GRANTS

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ABSTRACT

Innovation is a primary source of economic growth and is accordingly the target of substantial academic and government attention. Grants are a key tool in the government's arsenal to promote innovation, but legal academic studies of that arsenal have given them short shrift. Although patents, prizes, and regulator-enforced exclusivity are each the subject of substantial literature, grants are typically addressed briefly, if at all. According to the conventional story, grants may be the only feasible tool to drive basic research, as opposed to applied research, but they are a blunt tool for that task.

Three critiques of grants underlie this narrative: grants are allocated by government bureaucrats who lack much of the relevant information for optimal decision-making; grants are purely ex ante funding mechanisms and therefore lack accountability; and grants misallocate risk by saddling the government all the downside risk and giving the innovator all the upside. These critiques are largely wrong. Focusing on grants awarded by the National Institutes of Health (NIH), the largest public funder of biomedical research, this Article delves deeply into how grants actually work. It shows that—at least at the NIH—grants are awarded not by uninformed bureaucrats, but by panels of knowledgeable peer scientists with the benefit of extensive disclosures from applicants. It finds that grants provide accountability through repeated interactions over time. And it argues that the upside of grant-investments to the government is much greater than the lack of direct profits would suggest.

Grants also have two marked comparative strengths as innovation levers: they can support innovation where social value exceeds appropriable market value, and they can directly support innovation enablers—the people, institutions, processes, and infrastructure that shape and generate innovation. Where markets undervalue some socially important innovations, like

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cures for diseases of the poor, grants can help. Grants can also enable innovation by supporting its inputs: young or exceptional scientists, new institutions, research networks, and large datasets. Taken as a whole, grants do not form a monolithic, blunt innovation lever; instead, they provide a varied and nuanced set of policy options. Innovation scholars and policymakers should recognize and develop the usefulness of grants in promoting major social goals.

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I. INTRODUCTION

Grants play a key role in innovation policy. The federal government spent over $64 billion in 2016 in grants to support scientific research.[1] That sum is vastly more than the government spends on prizes (under $0.1 billion), nearly

1. *Historical Trends in Federal R&D*, AM. ASS'N FOR ADVANCEMENT SCI. https://www.aaas.org/programs/r-d-budget-and-policy/historical-trends-federal-rd [https://perma.cc/3P22-A45C] (last visited Mar. 9, 2019).

an order of magnitude greater than what it spends on research and development tax credits (about $10 billion), and comparable to what it spends on patents through a shadow tax on consumers (between $30 and $700 billion, though difficult to estimate).[2] Grants are especially prominent in the life sciences. The National Institutes of Health (NIH) is the world's largest public funder of biomedical research.[3] Every year, it administers over $29 billion in grant funding to over 300,000 researchers in over 2,500 institutions.[4] Through their scale and ubiquity, grants significantly shape the progress of science and innovation. Grants help determine which areas of science are studied and how, make or break the careers of academic and non-academic scientists alike, and guide the creation of new institutes and discipline-spanning resources.

So how should the grant system operate? When should we deploy grants instead of patents or prizes to drive innovation? Whom should we fund and what policies should govern that funding? These questions are not rhetorical: 2017 saw a high-profile fight between the Trump Administration and Congress about science funding levels[5] and an intense discussion in the scientific community about new NIH grant-funding policies.[6]

If these questions addressed changes to patent law, we could draw on an extensive literature about how patents shape innovation, what changes would have what impacts, and what we should think about when proposing new

2. Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303, 361, 371 (2013) (defining grants as including both funds directed to external researchers and funds spent on direct government research and basing patent expenditures on the patent-enabled supra-competitive pricing that constitutes a "shadow tax" on consumers of the patented good).

3. *See Grants & Funding*, NIH, https://www.nih.gov/grants-funding [https://perma.cc/8BJY-AZ4D] (last visited Mar. 9, 2019).

4. *See Budget*, NIH, https://www.nih.gov/about-nih/what-we-do/budget [https://perma.cc/PKP5-4WVZ] (last visited Mar. 9, 2019) [hereinafter NIH, *Budget*].

5. *See, e.g.*, Joel Achenbach & Lena H. Sun, *Trump Budget Seeks Huge Cuts to Science and Medical Research, Disease Prevention*, WASH. POST (May 23, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/05/22/trump-budget-seeks-huge-cuts-to-disease-prevention-and-medical-research-departments/ [https://perma.cc/UAY9-28Y5] (noting the early unfavorable reactions to Trump's proposed budget); Robert Pear, *Congress Rejects Trump Proposals to Cut Health Research Funds*, N.Y. TIMES (Sept. 11, 2017), https://www.nytimes.com/2017/09/11/us/politics/national-institutes-of-health-budget-trump.html [https://perma.cc/KA32-BCY3] (noting that Congress rejected Trump's proposed budget and introduced a bipartisan bill to increase spending).

6. *See, e.g.*, *Develop Your Budget*, NIH, https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm [https://perma.cc/6B4P-EFPK] (last visited Oct. 31, 2018) (providing instructions to create a budget and noting that there are "spending caps on certain expenses" in addition to salary caps); Sara Reardon, *NIH Announces Grant Limits*, 545 NATURE 142 (2017) (discussing the concerns of the scientific community in response to the NIH's new budget policy).

policies.[7] If these questions considered the structure or funding of prizes for achieving innovation goals, we could reach for another extensive literature tackling similar issues.[8] And if we wished to debate the relative merits of patents, prizes, pure market allocation, government procurement, tax subsidies for research-and-development, and grants, a substantial volume of scholarship addresses such comparative issues.[9] But the grant system itself? That occupies a much emptier shelf in the library of innovation law.[10]

In the uncommon instances where grants appear in this literature, they appear in comparative work evaluating the advantages and disadvantages of different policy mechanisms for promoting innovation. In this context, a consistent argument holds that grants suffer from an information disadvantage relative to patents, and, to a lesser extent, prizes and tax incentives, because they do not effectively aggregate private information.[11] A closely related point is that grants are particularly useful at funding basic research—that is, early-

7. *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977); Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985 (1999); Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255 (2009); John M. Golden, *Principles for Patent Remedies*, 88 TEX. L. REV. 505 (2010); Craig A. Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619 (2007); Colleen V. Chien, *From Arms Race to Marketplace: The Complex Patent Ecosystem and Its Implications for the Patent System*, 62 HASTINGS L.J. 297 (2010); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672 (2014).

8. *See* Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1003–05 (2014) (noting that "the past two decades have seen a virtual explosion of scholarship on prize systems, particularly within the economic and legal literatures on intellectual property, but also in political philosophy and public health" and providing extensive citations).

9. *See* Hemel & Ouellette, *supra* note 2, at 305 ("In recent years, articles comparing the relative merits of patents, prizes, and grants have consumed thousands of pages in law reviews and economics journals.") (citing Peter S. Menell & Suzanne Scotchmer, *Intellectual Property Law*, *in* 2 HANDBOOK OF LAW AND ECONOMICS 1473, 1530–34 (A. Mitchell Polinsky & Steven Shavell eds., 2007) (reviewing recent literature)).

10. *See, e.g.*, Laura Pedraza-Fariña, *The Social Origins of Innovation Failures*, 70 SMU L. REV. 377, 443 (2017) ("Legal scholarship on intellectual property and innovation law more broadly has paid comparatively little attention to how to design grants and prizes to foster innovation, and how grant-making interacts with other innovation policies—and patents in particular.").

11. *See* Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 11–14 (1969). This argument applies with equal force to other exclusivity-based incentive mechanisms, such as trade secrecy or regulatory exclusivity, since all exclusivity mechanisms rely on allowing the innovator to charge supra-competitive prices to capture a greater portion of the social welfare benefits of an innovation.

stage research without immediate commercial applications—because firms tend to undervalue basic research, which has substantial positive knowledge externalities.[12]

Within the innovation law literature's relatively sparse descriptions of grants, three critiques recur—sometimes as explicit critiques, sometimes as assumptions, sometimes as characterizations—about flaws in the grant system. To be clear, not all scholars writing about grants raise all these critiques, or make them uncritically. In this literature, grants are undertheorized, which is both the point and the challenge. I reviewed closely the existing, brief discussions of grants in the law-and-innovation literature, and common threads emerged.

Part II describes these critiques. First, grants are allocated by government bureaucrats who lack the market-value knowledge possessed by private firms and therefore make suboptimal decisions about allocating funding to projects.[13] Second, because grants provide non-contingent ex ante funding, they lack accountability and thus cannot ensure efficient and hard work by innovators.[14] And third, grants allocate risk suboptimally: the grantor takes essentially all of the downside risk of the project (if the innovation fails, the government is still out the money with nothing to show for it) and receives little of the upside benefit (if the project succeeds, the innovator licenses or commercializes the innovation, while the government misses out on the profits and may even end up paying high prices for the innovation).[15] Taken together, these critiques lead to the conclusion that while grants may be an adequate, if rather blunt, tool to drive basic research for which other innovation levers are unhelpful, those other levers are often preferable when available. Jonathan Adler, for instance, actively critiques the grant system on these grounds, concluding that "the federal government should shift a substantial portion of climate-related research and development funding from grants to prizes."[16] I suspect that these critiques are also responsible for the relative dearth of scholarship examining grants in depth. If grants are generally viewed as good for basic research but flawed relative to other incentive levers, why spend much time thinking about them?[17]

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12. *See infra* Part II.

13. *See infra* Section II.A.

14. *See infra* Section II.B.

15. *See infra* Section II.C.

16. Jonathan H. Adler, *Eyes on a Climate Prize: Rewarding Energy Innovation to Achieve Climate Stabilization*, 35 HARV. ENVTL. L. REV. 1, 4 (2011); *see infra* Part II.

17. There are other potential explanations. Laura Pedraza-Fariña and Stephanie Bair, for example, argue that legal scholars of innovation have focused on solving the free-rider problem to the exclusion of other innovation challenges. *See* Stephanie Bair & Laura Pedraza-

The reality of the current grant system belies these three critiques. Part III describes the grant system as it functions today, with substantial emphasis on grants awarded by the NIH—perhaps the world's most prominent grant funder—to researchers at other institutions, and rebuts each critique.[18] First, the mechanics of grant application, review, and funding refute the narrative that grants are allocated by information-poor bureaucrats. The grant system uses a rigorous process of peer review to determine which proposals will be funded. Part of this process involves detailed applications, which requires potential grant recipients to share their own private information about the likely costs and potential value of the proposed research. The evaluation itself leverages the expertise of scientists with relevant experience and knowledge. And the entire process is coordinated by agency representatives who combine their own scientific background with knowledge about the innovation priorities of the NIH and the government more generally.

Second, grantees are in fact accountable for grant-funded research. Each grant operates within a context of ongoing funding streams, reporting obligations, and repeat players. Even though any individual grant may lack its own strong accountability mechanisms, the practical need to get the next grant creates accountability for grant recipients.[19]

Third, the government gets more out of grants than the risk-allocation critique implies. It's true that the government does not usually profit directly from grant-funded innovations, whether they succeed or fail. But the government realizes a wide range of social benefits from innovation efforts, including the creation of negative knowledge, the generation of innovation structures, and the development of human capital.

Mistaken assumptions or inaccurate critiques change the relative desirability of grants as a substitute for other innovation levers when those levers fail. Consider patentable subject matter. Between 2012 and 2014, the Supreme Court held unpatentable a broad swath of inventions that could be

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Fariña, *Anti-Innovation Norms*, 112 NW. L. REV. 1069, 1076–78 (2018); *see also* Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 EMORY L.J. 1087, 1100 (2013) (similarly lamenting the narrow focus of legal-academic literature). Because grants do not address free-rider critiques directly, they may be of less interest to legal scholars with that focus.

18. I argue that basic lessons from the NIH are generalizable, *see infra* note 203 and accompanying text, but even to the extent they are not, understanding the workings of the world's largest public funder of biomedical research provides useful insight. *See* NIH, *supra* note 3.

19. The ongoing grant cycle has other benefits. For instance, the ongoing need to seek future grants impels grant recipients to generate publications that disclose results of funded work.

characterized as "laws of nature, natural phenomena, [or] abstract ideas."[20] These decisions prompted scholarly outcry: among other issues, what incentives would remain for inventions that subject to this characterization, like medical diagnostic methods or human genetic tests?[21] In fact, the Court raised exactly this question at oral argument.[22] As it turns out, many medical diagnostics and human genetic tests have been developed in large part by grant-funded researchers. Rather than worrying about decreased patent incentives, perhaps Congress should increase grant funding for these inventions instead.[23] If we think grants are fundamentally flawed innovation levers, they are less likely to seem like good substitutes when other levers fail. If, on the contrary, we are to use grants appropriately as a part of the innovation toolbox, we should know how they really work: when they are preferable substitutes, when they work poorly, and when they work best in concert with other innovation incentives.[24]

Part IV describes the rich tools the grant system supplies to policymakers, focusing on grants' two key comparative advantages. First, grants can support innovations whose social value exceeds their appropriable market value. This describes basic research; because later applications of basic research are variable and unpredictable, it has substantial spillovers (positive knowledge externalities), and is undersupplied by private firms relative to its social benefit.[25] Private firms also generate inadequate information about which basic research is worth funding. But a panel of experienced peer reviewers,

20. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 66 (2012) (citing Diamond v. Diehr, 450 U.S. 175, 185 (1981)); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 134 S. Ct. 2347, 2354 (2014).

21. *See* Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1907–13 (2016) (discussing the difficulties of obtaining patents in diagnostic methods); Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 264–78 (2015) (discussing how diagnostic methods have been categorized as "natural laws" rather than "applications").

22. *See* Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1116–17 (2015) (citing Justice Sotomayor's questions during oral argument of *Myriad* and *Mayo*).

23. *See id.* at 1137–41 (discussing other incentives that can take the place of absent patent incentives).

24. No innovation lever stands on its own; an innovation may be grant-funded in early phases, patented shortly thereafter, developed using secret processes and relying on tax-incentives, and even win a prize at the end. *See, e.g.*, Pierre Azoulay et al., *Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules*, 86 REV. ECON. STUD. 117, 140 (2019) (finding that a $10 million boost in NIH funding leads to around 2.5 additional patents).

25. *See generally* Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297, 302–04 (1959).

combined with disclosures from grant-seeking researchers, may be able to make precisely that determination. At a broader level, the market systematically undervalues some forms of innovation because market demand does not reflect social welfare value. A powerful example is innovation targeting diseases of the poor; because the poor often cannot pay for drugs, market signals do not reflect the social welfare benefits of developing those drugs. The grant system's reliance on non-price signals brings risks of inefficiency or cronyism, but its incorporation of non-market information also allows different, useful allocation of funds beyond what markets would pick.

Second, grants can directly support innovation enablers—the people, institutions, processes, and infrastructural resources involved in innovation—in a way largely unavailable to other forms of directed innovation incentives, especially patents and prizes. Basic research serves this role when it provides the grounding for later research, but it is only one example. Grants can develop human capital by providing training or otherwise enabling the research of young scientists who will have longer careers ahead of them. Grants can also target the processes or institutions of innovation by providing resources specifically for interdisciplinary research (to build collaborations and boundary-crossing networks) or for institutions (to provide physical or other resources for collections of individuals). Finally, they can support infrastructure, including datasets that enable future innovation, such as the Precision Medicine Initiative's All of Us dataset or the Human Genome Project (both NIH-funded).

When policymakers can leverage the grant system's strengths, grants can be an effective innovation lever. But the inverse is also true. In situations where private, market-based information accurately reflects the social value of an innovation, grants are probably not the best lever to drive that innovation because that private information can lead to an efficient allocation of innovative activity among firms and innovation targets.

This Article argues that the dominant picture of scientific grants in the innovation literature—the picture of a relatively straightforward and flawed tool mostly good for basic research—is far too simple. Grants form their own complex, massive set of innovation tools, with their own comparative strengths, and are a far larger, better, and more varied part of the innovation system than the innovation law literature has recognized.

II. GRANTS IN THE INNOVATION LAW LITERATURE

Grants are undertheorized in the legal innovation literature. Where they appear, it is principally as part of a comparison with other sorts of innovation incentives, though even those comparisons tend to focus on patents and

prizes, rather than grants.[26] Daniel Hemel and Lisa Ouellette, for instance, compare the innovation incentives of patents, prizes, grants, and tax R&D incentives.[27] They group incentives along three axes—who decides what innovation will be funded, who pays for the innovation, and when is the innovation funded—and conclude that each incentive is useful at different times.[28] Grants, they suggest, are most effective when the government is especially good at identifying costs and benefits and when social benefits exceed market signals of value—one of the two key strengths I describe here.[29] They also note an important timing feature of grants: ex ante funding can enable otherwise capital-constrained entities to innovate.[30] Joshua Sarnoff, Brett Frischmann, and Jonathan Adler have also considered grants in comparisons of innovation levers.[31] Characterizations of grants as an innovation incentive, whether comparative or otherwise, have tended to emphasize the information disadvantage faced by the grant system, but also the positive role of grants in funding basic research.

The basic information-asymmetry story proceeds as follows. Innovators determine whether to invest in a particular innovation based on their private

26. *Compare* Roin, *supra* note 8, at 1001–06 (providing approximately 4 pages worth of citations on prizes versus the patent system), *with* Hemel & Ouellette, *supra* note 2, at 320–21 (citing, in a prominent and thorough taxonomy of innovation incentives, only one unpublished manuscript and one law review article partially focused on grants). Camilla Hrdy has briefly addressed grants in the context of analyzing federal versus state and local incentives for innovation. *See* Camilla Hrdy, *Patent Nationally, Innovate Locally*, 31 BERKELEY TECH. L.J. 1301, 1357–63 (2016) [hereinafter Hrdy, *Patent Nationally*] (discussing federal financing for innovation, including grants, and arguing that such funding is limited to research with national benefits); *see also* Camilla Hrdy, *Commercialization Awards*, 2015 WIS. L. REV. 13, 52–53 (2015) [hereinafter Hrdy, *Commercialization Awards*] (discussing Small Business Innovation Research (SBIR) awards granted by federal research agencies like NIH).

27. Hemel & Ouellette, *supra* note 2, at 310–15.

28. *See id.* at 326–52.

29. *See id.* at 375–76. These two features are both involved in the grant system's ability to use different information than markets, described in Part IV.

30. *Id.* at 334–38.

31. *See* Sarnoff, *supra* note 17, at 1089–90 (considering a broad range of potential incentives in the climate-change context and noting the lack of empirical information on grant functioning); Joshua D. Sarnoff, *The Likely Mismatch Between Federal Research & Development Funding and Desired Innovation*, 18 VAND. J. ENT. & TECH. L. 363, 372 (2016) (lamenting the focus of innovation law scholarship on intellectual property and market solutions to innovation) [hereinafter Sarnoff, *Likely Mismatch*]; Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347, 352–53, 356, 389–90 (1999) (noting that grants are useful for the production of public goods but tax incentives are preferable in other situations); Adler, *supra* note 16, at 3–4 (comparing grants and prizes in the context of climate change technology and concluding that prizes are generally superior).

estimations of the cost of innovating and the innovation's market value.[32] Non-grant mechanisms alter this private-information-based calculus: patents allow firms to capture a larger fraction of the expected value of the innovation,[33] prizes typically set a known reward against the privately-estimated cost of innovating,[34] and tax incentives directly defray the cost of innovating.[35] Grants, on the other hand, provide ex ante funds to pay innovation costs directly and do not leverage private estimations of market value.

In 1983, Brian Wright showed formally that for patents to be superior to other innovation incentives, private firms must have more information than government funders.[36] Scholars tend to agree that private firms have such an information advantage.[37] Suzanne Scotchmer and Nancy Gallini, for instance, built on Wright's analysis and noted that grants are poor aggregators of private information.[38]

However, scholars have also long agreed that grants are important for funding basic research, though this agreement is grounded in the economics literature rather than the legal literature.[39] Basic research is aimed at increasing our scientific understanding of the world rather than focusing on useful products. In 1959, Richard Nelson noted that basic research has potential innovation benefits across a wide range of outputs and is often highly risky.[40] As a result, private industry tends to invest in basic research at socially suboptimal levels.[41] Kenneth Arrow reiterated this argument in 1962 and suggested that government funding of innovation helps resolve the problem, though such funding raises questions of how much to spend and how to

32. Hemel & Ouellette, *supra* note 2, at 326–27.

33. *See id.* at 327–28.

34. *See id.* at 327.

35. *See id.* at 328.

36. *See* Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691, 691 (1983). Among other things, Wright deliberately omits the possibility that the modeled innovation would provide information useful for future innovations and therefore of independent social value. *See id.* at 692 n.1.

37. *See, e.g.*, Hemel & Ouellette, *supra* note 9, at 327 ("Patents' ability to take advantage of private information is well recognized in the innovation-policy literature.").

38. Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Innovation System?*, 2 INNOV. POL'Y & ECON. 51, 54, 55–57 (2002).

39. *See, e.g.*, Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1721 (2008) (noting that grants "are probably the most important component of the innovation system, in supporting basic research"); *id.* at 1724 (claiming general agreement that grants are the right incentive for basic research, and that the only debate is about applied research).

40. *See* Nelson, *supra* note 25, at 304.

41. *See id.*

allocate it.[42] Despite these questions of allocation raised by Arrow, other incentive mechanisms, including patents and trade secrecy, are poor drivers of the production of basic knowledge, giving grants the comparative advantage.[43]

These assessments of grants, especially in comparison with other innovation policy levers, frequently incorporate three substantive critiques about how grants work. First is reliance on decision-making by government bureaucrats who often lack market actors' superior knowledge; second is the loss of accountability and incentives because grants rely on purely ex ante funding; and third is problematic risk-allocation because the funder bears the entire downside risk of the project and captures little of the upside benefit. Some find these critiques essentially dispositive; Jonathan Adler concludes that while "[f]ederal funding of science is worthwhile, particularly for basic scientific research[,] federal R&D money rarely produces commercially viable technologies or dramatic technological innovation."[44] The following Sections detail each critique.

A. BUREAUCRATIC DECISION-MAKING

Some criticize the grant system because it puts funding decisions in the hands of relatively uninformed government bureaucrats. As Adler puts it, "With government research grants . . . a federal agency typically determines the goal to be achieved, the means to achieve that goal, and who will receive funding to pursue it."[45] Frischmann agrees: "[T]he selection process for grants relies on the government's ability to assess the desirability of a project when compared with an array of others . . . ."[46] Lobbying groups have sometimes seized on this complaint; the director of the Traditional Values Coalition described NIH funding as "nameless, faceless bureaucrats doling out money

42. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 619, 623 (1962).

43. *See, e.g.*, Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1905–06 (2013) (noting the challenge of appropriating the benefits of basic knowledge); Eisenberg, *supra* note 21, at 256 (noting the inability of patents to claim basic biomedical knowledge used in diagnostics under current law); Peter Lee, *Social Innovation*, 92 WASH. U. L. REV. 1, 24–42 (2014) (describing limitations of patents in creating incentives for social innovation); *id.* at 47–52 (describing how government grants might help create such incentives).

44. Adler, *supra* note 16, at 30.

45. *Id.* at 14.

46. Frischmann, *supra* note 31, at 353; *see* Hemel & Ouellette, *supra* note 2, at 307 ("For grants . . . the government tailors the reward on a project-by-project or discovery-by-discovery basis.").

like a federal ATM . . . ."[47]

This critique can involve concerns of either inadequate information or cronyism. First, the government lacks information, at least relative to firms. Firms may have private knowledge about both the general costs and benefits of a potential innovation (relevant to the choice of which innovation to fund) and about their own costs in pursuing that innovation (relevant to the choice of which firm should pursue the innovation); the patent system especially leverages private knowledge by letting firms decide which innovation to pursue.[48] Conversely, the government's lack of this private information likely leads to suboptimal choices about what innovation to fund and who should undertake it.[49] Michael Abramowicz argues specifically in the context of orphan drugs that government officials are ill-equipped to distinguish efficient from inefficient innovation subsidies.[50] Zachary Liscow and Quentin Karpilow capture this general concern about information asymmetries when they note IP scholars' deep "skepticism toward the government 'picking winners' to encourage innovation in some technologies over others."[51]

Second, leaving funding decisions in the hands of bureaucrats may result in cronyism, favoritism, and political pressure shaping the process of grant-funding and scientific progress. Adler argues that historically, patrons of

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47. Rick Weiss, *NIH Faces Criticism on Grants*, WASH. POST (Oct. 30, 2003), https://www.washingtonpost.com/archive/politics/2003/10/30/nih-faces-criticism-on-grants/504677ed-4c30-498e-b458-c992ecf6c6f4/?utm_term=.df4269595c8d [https://perma.cc/65YK-JZRT]. The Coalition's concerns eventually led to Senate hearings. Rick Weiss, *Critics of NIH Studies Prompt Senate Hearings*, WASH. POST (Jan. 19, 2004), https://www.washingtonpost.com/archive/politics/2004/01/19/critics-of-nih-studies-prompt-senate-hearing/fa9de180-39ab-4dca-8757-34e7dfb80b4e/?utm_term=.4a2e01a478c7 [https://perma.cc/2UHY-J9KX].

48. *See* Gallini & Scotchmer, *supra* note 38, at 54–55 (explaining that IP has substantial benefits if firms have superior knowledge); *see also* Wright, *supra* note 36, at 703 (noting that patents benefit from "ex ante researcher information relating to the value of the invention").

49. *See* Adler, *supra* note 16, at 29 ("Allocating grant money effectively requires the grant-making entity to pick 'winners' and 'losers,' something the government has rarely done well."). Frischmann notes:

> [T]he selection process for grants relies on the government's ability to assess the desirability of a project when compared with an array of others . . . . If the research is expected to further a commercial end then tax incentives may be more effective than grants because final project selection is left to the best informed investor, the firm.

Frischmann, *supra* note 31, at 353.

50. *See* Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1366–67 (2011).

51. Zachary D. Liscow & Quentin Karpilow, *Innovation Snowballing and Climate Law*, 95 WASH. U. L. REV. 387, 390 n.9 (2017); *see also* Lee, *supra* note 43, at 52 ("[G]overnments are notoriously poor at 'picking winners.' ").

science preferred grants to prizes because grants entailed greater discretion, so that patrons could "reward their friends and allies and ensure that only those with the right ideas received funding."[52] Cronyism and corruption lead to many ills, including inefficiency, decreased trust in government, and lower innovation, as only ideas that match the idiosyncratic preferences of the funder receive funding.

B. UNACCOUNTABLE EX ANTE INCENTIVES

A second major critique relates to the ex ante nature of grant funding and its consequent lack of accountability. Grants provide funds ex ante to researchers without conditioning the funds on success.[53] Thus, the argument goes, grants provide less accountability and lower incentives to researchers to work hard and to use resources efficiently.[54] Sarnoff laments that "direct subsidies may be provided to university professors who fail to produce quality research" and thus "over-reward innovation efforts."[55] As Gallini and Scotchmer memorably describe it, in one-off grant contexts, "researchers might be inclined to 'take the money and run.' "[56] Hemel and Ouellette add that this unconditionality may cause problems earlier in the process, leaving grant-seeking researchers with lower incentives when choosing projects.[57]

The researcher, in this critique, has little skin in the game, in striking contrast to patents, prizes, or even R&D tax incentives. Under those regimes, the researcher must spend her own money to conduct the research or acquire funding from private sources with, presumably, strings attached.[58] And if she

52. Adler, *supra* note 16, at 23 (citing Robin Hanson, Patterns of Patronage: Why Grants Won over Prizes in Science 17 (July 28, 1998) (unpublished manuscript) (on file with Harvard Law School Library)); *see also id.* at 29 ("[T]raditional grant funding is more subject to political pressure[.]").

53. Indeed, if grants were conditioned on success, they would merely be prizes with precedent loans. Grants may condition continued funding on other requirements, such as continued reporting, documented expenditures, or something else; these complications will be described below. *See infra* Section III.B.2.a.

54. *See, e.g.*, Arrow, *supra* note 42, at 624 (noting this problem and describing potential mitigating factors); *see also* Sarnoff, *supra* note 17, at 1125.

55. Sarnoff, *supra* note 17, at 1125.

56. Gallini & Scotchmer, *supra* note 38, at 54 (making and then immediately critiquing this critique).

57. Hemel & Ouellette, *supra* note 9, at 334 (quoting Rachel Glennerster, Michael Kremer & Heidi Williams, *Creating Markets for Vaccines*, 1 INNOVATIONS: TECH., GOVERNANCE, GLOBALIZATION 67, 71 (2006)). Of course, the ability of researchers to later pursue patents on their innovations results in blending the incentive features of grants and patents.

58. *See* Hemel & Ouellette, *supra* note 9, at 334–37. As Hemel and Ouellette note, the case of tax incentives is slightly more complicated; they create approximately ex ante incentives

does not succeed in the research, she gets nothing—patents typically provide a route to profit only if a successful product is created, prizes go only to the victor, and R&D tax incentives are usually meaningless without underlying profits. Thus, she faces incentives to conduct her work efficiently, effectively, and successfully to recoup her own expended funds. Grants, in this view, provide few incentives in the same vein.

C. PROBLEMATIC RISK ALLOCATION

The third, related critique involves the allocation of risk in grant-funded research efforts. Brett Frischmann argues that "when utilizing grants, the government, as investor-principal, often bears the entire downside risk of an unsuccessful project."[59] Because of the unconditionality of grants, when a grant-funded researcher fails to innovate, the funder has no way to recover the expended funds. This critique implicitly relies on a private-contracting analogy, where the government, as innovation funder, has the same sort of profit-and-loss incentives as a private party. The reality, as discussed below, is more complex.[60]

The other half of this critique is that the grantor also receives little of any upside benefit of successful innovation. If the government funds groundbreaking research that results in a blockbuster drug, the government receives none of the profit—and in fact, is instead likely to pay much of that drug's future cost because it pays for a large fraction of health-care costs.[61] Under an older, contrasting model, the federal government retained robust rights in research it funded, though it rarely exploited them.[62] This model largely ended with the enactment of the Bayh-Dole Act of 1980.[63] Under Bayh-Dole, grant recipients keep patent rights to federally funded research, with the rationale that these private actors can more effectively act to commercialize

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that are available within the same year as the funding, but they require some source of stop-gap funding such as venture capital or other resources; and if a company fails or has no income, tax credits are worthless. *See id.* at 336–37. These concerns are mitigated by fully refundable tax credits, offered by some states. *See id.* at 337–38.

59. Frischmann, *supra* note 31, at 387 (cited with approval by Sarnoff, *supra* note 17, at 1118).

60. *See infra* Section IV.A.1.

61. *See, e.g.*, Roin, *supra* note 8, at 1039–44 (describing government payments for drugs through health insurance systems).

62. *See* Danielle Conway-Jones, *Research and Development Deliverables under Government Contracts, Grants, Cooperative Agreements and CRADAs: University Roles, Government Responsibilities and Contractor Rights*, 9 COMP. L. REV. & TECH. J. 181, 186–88 (2004) (describing the history of federal rights in funded research).

63. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended in various sections of 35 U.S.C.).

the nascent technology.[64] A vast literature considers the benefits of this move.[65] Notwithstanding whether this transfer of rights to private parties was necessary or beneficial on net, the fact remains that because the government does not retain rights to funded inventions, it lacks the ability to capture the upside of those inventions and often must pay to access them.[66]

This complaint about government inability to capture the upside of grant-funded research appears most forcefully in the public health literature, where scholars decry the lack of access to the products of government-funded research.[67] In the innovation literature, on the contrary, the cost of reduced access is often classified as a necessary evil to drive the commercialization effort.[68]

III. GRANTS IN PRACTICE (AT THE NATIONAL INSTITUTES OF HEALTH)

This Part describes how grants really work. It begins with a basic overview of the grants ecosystem. It then turns to the NIH, and describes in

64. 35 U.S.C. § 202 (2018); *see* Conway-Jones, *supra* note 62, at 188–92 (giving a history of technology transfer legislation and executive actions). The Bayh-Dole Act addressed only universities and nonprofits. The Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96480, 94 Stat. 2311 (codified at 15 U.S.C. § 1701), in a parallel structure, enabled government researchers to retain title to patents. And Executive Order 12618 extended the Bayh-Dole Act to for-profit corporations.

65. For a few places to start, see, for example, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289 (2003); Emily Michiko Morris, *The Many Faces of Bayh-Dole*, 54 DUQ. L. REV. 81 (2016); DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT (2004).

66. Under § 202(c)(4) of the Bayh-Dole Act, the federal funding agency shall receive a worldwide, nonexclusive, nontransferable, irrevocable, fully paid-up license to practice the invention on behalf of the United States (or have the invention practiced). However, the Bayh-Dole Act covers only federally funded research and may not cover other patented inventions necessary to practice the innovation.

67. *See, e.g.*, Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFF. 791 (2016) (describing the problem and proposing the use of 28 U.S.C. § 1498 (2018) to help address the concern).

68. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standard of Patentability*, 87 TEX. L. REV. 503, 507–15 (2009) (describing the rationale for patents to allow firms to recover the high costs of drug discovery); *but see, e.g.*, Glennerster et al., *supra* note 57, at 68–70, 77 (describing the desirability of minimizing deadweight loss from drug patents).

considerable detail the NIH grant-funding process, organized around the three critiques presented in Part I.

A. AN OVERVIEW OF GRANTS

External grants funded by the NIH are the focus of this Article, but some initial context is useful. The NIH is not the only funder of grants in the federal government, the federal government is not the only funder of grants, and grants are not the only way the federal government invests directly in research.

How do grants work, at a basic level? Typically, the sponsoring agency solicits applications for funding (at the NIH, frequently "requests for applications," or RFAs) at a particular level of generality, which can range from almost totally open calls for worthy research to very specific calls for proposals to address a particular issue.[69] Prospective grantees submit applications, which typically include information about their qualifications, the research they propose to undertake (often including preliminary data), and how much they expect it to cost—that is, how they expect to spend the grant funds. The grantor decides through some mechanism—much more on this later—which of the applications, if any, to fund, and then disburses the money either fully prospectively, in tranches, or as reimbursements once research expenses are incurred.[70] Often, grants come with obligations, which can range from acknowledging the funder to committing to make any resulting knowledge publicly available.[71]

Grants are not the only way the government directly funds innovation.[72] The government may also directly conduct intramural research by employing scientists at, for instance, National Laboratories or laboratories at the NIH or the Centers for Disease Control and Prevention.[73] If the federal government relies instead on non-governmental researchers, it uses grants when it wishes to fund research but does not "acquire . . . property or services for the direct benefit or use of the United States Government" and "substantial involvement" of the federal agency is not expected.[74] If the government will

69. *See infra* Section III.B.1.

70. *See* NIH, NIH GRANTS POLICY STATEMENT IIA-59 (2016) [hereinafter NIH GRANTS POLICY STATEMENT].

71. *See infra* Section III.B.2 (describing disclosure requirements).

72. Indirectly, the government funds innovation through several mechanisms already mentioned, including R&D tax credits and the enforcement of patent and trade secrecy laws (which fund research through ex post "shadow taxes" on users of the patented or secret technology). *See* Hemel & Ouellette, *supra* note 9, at 320–26.

73. *See* Sarnoff, *supra* note 17, at 1132–36 (describing the role of government agencies in promoting research and development).

74. 31 U.S.C. § 6304 (2018).

acquire goods or services, it uses the procurement system—a $440-billion-annual-spending behemoth[75]—instead.[76] If the federal agency expects to be substantially involved, such as in collaborations between National Laboratories and private industry, the agency uses Collaborative Research and Development Agreements (CRADAs) to direct the collaboration.[77] The federal government may also offer prizes, though these remain rare and limited.[78] While each of these different forms of direct government subsidy is substantial and important,[79] this Article focuses on federal extramural grants: the distribution of funding to innovators outside the government's walls without the expectation of government involvement or government receipt of goods or services. Such grants are especially important to university researchers.[80]

Although federal agencies are the dominant grant funders today, this was not always the case and they are not the only source of grant funding. Governments at any level, including federal, state, and local, may fund research grants.[81] Private not-for-profit organizations may also fund research grants.[82] Grants may be funded internally by universities or other research institutes out of their own funds.[83] Finally, grants may be funded by private industry, a funding source that has received increasing attention though it remains comparatively small.[84] International grant funding is similarly diverse, though

75. NAT'L CONTRACT MGMT ASS'N, ANNUAL REVIEW OF GOVERNMENT CONTRACTING 2 (2016).

76. *See* 31 U.S.C. § 6303 (2018); Conway-Jones, *supra* note 62, at 192-97 (detailing the rights and responsibilities of government and contractors in procurement agreements).

77. 31 U.S.C. § 6305 (2018).

78. *See* Hemel & Ouellette, *supra* note 9, at 317–18.

79. *See, e.g.*, Sarnoff, *Likely Mismatch*, *supra* note 31, at 375–80 (comparing several direct sources of government funding, focusing on direct funding over market regulation like patent law).

80. Barry Bozeman & Monica Gaughan, *Impact of Grants and Contracts on Academic Researchers' Interactions with Industry*, 36 RESEARCH POL'Y 694, 694 (2007).

81. *See, e.g.*, *All CIRM Grants*, CAL. INST. REGENERATIVE MED., https://www.cirm.ca.gov/grants [https://perma.cc/BC2F-R6ZG] (last visited March 10, 2019) (listing grants awarded by California's state-funded stem-cell research agency). For a description of how state and local governments provide innovation financing more generally, see Hrdy, *Patent Nationally*, *supra* note 26, at 1363–75.

82. *See* LILY E. KAY, THE MOLECULAR VISION OF LIFE (1993), *passim* (describing the support provided by the Rockefeller Foundation for the California Institute of Technology and its development of the field of molecular biology).

83. *See, e.g.*, *MCubed*, UNIV. MICH., http://mcubed.umich.edu/ [https://perma.cc/PR8R-ZDUU] (last visited March 10, 2019) (describing the university-funded MCubed grant program for intramural research).

84. Bozeman & Gaughan, *supra* note 80, at 694 ("[A]t no time during the history of the modern U.S. research university . . . has industry provided as much support for *university*

the relative balance between different governmental levels, not-for-profit, and for-profit funding may vary between countries.[85]

In the United States, federal research grants have grown tremendously in the last half-century.[86] In the first half of the twentieth century, private foundations provided most extramural funding; the Rockefeller Foundation, for instance, was mostly responsible for the early growth of molecular biology as a field.[87] After World War II, the federal science budget grew tremendously, and the government displaced private foundations to become the dominant funder of research.[88] Today, while the private sector spends more on research than the federal government does, it spends mostly within its own walls; the federal government remains the dominant source of extramural scientific grant funding, especially for basic research.[89]

Within the federal government, many agencies fund research through grants, including the Department of Defense, the Environmental Protection Agency, and the Department of Energy.[90] Two agencies especially focus on funding basic research: the National Science Foundation (NSF) and the NIH. The NSF funds research across many scientific fields, including substantial amounts of basic biological research.[91] But the largest funder of grant-based

research as any of the top five government funding agencies."). Private R&D funding as a whole is large, but mostly intramural. *See id.* (noting that industry is the leading source of R&D funding nationally). Nonetheless, industry grants have been perceived as having outsized importance relative to their size. *See id.* at 695; *see also* Mats Benner & Ulf Sandstrom, *Institutionalizing the Triple Helix: Research Funding and Norms in the Academic System*, 29 RES. POL'Y 291, 293 (2000) (noting how industry funding can change research trajectories).

85. An overview of the international grant system is beyond the scope of this Article. For a few useful resources, see, e.g., Christoph Grimpe, *Extramural Research Grants and Scientists' Funding Strategies: Beggars Cannot be Choosers?*, 41 RES. POL'Y 1448, 1450 (2012) (giving an overview of the European and German grant systems); SUSAN WRIGHT, MOLECULAR POLITICS 32–36, 60–63 (1994) (giving a history of the United Kingdom's grant-funding system in the twentieth century).

86. WRIGHT, *supra* note 85, at 21.

87. *Id.*; *see also* KAY, *supra* note 82, *passim*.

88. WRIGHT, *supra* note 85, at 21.

89. *See* Mike Henry, *US R&D Spending at All-Time High, Federal Share Reaches Record Low*, AM. INST. PHYSICS (Nov. 8, 2016), https://www.aip.org/fyi/2016/us-rd-spending-all-time-high-federal-share-reaches-record-low [https://perma.cc/VJG5-GRLA] (noting that private spending reached 69% of total R&D while federal spending dropped to 23%, but also noting that the federal government remains the top funder of basic research).

90. *See Grant-Making Agencies*, GRANTS.GOV, https://www.grants.gov/web/grants/learn-grants/grant-making-agencies.html [https://perma.cc/S8MZ-DN3N] (last visited March 10, 2019).

91. Richard Freeman & John Van Reenen, *What If Congress Doubled R&D Spending on the Physical Sciences?*, 9 INNOVATION POL'Y & ECON. 1, 6 (2009); Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 HIGH TECH. L.J. 1, 15–16.

research by far, focusing entirely on biomedical science, is the NIH, "the center of a vast research system unmatched in size and scope throughout the world."[92] The NIH comprises twenty-seven different Institutes and Centers (collectively, "Institutes"), each focused on a "specific disease area, organ system, or stage of life"; examples include the National Cancer Institute, the National Human Genome Research Institute, and the National Institute on Aging.[93] Of these, twenty-four make grant awards.[94] The NIH expends about $37.3 billion in biomedical research per year; 10% of that is spent on its own intramural research programs, and around 80% on extramural grants.[95] "[I]n the market for biomedical research, NIH is the 800 pound gorilla."[96]

B. TESTING THE THREE CRITIQUES AT THE NIH

Part II introduced three critiques of the grant system: they rely on bureaucratic decision-making; they are largely unaccountable due to ex ante funding; and they poorly allocate risk by giving the grantor most of the downside risk and little of the upside. These critiques largely fail to reflect the reality of the modern grant system, at least as practiced at the NIH. Uninformed bureaucrats do not make the principal funding decisions, which are instead effectively made by panels of well-informed peer scientists. Funding is only ex ante and (mostly) unaccountable for single grants, but researchers are repeat players and depend on the *next* grant as well, creating accountability.[97] And rather than misallocating downside risk entirely to the NIH and the upside entirely to the researcher, the NIH actually sees much more upside benefit—and researchers more downside cost.

1. Bureaucratic Decision-Making

How are grant decisions made at the NIH?[98] In brief: the NIH seeks grant applications, peer reviewers evaluate and compare the grant applications

92. WRIGHT, *supra* note 85, at 26.

93. For a full list of the twenty-seven institutes and centers, see *List of NIH Institutes, Centers, and Offices*, NIH, https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices [https://perma.cc/5TMP-2LTN] (last visited Mar. 11, 2019) [hereinafter *List of NIH Institutes*].

94. *Understanding the NIH: Finding the Right Fit for Your Research*, NIH, https://grants.nih.gov/grants/understanding-nih.htm [https://perma.cc/W5W6-ZGES] (last visited Mar. 11, 2019).

95. NIH, *Budget*, *supra* note 4.

96. Freeman & Van Reenan, *supra* note 91, at 19.

97. As mentioned above, grants do not act in isolation; researchers may also be able to patent useful inventions, which provides an additional incentive. However, this Article focuses on incentives internal to the grant system.

98. *See generally Grants Process Overview*, NIH, https://grants.nih.gov/grants/grants_process.htm [https://perma.cc/2VXH-ZYQW] (last visited Mar. 11, 2019).

submitted in response, and the NIH makes final funding decisions. In both the seeking of grant applications (that is, deciding what areas of innovation to fund) and the process of peer review (that is, deciding which innovators and projects specifically to fund), the NIH funding process belies the critique that grant-funding decisions are made by bureaucrats lacking relevant knowledge. This is especially true for the broad, open R01 research project grant program.[99] As Richard Freeman and John Van Reenen put it:

> At the heart of the American biomedical science enterprise are the R01 grants that the NIH gives to fund individual scientists and their teams of postdoctorate employees and graduate students. The system of funding individual researchers on the basis of unsolicited applications for research support comes close enough to economists' views of how a decentralized market mechanism operates to suggest that this ought to be an efficient way to conduct research compared, say, to some central planner mandating research topics. The individual researchers choose the most promising line of research on the basis of "local knowledge" of their special field. They submit proposals to funding agencies, where panels of experts—"study sections" in the NIH world—give independent peer review, ranking proposals in accordance with criteria set out by funding agencies and their perceived quality. Finally, the agency funds as many proposals with high rankings that it can within its budget constraints.[100]

This Section explores the grant-funding process.

a) Seeking Grant Applications

The first step of innovation funding is deciding what areas of innovation to fund. Some innovation incentives, like prizes, typically require that the target be fully identified beforehand. Others, like patents, require no ex ante identification by any administrator; private firms decide what opportunities to pursue. Grants might resemble prizes, in that the government identifies beforehand what it would like to fund. As we shall see, this is only partially true; at the NIH, some grant funding ("solicited" applications) looks like broadly-defined prizes, with innovation targets identified up front; other funding ("unsolicited" projects) resembles patents, in that the agency is open to a very wide range of possible projects. In either form, the NIH announces that it will accept applications in a "Funding Opportunity Announcement"

99. The NIH's "R" grants provide support for research projects. *See Research Grants (R)*, NIH, https://www.nimh.nih.gov/funding/grant-writing-and-application-process/research-grants-r.shtml [https://perma.cc/3T57-AH6H] (last visited Mar. 11, 2019).

100. Freeman & Van Reenen, *supra* note 91, at 18–19.

that lays out the parameters for what sorts of grants might be funded.[101]

Unsolicited grants allow individual innovators to suggest their own projects within very broad parameters. The NIH has created a standing set of "parent announcements" that last for a number of years, with standard application dates.[102] Under the announcements, researchers can propose their own project, so long as it fits within the very broad mission of the NIH and of the funding Institute (for instance, cancer-related research to be funded by the National Cancer Institute).[103] The broadest and most well-known of these parent announcements is the R01 Research Project Grant, which "supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s)."[104] Other standing parent announcements exist for smaller research projects, grants for training young scientists, fellowships, and professional development grants.[105] Overall, this set of funding represents a "deliberate policy of relying on the judgment of the scientific community as a whole, through investigator-initiated proposals, to determine the scientific agenda and identify the areas in which progress is most likely."[106] Historically, around 80 to 90% of NIH grant awards are

101. *See infra* notes 116–119 and accompanying text.

102. *What Does NIH Look For?*, NIH, https://grants.nih.gov/grants/what-does-nih-look-for.htm [https://perma.cc/C2TU-4FKR] (last updated May 24, 2016); *Parent Announcements (For Unsolicited or Investigator-Initiated Applications)*, NIH, https://grants.nih.gov/grants/guide/parent_announcements.htm [https://perma.cc/7JSK-UWLD] (last visited Mar. 11, 2019) [hereinafter *Parent Announcements*].

103. Proposals must fit the mission of an NIH Institute, so unsolicited grants are not a pure free-for-all. Nevertheless, the collective set of NIH Institutes covers a very wide swath of biomedical research: Institutes focus on general medical sciences, environmental health, diseases (cancer, alcohol abuse, drug abuse, allergies, infectious diseases, arthritis, musculoskeletal disease, skin disease, deafness, diabetes, digestive disease, kidney disease, mental health, neurological disorders, and stroke), minority populations, techniques (genomic research, biomedical imagining, bioengineering, nursing, clinical research, information technology, and translational science), life stages (aging, child health, and human development) and organ systems (eyes, hearts, lungs, blood, and teeth). *List of NIH Institutes*, *supra* note 93.

104. *NIH Research Grant Program (Parent R01), Announcement No. PA-06-160*, NIH, https://grants.nih.gov/grants/guide/pa-files/PA-16-160.html [https://perma.cc/3V9M-W2AP] (last visited Mar. 11, 2019) (announcing availability of R01 grants from 20 National Institutes as well as the National Library of Medicine; the National Center for Complementary and Integrative Health; and the Office of Research Infrastructure Programs' Division of Program Coordination, Planning and Strategic Initiatives for the three years beginning in May 2016).

105. *See Parent Announcements*, *supra* note 102 (listing parent announcements in the R (research), T (research training), K (career development), and F (fellowships) series, among others).

106. INSTITUTE OF MED., NIH EXTRAMURAL CENTER PROGRAMS: CRITERIA FOR INITIATION AND EVALUATION 49 (Frederick J. Manning, Michael McGeary & Ronald Estabrook eds., 2004).

unsolicited.[107]

The NIH also solicits research proposals, which look a bit more like prizes—albeit very broad prizes—inasmuch as they involve greater ex ante decision-making about what areas of innovation are worth funding. Solicited proposals are intended to address areas the agency thinks worth funding for a variety of reasons, including "to support research in an understudied area of science, to take advantage of current scientific opportunities, to address a high scientific program priority, or to meet additional needs in research training and infrastructure."[108] Soliciting research often deeply engages active researchers; Institutes frequently convene groups of scientists who discuss what research is ongoing, what opportunities exist, and what the Institute should fund.[109] One scientist described such a group conducted at the National Cancer Institute as a "really intense think tank" that realized a need "to bring different disciplines together and enable them to really think differently about cancer."[110] Once the group of scientists mapped roughly what the program should look like to accomplish this scientific/innovation goal, NCI staff "went back internal," and decided how precisely to shape the program.[111] The exact contours of this process vary substantially across Institutes.[112] Even where priorities are generated by NIH employees, many of them are trained as scientists in their own right.[113]

Solicited research programs also grow from top-down priorities. Congress

107. NIH, *Research Project Grants: New (Type 1) Awards and Percentage to Targeted Research* (1997–2017), https://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=25&catId=2 [https://perma.cc/VAF3-UVBK].

108. *What Does NIH Look For?*, NIH, https://grants.nih.gov/grants/what-does-nih-look-for.htm [https://perma.cc/3Y4G-V9H9] (last visited Mar. 11, 2019).

109. *See* INSTITUTE OF MED. & COMM. ON THE NIH RESEARCH PRIORITY-SETTING PROCESS, SCIENTIFIC OPPORTUNITIES AND PUBLIC NEEDS: IMPROVING PRIORITY SETTING AND PUBLIC INPUT AT THE NATIONAL INSTITUTES OF HEALTH 49–51 (1998) (describing various bottom-up procedures for setting research priorities at Institutes) [hereinafter IOM, PRIORITY SETTING].

110. Interview with Anonymous Senior Scientist (June 7, 2017) (on file with author).

111. *Id.*

112. *See* IOM, PRIORITY SETTING, *supra* note 109, at 51 (noting "tremendous variability" in Institutes' "systems for receiving advice, planning, and setting priorities . . . . [S]ome institutes appear to adopt plans developed by a proactive staff with the endorsement of advisory groups, whereas others follow closely the recommendations of external advisory groups").

113. *See* Marion Zatz, *A View from the NIH Bridge: Perspectives of a Program Officer*, 22 MOLECULAR BIOLOGY CELL 2661, 2662–63 (2011) ("Like many of my colleagues at the NIH, I came to this position following a career as an independent research scientist, where I developed many skills that are essential for being a successful researcher or teacher, and for being a [program officer].").

can directly set research priorities, either generally, by deciding how much money to appropriate to a particular Institute (and, accordingly, its broad research focus), or specifically, as the 21st Century Cures Act did in supporting the Precision Medicine Initiative.[114] The President or other White House officials can also drive priorities; President Obama directly proposed the Precision Medicine Initiative, aimed at generating and collecting the health data of a million Americans for future research purposes, and 2016's Cancer Moonshot, focused on fighting cancer.[115] The Human Genome Project was similarly the subject of high-level executive focus. The Directors of Institutes or of the NIH can also shape the agency's funding priorities.[116] Even if priorities are established politically, however, groups of active researchers are still involved in determining how the top-down priority should be implemented.

Once the funder has decided what opportunities to pursue, it issues a Funding Opportunity Announcement, typically as either a "Program Announcement"[117] or "Request for Application" (RFA).[118] A Program Announcement indicates an area of interest, and an RFA formally solicits grant applications "in a well-defined scientific area to accomplish specific program objectives."[119] It describes how much funding the NIH expects to make

114. 21st Century Cures Act, Pub. L. No. 114-255, § 1001(b)(4)(A), 130 Stat. 1033 (2016) (appropriating $1.455 billion for the Precision Medicine Initiative); *id.* at § 2011 (amending the Public Health Services Act to "encourag[e]" the Secretary of Health and Human Services "to establish and carry out . . . the 'Precision Medicine Initiative' ").

115. *See* Jacob S. Sherkow, *Cancer's IP*, 96 N.C. L. REV. 297 (2018) (describing the Cancer Moonshot and describing the intellectual property challenges arising in the context of cancer).

116. The NIH Director is involved in budget negotiations with Congress; Institute Directors have final say on areas of funding emphasis and can identify special areas of emphasis. *See* NIH, SETTING RESEARCH PRIORITIES AT THE NATIONAL INSTITUTES OF HEALTH 15 (1997). In addition, the Director has substantial influence over a designated funding source, the Common Fund, aimed at areas difficult for any single Institute to address on its own. *See About the NIH Common Fund*, NIH, https://commonfund.nih.gov [https://perma.cc/GX3T-GUTX] (last visited Mar. 11, 2019).

117. A Program Announcement is "a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support." *Glossary & Acronym List: Program Announcement (PA)*, NIH, https://grants.nih.gov/grants/glossary.htm#ProgramAnnouncement(PA) [https://perma.cc/Z6XH-GBTV] (last visited Mar. 11, 2019).

118. A Request for Application is "a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives." *Glossary & Acronym List: Request for Application (RFA)*, NIH, https://grants.nih.gov/grants/glossary.htm [https://perma.cc/NG99-9QUN] (last visited Mar. 11, 2019).

119. *Id.* An RFA can also solicit cooperative agreement applications. *Id.*

available, how many grants it expects to fund, and other logistical details.[120]

The process of seeking applications and thereby setting innovation target areas is markedly more complicated than suggested by the critique of the grant system. There is some truth to the idea that bureaucrats are making decisions; the staff of various institutes and centers are involved in setting priorities to determine what sorts of innovation may be funded, and in crafting the actual RFAs and Program Announcements that formally invite grant applications. And "the government," writ large, can influence what areas are funded: Congress can appropriate funds for particular projects (and, indeed, appropriates funds separately for each Institute, giving it a chance to prioritize the different broad missions), and the White House has been closely involved in establishing large-scale research programs.[121] Broad political controversies can also informally shape researcher behavior.[122] But this is far from the whole story. The Parent Announcements are broad, standing invitations to seek funding for whatever projects a researcher thinks worthy of funding that fits within that capacious mission of the NIH, and a majority of research or training applications submitted to the NIH fall within such investigator-initiated categories.[123] And even for the more focused Program Announcements and RFAs, practicing scientific researchers are involved in crafting the rationale for, and the shape of, solicitation for grant applications.

b) Peer Review

The second key funding issue involves individual projects: once areas of targeted innovation have been broadly identified, what specific projects should be funded, and who should undertake those projects? These two questions are tightly blended in the NIH's peer review system, the heart of the NIH's grant evaluation system. The NIH is required by law to use peer review to evaluate grants.[124] About 25,000 peer scientists review about 80,000 grant applications

120. *See id.*

121. *See supra* note 115, at 299–300 and accompanying text.

122. *See, e.g.*, Joanna Kempner, *The Chilling Effect: How Do Researchers React to Controversy?*, 6 PLOS MED. 1571, 1571 (2009) (finding that among researchers whose NIH grant proposals had been criticized as wasteful in a "highly publicized political controversy," about half later removed controversial words from grants and about a quarter avoided controversial topics); Rebecca Hersher, *Climate Scientists Watch Their Words, Hoping to Stave Off Funding Cuts*, NPR (Nov. 29, 2017), https://www.npr.org/sections/thetwo-way/2017/11/29/564043596/climate-scientists-watch-their-words-hoping-to-stave-off-funding-cuts [https://perma.cc/R5ED-4MDT] (noting a sharp decrease in the phrase "climate change" in NSF grants in reaction to the Trump administration's hostility to the topic).

123. *See* NIH GRANTS POLICY STATEMENT, *supra* note 70, at I-46.

124. *See* 42 U.S.C. § 289a (2018).

each year in two stages:[125] "initial peer review" for "scientific and technical merit" and Advisory Council Review, which includes broader policy considerations.[126] An application must be recommended for approval by both levels to be recommended for final funding by an Institute.[127] Of the two, the initial peer review is far more important for individual grants.

Initial peer review focuses on the science alone. When researchers submit a grant application, the NIH's Center for Scientific Review checks the application for technical details and conformance with the Funding Opportunity Announcement, then assigns the application to a Scientific Review Group for initial peer review.[128]

Scientific Review Groups (Groups) are mostly made up of non-government scientists with relevant scientific and technical expertise.[129] However, each Group is led by an NIH staff scientist, known as a Scientific Review Officer, who recruits reviewers, assigns applications to reviewers for pre-meeting review, and prepares summaries of the grant's evaluation.[130] The non-federal scientist peer reviewers receive the grant applications several weeks in advance of a peer review meeting.[131] Each is assigned particular applications to pre-review, which includes writing a critique and scoring the application preliminarily.[132]

Grant applications are scored on several criteria. The most important is "overall impact" ("likelihood for the project to exert a sustained, powerful influence on the research field(s) involved").[133] Several other criteria are scored; for research project grants, these are typically:[134]

125. NIH, NIH PEER REVIEW: GRANTS AND COOPERATIVE AGREEMENTS (2019).

126. *Peer Review*, NIH, https://grants.nih.gov/grants/peer-review.htm [https://perma.cc/K6ZK-WAEP] (last visited arch 11, 2019) [hereinafter NIH, *Peer Review*].

127. *See id.*

128. *See id.*

129. *See id.*

130. *See id.*

131. *See id.*

132. *See id.* The NIH provides copious guidance to its peer reviewers, including policies on avoiding conflicts of interest, evaluating proposal significance and impact, evaluating researcher plans to share data, and evaluating the rigor and transparency of a proposal. *See generally Consolidated List of Reviewer Documents*, NIH https://grants.nih.gov/grants/peer/reviewer_guidelines.htm [https://perma.cc/E5KX-GF8S] (last visited Mar. 11, 2019).

133. NIH, *Peer Review*, *supra* note 126.

134. *See Definitions of Criteria and Considerations for Research Project Grant (RPG/X01/R01/R03/R21/R33/R34) Critiques*, NIH, https://grants.nih.gov/grants/peer/critiques/rpg_D.htm#rpg_01 [https://perma.cc/9FGG-2V88] (last visited March 11, 2019) [hereinafter NIH, *Definitions of Criteria*]. Additional criteria may be provided for different grant types. *Id.*

Significance: scientific basis for the project, and how it could change and improve the field;

Investigator(s): experience and suitability of the researchers for the project, including experience and training (for young investigators) and demonstrated accomplishments (for established researchers);

Innovation: novel (in the field or broadly) paradigms, interventions, approaches, etc., to "challenge and seek to shift current research or clinical practice paradigms";

Approach: "well-reasoned and appropriate" "strategy, methodology, and analyses" and design of the project;

Environment: supportive scientific environment, including institutional support.[135]

The five criteria listed above, as well as overall impact, are numerically scored.[136] Additional criteria involve protections for human subjects, diversity, animal policies, and others, but these criteria are not scored.[137]

Once the assigned peer reviewers have given initial scores, those scores (typically just the overall impact score) are used to determine which applications will be discussed at the Group meeting; applications that do not make the cut (typically the bottom half) are "not discussed" and will not be funded.[138] At the meeting, the remaining grant applications receive a final overall impact score from each non-conflicted Group reviewer; these scores are averaged to obtain a final total score, which ranges from 10 (high impact) to 90 (low impact).[139]

The second level of peer review is by the National Advisory Council or National Advisory Board (together, "Council") associated with the potentially funding Institute.[140] Each Council comprises both scientists and public representatives with an interest in the scientific subject or disease.[141] The Council does not typically review individual grants; instead, NIH staff construct a grant-funding plan based on the results of the initial peer review

135. *Id.*

136. *See Notice NOT-OD-09-024: Enhancing Peer Review: The NIH Announces New Scoring Procedures for Evaluation of Research Applications Received for Potential FY2010 Funding*, NIH, https://grants.nih.gov/grants/guide/notice-files/not-od-09-024.html [https://perma.cc/CT4T-8ETT] (noting changes to grant scoring system from a 1-to-5 scale with 0.1 point increments to a 1-to-9 integer scale) (last visited Mar. 11, 2019).

137. NIH, *Peer Review*, *supra* note 126.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

scores, and the Council makes recommendations for changes.[142] The Council nominally considers broader issues, including the mission of the Institute, the balance of funding between different recipients, and priorities of different research areas.[143] However, Council review, while "not perfunctory," is "highly deferential to study section recommendations."[144]

Finally, the Director of the Institute makes the actual funding decision. This decision can be delegated, and often final decisions are made by units within an Institute (such as Divisions or Programs).[145]

Despite the formal three-stage process—initial peer review for scientific merit, Council review for broader considerations, and a Director's final call—in practice, the initial peer review almost completely determines the outcome for the vast majority of grants.[146] Applications are ranked by their final overall score, and Institute staff determine, based on available funding, what score is necessary for a grant to be funded by the Institute: the "payline."[147] For instance, if the payline for a grant is thirty, grants with final overall scores of thirty or below are typically funded, and applications with scores above thirty are not funded.[148] Paylines may also be expressed as percentile scores among all submitted grants. For many Institutes, the payline is publicly announced; the National Cancer Institute, for instance, announced that for 2016 it would fund R01 grants up to the 10th percentile and R21 exploratory grants up to the 7th percentile "without additional review."[149] There is *some* flexibility around paylines—the paylines are typically different for less-established researchers,

142. *See id.*

143. For instance, the Council specially reviews individual grant applications where the investigator already receives over $1 million in NIH grant funding, though this review does not constitute a funding cap. *Id.*

144. McGarity, *supra* note 91, at 10 (citing DARYL E. CHUBIN & EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 2 (1990)).

145. *See* Brian A. Jacob & Lars Lefgren, *The Impact of Research Grant Funding on Scientific Productivity*, 95 J. PUB. ECON. 1168, 1169 (2011).

146. *See id.* ("Generally, grants are awarded solely on the basis of priority score."); *see also NCI Funding Policy for RPG Awards FY16*, NAT'L CANCER INST., https://deainfo.nci.nih.gov/grantspolicies/FinalFundLtrArchive/finalfundltr2016.htm [https://perma.cc/AK7F-75UQ] (last visited Mar. 11, 2019) [hereinafter NCI, *2016 Funding Strategy*] ("Peer review evaluation of scientific merit will remain the primary consideration in these funding decisions, which will be made by NCI Scientific Program Leaders . . . following discussions with program staff.").

147. *See generally* NIH GRANTS POLICY STATEMENT, *supra* note 70, at I-73 (noting that some Institutes and Centers publish their paylines).

148. *See* Jacob & Lefgren, *supra* note 145, at 1171 ("[T]he realized cutoff in each situation depends on the level of funding for a particular institute, year, and mechanism, along with the number and quality of applications submitted.").

149. NCI, *2016 Funding Strategy*, *supra* note 146.

for instance,[150] and final funding decisions may involve a small fraction of "out-of-order" funding based on other priorities of the particular Institute's administration.[151] But the vast majority of grants have their fates determined by the initial peer review for scientific and technical merit. This helps address concerns of cronyism and corruption because panels of peers, not officials, largely determine funding.

Overall, then, the system differs markedly from the simplified version presented in the critique of grants. Are government bureaucrats making uninformed decisions about what scientific projects get funded? Not really. It is true that staff and leaders at the NIH are involved in the process: the Center for Scientific Review processes initial applications and assigns them to review groups, Scientific Review Officers run the Scientific Review Groups in the initial peer review, NIH staff collates scores and prepares funding reports for the Councils, and NIH Directors or their delegates make the final decisions. But the key determinant of funding is initial peer review. Several scientists with expertise in the field read applications; determine how they fare on significance, investigator qualifications, innovation, approach, scientific environment, and overall impact on the field; and write up scores, critiques, and reasoning. Then those scientists meet, discuss the most promising grants, and decide their final scores—which projects are most worthy. That's mostly it. Grants are ranked, and the grants judged most worthy are funded until the funding runs out (with a bit of wiggle room).

While the process does not involve the market aggregating private information held by firms, it does involve the aggregation of relevant information. The grant applicants themselves disclose what they know of the innovation's potential value and their own capacities in the grant application. Peer reviewers see that information, have their own information about the field, and often can directly compare projects proposed by different researchers in the same field. And agency personnel can provide broader perspectives about government information. This process is a far cry from the notion of an uninformed bureaucrat simply sitting in a room and "picking

150. *See id.* (noting that grants submitted by "early stage investigators" (discussed *infra* at Section IV.A.1) would be funded up to the 12th percentile, rather than the 10th percentile for other investigators); Jacob & Lefgren, *supra* note 145, at 1171 (noting that "there is clearly evidence of out-of-order funding. In [their] sample [of grant applications], 4% of individuals who scored above the cutoff received the grant, while 9% of those below the cutoff did not receive a grant or declined the award").

151. *See* Jacob & Lefgren, *supra* note 145, at 1169 ("Institute directors have the discretion to fund applications out of order on the basis of their subjective judgment of application quality, or other factors such as how an application fits with the institute's mission or whether there were a large number of applications submitted on a similar topic.").

winners."

c) Concerns of Peer Involvement in Funding Decisions

Peer review of grants certainly brings its own challenges, including bias, conformity, and accurate prediction, some of which parallel problems raised with peer review of research publications.[152] First, bias is frequently raised as a concern. Grant applications are generally not anonymous, not least because the funding decision depends in part on the qualifications of the researchers seeking funding. Because peer scientists are involved in deciding which projects receive funding, their decisions could be biased by personal animosity,[153] prejudices against the personal characteristics of the researcher seeking funding,[154] competitiveness against researchers in the same field,[155] political pressure,[156] or otherwise. Studies have found varying levels of evidence for such bias.[157]

Second, peer review may create subtle pressure against innovative science: peers may prefer grant proposals that do not rock the scientific boat.[158] Thomas Kuhn, an influential sociologist of science, noted that the scientific model involves communities of experts making their own decisions about what research would progress.[159] Nicolas Rasmussen notes that leaving those decisions in the hands of top scientists can have the effect of concentrating

152. *See generally* CHUBIN & HACKETT, *supra* note 144 (providing a review of peer review).

153. *See* McGarity, *supra* note 91, at 5.

154. *See, e.g.*, Erika C. Hayden, *Racial Bias Haunts NIH Grants*, 527 NATURE 286 (2015) (finding evidence of racial bias for NIH grant funding); Anna Kaatz et al., *Analysis of National Institutes of Health R01 Application Critiques, Impact, and Criteria Scores: Does the Sex of the Principal Investigator Make a Difference?*, 91 ACAD. MED. 1080 (2016) (finding little bias for R01 initial grants, but bias against women for R01 renewals).

155. *See* McGarity, *supra* note 91, at 52–54 (noting the potential for financial or research conflicts of interest). *But see Managing Conflict of Interest in NIH Peer Review of Grants and Contracts*, NIH, https://grants.nih.gov/grants/peer/peer_coi.htm [https://perma.cc/NEN5-L447] (last visited Mar. 11, 2019) (describing NIH policies for avoiding peer reviewer conflict of interest and providing links to several relevant policies).

156. *See* McGarity, *supra* note 91, at 7.

157. *See* Simon Wessely, *Peer Review of Grant Applications: What Do We Know?*, 352 LANCET 301, 304 (1998) (reviewing sixty-one papers on bias in grant applications and concluding, "[t]he main charge against peer review, that of institutional or sex bias, is generally unfounded, with a few exceptions"). *But see* Hayden, *supra* note 154 (noting evidence of racial bias); Kaatz, *supra* note 154 (noting evidence of sex bias).

158. *See, e.g.*, Joshua M. Nicholson & John P.A. Ioannidis, *Conform and Be Funded*, 492 NATURE 34 (2012); Michal Shur-Ofry, *Nonlinear Innovation*, 61 MCGILL L.J. 563, 577–78 (2016) (describing resistance among grantors to paradigm-shifting innovation).

159. THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 37 (2d ed. 1962); *see also* NICOLAS RASMUSSEN, GENE JOCKEYS: LIFE SCIENCE AND THE RISE OF BIOTECH ENTERPRISE 24 (2014) (discussing Kuhn).

scientific credit, power, and money.[160] McGarity draws out the implications of this for peer review of grant applications: "An important battleground in the war between the [new and old scientific] paradigms is the discretionary grants process. People who have spent their careers conducting research aimed at bolstering and extending the dominant paradigm are reluctant to direct resources toward research aimed at destroying it."[161] There may therefore be a preference toward more "mainstream" research proposals over those which buck convention.[162] Frischmann also notes this concern, arguing that innovation may suffer because of competitiveness of the grant system and the need for relatively "safe" proposals to ensure funding.[163]

The NIH explicitly fights back against any tendency to prioritize "safe" science; reviewers are required to numerically score a grant proposal for innovation, including the question, "Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?"[164] In addition, grant programs can specifically prioritize boundary-crossing interdisciplinary work, as described below.[165] But the concern persists.

Third, some doubt whether peer review is accurate: is it good at sorting out good ideas and grant applications from bad ones? The answer to this seems to be a cautious and qualified "yes." Figuring out whether peer review accurately identifies projects most likely to succeed is challenging; basic research, in particular, is typically likely to fail, and paradigm-changing research is perhaps the most likely to fail, almost by definition.[166] Evidence suggests that peer review can probably discriminate sound applications from seriously flawed applications.[167] However, beyond that distinction, scholars debate whether better-scored grants are actually more productive.[168]

160. RASMUSSEN, *supra* note 159, at 24.

161. McGarity, *supra* note 91, at 41.

162. *Id.* at 40; *see* Pedraza-Fariña & Bair, *supra* note 17, at 1097 (identifying this problem and describing it as an anti-innovation "research priority norm").

163. Frischmann, *supra* note 31, at 389 n.184 (citing STAFF OF HOUSE COMM. ON SCIENCE, 105TH CONG., 1ST SESS., UNLOCKING OUR FUTURE: TOWARD A NEW NATIONAL SCIENCE POLICY 19–20 (Comm. Print 1998)).

164. NIH, *Definitions of Criteria*, *supra* note 134.

165. *See infra* Section IV.B.3.

166. *See* Nelson, *supra* note 25, at 304.

167. *See* Ferric C. Fang, Anthony Bowen & Arturo Casadevall, *NIH Peer Review Percentile Scores are Poorly Predictive of Grant Productivity*, 5 eLIFE e13323 (2016).

168. *Compare id.* (finding little relationship between percentile score and grant productivity), *with* Danielle Li & Leila Agha, *Big Names or Big Ideas: Do Peer-Review Panels Select the Best Science Proposals?*, 348 SCIENCE 434 (2015) (finding a strong relationship between those

Overall, deep peer involvement, whether in the process of seeking applications and therefore identifying areas of innovation (broad or narrow) or in the process of choosing projects and individuals to fund, casts a substantially different light on the grant-funding process. Peer involvement in picking projects has its flaws; it might involve bias, it might suggest safe science, and it is certainly imperfect at identifying the best projects for funding. Similarly, the process of identifying areas of potential innovation, which relies both on peer involvement and on targeting by agency or other government actors with an eye toward social welfare priorities (or patronage, or pork), has its own flaws and idiosyncrasies. But of course, so does the principal alternative—a market-based system that relies on the incentives of private actors to decide what innovation is best to pursue, not based on evaluations of scientific merit or social welfare value, but on a calculus of what profits are appropriable through an imperfect intellectual property system or otherwise.[169] Grants aren't perfect; they're just different, and more interestingly different than is often assumed.

2. Unaccountable Ex Ante Incentives

Grants provide complex incentives for innovative effort. Several accounts critique grants as providing essentially only ex ante incentives, which may be less effective in motivating research effort because the innovator has fewer incentives to work efficiently.[170] As with grant funding, however, grant spending is more complicated. First, the NIH uses some modest tools to ensure that researchers are in fact working on what they proposed. Generally applicable anti-fraud laws also limit what researchers can do with government money, but typically apply only to behavior that significantly deviates from the purposes of the grant.[171] Second, and far more important, grants are not one-

measures).

169. *See, e.g.*, Kapczynski & Syed, *supra* note 43, at 1907 (arguing that "patent rights have the potential to predictably and systematically distort private investment decisions over innovations by overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones"); Ofer Tur-Sinai, *Technological Progress and Well-Being*, 48 LOY. U. CHI. L.J. 145, 156–59 (2016) (cataloging scholarly critiques of patents and markets as an innovation allocation mechanism); *id.* at 161–75 (arguing that even if patents and markets did well in satisfying preferences, they still do a relatively poor job of increasing well-being).

170. *See supra* Section II.B.

171. *See* False Claims Act, 31 U.S.C. §§ 3729–3733 (2018) (prohibiting making false claims); United States *ex rel.* Feldman v. van Gorp, 697 F.3d 78 (2d Cir. 2012) (finding fraud when an NIH-funded fellowship program at Cornell Weill Medical College deviated substantially from the grant application and continuing reports); U.S. Office of Inspector Gen., *Grant Fraud*, U.S. DEP'T HEALTH & HUM. SERVS., https://oig.hhs.gov/fraud/grant/index.asp [https://perma.cc/96XZ-TWEW] (describing grant fraud generally).

off events: researchers work as repeat players within a grant ecosystem where getting the next grant is an ongoing career imperative, and getting that next grant depends on productive outcomes from the current grant.[172]

a) Progress and Reporting Obligations

Grants do come with *some* continuing obligations that allow monitoring and control by the NIH. Rarely, grants have explicit requirements for progress that the NIH requires before additional funding is disbursed. For instance, a request for applications for high-risk, high-reward HIV vaccine research grants states that each application must include explicit Go/No-Go success criteria to be evaluated by the end of the second year of the nominally four-year grant; if the Go criteria are not met, the grant winds down with substantially decreased funding.[173] The center grants supporting the Human Genome Project also had robust accountability and control mechanisms to help drive a broad, expensive, collaborative enterprise.[174] But these mechanisms are unusual; most NIH grants include little more than reporting requirements.[175]

The NIH usually requires that grant recipients submit financial and progress reports at least annually.[176] Recipients must also disclose whether any potentially patentable inventions were made in the funded project, both under the Bayh-Dole Act and independently under NIH policy.[177] Grant recipients

172. In addition, of course, the grant system does not exist in isolation; researchers who produce patentable inventions can patent them and receive some of the resulting royalties. *See supra* notes 63–66 (discussing the Bayh-Dole Act). I view this incentive as one created by the patent system, however, and not as one internal to the grant system.

173. *Request for Application PAR-16-171: Innovation for HIV Vaccine Discovery (R01)*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://grants.nih.gov/grants/guide/pa-files/PAR-16-171.html [https://perma.cc/TXC6-MK5M] (last visited Mar. 11, 2019) [hereinafter, NIAID, *HIV RFA*].

174. *See* STEPHEN HILGARTNER, REORDERING LIFE: KNOWLEDGE AND CONTROL IN THE GENOMICS REVOLUTION 96–98 (2017) (noting that genome sequencing centers would be subject to annual progress reports, frequent scientific reviews, meetings with NIH Center Directors, and rigorous evaluations on which future funding would be contingent); *id.* at 98–104 (detailing scientific evaluation strategies).

175. *See* NIAID, *HIV RFA*, *supra* note 173 ("[A]pplications should be very different from conventional investigator-initiated R01 applications . . . . Applications that do not include Go/No-Go decision criterion/criteria will be considered incomplete and will not be reviewed.").

176. *See* NIH GRANTS POLICY STATEMENT, *supra* note 70, at IIA-135. For many rewards, including R01 grants, financial reports need only be submitted at the end of the full grant period. *Id.* at IIA-125–26.

177. *See id.* at IIA-130; *see also* 35 U.S.C. § 202 (2018). *But see* Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NAT. BIOTECHNOLOGY 953 (2012) (noting that many Bayh-Dole reporting mandates go unfollowed).

are also subject to audit.[178] Failure to follow reporting requirements, or failure to comply with other terms of the grant, can theoretically result in disallowing costs, withholding future grant awards, suspending the grant, or even terminating the grant.[179] At least in part, these reporting requirements should encourage grant recipients to work toward the goals of the grant, in contrast to a purely ex ante award with no oversight or reporting mechanisms at all.

b) Repeat Players

The most important reporting of grant progress comes not in response to the current grant but in applying for the next grant. Grants terms are measured in years; researcher careers are measured in decades (or, at least, most researchers hope so). Failure to get subsequent grants can result in the downsizing of a lab or the end of a career, making researchers repeat players.[180] As Gallini and Scotchmer noted, the "moral hazard" of non-contingent ex ante funding for a *single* grant "is overcome because future grants are contingent on previous success."[181] They argue that in practice, grants "operate much like prizes, with the wrinkle that a researcher must convince the sponsor in advance that his output might be worthy of a prize. For this purpose, his reputation might suffice, and in some cases, much of the research has already been completed."[182]

NIH grant-funding policy follows this pattern. The NIH scores grant applications on five main criteria, including "Investigator(s)" (the scientist running the project). "If [non-established], do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?"[183] In addition, many NIH grant types effectively require substantial preliminary data, which

178. *See* NIH GRANTS POLICY STATEMENT, *supra* note 70, at IIA-143–46.

179. *See id.* at IIA-135. Grant termination is rare, though NIH does not track such occurrences. *See* Jef Akst, *Wanted: Records of Revoked Grants*, SCIENTIST (Jan. 20, 2010), https://www.the-scientist.com/the-nutshell/wanted-records-of-revoked-grants-43553 [https://perma.cc/6EB7-GM4X]; *cf.* Jef Akst, *3 Calif Stem Cell Grants Revoked*, SCIENTIST (Nov. 3, 2009), https://www.the-scientist.com/the-nutshell/3-calif-stem-cell-grants-revoked-43763 [https://perma.cc/3TPS-QBGC] (noting the revocation of three grants by the California Institute of Regenerative Medicine for insufficient progress).

180. *See* Adam Ruben, *Another Tenure-Track Scientist Bites the Dust*, SCIENCE (Jul. 19, 2017), http://www.sciencemag.org/careers/2017/07/another-tenure-track-scientist-bites-dust [https://perma.cc/777E-4M9V] (giving an example of how failure to get a grant can end a career).

181. Gallini & Scotchmer, *supra* note 38, at 54.

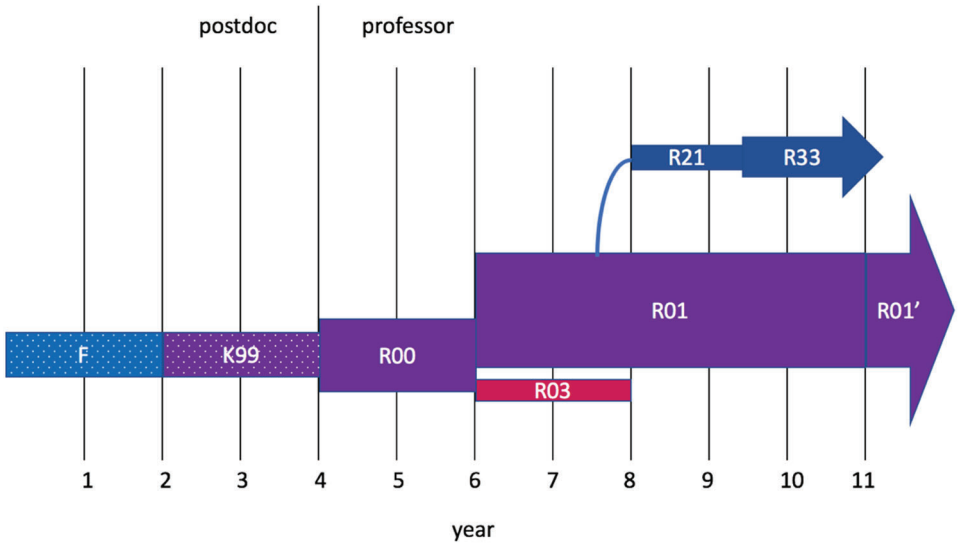
182. *Id.*; *see also* Hanson, *supra* note 52, at 5 ("[C]ompetitive grants, which fund much of today's best basic research, can be viewed as a small prize for thinking up a promising topic, coupled with a larger but still moderate grant for working on that topic.").

183. NIH, *Definitions of Criteria*, *supra* note 134.

serves to demonstrate (a) the project's feasibility; (b) the researcher's training and ability to generate data; and (c) the researcher's willingness to spend resources on the project even before this grant is funded.[184] This last point is in some tension with the idea that grants help free researchers from capital constraints,[185] but reinforces the serial nature of grant funding. Productivity under one grant—experiments conducted, expertise acquired, data generated, and papers published—is relevant to the NIH in deciding whether to fund the next grant, whether a competitive extension of the same project, a new grant for a related project, or an entirely different project led by the same experienced, productive researcher.

Figure 1 illustrates this pattern. It schematically shows the grants that might be received by a (rather successful) hypothetical researcher; we'll call her Jenn.

Figure 1: Schematic of serial and parallel grants



184. Many but not all grant types require preliminary data; for instance, R01 grants require fairly substantial preliminary data, but grants focused on small studies or phased innovation (R00, R21, and R21/33 grants) need not include preliminary data, particularly if the projects are exploratory or pilot studies. *See id.*

185. *See* Hemel & Ouellette, *supra* note 2, at 308. Without initial resources, securing preliminary results to obtain grant funding can be hard to do. The repeat nature of grants, discussed in the next Section, somewhat obviates this concern, with two caveats. First, it does not apply to initial entry to the grant system, and therefore may penalize new innovators who lack the resources to generate preliminary data on their first projects (especially if, unlike the example to follow, they do not follow a research-intensive path into becoming an innovator). Second, it may shape the direction of research, because preliminary results may not support future projects that are very far afield from the earlier work.

Initially, Jenn is supported by an F32 postdoctoral fellowship, which supports postdoctoral research and training. Jenn is working on Project Blue, under the direction of the head of her lab, Durona (the fact that Jenn is not the principal investigator is indicated by the stippling in the figure); Durona also certainly has her own funding, which supports Project Blue. Jenn uses the data acquired from that work to propose a related project, Project Purple; she applies for a K99/R00 Career Development Award, designed to help her transition into the role of an independent researcher. Getting this type of two-tiered award is contingent on Jenn's baseline qualifications, but also on how well she has done in her earlier work. It is therefore extremely challenging to get a K99/R00 grant without a record of peer-reviewed scientific publications (as well as a solid research plan and the other requirements for a grant).[186] Jenn gets the combination grant, and for two years she is funded by the K99 as a postdoctoral fellow in Durona's lab, still working under her mentorship (as the K99 requires). Then, contingent on Jenn's appointment as an independent, full time faculty member, she receives R00 funding to continue work on a broadened Project Purple in her own lab.

Two years later, Project Purple has borne fruit; the main project has developed, resulting in publications, more data, and more possibilities, and Jenn is ready to expand the project substantially. She applies for and receives an R01 Research Project Grant to continue and expand the main thrust of Project Purple: five years of substantial funding, enough to support a doctoral student and a postdoctoral fellow. But again, getting the R01 depends in large part on Jenn's research productivity while supported by the R00. Five years after getting the R01 for Project Purple, it expires; Jenn applies for a renewal (R01'), which is subject to the normal competitive grant process. For the continuation of Project Purple, Jenn's lab, and Jenn's own scientific career, productive work under each grant is essential. This is not to say that *success* is essential; the NIH knows that innovative research often fails. But future grants depend on actually doing the work.

Cross-grant contingency is not only serial but also parallel: many researchers work on multiple grants simultaneously. In an academic lab, the principal investigator who heads the lab may have working with him multiple doctoral students, multiple postdoctoral fellows, and perhaps a few technicians, working on different projects and supported by different grants—

186. The overall success rate for 2017 K99 applications was 23.4%, but that already excludes all the candidates who did not apply because their credentials were insufficient. *See* NIH, CAREER DEVELOPMENT AWARDS: APPLICATIONS, AWARDS, SUCCESS RATES, AND FUNDING, BY INSTITUTE/CENTER AND ACTIVITY CODE (2018).

all of which partially support the principal investigator herself. Typically, these grants will be staggered in time. Even if productive results from one grant are not directly prerequisite for a staggered grant on a different project, outcomes such as papers, awards, expertise, and prizes all matter in determining whether the investigator is likely to succeed in the parallel project, and therefore whether the funder should approve that other application.

Figure 1 also shows this dynamic. At the end of Jenn's R00, she has developed another interesting line of research, and applies for an R03 Small Grant to pursue it. Unfortunately, Project Red doesn't pan out and two years later the funding runs out. Meanwhile, Project Purple continues; a couple of years later, it suggests another line of inquiry, and Jenn applies for and receives an R21 Exploratory/Developmental Grant for Project Navy (that grant requires no preliminary data, but she uses some evidence from Project Purple to support the application anyway). After two years, she has enough data from the R21 on Project Navy to get the R33 Exploratory/Developmental Grant Phase II. For each of these parallel applications, Jenn doesn't have the same sort of robust earlier data that needs to underline the serial line of Project Purple grants above. But when the Scientific Review Group conducts its initial peer review of her application,[187] it will see what she published in the course of her Project Purple work, expertise she has acquired, the experience of any postdoctoral fellows she has hired to do work, and similar progress markers. They all matter for her success as a researcher, and they all matter to peer reviewers for other grants.

In sum, while the ex ante nature of any *one* grant largely follows the critique that grants have limited ability to drive post-award researcher effort, no single grant paints the whole picture. Instead, researchers are repeat players in a system where multiple grants matter, both in parallel and serially, on the same or related projects. In this broader context, the success or productivity of work under a particular grant has far-reaching consequences on future funding, both for the researcher and for others working in her lab.

3. Problematic Risk Allocation

The third critique suggests that grants poorly allocate downside and upside risk between the funder and the recipient; a more comprehensive understanding of what benefits and costs are relevant to the NIH suggests that this critique, too, is incomplete. Of course, much of the point of grants is that the government *explicitly* does not benefit directly from successful projects (if

187. *See supra* Section II.B.1.

it did, these instruments would be procurement contracts instead of grants).[188] Instead, grants have long been considered a way to create public goods from which the government does not directly benefit. Nevertheless, some have raised the concern that the allocation of downside and upside risk is problematic.[189] Poorly allocated risk can raise problems in both directions. If downside risk (that is, the risk of failure) is allocated entirely to the government, the researcher has decreased incentives to avoid failure. And if upside risk is allocated entirely to the researcher, the government may not reap much from its spending. Taken together, these two sides of risk allocation could also encourage researchers to pursue overly risky plans, since they capture most of the benefit of success but face little of the cost of failure. A richer conception of the grant system and the NIH's general mission reduces all three concerns.

Downside risk invites the most straightforward rebuttal. The government does not bear downside risk alone. Researchers also face downside risks from project failures. While the NIH does not require success from its funded projects—science is risky, and innovative science more so—nevertheless it is easier to generate data, and especially to publish in prestigious peer-reviewed journals, if research achieves its stated goals. This bias in favor of positive results has its own powerful negative consequences for science,[190] but it does keep some of the risk of failure squarely on the researcher. Failing to receive or renew grant funding results in a range of consequences that can hit a researcher hard, including shame among peers, the inability to hire (or the need to fire) subordinates, denial of tenure or promotion, and the end of a lab and a career.[191]

The question of upside risk allocation shifts substantially when taking into account the NIH's mission.[192] Consider an expensive NIH investment in research that leads to the development of a new drug. In all likelihood, a drug company licenses the exclusive rights to that drug, takes it to market, and reaps

188. *See supra* note 76 and accompanying text.

189. *See supra* Section II.A.3.

190. An exploration of the negative repercussions of the publication bias for favorable results is fascinating but outside the scope of this Article. For an introduction to the area, see Michal Shur-Ofry, *Access-to-Error*, 34 CARDOZO ARTS & ENT. L.J. 357 (2016); John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLoS MED. 696 (2005); *see also* Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 852–65 (2017) (discussing the related problem of irreproducibility in science).

191. *See* Ruben, *supra* note 180.

192. *See Mission and Goals*, NIH, https://www.nih.gov/about-nih/what-we-do/mission-goals [https://perma.cc/8WD4-9Q5D] (last visited Mar. 11, 2019) [hereinafter NIH, *Mission and Goals*].

billions in profit while the NIH and the government see no profits; in fact, the latter pays billions to the drug company through public health insurance.[193] This dynamic is subject to a powerful critique—why doesn't the government benefit from its grant funding?[194] Simply put, it does.[195]

There are several upsides to research that the government is well positioned to capture. The simplest is that research may solve a public problem; a new vaccine will keep people from getting sick, and the government may benefit both monetarily (paying less to take care of sick people) and in its role as representative of the public (which benefits by being healthier).

A second, well-recognized benefit is that research generates information that is a public good with substantial externalities; this is perhaps the strongest justification for grants generally.[196] This is true both for basic research, the value of which is very hard to capture but which enables other innovation, and for applied research, which creates the same sort of knowledge spillovers.[197] Generating this knowledge accords with the NIH's mission, which includes "expand[ing] the knowledge base in medical and associated sciences."[198] More broadly, the government in its role as social welfare coordinator and social

193. *See, e.g.*, U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: NIH-PRIVATE SECTOR PARTNERSHIP IN THE DEVELOPMENT IN TAXOL 13 (2003) ("NIH Invested Heavily in Taxol-Related Research, but Federal Financial Benefits Have Been Limited."). While Taxol related from a cooperative research and development agreement (CRADA) rather than a grant, the argument is essentially parallel, and recurs today. *See, e.g.*, Matt Richtel & Andrew Pollack, *Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits*, N.Y. TIMES (Dec. 19, 2016), https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?_r=1 [https://perma.cc/5349-B9C7] (asking, about government investment in CAR-T immunotherapy for cancer, "Are taxpayers getting a good deal?").

194. *See* Mariana Mazzucato, *How Taxpayers Prop up Big Pharma, and How to Cap That*, L.A. TIMES (Oct. 27, 2015), http://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html [https://perma.cc/N7FS-6XU5]; Gerard Anderson, *Big Pharma Should Support the NIH*, BALT. SUN (Apr. 17, 2015), http://www.baltimoresun.com/news/opinion/oped/bs-ed-medical-innovations-act-20150417-story.html [https://perma.cc/6PRP-8WNH].

195. Issues of drug pricing are complex and far outside the scope of this piece. For an overview, see generally Ari B. Friedman & Janet Weiner, *What's the Story with Drug Prices?*, PENN LDI (May 30, 2016), https://ldi.upenn.edu/healthpolicysense/what%E2%80%99s-story-drug-prices [https://perma.cc/7FCT-7GRU].

196. *See* Nelson, *supra* note 25, at 302–04.

197. *See* Frischmann, *supra* note 31, at 389 ("The uncontrollable risks are borne by the government and are, in a sense, considered small because spillovers are welcome."); *cf.* Danielle Li, Pierre Azoulay & Bhaven N. Sampat, *The Applied Value of Public Investments in Biomedical Research*, 356 SCIENCE 78, 78–80 (2017) (finding that around 10% of NIH grants are directly cited by patents and 30% are cited in publications that are themselves cited in patents; for patents on approved drugs, the rates are around 1% and 5%, respectively).

198. NIH, *Mission and Goals*, *supra* note 192.

representative realizes the benefits of those knowledge spillovers.

The public good of knowledge spillovers, however, is broader than that created by successful research. Negative information—what doesn't work, what paths are unproductive, and the like—is also useful information to both the government as a whole and to the NIH in particular. Among other things, it can help future grantees avoid fruitless research paths. Negative information can also be difficult for private firms to capture.[199]

Finally, and this upside is less often acknowledged, a substantial goal for the NIH is to build human and institutional capital in science. The NIH states that one of its four goals is "to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease."[200] As a matter of both national and NIH policy, we want more trained scientists around. Their knowledge and expertise helps drive innovation across many fields. It is a positive outcome when the NIH funds, trains, and develops scientists, even if research projects fail to produce immediately valuable findings. Jacob and Lefgren find empirical evidence of successful grant-funded development: receipt of a postdoctoral fellowship (NIH's F32 grant) increases the chance of a young scientist becoming a successful researcher by almost a quarter.[201]

These two realities of downside and upside risk—that researchers do suffer from failed projects and that even risky projects can generate negative knowledge and human capital—address the concern that risk allocation will push researchers toward overly risky research projects. However, even if risk allocation *does* push researchers toward riskier projects, such an effect may be justified for two reasons. First, a risk-allocation-based push toward riskier research may counterbalance the possibility that grant-funders could prefer "safer" research.[202] Second, riskier research is likely to be a less attractive target for private investment;[203] to the extent that grant funding is especially

199. *See* Kapczynski & Syed, *supra* note 43, at 1926–28 (noting the difficulty of capturing the benefits of negative knowledge through patents). *But see* Laura Pedraza-Fariña, *Spill Your (Trade) Secrets: Knowledge Networks as Innovation Drivers*, 92 NOTRE DAME L. REV. 1561, 1597–98 (2017) (discussing firm ability to capture negative knowledge through trade secrecy).

200. NIH, *Mission and Goals*, *supra* note 192.

201. Brian A. Jacob & Lars Lefgren, *The Impact of NIH Postdoctoral Training Grants on Scientific Productivity*, 40 RES. POL'Y 864, 873 (2011).

202. *See* Pierre Azoulay, Joshua S. Graff Zivin & Gustavo Manso, *Incentives and creativity: evidence from the academic life sciences*, 42 RAND J. ECON. 527, 531 (2011) (noting NIH grant funding incentives to pursue comparatively safe research). *But see* Hyunwoo Park, Jeongsik Lee & Byung-Cheol Kim, *Project selection in NIH: A natural experiment from ARRA*, 44 RES. POL'Y 1145, 1158 (2015) (finding that NIH selects and funds riskier projects than expected).

203. Nelson, *supra* note 25, at 302–04.

appropriate where private firms are unlikely to invest, riskier research needs grant funding more.

* * *

The NIH's vast system of grant funding reflects a richer and more complex reality than is captured in common depictions and critiques of grants. Funding decisions are not made principally by bureaucrats, but rather by panels of peer scientific experts working in concert with agency staff. Researchers respond to grant incentives not in a one-off, wholly ex ante vision that provides little drive for efficiency or success, but rather in an iterative context of serial and parallel grants where researchers are repeat players and success matters in receiving the next essential grant. And grants do not allocate downside risk just to the government and upside risk just to the grantee, but rather allocate a combination of upside and downside risks to each party.

To be sure, the experience of the NIH does not demonstrate that these critiques *never* hold—just that they do not hold at the NIH. A comparative survey of different grant systems is outside the scope of this work. However, there is reason to think that these insights are relatively generalizable. Peer review is widely used to allocate grant funds.[204] Where grant awards depend in part on prior work, and where such awards are insufficient to individually support an entire career, the repeat-player nature of the grant system should create accountability mechanisms—and those two conditions are likely to hold in most contexts. Finally, in most grant systems the recipients are likely to experience some downside risk of project failure (for the same reason), and the government to experience upside benefits.

Overall, grants are a more nuanced policy instrument than these critiques reflect. The next Part describes how they can and do help promote a broad set of innovation goals.

IV. GRANTS AS INNOVATION LEVERS

Grants can do much more than is commonly recognized. In fact, they already do. The two Sections of this Part each focus on one of the two key comparative strengths of grants: creating incentives for goods whose social welfare exceeds appropriable market value and directly supporting the development of innovation enablers. The paradigmatic version of a grant, in

204. *See, e.g.*, McGarity, *supra* note 91, at 15–37 (describing peer review systems at the National Science Foundation, the Environmental Protection Agency, and the National Endowment for the Arts); Grimpe, *supra* note 85, at 1450–51 (noting the presence of peer review in the German scientific grant system).

the NIH context, does both of these things: an R01 basic research grant creates information useful principally for later innovation, and markets value that information for less than its social-welfare value. Because this is the paradigmatic version, on which most conceptions of government grants are based and which has been the dominant version throughout the rest of this paper, I do not describe it in detail. Instead, this Section focuses on ways grants can, do, and could promote innovation in non-paradigmatic ways.

A. SOCIAL/MARKET VALUE MISMATCHES

Grants provide a useful tool to create incentives where social value exceeds appropriable market value. This comparative strength neatly inverts the lauded ability of patents and other exclusivity mechanisms to use market signals of social value. Patents, the argument goes, are useful and efficient innovation incentives because the value a firm can realize from a patented innovation increases with the social value of the innovation, as measured by the market price and demand for that innovation.[205] But of course that argument doesn't always hold. Sometimes—some very important times—the value a firm can capture through patents doesn't reflect the social value of the innovation. One such mismatch exists when market demand fails to reflect social value because of a lack of willingness or ability to pay, as with treatments for diseases of the poor. A second mismatch happens when, although market demand might match social demand, existing appropriation mechanisms do not allow firms to appropriate an innovation's value—in effect, when existing intellectual property mechanisms fail, as with medical diagnostics.[206] Two sets of requirements shape the NIH's ability to drive innovation in these areas: the Bayh-Dole Act's requirements governing patent rights in innovations funded by government grants and the NIH's data-sharing requirements.

The Bayh-Dole Act allows universities to retain rights to inventions funded by federal grant money.[207] Instead of the federal government retaining patent rights, the Bayh-Dole Act lets universities or other nonprofits patent grant-funded innovations and license the patents to private firms for development.[208] The scheme aims to promote the commercialization of inventions by private firms, though the extent to which Bayh-Dole is necessary or beneficial is the

205. *See supra* notes 36–38 and accompanying text.

206. *See supra* note 21; *infra* Section III.A.2. One can also describe infrastructure investment, with its positive externalities, as a good whose appropriable market value does not scale with its social value. Because grants target innovation infrastructure and other enablers in a particularly distinct way, this opportunity is discussed in the next Section.

207. 35 U.S.C. § 202.

208. *Id.* For-profit grant recipients were added to the scheme by executive order. Exec. Order No. 12618, 52 C.F.R. 48661 (1987).

subject of considerable debate.[209] The government retains the right to "march in" and license the invention to another licensee if it is not made "reasonably available" by the commercializing entity, and also retains a nonexclusive license to make the invention available for government purposes.[210] The march-in right, however, has never been exercised,[211] and the government's own licensing ability has long laid dormant, though recent scholarship has attempted to revive it.[212] As Ayres and Ouellette note, the Bayh-Dole regime may have the effect of using public funding to create public goods, but then creating rewards greater than needed to develop them in the private context.[213]

The NIH's data-sharing policies also shape the availability of the fruits of grant-funded research. NIH policy requires researchers to make peer-reviewed publications resulting from grant-funded research freely available to the public one year after initial publication.[214] In addition, any "unique research resources" made with NIH funding, such as new cell lines or genetic databases, should "be made readily available for research purposes to qualified individuals within the scientific community."[215] These policies help insure that grant-funded research becomes available but consequently limit the availability of trade secrecy as a non-patent appropriation mechanism.

209. *See, e.g.*, Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271 (2017) (describing the inefficiency of the Bayh-Dole system and proposing a market mechanism for licensing of grant-funded inventions); Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. & BIOSCIENCES 282 (2017) (justifying the Bayh-Dole regime as useful to respond to challenges of global freeriding); Frischmann, *supra* note 31, at 399–413 (describing and critiquing the Bayh-Dole system of mixed grants and privately licensed patents); Stephen M. Maurer & Suzanne Scotchmer, *Procuring Knowledge*, *in* INTELLECTUAL PROPERTY AND ENTREPRENEURSHIP, 1, 26 (2004) (noting that if the Bayh-Dole Act solves any problem, it solves a problem with intellectual property law).

210. *See* 35 U.S.C. § 203 (2018); 28 U.S.C. § 1498 (2018); *see also* Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016) (describing the history of § 1498 and arguing that the federal government can use it today to buy generic versions of expensive drugs for far less than their list prices).

211. Ayres & Ouellette, *supra* note 209, at 321; *see also* Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015).

212. *See* Brennan et al., *supra* note 210, at 280.

213. *See supra* note 209.

214. NIH GRANTS POLICY STATEMENT, *supra* note 70, at IIA-116.

215. *Id.* at IIA-117; *see* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72090 (Dec. 23, 1999).

1. Social Value Exceeding Market Value

Grants can fund innovation whose social welfare value exceeds the market value of the product. Rachel Sachs notes,

> Where the general population's willingness and ability to pay for a particular drug track the social value it contributes, patents are thought to provide a relatively efficient way of incentivizing the development of socially valuable drugs. But each of these factors—willingness to pay and ability to pay—presents a well-known bias, through which innovation incentives will be directed away from certain types of treatments or diseases with high social salience.[216]

Willingness to pay creates a mismatch between social and private value. For some innovations, social benefits exceed individual benefits; for example, vaccines protect both the vaccinated individuals and others in society through the process of herd immunity.[217] Optimism bias may also decrease willingness to pay because people don't think they will get sick, and therefore underpay for preventive measures, decreasing incentives for scientists to develop those measures.[218] Finally, short-term bias may cause individuals to systematically undervalue expensive cures as opposed to ongoing treatments, which are cheaper per instance but costlier over time.[219] These distortions are not limited to the biomedical context—individuals may undervalue vehicle safety innovations that protect other drivers, upgrades that prevent house deterioration down the road, and technologies like solar roofs that pay for

216. Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 168–69 (2016). Sachs suggests that insurance reimbursement may suggest another avenue to create incentives for this type of innovation. *Id.* at 178–93. Amy Kapczynski expands this argument generally in Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970 (2012).

217. Sachs, *supra* note 216, at 169.

218. *Id.* at 169–70 (citing Cass R. Sunstein, *Willingness to Pay vs. Welfare*, 1 HARV. L. & POL'Y REV. 303, 325 (2007)).

219. *Id.* at 170. As Sachs notes, the story of Sovaldi, a drug which cures Hepatitis C, which itself primarily afflicts the poor, is somewhat miraculous. The typical story of drug market incentives suggests that firms should not be especially interested in a drug that treats a disease mostly afflicting those without substantial resources to pay, nor a drug that cures a chronic disease rather than treating it profitably for a long time. Sovaldi is both, and even its frequently-cited high sticker price represents a substantial savings over current treatment options. *See* Nicholas Bagley, *Does It Break the Law to Charge a Lot for a Cure?*, INCIDENTAL ECONOMIST (Jan. 28, 2016), http://theincidentaleconomist.com/wordpress/does-it-break-the-law-to-charge-a-lot-for-a-cure/ [https://perma.cc/32RS-RCXB] (quoting an email from Rachel Sachs to this effect). Outside biomedical innovation, climate change technology provides tremendous social benefits in the future, but current costs make appropriate market valuation of climate-change innovation challenging. *See generally* Ofer Tur-Sinai, *Patents and Climate Change: A Skeptic's View*, 48 ENV. L. REV. 211 (2018).

themselves in long-term energy savings.[220]

Ability to pay also limits market incentives and makes them inadequate for some socially valuable innovations. Consider Chagas, chikungunya, and other Neglected Tropical Diseases, which in the United States afflict mostly the poor and underinsured;[221] mental illness is similarly more prevalent among those populations.[222] Because those who can't pay for drugs can't create market demand, we should expect investment in treatments for those diseases to be substantially less than the social value of such innovation.[223]

These are not the only ways that market demand can create problematic incentives to pursue certain types of innovation. As Kevin Outterson has long argued, antibiotic resistance is a tremendous problem of global scale, caused in part by warped incentives for development of new antibiotics.[224] Antibiotic overuse limits the value of antibiotics for future users, but sellers of new antibiotics profit more from selling lots of the antibiotics before resistance sets in, rather than limiting their use.[225] Accordingly, new antibiotics aren't kept in reserve, and society loses the very large benefit of having a robust arsenal of last-resort antibiotics.[226] Unfortunately but perhaps unsurprisingly, the past several decades have seen little in the way of new antibiotics, and the looming threat of global antibiotic resistance is increasingly worrisome.[227]

Grants can step in to support research in these areas of unmet need. In 2012, for instance, the National Institute for Allergy and Infectious Diseases funded eight Tropical Medicine Research Centers through P50 Research Center grants.[228] The Centers are located in regions where the neglected tropical diseases are prevalent: Brazil, India, Ghana, and Peru.[229] These grants

220. *See* Howard Kunreuther & Elke U. Weber, *Aiding Decision Making to Reduce the Impacts of Climate Change*, 37 J. CONSUMER POL'Y 397, 402–04 (2014).

221. Sachs, *supra* note 216, at 154, 170–71.

222. *Id.* at 170–71.

223. *See, e.g.*, Stiglitz, *supra* note 39, at 1718 ("One of the problems of being poor is that you do not have any money and therefore cannot spend a lot of money on drugs, even though if you do not buy the drugs you may die.").

224. *See generally* Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613 (2010).

225. *Id.* at 627.

226. *Id.*

227. *See* Dalia Deak et al., *Progress in the Fight Against Multidrug-Resistant Bacteria? A Review of U.S. Food and Drug Administration-Approved Antibiotics, 2010–2015*, 165 ANNALS INTERNAL MED. 363, 369–71 (2016) (noting disappointing development of new antibiotics).

228. *Tropical Medicine Research Centers – Program Overview*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES, https://www.niaid.nih.gov/research/tmrc-program-overview [https://perma.cc/Q49Y-7W7L] (last visited Mar. 11, 2019).

229. *Id.*

both support useful research in these areas of unmet need and "build capacity to enable [the Centers] to conduct future clinical trials, implement new treatment and prevention strategies, and develop novel vector control strategies."[230] In other words, the NIH aims to use grant funding to establish the capacity for future useful work even after initial funding has ended.[231] The Institute funds training to build research capacity, focusing on institutions in developing nations.[232]

Grants are unlikely to fully solve any of these problems of inadequate demand. But they provide useful innovation tools. Outterson and Aaron Kesselheim recognize that grants can play a role, within a complex system of tailored incentives, in supporting underlying research to reduce the cost of developing new antibiotics.[233] In a pleasant example of putting theory into practice, Outterson—in the years since he helped bring antibiotic resistance incentive problems to greater salience—has become the Executive Director of a $350-million grant-funded project aimed at increasing innovation in antibiotic development, including efforts that are too risky or paradigm-challenging for private development, as well as relatively mainstream efforts that suffer from the incentive problems described above.[234]

This type of grant-funding raises important questions: Who identifies underfunded innovations whose social value exceeds market value, and how? These questions may be especially challenging for applied research that does not obviously promote the same sorts of knowledge spillovers as basic research. Here, the first critique of grants—bureaucrats make funding decisions—has more bite.[235] But that may be precisely the point. This type of social welfare problem—social value that exceeds market price signals—is *exactly* the type of problem that market actors with private knowledge are ill-

230. *Id.*

231. *Id.*

232. *See Funding Opportunity Announcement PAR-17-057: Global Infectious Disease Research Training Program (D43)*, NIH, https://grants.nih.gov/grants/guide/pa-files/PAR-17-057.html https://perma.cc/27K8-J49U] (last visited Mar. 11, 2019).

233. Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFF. 1689, 1694 (2010). Kesselheim and Outterson also respond to the risk allocation concern described *supra*, suggesting that "[f]or drugs that ultimately emerge from public investment programs, the government should receive an appropriate share of the enhanced reimbursement by payers." *Id.*

234. *See* Kevin Outterson et al., *Accelerating Global Innovation to Address Antibacterial Resistance: Introducing CARB-X*, 15 NATURE REV. DRUG DISCOVERY 589 (2016).

235. *See supra* Section II.B.1; *cf.* Abramowicz, *supra* note 50, at 1366–67 (arguing that orphan drug development should be subsidized only when they are inefficient and that government officials are likely unable to make that determination).

suited to fix.[236] The specialized knowledge of scientist peer reviewers might have more traction, but really, this is a problem about social welfare and identifying substantial unmet needs on a broader level. While the government (or philanthropic organizations) might do this inefficiently, it can make that social choice in a way that private firms won't.[237]

Even accepting that the government might be the right entity to make this sort of resource allocation call, how should it go about the task? Sachs argues that this sort of centralized decision-making is an opportunity for interagency collaboration to leverage different sources of knowledge and expertise.[238] With respect to under-addressed diseases, she notes that the Centers for Medicare and Medicaid Services (CMS) possess extensive information useful for NIH decisions on funding allocation, including on disease burdens; existing drugs; and, in combination, which diseases are currently underserved.[239] Unfortunately, such interagency collaboration is relatively underdeveloped,[240] but the collective expertise of CMS, the Centers for Disease Control, and other relevant agencies could help direct the funding allocation decisions of the NIH to address unmet biomedical needs with substantial potential social welfare gains.

2. Appropriability Failures

Grants can also pick up the incentive slack where markets value an innovation adequately, but firms cannot appropriate enough of its value to justify investment. The problem of appropriating the value of an information good is a fundamental justification for intellectual property. Ideally, intellectual property allows firms to appropriate social value of nonexclusive, nonrivalrous information goods by creating an exclusivity mechanism.[241] But intellectual

236. In some cases, of course, no entity, whether private or public, will have a good answer as to the social value of a potential innovation. In such cases, whoever is making the decision must simply muddle through—as happens anyway. *See, e.g.*, Charles E. Lindblom, *The Science of "Muddling Through"*, 19 PUB. ADMIN. REV. 79 (1959) (explaining the difficulty in determining the social value of a policy).

237. *Cf.* Pedraza-Fariña, *supra* note 10, at 439–41 (proposing that the grant system issue calls for scientists to propose important cross-disciplinary problems that need to be solved).

238. Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 1993–96 (2018).

239. *Id.* at 2028.

240. *See id.* at 2038–41; *see generally* Laura Pedraza-Fariña, *Constructing Interdisciplinary Collaboration: The Oncofertility Consortium as an Emerging Knowledge Commons*, *in* GOVERNING MEDICAL KNOWLEDGE COMMONS 259 (Kathy Strandburg, Brett Frischmann, & Michael Madison eds., 2017) (discussing failures in interagency collaboration in the context of the NIH Roadmap grants) [hereinafter Pedraza-Fariña, *Oncofertility*].

241. *See generally* Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (discussing the different justifications that exist for having

property mechanisms don't always work. Where they fail, grants can step in, even if the innovation is relatively late in the development pipeline.[242]

To take one prominent example, medical diagnostics are a tough target for current patent law; grants could help. Diagnostics range from simple blood tests used in everyday care to the use of next-generation sequencing and complex multigene panels to pinpoint the cause of cancer. Often, the science underlying a diagnostic test is developed with grant funding. For instance, the Supreme Court's 2012 case about diagnostic methods patents, *Mayo v. Prometheus*, turned on a relationship between the proper dosing of a drug and the amount of a drug-related metabolite in the patient's blood.[243] That relationship was identified through grant-funded research, though the Court did not note that.[244] When the Court held in *Mayo* that the resulting diagnostic test was unpatentable as essentially stating a natural law (the underlying relationship) and telling doctors to "apply it,"[245] scholars (including me) noted that this description could cover many diagnostic tests, and worried that patents would no longer provide adequate incentives for firms to develop diagnostic tests and bring them into the market and into clinical use.[246] Some have suggested changing patent law to allay this concern.[247] But grants may do the job without needing to change patent law.[248]

Grants could support the process of bringing scientific relationships into use as diagnostic tests. For some diagnostics, not much needs to be done to go from relationship to test: once scientists identify genetic mutations associated with a disease (often using grant money), doctors can then identify

exclusive intellectual property).

242. *See* Ouellette, *supra* note 22, at 1131–32, 1134–35, 1139.

243. Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66, 73–75 (2012) (describing diagnostic technology in question).

244. *See* Marla C. Dubinsky et al., *Pharmacogenomics and Metabolite Measurement for 6-Mercaptopurine Therapy in Inflammatory Bowel Disease*, 118 GASTROENTEROLOGY 705, 713 (2000) ("Supported by the Charles Bruneau Foundation . . . Fonds de la Recherche en Santé du Québec . . . and Fonds pour la Formation de Chercheurs et l'Aide à la Recherche . . . .").

245. *Mayo*, 566 U.S. at 72–73.

246. *See, e.g.*, Eisenberg, *supra* note 21; Sachs, *supra* note 21; W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*, 37 CARDOZO L. REV. 1401, 1425–26 (2016).

247. *See, e.g.*, Jeffrey A. Lefstin, Peter S. Menell & David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551 (2018) (outlining a workshop aimed at changing aspects of patent law).

248. Changing patent law back to a pre-*Mayo* state would bring its own complications. *See, e.g.*, Price, *supra* note 246, at 1444–45 (briefly discussing these problems and citing more in-depth analyses). At a minimum, the Supreme Court seems uninterested in this possibility, having reaffirmed *Mayo* in *Alice*; change would require Congressional action.

the mutation after obtaining the patient's genetic sequence.[249] In those cases, additional grants may not even be needed. If more research needs to be done—exploring how well existing assays measure the relationship, whether the relationship accurately predicts status in various groups, and whether measurements can be used to improve clinical outcomes—grants can support this work without relying on patent incentives. And where doctors need new technology to apply newly discovered scientific relationships, patent law can still provide the market-calibrated incentives it does for other biomedical technologies—but focused on the technology, not the underlying relationship. For diagnostics, then, grants can support intermediate-cost technologies where some incentive is needed but other incentives are unavailable.

* * *

Grants are not unique in their ability to create incentives for innovation where social value exceeds appropriable market value. Prizes, in particular, can also provide incentives for such innovation, because they typically do not rely on exclusivity or matching market demand.[250] Indeed, prizes may work better in some circumstances where parallel effort between many research teams is demanded,[251] though they do not particularly help capital constrained firms.[252] R&D tax credits also create incentives for innovation where social value exceeds appropriable market value, though they do so by reducing innovation costs across the board rather than by targeting particular areas of likely social benefit. The point is not that grants are the only mechanism that can create incentives to solve this type of innovation problem, but that grants are a useful tool in this area, and that they use a different set of decision processes to create incentives. Grants *are* unique, however, in a different area.

249. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1338 (Fed. Cir. 2011) (describing role of DNA testing in diagnostics). In a parallel to *Mayo*, the Supreme Court held in *Myriad* that unaltered genomic DNA is unpatentable, making simple genetic tests of the "here's an important mutation; find it to diagnose a problem" variety similarly unpatentable. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013) (holding that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated"). Today, doctors don't typically interpret genetic results on their own—genetic counselors act as intermediaries to interpret genetic testing results. A business model could rely on providing that intermediary service. *Cf.* Rachel E. Sachs, *Divided Infringement and the Doctor-Patient Relationship*, IP THEORY (forthcoming) (noting the difficulty of enforcing diagnostic methods patents in models with such intermediaries). But there is nothing to stop information about well-characterized mutations from becoming as routinely interpreted as, for instance, high cholesterol levels, once genetic sequencing becomes more common.

250. *See* Adler, *supra* note 16, at 12–13.

251. *Id.* at 13–14.

252. *See* Hemel & Ouellette, *supra* note 2, at 336.

B. INNOVATION ENABLERS

Grants can support the people, institutions, processes, and infrastructure that enable innovation and shape its direction. Let me unpack that through a comparison with other innovation incentives. Patents focus on particular inventions: a patent protects the invention itself from appropriation by someone other than the patentee. Similarly, prizes address a particular product or outcome, like creating an accurate clock, finding a way to preserve food for a long period of time, creating a reusable vehicle for space flight, or the like.[253] Trade secrecy protects information, whether that be a way of manufacturing a challenging drug or a carefully assembled list of potential customers.[254] Each of these creates an incentive to develop the thing, the product, the output—and the rest of the innovation process is shaped around that incentive. Grants are different. They *can* focus on particular projects; indeed, many do. But grants can also fund individuals directly, allowing that individual to innovate in whatever way she sees best, whether that be toward a commercially viable product, basic knowledge production, or a set of several linked possibilities. Grants can aim squarely to build institutions, supporting centers or networks that can then pursue their own institutional research and innovation goals. They can shape innovation processes and build resources that enable fields to move forward. In this flexibility of focus, grants diverge sharply from patents, trade secrets, and prizes.[255] This Section describes four potential grant targets besides projects themselves: people, institutions, processes, and infrastructural datasets.

253. *See, e.g.*, LONGITUDE PRIZE, https://longitudeprize.org/ [https://perma.cc/HL7C-YKN7] (last visited Mar. 11, 2019) (detailing the Longitude Prize, originally for ship navigation but currently for overcoming antibiotic resistance); Stephen Schaber, *Why Napoleon Offered a Prize for Inventing Canned Food*, NPR (Mar. 1, 2012) https://www.npr.org/sections/money/2012/03/01/147751097/why-napoleon-offered-a-prize-for-inventing-canned-food [https://perma.cc/LTE5-H9X4] (describing Napoleon's 1795 prize for improvement of food preservation methods); Tina Rosenberg, *Prizes with an Eye Toward the Future*, N.Y. TIMES (Feb. 29, 2012), https://opinionator.blogs.nytimes.com/2012/02/29/prizes-with-an-eye-toward-the-future/ [https://perma.cc/S8LZ-JY32] (noting the X Prize for private spaceflight); *see generally* Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401, 402–06 (2016) (describing the use of innovation prizes in general, including Longitude Prize and X Prize).

254. *See* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1044–45 (2016) (explaining trade secrecy in relation to biologics manufacturing); *see also* Robert G. Bone, *The (Still) Shaky Foundations of Trade Secret Law*, 92 TEX. L. REV. 1803, 1805–06 (2014) (describing trade secret doctrine).

255. Inasmuch as tax incentives create fungible incentives for any type of research undertaken by an entity which would otherwise owe income taxes, they function as an entity-targeted incentive rather than an outcome-focused incentive. *See* Hemel & Ouellette, *supra* note 2, at 321–26.

1. People

Two types of people might merit particular focus in terms of funding innovation: the exceptional and the young. Orthogonally, grants can support individuals either directly, without regard to project, or by weighing individual characteristics in addition to project merit.

a) The Exceptional and the Young

Why focus on exceptional individuals and the young? For the first, we might find it worthwhile to target truly exceptional individuals for grant support. That is, if we can identify the best scientists, we might judge them particularly good targets for grant funding because we think their projects are likely to be particularly influential.[256] We might also think them likely to produce, on average, more good ideas than other researchers; helping them pursue those projects rather than struggle for funding would increase social benefits.[257]

Separately, we might benefit from targeting younger scientists for grant support. Freeman and Van Reenen point to three reasons that younger scientists should be particular targets of grant funding: (1) in many fields, especially highly technical fields, researchers do their best work when they are relatively young, (2) providing funding early in a young scientist's career increases the odds that she will continue to pursue science, and (3) funding for scientists is among other things an investment in human capital.[258] All things being equal, a younger scientist has more time left in her career to use that capital (and to produce social benefits from that investment) than an older scientist.[259] Grant support is crucial to the careers of young scientists; as McGarity describes it, "[y]ounger scientists at prestigious institutions have no hope of becoming tenured if they do not have at least one NIH or NSF grant."[260]

256. *See* Maurer & Scotchmer, *supra* note 209, at 17–18 (describing the need to identify the most creative individuals), 22–23 (arguing that researchers with the most fertile minds will self-select into the grant system).

257. *Id.* at 23–24.

258. For empirical evidence that human capital investments are more important to innovation than physical capital investments, see Fabian Waldinger, *Bombs, Brains, and Science: The Role of Human and Physical Capital for the Creation of Scientific Knowledge*, 98 REV. ECON. & STAT. 811, 811 (2016).

259. Freeman & Van Reenen, *supra* note 91, at 22–23.

260. McGarity, *supra* note 91, at 65 ("Denying a grant to a more established researcher can close his or her laboratory and effectively end his or her career as a productive researcher."); *see* Freeman & Van Reenan, *supra* note 91, at 19. Of course, grants are also important to later researchers.

Unfortunately, the current reality is that younger scientists have a hard time getting grant funding. The average age at which a PhD scientist gets her first R01 grant has been around 42 for several years; in 1980 it was 36.8.[261] Freeman and Van Reenen calculate that younger scientists have approximately tenfold worse chances of winning an R01 grant than scientists over 45.[262] This fact has worried scientists and policymakers, leading to policy changes including the mechanisms described in the next Section.[263]

b) Person-Focusing and Project-Weighting

A preference for a particular type of individual in grant funding can be implemented in at least two ways. First, grants can fund an individual separate from any project, to enable her to innovate, or to train her and therefore increase her human capital. Second, grant funding decisions can still focus on projects, but can heavily weight particular researcher characteristics.

Table 1: Examples of Grants Targeting People

	Person-focused		**Project preference**
	Training	*Enabling*	
Exceptional	n/a	HHMI, MacArthur	Implicit advantage
Young	F31, F32	n/a	ESI rules

Some individual-targeted grants focus entirely on enabling innovation by the individual. Training grants are common and aim to increase the expertise and human capital of the funded individual. The NIH offers several types of training grants, such as the F31 grant for supervised research training of doctoral candidates, the F32 grant for postdoctoral fellows "to broaden their scientific background and extend their potential for research," and the F33 Senior Fellow grant to help "experienced scientists to make major changes in the direction of research careers, or to acquire new research capabilities."[264] These grants are "training awards and not research awards."[265] They do not

261. *See Average Age and Degree of NIH R01-Equivalent First-Time Awardees Fiscal Years 1980-2016*, NIH, https://grants.nih.gov/grants/new_investigators/Average_age_initial_R01.xls [https://perma.cc/63JU-9FNY] (last visited Mar. 11, 2019).

262. Freeman & Van Reenen, *supra* note 91, at 21.

263. *See, e.g.*, Ronald J. Daniels, *A Generation at Risk: Young Investigators and the Future of the Biomedical Workforce*, 113 PROC. NAT'L ACAD. SCI. 313 (2015) (describing the effects of declining research grants to young researchers to the biomedical industry).

264. *Individual Fellowships*, NIH, https://researchtraining.nih.gov/programs/fellowships [https://perma.cc/GS28-HBB4] (last visited Mar. 11, 2019).

265. NIH GRANTS POLICY STATEMENT, *supra* note 70, at IIB-37.

focus on the project, but rather the candidate's potential and need for training as well as how the proposed training, sponsor, and environment will address that need.[266] The K series grants similarly serve career development goals.[267] This group of grants focuses entirely on individuals and on enabling future innovation by building human capital.[268]

A different type of individual-enabling grant simply provides resources and an open mandate to an exceptional individual. The reasoning is that exceptional individuals, given freedom and resources, will tackle hard, risky problems and may produce exceptional results.[269] The NIH doesn't focus on this type of award, but other funders sometimes do. The Howard Hughes Medical Institute is perhaps the most substantial such funder and the MacArthur Foundation the closest follower of an individual-focused model. Howard Hughes, with the motto "People, Not Projects," identifies outstanding biomedical innovators, selects them as Howard Hughes Medical Investigators (currently there are around 300), and provides them with substantial funding—around $1 million per year—for renewable seven-year terms.[270] Howard Hughes aims to give "our scientists the time and freedom to pursue difficult, long-range questions,"[271] and at least some evidence suggests that this strategy works.[272] The MacArthur Foundation provides even purer grant funding to exceptional individuals, commonly known as Genius Grants.

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266. *Id.*

267. *Id.* at IIB-80 (e.g., K01 grants for advanced research training and additional experience).

268. *Id.*

269. Patents can also highly reward the exceptional scientist, of course, but that depends on the research creating appropriable rewards; prizes depend on *post-hoc* recognition and typically do not provide funds to support research going forward.

270. *See Fast Facts*, HOWARD HUGHES MED. INST., https://www.hhmi.org/press-room/fast-facts [https://perma.cc/A3WS-F2EZ] (last visited Mar. 11, 2019) (noting 292 current HHMI investigators); *HHMI Bets Big on 19 New Investigators*, HOWARD HUGHES MED. INST., https://www.hhmi.org/news/hhmi-bets-big-on-19-new-investigators [https://perma.cc/TAU3-UQ58] (last visited Mar. 11, 2019) (noting approximately $8 million in grants over a seven-year term for each Investigator). Technically, the researchers become HHMI employees, suggesting something more like a patronage model than classical grant funding. *See Our Scientists*, HOWARD HUGHES MED. INST., http://www.hhmi.org/scientists [https://perma.cc/DSS8-9J7C] (last visited Mar. 11, 2019). But they remain at their home institutions and retain their home appointments, and receive substantial funding to continue research in that context, making the appointment look very much like a person-focused grant. *Id.*

271. *Biomedical Research Programs*, HOWARD HUGHES MED. INST., http://www.hhmi.org/programs/biomedical-research [https://perma.cc/5E8M-7Y9H] (last visited Mar. 11, 2019).

272. *See* Azoulay, Zivin & Manso, *supra* note 202, at 528–29 (noting substantial differences in funding mechanisms and finding that Howard Hughes Medical Investigators produced more high-impact publications than NIH-funded scientists with similar accomplishments).

It provides "$625,000, no-strings-attached" five-year grants based on "[e]xceptional creativity" and the potential for substantial future work.[273] The Foundation "does not require or expect specific products or reports" from recipients.[274]

A different approach prioritizes projects by taking into account the characteristics of the individual researchers. The clearest example of this explicit prioritization comes in the NIH's special rules for grant applications by New and Early Stage Investigators—respectively, those who have not yet won a major research award and those within ten years of finishing their terminal degree.[275] For several years, the NIH has tried to reduce the age at which young scientists win their first major grants. The NIH clusters grant applications from New Investigators in peer review, so it can compare researchers with similar experience.[276] At least half of researchers receiving their first R01 or equivalent grant must be within ten years of finishing their terminal degree.[277] Finally, NIH Institutes make funding decisions aimed to achieve similar success rates for new grant applications by New Investigators and established investigators.[278] For instance, the National Cancer Institute's 2016 funding policy funded grants to the 10th percentile for established investigators but the 12th percentile for Early Stage Investigators—effectively putting a thumb on the scale for young researchers.[279] These policies generally reflect the goal of providing funding to younger scientists to invest in their futures—a goal that grants are uniquely suited to advance.[280]

273. *About MacArthur Fellows Program*, MACARTHUR FOUND., https://www.macfound.org/programs/fellows/strategy/ [https://perma.cc/6L9N-L5BF] (last visited Mar. 11, 2019).

274. *Id.*

275. *Early Stage Investigator Policies*, NIH, https://grants.nih.gov/policy/new_investigators/index.htm [https://perma.cc/3HFY-DTL7] (last visited Mar. 11, 2019). For researchers who are medical doctors, Early Stage Investigators are those within ten years of finishing their medical residency. *See id.* To the best of my knowledge, no similar program exists for exceptional individuals—but exceptional researchers would be expected to submit exceptional grant applications in any case, and so should have an implicit advantage anyway.

276. *See id.*

277. *Id.*

278. *See id.*

279. NCI, *2016 Funding Strategy*, *supra* note 146. The NIH Director also has a set of grants to support extraordinary individuals, some of which, like the DP1 NIH Director's Pioneer Award, are specifically targeted at exceptional young researchers Grants. *See Types of Grant Programs*, NIH, https://grants.nih.gov/grants/funding/funding_program.htm [https://perma.cc/TZ3T-BDWV] (last visited Mar. 11, 2019) [hereinafter NIH, *Activity Codes*] (providing overview of NIH Activity Codes).

280. Some prizes are explicitly targeted at the young, such as the Fields medal or the John Bates Clark medal, rewarded to outstanding mathematicians and economists, respectively,

1. Institutions

Grants can also target broader innovative entities, providing funding to institutions to enable future innovation. NIH grants typically fund research within a laboratory environment, whether in an academic institution, a hospital, or private industry. And indeed, NIH support for labs is critical; grants provide support for equipment, salaries, and research supplies, and are especially important in capital-constrained environments.[281] This ability of grants to purchase the equipment necessary for research has even been raised as a justification for the historical move from a prize-based to a grant-based innovation system.[282] More broadly, grants can enable the creation of new institutions, support the efforts of existing institutions, or allow existing institutions to increase their capacity. Similar to the focus on exceptional individuals described above, the NIH can identify institutions that are likely to be especially productive and help them increase their capabilities.

The NIH provides many grants specifically targeted at increasing institutional capabilities. The G11 grant helps institutions improve their research infrastructure by providing funds for them to establish an office of sponsored research to work with grant funders.[283] M01 grants support "General Clinical Research Center[s] where scientists conduct studies on a wide range of human diseases using the full spectrum of the biomedical science," and can fund renovation, staff salaries, equipment, and supplies.[284] P01 grants support research programs, P30 grants support administrative cores for centers, P51 grants support primate research colonies, and P60 grants support comprehensive centers—the list goes on.[285] Suffice it to say, the NIH can and does target institutions, centers, and programs of different sizes and foci, all to further the goal of enabling innovation by those best suited to innovate. As with focusing on individuals, this institution-supporting role is essentially unique to grants.

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under the age of forty. *Fields Medal*, INT'L MATHEMATICAL UNION, https://www.mathunion.org/imu-awards/fields-medal [https://perma.cc/4VSW-EWA4] (last visited Mar. 11, 2019); *John Bates Clark Medal*, AM. ECON. ASS'N, https://www.aeaweb.org/about-aea/honors-awards/bates-clark [https://perma.cc/5LG3-DQU4] (last visited July 2, 2017). However, such prizes generally do not provide substantial funds for either training or research going forward.

281. Hemel & Ouellette, *supra* note 2, at 334–38.

282. *See, e.g.*, Hanson, *supra* note 52, at 7–8.

283. *See* NIH, *Activity Codes*, *supra* note 279 (G11 grant description available from dropdown list).

284. *Id.* (M11 grant description available from dropdown list).

285. *Id.*

2. Processes

Grants can influence the processes through which innovation takes place; in particular, they can create incentives for collaboration and interdisciplinary work. Again, this focus differs from other incentives; patents, prizes, and tax R&D incentives tend not to take account of innovation environment. Collaboration may impact the value of these rewards—joint inventorship changes the control mechanisms for patents, and of course joint creation splits the reward of any of these mechanisms—but other policy levers do not specifically encourage collaboration.[286] Grants, by contrast, can and do.

Grants can generally target collaborative work where researchers from different labs or institutions work together on a funded project. Encouragement can be explicit, such as requirements that recipients participate in collaborative research networks.[287] Elias Zerhouni, the Director of the NIH, launched the 2002 Roadmap for Medical Research Initiative specifically to encourage and fund collaborative team science.[288] Grants may also implicitly encourage collaboration by preferentially funding projects that require collaborative work.[289]

An important subset of process-focused grants promotes interdisciplinary work. Boundary-crossing work can push forward the frontiers of science and innovation.[290] However, interdisciplinary work is hard; it is challenging to master multiple disciplines or to reach across disciplinary lines, and interdisciplinary researchers may encounter resistance from peers and scientific institutions.[291] Such work is also "high-risk, high-reward," suggesting

286. *See* Gregory N. Mandel, *To Promote the Creative Process: Intellectual Property Law and the Psychology of Creativity*, 86 NOTRE DAME L. REV. 1999, 2001 (2011) ("Problematically, the laws of joint authorship and joint inventorship in intellectual property actually dissuade certain collaboration.").

287. Interview with Anonymous Senior Scientist (June 7, 2017) (on file with author) (describing grant requirement that recipients participate in a research network and noting that it led to productive collaborative work).

288. *See generally* Elias A. Zerhouni, *The NIH Roadmap*, 302 SCIENCE 63 (2003).

289. *See* Robin Barr, *R01 Teams and Grantee Age Trends in Grant Funding*, NIH NAT'L INST. ON AGING (April 22, 2015), https://www.nia.nih.gov/research/blog/2015/04/r01-teams-and-grantee-age-trends-grant-funding [https://perma.cc/F7JB-6EWL] (noting that the modal top-scoring R01 grant in 2005 had one principal investigator; in 2015 it had four).

290. *See* JULIE THOMPSON KLEIN, INTERDISCIPLINARITY: HISTORY, THEORY, AND PRACTICE 12 (1990); Pedraza-Fariña, *supra* note 10, at 439–41; *see also* Michal Shur-Ofry, *Connect the Dots: Patents and Interdisciplinarity*, 51 MICH. J.L. REFORM 55, 62–65 (2017).

291. *See* Pedraza-Fariña, *supra* note 10, at 423–24 (discussing social barriers to interdisciplinary innovation). There is a rich literature outside law on interdisciplinarity. *See, e.g.*, Susan Leigh Star & James R. Griesemer, *Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39*, 19 SOCIAL

that innovation incentives are likely to be useful in promoting investment. Unfortunately, patents aren't especially good at promoting interdisciplinary work; Michal Shur-Ofry writes that patent law generally regards interdisciplinary combinations "not as a potential source of groundbreaking innovation, but at most, as an excusable flaw."[292]

Grants, on the other hand, can directly target and facilitate interdisciplinary work.[293] Laura Pedraza-Fariña examines an NIH grant program that aimed squarely at interdisciplinary work.[294] She focuses on one part of Zerhouni's Roadmap, the Interdisciplinary Research Consortia grants, which funded nine interdisciplinary consortia between 2005 and 2012.[295] Pedraza-Fariña recounts the formation of the Oncofertility Consortium, a network of researchers focused on solving the problem of oncofertility—that is, how can we ensure that cancer patients can still have children after their treatment?[296] Oncofertility is a knotty scientific problem, and a tough interdisciplinary one: oncologists, reproductive endocrinologists, and basic research scientists have substantially different approaches and areas of expertise.[297] Pedraza-Fariña describes how the grant program, which specifically called for interdisciplinary applications, served as a "catalyst to collaboration—providing short-term, seed funding to enable cross-disciplinary collaboration."[298] It did so by combining several different grant types, including some types described above: a U54

STUD. SCI 387 (1989) (coining the term "boundary object"); TRADING ZONES AND INTERACTIONAL EXPERTISE: CREATING NEW KINDS OF COLLABORATION (Michael E. Gorman ed., 2010) (discussing framework for fostering interdisciplinary collaborations).

292. Shur-Ofry, *supra* note 290, at 72; *see* Pedraza-Fariña, *supra* note 10, at 436–38 (arguing that patent doctrine is actively hostile to interdisciplinary innovation and suggesting modifications); Mandel, *supra* note 286; Jacob S. Sherkow, *Negativing Invention*, 2011 BYU L. REV. 1091, 1094–95 (2011) (noting that interdisciplinary combinations are less susceptible to "analogous arts," and have the effect of "negativing" inventions).

293. *See* Pedraza-Fariña, *supra* note 10, at 442 ("[G]overnment grants or prizes can be structured to incentivize the identification of problems whose solution requires the combined expertise from multiple disciplines and subdisciplines."). Note that collaboration and interdisciplinarity are not targets only of NIH grants, nor indeed only of federal grants; they can be targeted by any grant funder. *See, e.g.*, *MCubed*, UNIV. MICH., *supra* note 83 (noting that funding will be provided only to teams of at least three faculty researchers from at least two different campus units).

294. *See generally* Pedraza-Fariña, *Oncofertility*, *supra* note 240.

295. *Id.* at 260 (citing *Interdisciplinary Program Snapshot*, NIH, https://commonfund.nih.gov/Interdisciplinary [https://perma.cc/8U8V-JJ28]). Because obtaining cross-disciplinary grants from individual disease-focused NIH Institutes is hard, the broader Interdisciplinary Research program was funded by the Common Fund, a central pool of money used for larger strategic NIH initiatives. *Id.*

296. *Id.* at 260.

297. *Id.* at 260–61.

298. *Id.* at 261.

Cooperative Agreement for a specialized center to support a centralized administrative core to organize and coordinate the team,[299] four R01 Research Project grants to support basic research into female follicles,[300] two P30 Center Core grants to fund a core for maintaining and distributing patient samples and other materials and to fund the National Physician's Cooperative (the network of participants), an R25 Education Project grant to fund an "educational module," and three different grants (a T90 Interdisciplinary Research Training Award, an R90 Interdisciplinary Regular Research Training Award, and a K01 Research Scientist Development Award - Research & Training) to fund training for oncofertility specialists.[301] The Interdisciplinary Research Consortia program leveraged several different grant regimes with the goal of not only supporting interdisciplinary collaboration, but also of catalyzing something that would last long-term. In short, the grant program tried to use a jolt of focused funding to create something novel and sustainable.

And it worked. As Pedraza-Fariña documents, the Oncofertility Consortium developed specifically in response to the Interdisciplinary Research Consortia program's call for applications. Although the scientists involved knew each other, "none of them . . . had embarked on a collaboration of this magnitude, nor held a focused discussion on how to address fertility preservation questions in a concerted manner prior to applying for the oncofertility consortium grant."[302] Although the Interdisciplinary Research Consortia program ended in 2012, the Oncofertility Consortium continues today.[303] In addition, the Consortium has built infrastructure that can be used going forward and has spawned other ongoing collaborations.[304]

The Oncofertility Consortium was not the only interdisciplinary consortium funded by the NIH's program. The program also funded consortia focused on the molecular mechanisms of stress; the science of aging with a focus on cancer, organ design and engineering; and obesity and metabolic disorders, among others.[305] At least some are still active today.[306] And as

299. *Id.* at 280.

300. *Id.* at 262 n.20.

301. *Id.* at 280.

302. *Id.* at 275.

303. THE ONCOFERTILITY CONSORTIUM, http://oncofertility.northwestern.edu/ [https://perma.cc/B493-SUKY] (last visited Mar. 11, 2019).

304. Pedraza-Fariña, *Oncofertility*, *supra* note 240, at 283.

305. *See Interdisciplinary Research Consortia*, NIH, https://commonfund.nih.gov/Interdisciplinary/consortia [https://perma.cc/FM58-MWH3] (last visited Mar. 11, 2019).

306. In comparison with the still-vital Oncofertility Consortium, see, for example, *Taskforce for Obesity Research at UT Southwestern (TORS)*, U.T. SOUTHWESTERN, https://www.utsouthwestern.edu/education/medical-school/departments/center-human-

Pedraza-Fariña points out, overcoming initial hurdles to collaboration may be much of the battle; even if particular consortia end, the possibility of interdisciplinary collaboration remains easier after the initial structural work has been done—work that grants can specifically target and support.[307]

3. Infrastructure

Finally, grants can specifically target infrastructural goods to create broad support for future innovation. Brett Frischmann characterizes infrastructural goods by three key traits: (1) they "may be consumed nonrivalrously for some appreciable range of demand"; (2) they are valuable largely because they are inputs into downstream productive activities; and (3) such activities may produce a wide range of goods, including public goods, social goods, and private goods.[308] Infrastructural goods are socially valuable because they enable a broad range of activities and have many spillovers; they are public goods and enable others to generate public goods.[309] But that's why the incentives to invest in infrastructural goods tend to be too low. On the supply side, it is hard for infrastructure investors to appropriate the full social benefits of their investment: infrastructure has spillover benefits that are hard to capture.[310] And on the demand side, even if infrastructure investors could appropriate all the private demand for the infrastructural good, users are unlikely to be willing to *pay* the full social value for access to the infrastructure, because they may be creating public goods whose benefits *they* cannot appropriate.[311] All of which is to say: infrastructural goods have substantial social benefits, but it is rare for private entities to have the right incentives to either create the infrastructure in the first place or allow broad enough, cheap enough use that downstream users create the largest social value.[312]

Enter grants. The government can get involved to help overcome the challenges with private incentives for infrastructure.[313] Sometimes that is direct construction; for example, the federal government built and runs the interstate highway system.[314] Sometimes not; grants can provide a powerful way to

nutrition/obesity-alliance.html [https://perma.cc/LF23-VR2X] (last visited Mar. 11, 2019) (showing no publications after 2012 and no conference meetings after 2014).

307. Pedraza-Fariña, *Oncofertility*, *supra* note 240, at 283–84.

308. BRETT M. FRISCHMANN, INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES 61–62 (2013).

309. *Id.* at 68–69.

310. *Id.* at 14–15.

311. *Id.* at 71–72.

312. *See id.* at 98.

313. *Id.* at 14–15.

314. *Id.* at 189–90.

leverage non-governmental expertise in large, infrastructural projects designed to create resources that will broadly enable future scientific endeavors.[315] These projects tend to be motivated by the centralized belief—held by both administrators and scientists—that the infrastructure project will create substantial social value. Prominent NIH programs have thus used grants to drive large-scale scientific infrastructure projects and to make their fruits broadly available.[316]

The Human Genome Project, which started at the end of the 20th century, is a key example.[317] The Project was a massive undertaking that aimed to sequence the entire human genome.[318] The explicit goal of the project was to create infrastructure for future research, "to provide researchers with powerful tools to understand the genetic factors in human disease, paving the way for new strategies for their diagnosis, treatment and prevention."[319] Liscow and Karpilow highlight the potential for government spending to shift the course of future innovation: where legacy technologies (in their example, high-pollution fossil fuel technology) benefit from a large existing stock of knowledge, concentrated government efforts to support knowledge generation in a new technology can shift future innovation in a socially desirable direction.[320]

The Human Genome Project followed this pattern, creating benefits beside the genome map itself. The production of a human genome sequence enabled a large set of downstream uses, including developments in pharmacogenomics and genetic testing.[321] It helped shift innovation away from

315. *See generally* Jorge L. Contreras, *Leviathan in the Commons: Biomedical Data and the State*, *in* GOVERNING MEDICAL KNOWLEDGE COMMONS 19 (Kathy J. Strandburg, Brett M. Frischmann & Michael J. Madison eds., 2017) (describing the ways government actors shape biomedical data resources beyond merely supporting their creation).

316. *See* Jorge L. Contreras, *Bermuda's Legacy: Policy, Patents, and the Design of the Genome Commons*, 12 MINN. J.L. SCI. & TECH. 61 (2011) (describing the evolution of data release policies for genomic data starting with the 1996 Bermuda Principles); Jorge L. Contreras, *Constructing the Genome Commons*, *in* GOVERNING KNOWLEDGE COMMONS 99, 102 (Brett M. Frischmann, Michael J. Madison & Kathy J. Strandburg eds., 2014) (describing genomic data as a commons with a "unique polycentric governance institution").

317. *See* HILGARTNER, *supra* note 174 (describing the history of the Genome Project, focusing on the creation and change of knowledge-control regimes).

318. Of course, there is no one human genome; almost everyone's is different. The Project aimed to generate a generalized consensus sequence upon which variations could be mapped.

319. NIH, FACT SHEET: HUMAN GENOME PROJECT 1 (Oct. 2010), https://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf [https://perma.cc/NY3D-2XEQ] [hereinafter NIH, FACT SHEET].

320. Liscow & Karpilow, *supra* note 51, at 392–93.

321. *See* NIH, FACT SHEET, *supra* note 319 (noting thousands of disease genes discovered, thousands of new genetic tests, hundreds of biotechnology products in clinical trials, and

the use of inexact or problematic proxies, like using race as a proxy for unmeasured genetic traits, and toward more direct genetic diagnostics.[322] The Human Genome Project also created a guaranteed demand for technological advances that otherwise might be too risky, including novel genetic sequencing technology.[323] The project explicitly sought to develop technology and information infrastructure, eventually leading to lower costs despite the initial outlay.[324]

A private effort to sequence the human genome, Celera Genomics, illustrates the role of the government in such infrastructure projects. Celera Genomics entered the fray several years after the Human Genome Project began, aiming to complete its sequence much faster than the publicly funded effort.[325] But Celera Genomics' own effort—while impressive, fast, and generating and leveraging its own technological advances—itself relied substantially on publicly funded sequence data infrastructure resources.[326] According to Steven Hilgartner's history of the Human Genome Project, approximately 60% of the completed sequence shared in Celera's Science paper was in fact downloaded from the Human Genome Project's publicly available dataset.[327] The differences between the two projects also illuminate the benefits of publicly funded, relatively open management of infrastructural resources.[328] The publicly funded effort helped develop the technology that supported the private effort—which then developed its own tremendously useful technology and created an important comparator sequence.[329] But even once both sequences existed, Celera's management of its own sequence as a private resource with paid access limited the sequence's uses to those with the resources to pay, and, likely, to a subset of uses with more potential for immediate commercial gain rather than basic research or other projects with

ongoing enabled scientific research).

322. *See* W. Nicholson Price II, Note, *Patenting Race: The Problems of Ethnic Genetic Testing Patents*, 8 COLUM. SCI. & TECH. L. REV. 119, 134–37 (2007).

323. *Cf.* Glennerster, Kremer & Williams, *supra* note 57, *passim* (describing advance purchase commitments as a mechanism to create incentives for firms to develop vaccines that otherwise might be too risky to draw enough investment).

324. *See* HILGARTNER, *supra* note 174, at 50.

325. *Id.* at 206–10.

326. *Id.* at 221.

327. *Id.*

328. *See supra* notes 308–313 and accompanying text.

329. *See* Int'l Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001) (announcing the Human Genome Project's completed sequence); *see also* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304 (2001) (announcing Celera's completed sequence).

greater spillovers.[330]

Today, grants can help develop precision medicine and complex algorithms based on medical big data. The Precision Medicine Initiative aims to advance our knowledge of precision medicine, providing "the right treatments to the right patients at the right time."[331] It does this by supporting basic scientific research along these lines and also by partnering with many institutions to gather extensive genetic and health information, as well as biospecimens, on over one million volunteers—the "All of Us" cohort—as an infrastructural resource for future innovation.[332] As Sachs notes, such large infrastructural initiatives can also focus other stakeholder efforts; the Precision Medicine Initiative has stimulated non-governmental investors to commit over $200 million.[333]

A step further in the future, complex medical algorithms have the potential for tremendous benefits to the health care system, including improving patient care, optimizing resource allocation, suggesting new possibilities for treatment, and identifying problems or unknown benefits of existing drugs.[334] But current innovation incentives are problematic. Patents are often unavailable, and relying on secrecy for databases or algorithms creates an array of problems.[335] In addition, market signals of demand may substantially underrepresent social value, particularly for the collection and use of data for underserved populations, including poor and minority populations.[336] NIH grants could support the development of infrastructure, focusing on assembling and curating data, especially for underserved populations, and making it broadly

330. HILGARTNER, *supra* note 174, at 212–13.

331. *See Precision Medicine*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/precisionmedicine-medicaldevices/default.htm [https://perma.cc/9ZMZ-GK2E] (last visited Mar. 11, 2019).

332. *Scientific Opportunities*, NIH, https://allofus.nih.gov/about/scientific-opportunities [https://perma.cc/H7EX-6V6A] (last visited Mar. 11, 2019) ("The program will set the foundation for new ways of engaging research participants, sharing health data and information, and employing technology advances to mine the information for comprehensive results."); *see Awardees*, NIH, https://allofus.nih.gov/funding/awardees [https://perma.cc/PA8E-TZNW] (last visited Mar. 11, 2019) (noting award of a U24 Cooperative Agreement to the Mayo Clinic to host a specimen biobank).

333. Sachs, *supra* note 238, at 2002 (citing Press Release, White House, FACT SHEET: Obama Administration Announces Key Actions to Accelerate Precision Medicine Initiative (Feb. 25, 2016)).

334. W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 434–37 (2015) (discussing "black-box medicine" and the use of opaque computational models to make decisions related to health care).

335. Price, *supra* note 246, at 1419–36.

336. *See supra* Section IV.A.1.

available to the research community.[337] The "All of Us" cohort provides a start, but the NIH could go even further, broadening the reach of potential data, populations included, and research analyses supported.

V. CONCLUSION

Grants are a useful tool in the innovation toolbox. Although there is some truth to common critiques—bureaucrats are involved in decisions, individual grants are indeed ex ante funding with relatively low accountability, and the government doesn't profit directly from grant-funded research—the reality is much more complex, and the critiques mask this complexity. Funding decisions are largely made by scientists based on scientific merit, the repeat-player nature of grants creates accountability, and the government and society reap substantial indirect benefits from grants whether they succeed or fail. Moreover, the grant application process and the peer review process bring considerable information and expertise to bear on government choices about what projects to fund.

While I am enthusiastic about what the grant system has to offer, I do not mean to suggest, a naïve Pollyanna, that the system is wrinkle-free. The three critiques have some truth to them and the system has other problems. The system of repeat players can privilege experience and erect barriers to entry for new innovators, especially innovators who do not tread the typical path.[338] Seeking grants can consume inordinate amount of a researcher's time and energy;[339] postdoctoral fellows can be trapped in fellowships or chased from science by the unavailability of grants.[340] And the hunt for scarce money can warp research priorities despite the best efforts of funders and peer reviewers. Grants are not perfect.

Nevertheless, the overall system, the aggregation of scientific knowledge

337. *See, e.g.*, W. Nicholson Price II, *Risk and Resilience in Health Data Infrastructure*, 16 COLO. TECH. L.J. 65, 77–83 (2017) (discussing the benefits of investment in health data infrastructure).

338. *See supra* notes 158–165 and accompanying text.

339. *See, e.g.*, *Dr. No Money: The Broken Science Funding System*, SCI. AM. (May 1, 2011), https://www.scientificamerican.com/article/dr-no-money/ [https://perma.cc/TRB9-G5ML] (arguing that scientists spend too much time raising funds instead of doing experiments); Matt Welsh, *The Secret Lives of Professors*, MATT-WELSH.BLOGSPOT (May 24, 2010), http://matt-welsh.blogspot.com/2010/05/secret-lives-of-professors.html [https://perma.cc/NCQ6-FLF8] (discussing the marketing and fundraising aspect of science).

340. *See, e.g.*, Muhammed Z. Ahmed, *The Postdoc Crisis*, SCIENTIST (Jan. 4, 2016), https://www.the-scientist.com/opinion/opinion-the-postdoc-crisis-34259 [https://perma.cc/6WQW-KKSN] (arguing that postdoctoral fellows have few prospects in academia because of funding issues).

and priorities—with input from the government as to social benefit—is not inferior to determinations that arise from private market aggregation of private knowledge; it's just different. The grant system has its own flaws and foibles, but also, importantly, presents an alternative decision-making process that avoids the flaws and foibles of the market-dominated systems of other innovation levers. If our only goal is the cheapest development of drugs for the wealthy, then we can probably rely only on market mechanisms to allocate innovation and do just fine. But if we care more broadly about the formation of new scientific fields before the promise of obvious commercial profits, the development of drugs for the poor, the creation of difficult-to-exclude knowledge, the nourishment of mobile young scientists, the creation of interdisciplinary networks, or the pursuit of other goals that the market and private knowledge can neither appropriately value nor staff, then grants provide an attractive set of policy options. Grants are not the only way to pursue these goals, but they use a different way of gathering information and allocating resources that make such pursuits more straightforward.

A complete understanding of the role of grants in the innovation ecosystem demands more study, both theoretical and empirical. In addition to comparisons of grants with other innovation levers that incorporate a more nuanced view of grants, future studies could examine more closely how different levers function together.[341] Innovation levers don't work in a vacuum; trade secrets exist before patents, researchers can patent results of both grant-funded research and private research subsidized through the tax system, prizes kick in at the end, and grants can stretch across multiple innovative efforts. We should understand how these levers work in concert—or how they compete against and distort one another.[342] Such scholarship could include large-scale quantitative analyses of many actors across the economy, small-scale examinations of specific innovation contexts,[343] or theoretical conceptions of how different levers can and should interact.[344] The political

341. Brett Frischmann, Michael Madison, and Kathy Strandburg's work on studying innovation commons involves this sort of thick, cross-lever innovation exploration, though focused on the role of information commons. *See generally* GOVERNING MEDICAL KNOWLEDGE COMMONS (Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison, eds., 2017).

342. *See, e.g.*, Price & Rai, *supra* note 254 (describing innovation-stifling effects from the intersection of patents, trade secrecy, and regulatory product definitions).

343. *See, e.g.*, Sarnoff, *Likely Mismatch*, *supra* note 31, at 374–80 (noting the context specificity of innovation incentives); Gallini & Scotchmer, *supra* note 38 (same); Hemel & Ouellette, *supra* note 2, at 378–80 (discussing the mix of innovation levers deployed in the context of orphan drugs).

344. *See, e.g.*, Daniel J. Hemel & Lisa L. Ouellette, Innovation Policy Pluralism (2017) (unpublished manuscript) (on file with author) (theorizing and describing examples of the

economy of grants—routinely receiving bipartisan support from Congress, but nonetheless vulnerable to political vicissitudes and potentially changing funding[345]—further shapes their place in the innovation policy toolbox and deserves closer examination in this literature. Finally, studies of grants as part of the innovation policy toolbox should consider the nitty-gritty details of how grants work best on the ground, incorporating empirical studies from the economics of innovation into the design of research policy.[346] Improving grant functioning could even involve its own experimentation, changing funding mechanisms for just a subset of innovators and evaluating the results.[347] Grants are a key part of the innovation ecosystem, but they are often not treated that way by the literature on innovation law and policy. It is time for that to change.

mixture of intellectual property and non-IP mechanisms in innovation policy).

345. *See* Deepak Hegde & David C. Mowery, *Politics and Funding in the U.S. Public Biomedical R&D System*, 322 SCIENCE 1797 (2008) (noting some evidence of the politicization of the grants process); Pear, *supra* note 5 (reporting that Congress rejected President Trump's proposal to cut N.I.H funding and instead increased funding).

346. *See, e.g.*, Freeman & Van Reenan, *supra* note 91 (examining the impact of the 1998–2003 doubling of the NIH budget on the biomedical sciences); Michael Levitt & Jonathan M. Levitt, *Future of Fundamental Discovery in US Biomedical Research*, 114 PROC. NAT'L ACAD. SCI. 6498 (2017) (finding bias against awarding grants to younger applicants, in favor of older principal investigators).

347. *See* Pierre Azoulay, Joshua S. Graff Zivin & Gustavo Manso, *National Institutes of Health Peer Review: Challenges and Avenues for Reform*, *in* 13 INNOVATION POLICY & THE ECONOMY 1, 13–16 (Josh Lerner & Scott Stern eds., 2013) (examining peer-review practices in light of NIH's bias for funding older scientists and the innovativeness of that funded research).