Available at: https://www.cbo.gov/publication/56978.

that includes all innovations that benefited directly or indirectly from any public funding, *every* new medical product that reaches the US public is publicly funded. Even firms that do not claim any R&D tax incentives still benefit from government insurance and reimbursement programs. And it is difficult to imagine any medical technology that does not indirectly build on NIH-funded basic science. But most of these innovations also depend on even more substantial private funding.

Assessing the relative impacts of public- and private-sector research efforts is also challenging because of the growing number of public-private partnerships. For example, under a cooperative research and development agreement (CRADA), federal and non-federal entities can share facilities, personnel, and other resources such as IP in a long-term cooperative project, with funding sometimes contributed by the non-federal partner (but not by the federal government).[38]

In short, biomedical innovation in the United States currently depends on both public and private funding, as well as public-private collaborations under CRADAs and other mechanisms. Public funding plays the largest role in basic science discoveries that indirectly lead to more applied innovations, while private funding dominates late-stage development.

One could imagine disentangling these different forms of support into a more fine-grained "public funding" metric, which might for example determine that a particular pharmaceutical was 13 percent publicly funded. Of course, any such metric would require difficult calculations and arbitrary choices about how to allocate the costs of basic research, failed but related projects, and overhead. More importantly, it is unclear why this metric would be *useful* for informing relevant policy decisions because public funding in the United States is currently more focused on correcting market failures than on fully covering the costs of developing and commercializing medical products. For example, the fact that a given drug was 13 percent publicly funded does not mean that the manufacturer's private rewards should be reduced by 13 percent—such a reduction would merely reinstate the market distortions that public funding should be targeted to correct. And public funding should not be the metric to determine who may access the drug or whether the drug's clinical trial information must be publicly disclosed—widespread access and disclosure are valuable even for entirely privately funded medical products.

This is not to say that measuring public R&D funding is fruitless. As noted previously, understanding how a particular funding mechanism connects to real-world outcomes (such as whether NIH grants crowd out private-sector investment) is critical for improving that mechanism going forward.[39] Others are interested in the role public funding plays in providing the government with legal or normative leverage over private-sector actors to strategically serve

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[38] National Institute of Mental Health (2023). "How and When to Use a CRADA." National Institutes of Health, Bethesda, MD. Available at: https://www.nimh.nih.gov/research/research-conducted-at-nimh/collaborations-and-partnerships/cooperative-and-development-research-agreements/how-and-when-to-use-a-crada.

[39] Azoulay *et al*., *supra* note 22.

other innovation policy goals.[40] But the extent to which medical innovations are "publicly funded" should not distract policymakers from the key first-order goals of biomedical innovation policy: saving lives and improving health, including by better aligning innovation incentives with social value and increasing access to valuable medical technologies.

3. US legal framework for public research and IP

The forms of public funding for biomedical research described in Section 2 are generally used as a complement to and not a substitute for IP protections such as patents, trade secrets, and FDA-administered regulatory exclusivity. Patents are used to protect medical inventions ranging from pharmaceutical compounds to AI-based diagnostic methods. (Utility patents are the key form of patent protection in this area, but design patents and plant patents can also be used to protect certain medical innovations, such as the ornamental design of a new medical device or a new variety of therapeutic plant.) Secrecy can be used to protect many kinds of information and know-how, either through formal assertions of trade secrecy protection under state or federal law, or through simply failing to disclose the information in ways that others could use. And regulatory exclusivity administered by the FDA prevents generic or biosimilar firms from relying on data submitted by a pioneer firm for a certain period (such as five years for a small-molecule drug with a new active ingredient and twelve years for a biologic drug), and sometimes prevents the FDA from approving an equivalent drug even with its own clinical trial data (such as for seven years after approval of an orphan drug).

In many cases, these forms of IP are mixed with non-IP incentives without restrictions. There are no limits on a firm's ability to use IP while simultaneously claiming R&D tax credits, receiving reimbursement from government insurance programs, or selling a completed product to the government in a procurement contract. And there are no separate legal rules governing regulatory exclusivity for FDA-approved products involving public funding. But there are US laws governing IP protections for innovations that received direct ex ante public funding, which are described in this section. Section 3.1 describes how inventions stemming from direct federal funding may generally be patented and exclusively licensed, subject to some government rights that have rarely been exercised. Section 3.2 then explains the greater federal efforts to require public access to the *information* resulting from publicly funded research, although enforcement has been lax and there are exceptions to protect certain information as trade secrets.

3.1 Patents under the Bayh-Dole and Stevenson-Wydler Acts

In 1980, Congress passed the Bayh-Dole Act to standardize policies related to patenting federally funded inventions, including inventions developed under traditional R&D grants and

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[40] Morten C. (2023). *Written Statement Before the United States Senate Committee on Health, Education, Labor & Pensions (HELP): Hearing Entitled "Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?"* Available at: https://www.help.senate.gov/imo/media/doc/Morten%20-%20Full%20written%20statement.pdf.

those developed under government R&D contracts. The stated goals of Bayh-Dole include "promot[ing] the utilization of inventions arising from federally supported research or development" and "promot[ing] collaboration between commercial concerns and nonprofit organizations."[41]

To accomplish these goals, Bayh-Dole allows extramural grant recipients to patent inventions created under those grants.[42] These patents may be exclusively licensed, with a preference for licensing to domestic manufacturers.[43] The Stevenson-Wydler Act of 1980 and Federal Technology Transfer Act of 1986 provide similar encouragement for patenting inventions developed intramurally in federal laboratories—such as NIH research institutes—or as part of CRADAs between federal laboratories and private firms.[44] Royalties earned from licensing publicly funded patents must be shared with the inventors both at nonprofit external contractors such as universities and at internal government laboratories.[45] These policies are implemented through contractual clauses placing conditions on public funding, which may be tailored to the circumstances of each agreement.[46]

The evidence base regarding the causal impact of patenting publicly funded inventions on innovation and commercialization is weak. Providing some degree of patent-based exclusivity as a commercialization incentive may be needed for most traditional pharmaceuticals, given the costs of clinical trials and the current concentration of drug development capacity in the private sector. But for the many publicly funded patents licensed *nonexclusively*—for which exclusivity is evidently *not* needed for commercialization—it remains unclear what social benefits they provide.[47] For example, there is no evidence that the financial incentive of patent royalties has any measurable impact on US university inventors.[48]

The Bayh-Dole and Stevenson-Wydler frameworks reserve several rights for the US Government. In particular, for patents obtained by external contractors or CRADA partners, the government retains a "nonexclusive, nontransferable, irrevocable, paid-up license."[49] In both contexts, the government also retains a right to "march-in" and issue additional licenses on "terms that are reasonable under the circumstances," including where necessary to meet "health or safety needs" that are not "reasonably satisfied" by the patent owner.[50]

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[41] 35 USC Section 200.
[42] 35 USC Section 202(a).
[43] 35 USC Section 204.
[44] 35 USC Sections 3710-3710d.
[45] 35 USC Section 202(c)(7)(B); 15 USC Section 3710c(a)(1)(A)(i).
[46] 37 C.F.R. Section 401.14.
[47] Ouellette L.L. and Weires R. (2019). "University Patenting: Is Private Law Serving Public Values?" *Michigan State Law Review*, Vol. 2019, No. 5, pp. 1329-1387.
[48] Ouellette L.L. and Tutt A. (2020). "How Do Patent Incentives Affect University Researchers?" *International Review of Law and Economics*, Vol. 61, Article No. 105883, pp. 1-20.
[49] 35 USC Section 202(c)(4); 15 USC Section 3710a(b)(1)(A).
[50] 35 USC Section 203(a); 15 USC Section 3710a(b)(1)(B)-(C).

So far, the NIH has declined every request to exercise march-in rights,[51] although the threat of march-in has encouraged private firms to make price reductions in several instances.[52] In December 2023, the Biden Administration proposed a framework that would allow the NIH and other agencies to exercise march-in rights if the high price of a drug makes it inaccessible to the US public.[53] In most cases, however, exercising government rights to publicly funded patents would not be effective because most products subject to a public patent are *also* protected by private-sector patents as well as by regulatory exclusivity and trade secret protection.[54] For example, as noted above, less than 2 percent of new small-molecule drugs approved by the FDA from 1981 to 2014 had exclusively public patents.[55]

In part because of the limitations of march-in, commentators concerned with patents limiting public access to biomedical innovations in the United States have recently highlighted a different legal approach. Whenever any patent—not just a publicly funded patent—is used "by or for the United States," Title 28 of the United States Code, Section 1498 specifies that the patentee's only remedy is a suit for money damages ("reasonable and entire compensation") in the US Court of Federal Claims.[56] Thus, patent infringement by the federal government may not be enjoined, effectively allowing a compulsory license for government use. The government historically has made little use of this provision in the medical context.

Many COVID-19-related procurement contracts authorize "use and manufacture of any invention described in and covered by a United States patent,"[57] and whether Section 1498 applies to these contracts is currently being litigated in the context of Arbutus's suit for patent infringement against Moderna's COVID-19 vaccine.[58] There is also scant case law on how "reasonable and entire compensation" should be determined for medical products, including whether lost profits damages should be available. Several scholars have proposed that Section 1498 could be used by the government to procure generic versions of patented pharmaceuticals in exchange for paying only reasonable royalties to the patent-holding

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[51] National Institutes of Health (2023). Technology transfer "Policies & Reports." National Institutes of Health, Bethesda, MD. Available at: https://www.techtransfer.nih.gov/policy/policies-reports.
[52] Knowledge Ecology International (2019). "Several March-in and Royalty Free Rights Cases, Under the Bayh-Dole Act." Available at: https://www.keionline.org/cl/march-in-royalty-free.
[53] National Institute of Standards and Technology (2023). "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights." 88 Fed. Reg. 85,593, Dec. 8, 2023.
[54] Sachs R. (2016). "March-in Rights Alone Won't Solve Our Drug Pricing Problems." *Bill of Health*, Jan. 16, 2016. Available at: https://blog.petrieflom.law.harvard.edu/2016/01/12/march-in-rights-alone-wont-solve-our-drug-pricing-problems.
[55] Durvasula *et al*., *supra* note 16.
[56] 28 USC Section 1498(a).
[57] Love, J. (2022). "KEI Review of 62 COVID 19 Contracts Reveals 59 Authorizations for Non-Voluntary Use of Third Party Patents Under 28 USC 1498." *Knowledge Ecology International*, July 20, 2022. Available at: https://www.keionline.org/37987.
[58] Brachmann S. (2023). "Pharma Companies, US Government Spar Over Application of Section 1498 to Patent Infringement Claims Against Moderna's COVID-19 Vaccine." *IP Watchdog*, March 8, 2023. Available at: https://ipwatchdog.com/2023/03/08/pharma-companies-u-s-government-spar-application-section-1498-patent-infringement-claims-modernas-covid-19-vaccine/id=157459.

companies,[59] including in national health emergencies.[60] However, these proposals acknowledge that Section 1498 does not address non-patent forms of IP, including FDA-administered regulatory exclusivity or trade secret protection, which would limit its practical effect in many cases.

3.2 Trade secrets and access to research results

Firms use secrecy to protect many medical research results, including clinical trial data, genome sequences, diagnostic algorithms and their training data, manufacturing innovations, tacit knowledge (i.e., information that is difficult to codify), and other know-how. The importance of trade secrets depends both on the strength of other forms of IP protection and on the degree to which technology transfer depends on tacit rather than codified knowledge. For example, trade secrets are more important for complex biologic drugs than for small-molecule drugs.

In contrast to the relatively uniform rules governing patents on federally funded research, the legal framework governing trade secrets and access to public research involves numerous federal and state laws and regulations that apply differently in different contexts. But also in contrast to the US Government's relatively hands-off approach to patents on publicly funded research, more substantial efforts have been made to promote public access to at least some of the information and data generated by federal R&D spending. As Jorge Contreras has summarized, the government plays many different roles in creating and maintaining biomedical data commons, including as a creator and funder of relevant data, a convenor of private-sector actors, and a curator of scientific data repositories.[61]

Trade secrets generally have been exempted from federal and state public records laws. The federal Freedom of Information Act (FOIA) has an exemption for "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[62] Requests under state public records laws for publicly funded information on animal tests, patient records, and contracts have been denied due to exceptions for trade secrets.[63] There are also specific protections for certain trade secrets obtained by federal agencies such as the FDA. Under the Trade Secrets Act, a federal employee who discloses confidential information "to any extent not authorized by law" faces criminal liability.[64] And under the Food, Drug, and Cosmetic Act, the FDA may not disclose information it obtains concerning "any method or process which as a

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[59] Brennan H., Kapczynski A., Monahan C.H., and Rizvi Z. (2016). "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health." *Yale Journal of Law and Technology*, Vol. 18, pp. 275-354.
[60] Morten C.J. and Duan C. (2020). "Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises." *Yale Journal of Law and Technology*, Vol. 23, pp. 1-96.
[61] Contreras J.L. (2017). "Leviathan in the Commons: Biomedical Data and the State." *Governing Medical Knowledge Commons*. Cambridge University Press (Strandburg K.J., Frischmann B.M., and Madison M.J. eds.), pp. 19-45.
[62] 5 USC Section 552(b)(4).
[63] Ghosh S. (2020). "Bayh-Dole Beyond Patents." *Research Handbook on Intellectual Property and Technology Transfer*, Edward Elgar Publishing, Cheltenham, UK (Rooksby J.H. ed.), pp. 69-91.
[64] 18 USC Section 1905.

trade secret is entitled to protection," such as information about pharmaceutical manufacturing processes.[65]

On the other hand, information related to medical innovations is often of public interest. Various statutes and regulations, including the Food and Drug Administration Amendments Act of 2007,[66] require drug and device sponsors to preregister most clinical trials—including privately funded trials—and submit summary results at the NIH's ClinicalTrials.gov website.[67] In its implementing regulations, the NIH explicitly rejected the argument that trade secrecy protection should exempt firms from submitting results.[68] Some scholars have argued that the FDA should demand even more disclosure, including about clinical trial data,[69] manufacturing innovations,[70] and AI-enabled medical software.[71]

In addition, research results generated under federal grants are subject to additional disclosure requirements, which were made stricter during the COVID-19 pandemic. The NIH's 2003 Data Sharing Policy stated an expectation that data resulting from NIH-funded research would be publicly shared,[72] and starting in 2009 the NIH Public Access Policy required that all publications resulting from NIH funding be publicly accessible in the National Library of Medicine's PubMed Central within 12 months of publication.[73] In 2013, the Office of Science and Technology Policy (OSTP) required all agencies to develop their own policies to improve public access to data and publications resulting from federally funded research, including free access to papers within 12 months of publication,[74] and a new policy issued by the OSTP in 2022 requires publications and their supporting data to be publicly accessible without any embargo period by 2026.[75] In line with this desire for greater disclosure, all NIH grant

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[65] 21 USC Section 331(j).
[66] 42 USC Section 282(j).
[67] National Institutes of Health (2021). "Why Should I Register and Submit Results?" National Institutes of Health, Bethesda, MD. Available at: https://clinicaltrials.gov/ct2/manage-recs/background.
[68] Clinical Trials Registration and Results Information Submission. 81 Fed. Reg. 64,981 (2017).
[69] Morten C.J. and Kapczynski A. (2021). "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines." *California Law Review*, Vol. 109, No. 2, pp. 493-558.
[70] Price W.N., II and Rai A.K. (2016). "Manufacturing Barriers to Biologics Competition and Innovation." *Iowa Law Review*, Vol. 101, No. 3, pp. 1023-1063.
[71] Rai A.K., Sharma I., and Silcox C. (2020). "Accountability, Secrecy, and Innovation in AI-Enabled Clinical Decision Software." *Journal of Law and the Biosciences*, Vol. 7, No. 1, lsaa077, pp. 1-26.
[72] National Institutes of Health (2003). "Final NIH Statement on Sharing Research Data." NOT-OD-03-032. Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.
[73] National Institutes of Health (2021). "NIH Public Access Policy Details." National Institutes of Health, Bethesda, MD. Available at: https://publicaccess.nih.gov/policy.htm.
[74] Holdren, J.P. (2013). "Increasing Access to the Results of Federally Funded Scientific Research." Office of Science and Technology Policy, Washington, DC. Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.
[75] Nelson A. (2022). "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research." Office of Science and Technology Policy, Washington, DC. Available at: https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf.

applications submitted after 2023 must have a more detailed data management and sharing plan.[76] The OSTP has not addressed how these access provisions should be funded.

Data developed under federal contracts are also subject to data-sharing requirements with the government. Data rights are typically governed by the Federal Acquisition Regulation (FAR) in contracts with civilian agencies, and by the Defense Federal Acquisition Regulation Supplement (DFARS) in contracts with the DOD.[77] Both sets of standard contract terms grant the government "unlimited rights" in technical data produced with government funds, meaning "rights to use, modify, reproduce, release, perform, display, or disclose" the data "in whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so."[78] For data produced under the contract partially or entirely with private funds, DFARS gives the government a more limited right to use the data for "government purposes."[79]

4. Public research and COVID-19

Innovation policymaking is often fundamentally different during a crisis, as was the case when the COVID-19 pandemic emerged in early 2020.[80] The US Government was the largest global source of public funding for COVID-19-related R&D and public procurement of COVID-19 vaccines and therapeutics. In contrast to the typical model, in which late-stage development is almost exclusively funded by the private sector, the US Government was involved in all stages of development of these products. During the first year of the COVID-19 pandemic, the NIH spent around $2 billion on COVID-19 research, and another $15 billion was spent on "Operation Warp Speed" manufacturing and procurement contracts through a partnership between the DOD and HHS's Biomedical Advanced Research and Development Authority (BARDA).[81] Some of this funding was direct ex ante spending on R&D such as clinical trials, but a large portion—including from Operation Warp Speed—was for a form of ex post reward: procurement orders that were conditional on the product successfully receiving FDA emergency use authorization or approval.

The most substantial and successful portion of federal COVID-19 funding was spent on vaccines, including R&D and procurement for the Moderna vaccine and procurement for the Pfizer/BioNTech vaccine. However, the US also invested in therapeutics, diagnostics, and other

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[76] National Institutes of Health (2023). "Data Management & Sharing Policy Overview." National Institutes of Health, Bethesda, MD. Available at: https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview.
[77] Cassidy S.B., Hastings A.B., and Plitsch J.L. (2017). "What Every Company Should Know About IP Rights When Selling to the US Government." *Landslide*, Vol. 9, No. 6, July/August 2017. Available at: https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2016-17/july-august/what-every-company-should-know-about-ip-rights-when-selling-us-government.
[78] FAR 52.227-14(a); DFARS 252.227-7013(a)(16), – 7014(a)(16).
[79] DFARS 252.227-7013(b)(2)(i)–(ii), – 7014(b)(2)(i)–(ii).
[80] Gross D.P. and Sampat B.N. (2022). "Crisis Innovation Policy from World War II to COVID-19." *Entrepreneurship and Innovation Policy and the Economy*, Vol. 1, No. 1, pp. 135-181.
[81] Sampat B.N. and Shadlen K.C. (2021). "The COVID-19 Innovation System." *Health Affairs*, Vol. 40, No. 3, pp. 400-409.

health technologies, and the resulting products were generally free to US residents. The history of these investments has been described in detail elsewhere, including by Sachs, Ouellette, Price, and Sherkow[82] and in an earlier WIPO-supported study by Rena Conti on the creation of COVID-19 vaccines.[83] This section focuses more narrowly on US policies related to IP and public access to publicly supported R&D. Section 4.1 describes public support for vaccine development and Section 4.2 focuses on therapeutics. Section 4.3 then turns to public development of information not tied to a specific pharmaceutical product, such as public health information on disease transmission and the value of masking and distancing. Overall, the successes and failures of these policies had little to do with IP law and more to do with how the government chose to invest its financial and organizational resources.

4.1 Vaccines

The seven vaccine companies that entered Operation Warp Speed contracts in 2020 were Moderna, Pfizer/BioNTech, Janssen (a subsidiary of Johnson & Johnson), Novavax, AstraZeneca, Sanofi Pasteur/GSK, and Merck/IAVI.[84] The US Government also entered Operation Warp Speed contracts for vaccine supplies such as glass vials and syringes. The FDA granted emergency use authorization for the Moderna and Pfizer vaccines in December 2020, for Janssen's in February 2021, and for Novavax's in July 2022. Full FDA approval was granted to Pfizer's vaccine in August 2021 and to Moderna's in January 2022. The AstraZeneca and Sanofi vaccines never received FDA authorization but were authorized for use in the European Union in January 2021 and October 2022, respectively. The Merck/IAVI vaccine was discontinued in January 2021 because it did not demonstrate sufficient efficacy.

The details of these contracts varied; for example, payment to Pfizer was only for procurement of completed and authorized vaccines (with no payment if the vaccine failed), while other companies received support for various stages of vaccine R&D or manufacturing in addition to procurement of successful vaccines. Companies that did not receive FDA authorization or provide the contracted-for supply did not receive the total contract award. For example, Novavax reported in 2023 that because it has not met all its Operation Warp Speed milestones, it may not receive the remaining $416 million it had anticipated under the contract, and it warned investors of "substantial doubt" about its "ability to continue as a going concern."[85]

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[82] Sachs R.E., Ouellette L.L., Price W.N., II, and Sherkow J.S. (2023). "Innovation Law and Covid-19: Promoting Incentives and Access for New Health Care Technologies." *COVID-19 and the Law: Disruption, Impact and Legacy*, Cambridge University Press, Cambridge, UK (Cohen G., Gluck A., Kraschel K., and Shachar C. eds.), pp. 225-236.
[83] Conti R.M. (2021). "The Determinants of COVID-19 Vaccine Development Success." World Intellectual Property Organization, Geneva, Switzerland (WIPO/GC/COVID-19/GE/22/WWW/572491). Available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=572491.
[84] Congressional Research Service (2021). "Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials." Washington, DC. Available at: https://crsreports.congress.gov/product/pdf/IN/IN11560.
[85] Novavax, Inc. (2023). Annual report to the Securities and Exchange Commission (Form 10-K). Available at: https://www.sec.gov/ix?doc=/Archives/edgar/data/1000694/000100069423000005/nvax-20221231.htm.

Operation Warp Speed has sometimes been referred to as "de-risking" vaccine investments, but "risk-reducing" is a more accurate descriptor. Public funding did not cover all costs, and procurement awards were contingent upon success, so manufacturers still bore the substantial risk of failure. For example, Moderna received enormous public funding in 2020 for vaccine development, but its private R&D expenses of nearly $1.4 billion exceeded all sources of revenue such that Moderna had a net loss of $0.75 billion, which would have been difficult to recover if their clinical trials had failed.[86]

In addition, the COVID-19 vaccines were built on sizeable pre-pandemic investments in vaccine technology, including substantial funding from private-sector sources. The extent to which Moderna's COVID-19 vaccine might be considered "publicly funded" depends on how these different contributions are valued. For example, Moderna received $60 million in grants from 2016 to 2019—primarily from the DOD, HHS, and the Bill & Melinda Gates Foundation—but that grant revenue represented a small portion (less than four percent) of its $1.64 billion in R&D expenses over the same period.[87] Moderna also benefited from a CRADA with NIH's National Institute of Allergies and Infectious Diseases dating to 2015, which did not provide any funding but did provide valuable technical expertise.[88] By the end of 2019, Moderna had accumulated losses of $1.5 billion in its efforts to develop a novel medical product based on mRNA, the technology that eventually led to its COVID-19 vaccine. The extent of "public funding" for that vaccine could be calculated based on the percentage of public versus private funding since the start of the pandemic, or since the start of the Moderna-NIH collaboration on mRNA technologies. Alternatively, it could be based on the scientific value of different actors' contributions, with some scholars arguing that the key scientific advances emerged from NIH and university scientists[89] or from earlier discoveries not specifically related to vaccines.[90] By any measure, the amount of public funding received by vaccine manufacturers was only a fraction of the vaccines' resulting social value.[91]

The Operation Warp Speed contract language was generally based on the FAR or DFARS contract language, with the contractor retaining IP ownership but granting some rights to the

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[86] Moderna, Inc. (2021). Annual report to the Securities and Exchange Commission (Form 10-K). Available at: https://www.sec.gov/ix?doc=/Archives/edgar/data/1682852/000168285221000006/mrna-20201231.htm.
[87] Moderna, Inc. (2020). Annual report to the Securities and Exchange Commission (Form 10-K). Available at: https://www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm.
[88] Moderna Therapeutics Inc.— Vaccine Research Center, National Institute of Allergy and Infectious Diseases (2015). "Confidential Disclosure Agreement." Available at: https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html.
[89] Morten C. (2023). Written statement before the United States Senate Committee on Health, Education, Labor & Pensions (HELP), hearing entitled "Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?" Available at: https://www.help.senate.gov/imo/media/doc/Morten%20-%20Full%20written%20statement.pdf.
[90] Dolgin E. (2021). "The Tangled History of mRNA Vaccines." *Nature*, Vol. 597, No. 7876, pp. 318-324.
[91] Fink C. (2022). "Calculating Private and Social Returns to COVID-19 Vaccine Innovation." World Intellectual Property Organization, Geneva, Switzerland (WIPO Economic Research Working Paper No. 68). Available at: https://www.wipo.int/publications/en/details.jsp?id=4595.

government, typically including Bayh-Dole patent march-in rights and some form of data rights. But because many of these contracts were based on agencies' "other transaction" authority—for agreements that are not traditional procurement contracts, grants, or cooperative agreements—they did not need to comply with Bayh-Dole or many procurement regulations.[92]

In her analysis of the IP provisions of vaccine contracts, Ana Santos Rutschman notes that they often distinguish between the "background" IP that one party controlled prior to the contract, which is typically shared through a nonexclusive license for the duration of the agreement, and "foreground" IP developed during an R&D collaboration, which may be owned by one party or jointly owned.[93] For example, an agreement between the US Government and Novavax granted each party a nonexclusive, nontransferable license to background IP (such as Novavax's IP related to the vaccine candidate it had funded), with the license limited to the rights necessary to perform contract obligations.[94] The agreement also granted Novavax ownership of all foreground IP developed under the agreement, with a nonexclusive, nontransferable license to the United States. In contrast, the first procurement agreement with Pfizer specifies that it "does not grant to the Government any license to practice the Background Inventions" and that "it is not funding the research of development of the vaccine," so that "the Bayh-Dole Act does not apply."[95]

Rutschman also observes that the vaccine contracts provide proprietary rights over data such as clinical trial results, sometimes describing them as forms of IP and sometimes as distinct property rights. For example, one of Moderna's vaccine development agreements provides the government with "unlimited rights to data funded under this contract,"[96] and a Novavax agreement grants "a Government purpose rights license to Subject Data that will convert to an unlimited rights license . . . after three (3) years from the date of delivery."[97] A contract with Janssen for vaccine manufacturing grants the government more limited "Government Purpose Rights in Data developed exclusively with Government funds under this Project Agreement," and it explicitly specifies that "data" does not include "production/manufacturing know-how, trade secrets, clinical data, or financial, administrative, cost, pricing or management information."[98] Pfizer's procurement contract grants the government an even more limited

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[92] Congressional Research Service (2020). "Legal Issues in COVID-19 Vaccine Development." Washington DC. Available at: https://crsreports.congress.gov/product/pdf/R/R46399/5.
[93] Rutschman A.S. (2023). "Vaccine Contracts in the Context of Pandemics and Epidemics." *New York University Journal of International Law and Politics*, Vol. 55, No. 3, pp. 689-738.
[94] US Department of Defense – Novavax (2020). "COVID-19 vaccine development agreement." Available at: https://ghiaa.org/provision_document/novavax-us-army-agreement-for-research-development-of-covid-19-vaccine-3.
[95] Department of the Army – Pfizer (2020). "COVID-19 vaccine procurement agreement." Available at: https://www.keionline.org/misc-docs/DOD-ATI-Pfizer-Technical-Direction-Letter-OTA-W15QKN-16-9-1002-21July2020.pdf.
[96] BARDA – Moderna (2020). COVID-19 vaccine development agreement. Available at: https://ghiaa.org/provision_document/moderna-barda-contract-for-development-of-mrna-vaccine-3.
[97] US Department of Defense – Novavax, *supra* note 94.
[98] US Department of Defense – Janssen (2020). "COVID-19 Vaccine Large Scale Manufacturing Agreement." Available at: https://ghiaa.org/provision_document/us-department-of-defense-janssen-covid-19-vaccine-large-scale-manufacturing-agreement.

nonexclusive license for data use (not disclosure) "only to the extent necessary for the Government to perform its obligations under this Agreement."[99]

The initial COVID-19 vaccine rollout in the United States was tragically slow, including due to demand that far outstripped supply.[100] By the summer of 2021, however, COVID-19 vaccines were widely and freely available to all US residents who wanted them. Even with uptake limited by vaccine hesitancy, the US vaccination campaign is estimated to have saved over a million lives in the first year.[101] Globally, vaccine shortages persisted for far longer, with relatively little effort by the United States to address the problem.

One widely discussed proposal to promote global vaccine access was waiving the requirements of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement at the World Trade Organization (WTO), which generally requires all but the least-developed nations to offer patents on all technologies. However, even the most expansive rights to vaccine patents and technical data would not have enabled another firm to make its own version of an existing COVID-19 vaccine.[102] The FDA regulates vaccines as "biologics," and the Biologics Price Competition and Innovation Act of 2010 (BPCIA) creates the possibility of a regulatory pathway for the generic version of a biologic, known as a "biosimilar." A biosimilar can only enter the market after twelve years of "data exclusivity," starting from when a brand-name biologic is first licensed by the FDA. But this pathway is not yet open to vaccines because the FDA and its counterparts abroad have not issued regulations indicating how a firm would show that its vaccine is biosimilar to an existing vaccine. Because vaccines cannot currently be biosimilars, marketing the new vaccine would require a new set of clinical trials to show that it is safe and effective. Expanding access to an existing vaccine currently can only be done under the authority of the original vaccine sponsor, such as under a joint venture where the original sponsor contracts with an additional manufacturer. As scholars such as Ken Shadlen have highlighted, IP can facilitate these kinds of partnerships.[103]

Thus, when many countries continued to face vaccine shortages in the fall of 2021, the US Government urged the most successful vaccine manufacturers—Pfizer and Moderna—to enter such joint ventures. This pressure led to Pfizer agreeing to sell more doses at a not-for-profit

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[99] Department of the Army – Pfizer, *supra* note 94.
[100] Ouellette L.L., Price N., Sachs R., and Sherkow J.S. (2021). "What Can Policymakers Learn from the Disastrously Slow COVID-19 Vaccine Rollout?" *Written Description*, Jan. 12, 2021. Available at: https://writtendescription.blogspot.com/2021/01/what-can-policymakers-learn-from.html.
[101] Schneider E.C., Shah A., Sah P., Moghadas S.M., Vilches T., and Galvani A.P. (2021). "The US COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?" *Commonwealth Fund*, Dec. 14, 2021. Available at: https://www.commonwealthfund.org/publications/issue-briefs/2021/dec/us-covid-19-vaccination-program-one-year-how-many-deaths-and.
[102] Ouellette L.L. (2021). "Stanford's Lisa Ouellette on Waiving COVID-19 Vaccine Patents." *Legal Aggregate*, May 4, 2021. Available at: https://law.stanford.edu/2021/05/04/stanfords-lisa-ouellette-on-waiving-covid-19-vaccine-patents.
[103] Shadlen K. (2020). "To Speed New COVID Vaccines, Look to Patenting." *Issues in Science and Technology*, Aug. 11, 2020. Available at: https://issues.org/covid-vaccines-development-distribution-patenting-shadlen.

price rather than contracting with additional manufacturers, and it led to no progress with Moderna, to reported "deep frustration" on the part of the government officials.[104] Some commentators argued that the government could have forced knowledge transfer under the Defense Production Act,[105] but it did not attempt to do so, or to create stronger incentives for firms like Pfizer and Moderna to scale up production more rapidly. The United States also provided scant support early in the pandemic for COVAX, an international effort to provide global access to COVID-19 vaccines. By 2022, when the distribution of existing doses became more of a bottleneck than the number of doses, the United States also failed to tackle the problem.[106] The TRIPS waiver discussion may have distracted from discussions about more effective steps the US Government could have taken to promote global vaccine production and distribution.

The US Government did, however, challenge Moderna's ownership of potential patent rights related to its mRNA-based vaccine. As noted above, Moderna had been working with scientists from the NIH's National Institute of Allergies and Infectious Diseases on mRNA technology since 2015, and in 2021 the NIH tried to get three of its researchers named on one of Moderna's patent applications.[107] Later that year, Moderna decided to abandon the patent application rather than pay the issuance fee to obtain the patent, although it filed a continuation application to preserve its ability to obtain a patent later.[108] In 2023, while this dispute was ongoing, Moderna separately agreed to pay $400 million to the NIH—to be shared with two universities—for their role in developing the mRNA technology.[109] At that point, Moderna had sold around $36 billion worth of COVID-19 vaccines worldwide.

4.2 Therapeutics

In contrast to its relative success in spurring COVID-19 vaccine development, the US Government devoted less attention to directly funding COVID-19 therapeutics or facilitating others' efforts along these lines. Clinical trials to test therapeutics in the United States were fragmented and faced costly regulatory barriers, and many patients were treated with

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[104] Nolen S. and Stolberg S.G. (2021). "Pressure Grows on US Companies to Share Covid Vaccine Technology." *New York Times*, Sept. 22, 2021. Available at: https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html.
[105] Rizvi Z., Ravinthiran J., and Kapczynski A. (2021). "Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide." *Health Affairs Forefront*, Aug. 6, 2021. Available at: https://www.healthaffairs.org/do/10.1377/forefront.20210804.101816/full.
[106] Wingrove J., Paton J., and Sguazzin A. (2022). "Failure to Address a Global Surplus of COVID Vaccines Raises the Risk of New Variants Emerging, Health Experts Warn." *Fortune*, May 11, 2022. Available at: https://fortune.com/2022/05/11/covid-19-vaccines-global-surplus-new-variants.
[107] Stolberg S.G. and Robbins R. (2021). "The N.I.H. Says it Isn't Giving up in its Patent Fight with Moderna." *New York Times*, Nov. 10, 2021. Available at: https://www.nytimes.com/2021/11/10/us/politics/moderna-vaccine-patent-nih.html.
[108] Davis R. (2021). "Moderna Backs off COVID Vaccine Patent in Dispute with NIH." *Law360*, Dec. 19, 2021. Available at: https://www.law360.com/articles/1450176/moderna-backs-off-covid-vaccine-patent-in-dispute-with-nih.
[109] Mueller B. (2023). "After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique." *New York Times*, Feb. 23, 2023. Available at: https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html.

candidates such as hydroxychloroquine, remdesivir, and convalescent plasma before more rigorous evidence emerged—mostly from other countries such as the UK—about the limited efficacy of these interventions.[110]

The US did enter some Operation Warp Speed contracts for monoclonal antibody treatments in the fall of 2020; however, as of October 2020, the value of these contracts was less than $1 billion, compared with $10 billion for six vaccines.[111] Of the four companies that appear to have entered these initial contracts,[112] Eli Lilly and Regeneron were the most successful; they received FDA emergency-use authorization for their therapeutic antibody products in November 2020 (later revoked due to lack of efficacy against the omicron variant).[113] AstraZeneca eventually received emergency-use authorization for pre-exposure prophylaxis (not treatment) in December 2021 (also later revoked), and SAb Biotherapeutics's antibody product never received authorization. As in the vaccine context, the scope of these contracts varied; for example, Eli Lilly's contract was only for procurement, whereas Regeneron, AstraZeneca, and SAb Biotherapeutics received additional support, such as for late-stage clinical trials or manufacturing.

Even Eli Lilly's and Regeneron's successful antibody products faced numerous distribution challenges, including because delivering antibodies to a patient is a complex and time-consuming process involving intravenous administration.[114]

It was not until December 2021 that the FDA authorized the first COVID-19 treatments in pill form, Pfizer's Paxlovid and Merck's and Ridgeback Biotherapeutics's molnupiravir, of which Paxlovid ended up being far more clinically successful. Public funding played some role in the development of molnupiravir: the antiviral compound was initially discovered before the pandemic with NIH funding at Emory University and licensed to Ridgeback, which then collaborated with Merck to fund all post-licensing development.[115] In June 2021, the Biden Administration entered an advance purchase contract for molnupiravir, but this was only for procurement, not manufacturing, and was contingent on the drug receiving FDA emergency use

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[110] Sachs R., Sherkow J.S., Ouellette L.L., and Price N. (2021). "What Can Policymakers Learn from the UK's RECOVERY Trial to Improve Clinical Research for COVID-19 and Beyond?" *Written Description*, May 3, 2021. Available at: https://writtendescription.blogspot.com/2021/05/what-can-policymakers-learn-from-uks.html.

[111] Brennan Z. (2020). "Warp Speed's Focus on Vaccines May Have Shortchanged Antibody Treatments." *Politico*, Oct. 2, 2020. Available at: https://www.politico.com/news/2020/10/02/warp-speed-covid-antibody-treatments-425649.

[112] Slaoui M., Greene S.E., Woodcock J. (2020). "Bridging the Gap at Warp Speed — Delivering Options for Preventing and Treating Covid-19." *New England Journal of Medicine*, Vol. 383, pp. 1899-1901.

[113] Centers for Medicare & Medicaid Services (2023). "COVID-19 Monoclonal Antibodies." Centers for Medicare & Medicaid Services, Baltimore, MD. Available at: https://www.cms.gov/monoclonal.

[114] Price N., Sachs R., Sherkow J.S., and Ouellette L.L. (2021). "Why Aren't Therapeutic Antibodies Being Used More to Treat COVID-19?" *Written Description*, Jan. 29, 2021. Available at: https://writtendescription.blogspot.com/2021/01/why-arent-therapeutic-antibodies-being.html.

[115] Ouellette L.L., Price N., Sachs R., and Sherkow J.S. (2021). "Molnupiravir May Become the First COVID-19 Pill. What Took So Long?" *Written Description*, Nov. 5, 2021. Available at: https://writtendescription.blogspot.com/2021/11/molnupiravir-may-become-first-covid-19.html.

authorization or approval.[116] Pfizer entered a similar purchase contract for Paxlovid in November 2021,[117] but it did not receive public funding for Paxlovid's development.

The government received at most limited IP rights through its contracts on COVID-19 therapeutics. For example, procurement contracts with Eli Lilly[118] and Merck[119] state that the firms would provide the government with a nonexclusive license to all relevant IP and data rights, but only if they first decided to terminate their own manufacturing or sale of the product concerned. Contracts with Regeneron[120] and AstraZeneca[121] that went beyond procurement explicitly specified that they were not subject to the Bayh-Dole Act; AstraZeneca's contract further disclaimed any government march-in rights, and Regeneron's contract limited march-in to cases where it "is unwilling or unable to manufacture or supply" the product. The government contract with Pfizer for Paxlovid provided no government IP rights, but it did provide a "Most Favored Nation Clause" that guaranteed the US Government would not pay more than the governments of six other wealthy countries (Canada, France, Germany, Italy, Japan, and the UK).[122]

4.3 Public health information

The COVID-19 innovation policy literature has focused mainly on concrete pharmaceutical interventions such as vaccines and therapeutics, which fit easily within a traditional IP framework. Vaccines and therapeutics can be protected with patents and other IP, and the IP owner can generally exclude others from making or using the inventions without permission. But especially in the first year of the pandemic before vaccines were available, some of the

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[116] HHS Press Office (2021). "Biden Administration Announces US Government Procurement of Merck's Investigational Antiviral Medicine for COVID-19 Treatment." US Department of Health and Human Services, Washington, DC. Available at: https://web.archive.org/web/20220307094158/https://www.hhs.gov/about/news/2021/06/09/biden-administration-announces-us-government-procurement-mercks-investigational-antiviral-medicine-covid-19-treatment.html.

[117] Pfizer (2021). "Pfizer to Provide US Government with 10 Million Treatment Courses of Investigational Oral Antiviral Candidate to Help Combat COVID-19." Nov. 18, 2021. Available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-provide-us-government-10-million-treatment-courses.

[118] Eli Lilly – US Government Natick Contracting Division (2020). Monoclonal antibody procurement agreement. Available at: https://www.keionline.org/misc-docs/FOIA/DoD-Eli-Lilly-Contract-W911QY21C0016-27Oct2020.pdf.

[119] Merck – US Government Natick Contracting Division (2021). Molnupiravir procurement agreement. Available at: https://www.keionline.org/misc-docs/FOIA/DOD-Merck-Contract-W911QY21C0031-7Jun2021.pdf.

[120] Regeneron – Advanced Technology International (2020). Monoclonal antibody manufacturing agreement. Available at: https://www.sec.gov/Archives/edgar/data/872589/000180422020000030/regn-ex102x09302020x10q.htm.

[121] AstraZeneca – US Government Natick Contracting Division (2020). Monoclonal antibody prototype project agreement. Available at: https://www.keionline.org/misc-docs/FOIA/DOD-AstraZeneca-Contract-W911QY2190001-9Oct2020.pdf.

[122] Lupkin S. (2022). "Feds' Contract with Pfizer for Paxlovid has Some Surprises." *NPR*, Feb. 1, 2022, https://www.npr.org/sections/health-shots/2022/02/01/1075876794/feds-contract-with-pfizer-for-paxlovid-has-some-surprises.

most valuable COVID-19-related R&D was related to public health information that was not tied to a concrete product and would have been difficult to protect with IP. For example, decisions by both public health officials and individuals trying to manage their own risk depended on information about the spread of the virus and the relative value of masking, ventilation, handwashing, social distancing, and other measures to reduce transmission.

As explained nearly a decade ago by Amy Kapczynski and Talha Syed, because this kind of public health information is generally "nonexcludable" through IP, it is under-incentivized by traditional market rewards, making a case for non-IP incentives such as public funding.[123] In the COVID-19 context, the US Government funded many studies on nonpharmaceutical interventions for addressing the pandemic, and the NIH's Public Access Policy (described in Section 3.2) helped ensure free access to these results. In addition, in June 2020, the National Library of Medicine launched the NIH Preprint Pilot to make voluntarily posted preprints reporting NIH-supported COVID-19 research available in PubMed Central.[124] By February 2023, the resulting 3,500 preprints were viewed 7 million times (not counting times viewed through the original preprint server or the eventual publication), and in 2023 the pilot was expanded to include all NIH-supported research.[125]

The results of publicly funded research studies were generally quickly and freely shared. The White House Office of Science and Technology Policy has lauded how the "shift in practice during COVID-19 demonstrated how delivering immediate public access to federally funded research publications and data can provide near real-time returns on American taxpayer investments in science and technology."[126] Nonetheless, the government could have done more to improve the reliability or clarity of these results, including by systematically directing public funding toward nonexcludable information for which underinvestment is most acute,[127] providing coordination for studies that depend on large-scale randomized trials,[128] and helping curate the resulting information to improve public trust in health decisions.[129]

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[123] Kapczynski and Syed, *supra* note 23.
[124] Funk K. (2020). "The NIH Preprint Pilot: A New Experiment for a New Era, National Library of Medicine." Bethesda, MD. Available at: https://nlmdirector.nlm.nih.gov/2020/06/09/the-nih-preprint-pilot-a-new-experiment-for-a-new-era.
[125] Funk, K. (2023). "NIH Preprint Pilot Expands to Include Preprints Across NIH-funded Research." National Library of Medicine, Bethesda, MD. Available at: https://nlmdirector.nlm.nih.gov/2023/02/08/nih-preprint-pilot-expands-to-include-preprints-across-nih-funded-research.
[126] Nelson, *supra* note 75.
[127] Ouellette L.L., Price N., Sachs R., and Sherkow J.S. (2020). "Nonexcludable Innovations and COVID-19." *Written Description*, May 27, 2020. Available at: https://writtendescription.blogspot.com/2020/05/nonexcludable-innovations-and-covid-19.html.
[128] Sachs *et al*., *supra* note 110.
[129] Ouellette L.L., Price N., Sachs R., and Sherkow J.S. (2020). "How Can Health Regulators Maintain Public Trust When Facing Scientific Uncertainty?" *Written Description*, June 24, 2020. Available at: https://writtendescription.blogspot.com/2020/06/how-can-health-regulators-maintain.html.

5. Best practices to prepare for the next pandemic

The alarming spread of COVID-19 has exposed and magnified the problems of an unprepared world. Excess mortality associated with COVID-19's first two years has been estimated at nearly 15 million globally and over 1 million in the United States,[130] with an economic cost to the United States of over $10 trillion.[131] COVID-19 has also exposed pervasive structural inequality, including by income and race, both within and across countries.[132] The tragedy of uneven access to healthcare has been compounded by a virus that disproportionately strikes the most vulnerable in society. But this tragedy also presents an opportunity to reexamine and improve biomedical innovation institutions.

This catastrophe was foreseeable and is likely to be repeated. Before COVID-19 spread across the globe, experts and global leaders urged much larger public investments in pandemic preparedness,[133] and the Global Preparedness Monitoring Board (GPMB)—an expert group convened by the World Bank and WHO—concluded that the "world is not prepared" for the "very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen killing 50 to 80 million people and wiping out nearly 5 percent of the world's economy."[134] COVID-19's emergence does not make the emergence of another devastating infectious disease less likely. Indeed, the GPMB noted that from 2011 through 2018, the WHO tracked 1,483 epidemic events in 172 countries, and that the number of infectious disease outbreaks is increasing. Policymakers should be better prepared for the next health emergency, including by learning from the new public funding models and IP-related issues that emerged during COVID-19.

As introduced above, reform of IP and innovation systems to better prepare for future health emergencies should be guided by two fundamental goals: (i) better aligning the incentives for innovation with the social value of the resulting innovations and (ii) providing broad access to the fruits of innovative research. The incentives for medical innovation and the choice of how access to those innovations is allocated are two separate policy questions. The US approach to both questions could be improved.

On the incentive side, there are many ways that incentives are not well aligned with social value, such as underpowered incentives for vaccines and other preventives and overpowered

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[130] Council of Economic Advisers (2022). "Excess Mortality During the Pandemic: The Role of Health Insurance." White House, Washington DC. Available at: https://www.whitehouse.gov/cea/written-materials/2022/07/12/excess-mortality-during-the-pandemic-the-role-of-health-insurance.
[131] Bruns R. and Teran N. (2022). "Weighing the Cost of the Pandemic, Institute for Progress." Available at: https://progress.institute/weighing-the-cost-of-the-pandemic.
[132] Yearby R. and Mohapatra S. (2020). "Law, Structural Racism, and the COVID-19 Pandemic." *Journal of Law and the Biosciences*, Vol. 7, No. 1, lsaa036.
[133] Friedman F. (2020). "We Were Warned." *Atlantic*, March 18, 2020. Available at: https://www.theatlantic.com/politics/archive/2020/03/pandemic-coronavirus-united-states-trump-cdc/608215.
[134] Global Preparedness Monitoring Board (2019). "A World at Risk: Annual report on global preparedness for health emergencies." Available at: https://www.gpmb.org/docs/librariesprovider17/default-document-library/annual-reports/gpmb-2019-annualreport-en.pdf.

incentives for products with negative externalities. Policymakers could address these incentives both through direct ex ante funding via the NIH that is more targeted to correcting existing distortions, and through ex post rewards such as Medicare and Medicaid reimbursements linked to a product's demonstrated social value compared with the existing standard of care.[135] Improving these rewards matters: Although there is no rigorous evidence that stronger patent rights increase research investments, a robust literature has documented that increasing the financial returns to patented products leads to increased innovation in the pharmaceutical industry.[136] To be clear, this innovation is not always welfare-enhancing, as in the case of "evergreening" developments that bring little added value for patients—the point is that firms tend to produce more of the innovations that receive larger financial rewards, so those rewards should be more aligned with the extent to which a product improves health and saves lives.

On the access side, the moral and economic case for making preventives and treatments broadly accessible is compelling, including for patients living outside the United States. US biomedical innovation institutions have often fallen short of this goal. Importantly, this goal of widespread access to medical innovations should be applied regardless of the amount of public funding (however defined) a given innovation received. In some cases, placing limits on IP rights and promoting generic competition can lead to new entrants that drive down prices and increase affordability for patients. Complementing these limits on IP rights with encouragement to engage in voluntary technology transfer—or affirmative obligations to do so—might further promote access.[137]

In other cases, competition is either technically or economically difficult or impossible even without IP protections. Consider, for example, the hundreds of off-patent, off-exclusivity small-molecule drugs that have no generic competitors,[138] the natural-monopoly characteristics of many biologic markets,[139] and the lack of *any* regulatory pathway for biosimilar vaccines.[140] But affordability for patients need not be in tension with IP rights or with large value-based rewards for developers—these are independent policy choices, and competitive entry is not the only tool to promote access. For example, the COVID-19 vaccine experience in the United States illustrates that high rewards to developers can be coupled with widespread access. Current US

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[135] Hemel and Ouellette. "Valuing Medical Innovation." *supra* note 5.
[136] For a detailed review, see Hemel and Ouellette, "Valuing Medical Innovation," *supra* note 5.
[137] Price W.N., II, Rai A.K., and Minssen T. (2020). "Knowledge Transfer for Large-Scale Vaccine Manufacturing." *Science*, Vol. 369, No. 6506, pp. 912-914; Fisher W.W., III *et al*. (2023). *Report of the Task Force on Voluntary Licensing and Access to Medicines*. Available at: https://ipxcourses.org/GAiA/VLAM_Report_v1.1.pdf.
[138] US Food and Drug Administration (2022). "List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic, US Food and Drug Administration." Silver Spring, MD. Available at: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic.
[139] Atteberry, P., Bach P.B., Ohn J.A., and Trusheim M.R. (2019). "Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition." *Health Affairs Forefront*, Apr. 15, 2019. Available at: https://www.healthaffairs.org/do/10.1377/forefront.20190405.396631.
[140] Sherkow J.S., Ouellette L.L., Price N., and Sachs R. (2021). "Are Patents the Cause of—or Solution to—COVID-19 Vaccine Innovation Problems? (No!)." *Written Description*, Mar. 4, 2021. Available at: https://writtendescription.blogspot.com/2021/03/are-patents-cause-ofor-solution-tocovid.html.

healthcare policy generally fails to achieve this goal more broadly, but efforts to expand Medicaid and Medicare and to reduce out-of-pocket costs for patients are steps in this direction.

Similar principles should guide public access to information related to new medical technologies, such as clinical trial data. In particular, disclosure should be required whenever it would enhance social welfare, including not only static effects (which generally favor disclosure) but also dynamic effects (such as the potential effect of mandated disclosure on whether the data will be generated in the first place[141]). The current lack of evidence on negative dynamic effects of disclosure suggests a presumption in favor of greater disclosure, with the burden on firms to provide evidence of any negative effects. As noted in Section 3.2, US policymakers have already taken steps toward requiring public access to publications and data resulting from federally funded research, and further access mandates could be informed by the policies adopted by nonprofit R&D funders that have faced similar issues.[142] But there is also value to disclosure of privately funded data. Whether data was "publicly funded" ought to matter to the cost-benefit analysis of its disclosure only insofar as the public funding affects the dynamic-efficiency costs or social benefits of disclosure.[143] It thus may make more sense to attach disclosure requirements to FDA approval than to receipt of a federal grant.

The optimal policies for implementing these fundamental goals are different in "normal" times and once the next global health emergency is upon us. In a crisis with large daily social losses, policymakers need to rapidly mobilize all sectors of the research community to quickly deliver solutions from the existing knowledge stock under conditions of uncertainty about how long the crisis will last—including the risk that a vaccine or other intervention might not be developed until after the acute phase of a pandemic has passed.[144] For example, following the 2009 H1N1 pandemic, the United States and several European governments reneged on promises to purchase vaccines against the virus from pharmaceutical companies, leaving those firms "holding the bag which contained hundreds of millions of dollars of development costs."[145] Similarly, the firms that pursued an Ebola vaccine in 2014 ended up taking substantial losses after the threat of the virus dissipated.[146] Before the next pandemic, it is thus important both to build the existing stock of knowledge related to prevention and treatment of infectious diseases and to create a predictable and credible framework for how solutions will be funded and disseminated during the crisis, and how research efforts will be coordinated.

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[141] Price W.N., II and Minssen T. (2015). "Will Clinical Trial Data Disclosure Reduce Incentives to Develop New Uses of Drugs?" *Nature Biotechnology*, Vol. 33, No. 7, pp. 685-686.
[142] Bill and Melinda Gates Foundation (2023). "Global Access Statement." Available at: https://www.gatesfoundation.org/about/policies-and-resources/global-access-statement.
[143] Sherkow, J.S. (2018). "Cancer's IP." *North Carolina Law Review*, Vol. 96, No. 2, pp. 297-380.
[144] Gross and Sampat, *supra* note 80.
[145] Economist (2020). "Can the World Find a Good Covid-19 Vaccine Quickly Enough?" *Economist*, Apr. 16, 2020. Available at: https://www.economist.com/briefing/2020/04/16/can-the-world-find-a-good-covid-19-vaccine-quickly-enough.
[146] Apuzzo M. and Kirkpatrick D.D. (2020). "Covid-19 Changed How the World Does Science, Together." *New York Times*, Apr. 14, 2020. Available at: https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html.

As steps toward creating more robust biomedical innovation systems in the United States, the Biden Administration proposed an ambitious American Pandemic Preparedness Plan in 2021,[147] and included $20 billion in funding for pandemic prevention and preparedness in its 2024 budget request.[148] Political hurdles have made it challenging to accomplish even these small changes, much less a more ambitious global health agenda. But hopefully policymakers can learn from the world's collective failures and successes in response to the COVID-19 pandemic to improve how IP and innovation policy can promote innovation, access to medical technologies, and public availability of research results before the next health emergency strikes.

[147] Sherkow J.S., Ouellette L.L., Price N., and Sachs R. (2021). "How Would the Proposed American Pandemic Preparedness Plan Help Address Underinvestment in Pandemic-Related Innovation?" *Written Description*, Sept. 27, 2021. Available at: https://writtendescription.blogspot.com/2021/09/how-would-proposed-american-pandemic.html.

[148] White House Office of Management and Budget (2024). *Budget of the US Government: Fiscal Year 2024*. Available at: https://www.whitehouse.gov/wp-content/uploads/2023/03/budget_fy2024.pdf.