

ADMINISTERING HEALTH INNOVATION

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Scholars and policymakers have recently begun to focus on the role federal agencies charged with health-related missions can play in the development of innovative health technologies and promotion of access to those technologies. Appreciating the expertise of agencies like the National Institutes of Health, Food and Drug Administration, and Centers for Medicare and Medicaid Services has expanded the range of tools contemplated by scholars who had previously focused largely on the United States Patent and Trademark Office.

Yet much of this attention has so far focused on the capacities of single agencies, acting alone. This Article expands the existing scholarly focus, considering not only the potential innovation-related goals to be achieved if each agency acts alone, but also the potential for collaboration across agencies. This Article advances that conversation, drawing not only on the health innovation policy literature but also on the growing administrative law literatures focusing on inter-agency and intra-agency coordination models.

This Article develops a taxonomy of potential modes of collaboration, demonstrating how these agencies, which lack formally shared regulatory authority over the innovation space, nonetheless may collaborate to promote incentives for innovation. These agencies do sometimes collaborate to advance goals which are common to the agencies. But they can do more. These agencies may complement each other, accomplishing together socially valuable ends that cannot be accomplished alone. By considering each agency's core competency, this Article develops specific proposals for agencies to work together going forward.

This Article goes on to consider legal barriers to existing collaboration and potential procedural mechanisms for enhancing collaboration between these agencies to achieve health innovation policy goals. Ultimately, it argues that a combination of reforms, both internal to and external to the executive branch, might be most useful in advancing these aims.

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INTRODUCTION

Few problems in healthcare policy have galvanized bipartisan attention in the way that drug pricing has recently. In the wake of scandals involving both sky-high prices for new drugs¹ and enormous price increases on old drugs,² the American people and politicians on

¹ STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM (Comm. Print 2015) (prepared by the Staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley).

² Aaron E. Carroll, *The EpiPen, a Case Study in Health System Dysfunction*, N.Y. TIMES (Aug. 23, 2016), <http://www.nytimes.com/2016/08/24/upshot/the-epipen-a-case-study-in-health-care-system-dysfunction.html>; Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <http://www.nytimes.com/2015/09/21/business/a->

both sides of the aisle agree that something must be done. A range of new policies has been proposed on the subject, policies that would give Medicare the ability to negotiate drug prices,³ speed generic drugs to market,⁴ or punish companies for price increases on existing drugs.⁵

Unfortunately, most of these proposals are unlikely to have a significant impact on the drug pricing problem.⁶ Proposals like these, targeted at the actions of a single administrative agency or institutional actor, address only one piece of a broader innovation policy puzzle. Proposals that would enable agencies to work together—to gather and share information, to set priorities for research, and to approve new products—have far greater potential to lower the costs of developing new health care technologies and to simultaneously improve patient access to such technologies. Solving the drug pricing problem and other health technology questions requires a new view of the relationship between administrative agencies and innovation incentives.

Rather than focusing on the innovation capacities of single agencies acting alone, this Article considers the potential of the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) to promote both the development of new, innovative health technologies and access to those technologies in collaboration with each other. This Article draws not only on the health innovation policy literature but also on the growing administrative law literatures focusing on interagency and intra-agency coordination models. Yet in many ways this Article goes further, arguing that although simple coordination is itself desirable, active collaboration that goes beyond mere coordination can make possible a far broader range of innovative outcomes than can the actions of any single agency acting alone.

Existing scholarship has considered the expertise of these agencies

[huge-overnight-increase-in-a-drugs-price-raises-protests.html](#).

³ Improving Access to Affordable Prescription Drugs Act, S. 771, 115th Cong. § 201 (2017); David Morgan, *Obama Administration Seeks to Negotiate Medicare Drug Prices*, REUTERS (Feb. 2, 2015, 11:35 AM), <http://www.reuters.com/article/us-usa-budget-medicare-idUSKBN0L61OW20150202>.

⁴ Creating and Restoring Equal Access to Equivalent Samples Act of 2016, S. 3056, 114th Cong. § 3(b) (2016); Press Release, U.S. Food & Drug Admin., FDA Tackles Drug Competition to Improve Patient Access (June 27, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm564725.htm>.

⁵ See Improving Access to Affordable Prescription Drugs Act, *supra* note 3, § 202; Thomas Kaplan, *Hillary Clinton Unveils Plan to Address 'Excessive' Increases in Drug Prices*, N.Y. TIMES (Sept. 2, 2016), <https://www.nytimes.com/2016/09/03/us/politics/hillary-clinton-epipen-mylan.html>.

⁶ See, e.g., Letter from Peter R. Orszag, Dir., U.S. Cong. Budget Office, to Ron Wyden, U.S. Senator (Apr. 10, 2007), <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf> (explaining that “[b]y itself, giving the Secretary broad authority to negotiate drug prices would not provide the leverage necessary to generate lower prices . . . and thus would have a negligible effect on Medicare drug spending”).

and recast their missions as innovation-promoting ones, expanding the range of tools contemplated by scholars who had previously focused largely on the role of the Patent and Trademark Office (PTO).⁷ To be sure, the PTO and other agencies do take actions that influence the course of innovation.⁸ However, scholars of health innovation policy ought to (and increasingly do) focus on these health-related agencies—the NIH, FDA, and CMS—for at least four related reasons.

First, within the context of health technologies these three agencies loom relatively large when compared with the PTO or consumer protective agencies like the Federal Trade Commission (FTC). This is not true in all fields of technology. The PTO administers the patent system, a generally uniform innovation incentive,⁹ and so in technological fields without large federal bureaucracies, the PTO may well be of primary importance or the FTC's enforcement authority may assume a greater role. However, in the context of health technologies, patents are but one baseline piece of a larger innovation ecosystem, and the other levers in the ecosystem are primarily governed by these three agencies.

Second, the one-size-fits-all patent system is a blunt tool for incentivizing innovation both generally and in health technologies in particular. Diagnostics,¹⁰ medical devices, and pharmaceuticals are not equally in need of a broad twenty-year term of patent protection,¹¹ yet

⁷ Few scholars focusing on patent law and innovation focus solely on the PTO. It is critical to consider the ways in which substantive patent law is created and interpreted in the courts, chiefly the Federal Circuit and (more recently) the Supreme Court. See, e.g., Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1041 (2003). But from the perspective of potential ex ante policymaking, I focus here on the institutional capacities of the PTO itself and provide examples in the footnotes of significant court interventions.

⁸ There are a wide range of other, smaller agencies involved in innovation generally, and health innovation in particular, like the Defense Advanced Research Projects Agency and the Biomedical Advanced Research and Development Authority. Even the Internal Revenue Service is involved as it administers tax cuts that are often a part of the research and development process. However, these incentives tend to operate on a smaller scale and outside the core purpose of these agencies. See generally, e.g., Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents—Prizes Debate*, 92 TEX. L. REV. 303 (2013).

⁹ For a more general treatment of this issue, see Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845 (2006); Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009).

¹⁰ *But cf.* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 256 (2015) (“[M]ost important advances in [diagnostic testing] lie outside the boundaries of patent-eligible subject matter.” (footnote omitted)).

¹¹ Compare, e.g., SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH & SOC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., *GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 1* (2010) (“[T]he prospect of patent protection of a genetic research discovery does not play a significant role in motivating scientists to conduct genetic research.”), with Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003) (“Strong patent rights are necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market.”).

the patent system lacks the ability to award purposively longer or broader patents to innovators that need them to encourage innovation.¹² By contrast, as explained in Part I, the innovation incentives administered by the NIH, FDA, and CMS are often finely specified and can award different amounts of grant money, different lengths of exclusivity, and different reimbursement amounts where warranted by the type of innovation and even by the particularities of the invention itself.

Third and relatedly, the NIH, FDA, and CMS themselves have more substantive authority to create and tailor these innovation incentives than does the PTO, in two ways. The PTO first lacks substantive rulemaking authority¹³ and the ability to tailor the patent system by area of technology.¹⁴ Meanwhile, the NIH, FDA, and CMS can all develop guidelines about which types of innovations will receive their support. But the PTO also lacks the institutional expertise to administer field-specific innovation-related programs of this type. Although the PTO has now begun to develop at least some related expertise with the creation of the Office of the Chief Economist,¹⁵ it cannot yet compete with agencies like the NIH, FDA, and CMS, which make both macro and micro decisions every day about where to allocate innovation resources.

Fourth and perhaps most importantly, these health-related agencies have the ability to promote innovation more broadly than the PTO is capable of. To be sure, “innovation” is a slippery and much-debated concept, but having a clear idea of agency capacity is helpful in defining this Article’s focus. Scholars have recognized that patents are most effective at encouraging innovation into highly excludable goods (like pharmaceuticals),¹⁶ and even then only where the relevant patient population has the ability to pay for the products.¹⁷ But patents are not particularly good at encouraging innovation where the social value of

¹² Burk & Lemley, *supra* note 11, at 1622–23; *see also* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 39, 46 (2001).

¹³ *See, e.g.*, Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1755 (2011).

¹⁴ Importantly, the courts, specifically the Federal Circuit, have helped tailor patent law to different fields of technology, although their efforts to do so are limited by factors including the facially technologically neutral nature of the statutes. *See* Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L.J. 1483, 1488 (2015) (arguing that non-PTO administrative agencies can provide expertise with industry-specific patent tailoring). *See generally* Burk & Lemley, *supra* note 11.

¹⁵ Robert P. Merges, *Kappos Legacy and PTO-Academia Relations*, IPWATCHDOG (July 28, 2014), <http://www.ipwatchdog.com/2014/07/28/kappos-legacy-and-pto-academia-relations/id=50554>.

¹⁶ Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1907 (2013).

¹⁷ Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSP. 67, 75 (2002).

the technology cannot be captured by the patent-holder.¹⁸

This Article focuses on this class of innovations, those health technologies where private market signals are not likely to be reflective of social value. These administrative agencies have a key role to play where novel health technologies would primarily benefit the poor,¹⁹ or whose development can be expected to be particularly lengthy,²⁰ or where the innovation is nonexcludable in some way (like a surgical method).²¹ In such cases, pharmaceutical or medical device companies can be expected to underinvest in technology relative to the societal burden of disease, because of the distortions created by the market and the patent system. These agencies can help restore that balance.

This Article proceeds in four Parts. Part I considers the ways in which the NIH, FDA, and CMS individually contribute to the progress of innovation in health technologies. Part I organizes and directs the existing literature and policy efforts to consider the different categories and types of innovative efforts these agencies have engaged in. Part II moves on to the ways in which these agencies contribute to innovation collaboratively, developing a taxonomy of the ways in which the NIH, FDA, and CMS collaborate at present. Part III takes the discussion from the descriptive to the theoretical, considering how these agencies, which lack formally shared regulatory authority over the innovation space, should expand the range of their collaborations to promote incentives for innovation. Part IV completes the analysis by considering potential procedural mechanisms for enhancing collaboration between these agencies for the purpose of achieving health innovation policy goals. Ultimately, it argues that a combination of reforms both internal and external to the executive branch might be most useful in achieving these goals.

I. ADMINISTRATIVE AGENCIES AS INDIVIDUAL ACTORS IN THE INNOVATION ECOSYSTEM

Scholars of innovation policy are paying increasing attention to the ways in which agencies like the NIH, FDA, and CMS may all promote innovation-related goals, even as they were set up to serve a variety of other purposes.²² The process of innovation in health technologies is

¹⁸ Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 192–93 (2016).

¹⁹ Kremer, *supra* note 17, at 75.

²⁰ Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2074 (2015).

²¹ Kapczynski & Syed, *supra* note 16, at 1907–08.

²² See generally, e.g., Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007); Yaniv Heled, *Patents vs. Statutory Exclusivities*

mediated through a complex federal bureaucracy, with these administrative agencies playing key roles in the development, approval, and reimbursement of health technologies of all types. This Part primarily considers the ways in which each of these three agencies individually serves to promote health innovation, emphasizing the different policy levers available to the agencies in question.

A. National Institutes of Health

In some ways, the NIH's role in the innovation ecosystem is simple to explain: it pays for research. To be more precise, it pays for an enormous amount of the biomedical research performed in the United States, disbursing more than \$30 billion in research funding each year.²³ Yet this simple story must be disaggregated into its component parts. The vast majority of the funds awarded by the NIH function as what scholars sometimes call "push" incentives.²⁴ These funds subsidize research inputs, paying for general research and specific development of health technologies before those products come to market.²⁵ However, this research is of many different kinds, each of which is worth considering separately. Further, the NIH is beginning to explore the potential of awarding funds as a prize to a company after a product is developed, what scholars may refer to as a "pull" incentive.²⁶ This Section will explore each of these aspects of the NIH's portfolio.

The front-end, "push" research supported by the NIH is of at least three different types: basic, applied or translational, and regulatory. First, just over half of the NIH's budget funds basic research, designed to improve our understanding of particular diseases, bodily processes, and human pathologies without focusing on the development of particular products.²⁷ Before scientists can discover treatments for a

in Biological Pharmaceuticals—Do We Really Need Both?, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013); Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115 (2015); Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 HOUS. L. REV. 1037 (2008); Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881 (2016); Kapczynski & Syed, *supra* note 16.

²³ *What We Do: Budget*, NAT'L INSTITUTES HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> (last updated Apr. 11, 2018).

²⁴ See, e.g., Kremer, *supra* note 17, at 82.

²⁵ *Id.*

²⁶ *Id.* For a more detailed treatment of these issues, see MICHAEL KREMER & RACHEL GLENNERSTER, *STRONG MEDICINE: CREATING INCENTIVES FOR PHARMACEUTICAL RESEARCH ON NEGLECTED DISEASES* (2004).

²⁷ Mike Lauer, *NIH's Commitment to Basic Science*, NAT'L INSTITUTES HEALTH: OPEN MIKE (Mar. 25, 2016), <https://nexus.od.nih.gov/all/2016/03/25/nih-commitment-to-basic-science>.

disease (diabetes, for instance), they must understand how the disease functions in the human body. What has gone wrong in a person's pancreas and islet cells to cause them to develop diabetes? How do those cells normally function? What are the symptoms of the disease, and how does it progress? Are some people more likely to develop the disease than others, and if so, why? Basic research questions like these are critical to the advancement of knowledge that only later leads to approved treatments.

Basic research has at least two special characteristics that make it particularly well-suited for support from the federal government. First, in many ways it is best understood as a public good. Basic research produces information, not products, and that information can and should be made available as widely as possible both to enable other scientists to make further basic science discoveries and to ensure that many companies with different ideas can rely on accurate scientific information in attempting to develop new therapies. Economists have long recognized that classic public goods like clean air and national security will be underfunded by private actors due to free-rider problems,²⁸ and so as a result they are typically provided and supported by governments. So too with basic research of this type.

The second characteristic of basic biomedical research in particular is that it is extremely risky. Basic research may fail, scientists may discover something other than what they set out to find, and even successful research may take years to pay dividends. Scholars have argued that the long-term, uncertain nature of basic research makes it a good target for public funding.²⁹ Essentially, the private market will view any potential dividends as both too uncertain and too far in the future to merit investment.³⁰

The NIH devotes a little less than half of its budget to applied research,³¹ much of which seeks to translate basic research findings into medical practice. Although the line between basic and applied research is sometimes blurry, much of the NIH's research related to specific health technologies clearly falls into the "applied" category. This includes research identifying potential new drugs by screening libraries of compounds, studying existing drugs for new uses, or supporting clinical trials of new drugs, devices, or diagnostics. Organizationally, the NIH has devoted an entire center to translational research through the National Center for Advancing Translational Sciences (NCATS).³²

²⁸ Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, 2 INNOVATION POL'Y & ECON. 51, 53-54 (2002).

²⁹ See, e.g., Kapczynski & Syed, *supra* note 16, at 1907-08.

³⁰ Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297, 304 (1959).

³¹ Lauer, *supra* note 27.

³² Press Release, Nat'l Insts. of Health, NIH Establishes National Center for Advancing

Much, though certainly not all, of NCATS's work focuses on areas of research that are likely to be underfunded if private companies are the only source of investment, as was true in the basic research context. Consider NCATS's New Therapeutic Uses Program as one example.³³ Its goal is to engage in a practice that is often referred to as drug repurposing: to identify new uses for drugs that have already been approved or that have taken substantial steps toward being approved.³⁴ Scholars like Professor Becky Eisenberg have previously explained that drug companies lack sufficient incentives to continue to study their approved drugs for new uses, because patents or FDA exclusivity periods covering those new uses are difficult to enforce, making investments in additional clinical trials difficult to recoup.³⁵ In some ways, the goal here is similar to the goal in the basic research context: not necessarily to develop new drugs, but to develop new information about existing drugs. To the extent that such information will be underproduced by the private sector, this is another fruitful area for public funding.³⁶

Other NCATS programs have similar characteristics. NCATS's support of small businesses through the Small Business Innovation Research program may help democratize biomedical research, providing support to ideas with high social value but low commercial value that may be less attractive to traditional medical technology companies.³⁷ Further, NCATS's projects in the area of rare diseases help create infrastructure, such as repositories of patient data,³⁸ and

Translational Sciences (Dec. 23, 2011), <https://www.nih.gov/news-events/news-releases/nih-establishes-national-center-advancing-translational-sciences>. Additional research is run through the NIH Clinical Center, where clinical trials are performed. See *About the Clinical Center*, NAT'L INSTITUTES HEALTH, <http://clinicalcenter.nih.gov/about1.html> (last updated Feb. 7, 2018). Still more research is funded through specialized programs within particular institutes, such as the National Cancer Institute's Translational Research Program. *Welcome to the Translational Research Program (TRP)*, NAT'L CANCER INST., <http://trp.cancer.gov> (last visited May. 18, 2018).

³³ *About New Therapeutic Uses*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIENCES, <https://ncats.nih.gov/ntu/about> (last updated Apr. 25, 2018).

³⁴ *Id.*

³⁵ Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 722–23 (2005). Importantly, this analysis may only be true for drugs that have been previously approved. The New Therapeutic Uses program is broader, encompassing drugs that have not yet been approved. For such drugs, it is less clear why companies lack sufficient incentives to solve this problem on their own. Even if patents on their compounds have run out, they will receive full FDA exclusivity periods upon approval.

³⁶ See Kapczynski & Syed, *supra* note 16, at 1923–28 (articulating the even more severe disincentives to produce negative information about existing drugs, such as information about side effects or a drug's efficacy relative to other medicines).

³⁷ *About Small Business Opportunities*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIENCES, <https://ncats.nih.gov/smallbusiness/about> (last updated May 7, 2018); see also *infra* text accompanying note 40 (describing NIH's prize program for undergraduate biomedical engineering students).

³⁸ *Rare Diseases Registry Program (RaDaR)*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL

encourage collaboration through building networks of scientists working on these conditions.³⁹ Here NCATS can also play a complementary role to the private sector by curating the relevant information and creating the conditions necessary for the process of drug discovery and commercialization.

Although it is commonly assumed that clinical trials are only overseen by private companies seeking to commercialize products, sometimes the NIH does fund and engage in clinical trials itself. Yet here again most of the work performed by the NIH is devoted to studies whose design will in some form be less attractive to the private sector. Maybe the technology under study is not a device or drug but a method of treatment, which is not so easily monetized by the private sector.⁴⁰ Or perhaps the clinical trial is so lengthy that no pharmaceutical company is willing to engage in it, as by the time the trial ends, any patents on the drug in question will have expired.⁴¹ In either case, the NIH's work complements the private sector's activities.

The third category of NIH research, regulatory science, has received considerably less attention in the scholarly literature, but it may be the most important in terms of the NIH's interactions with other agencies. Essentially, regulatory science seeks to study and develop new information, tools, and methods for use in the regulatory process, primarily the FDA regulatory process. The NIH's existing regulatory science programs run all along the spectrum of regulation. For example, the NIH's Tobacco Regulatory Science Program helps answer basic scientific questions about tobacco products that underlie much of the FDA's regulation in this area.⁴² The Program helps answer questions about toxicity thresholds for different chemicals, the impact of product characteristics on decisions to start smoking, and the use of products like cigars, smokeless tobacco, and e-cigarettes.⁴³ The results of these studies may both help set FDA priorities and may support specific rules that the FDA seeks to promulgate.

Other regulatory science initiatives study the process of regulation

SCIENCES, <https://ncats.nih.gov/radar> (last updated Mar. 13, 2018).

³⁹ *Rare Diseases Clinical Research Network (RDCRN)*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIENCES, <https://ncats.nih.gov/rdcrn> (last updated May 18, 2018). For a more rigorous treatment of these issues, see BRETT M. FRISCHMANN, *INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES* (2012).

⁴⁰ See *infra* text accompanying notes 189–90 for a discussion of talk therapy, one such intervention.

⁴¹ See Budish, Roin & Williams, *supra* note 20, at 2074 (noting that for clinical trials lasting longer than twenty years—the term of a patent—“essentially 100 percent are publicly funded”).

⁴² *Tobacco Regulatory Science Program (TRSP)*, NAT'L INSTITUTES HEALTH, <https://prevention.nih.gov/tobacco-regulatory-science-program> (last updated May 18, 2018).

⁴³ *Tobacco Regulatory Science Program: Research Priorities*, NAT'L INSTITUTES OF HEALTH, <https://prevention.nih.gov/tobacco-regulatory-science-program/research-priorities> (last updated Mar. 13, 2017).

itself, seeking to make it more effective or efficient. The NIH has funded projects to speed the pre-clinical phase of the drug development process through their Tissue Chip for Drug Screening program, designed to more accurately model the functioning of human organs and reduce the time and expense of the pre-clinical phase.⁴⁴ Even later in the drug approval process, the NIH has awarded grants for the study of innovative clinical trial designs,⁴⁵ where the idea is to develop methods of conducting clinical trials that improve efficiency and patient safety. Here, too, this research is likely to be underprovided by the private sector, as any one company's efforts in this space would redound to the benefit of its competitors.

Although the vast majority of NIH funding is disbursed as front-end push funding of the type described above, the NIH has displayed at least some interest in awarding funds after a product or method has been developed or at least conceived, as a prize or pull mechanism.⁴⁶ The NIH recently awarded prizes for the conception and development of methods for analyzing single cells within a large population⁴⁷ and for biomedical engineering advances,⁴⁸ and it has announced a \$20 million prize for the development of a rapid point-of-care diagnostic designed to reduce antibiotic prescribing.⁴⁹ To be sure, the NIH's expertise in prize administration is still inchoate. But the 2016 21st Century Cures Act⁵⁰ directs the NIH to devote more resources toward so-called

⁴⁴ See *Regulatory Science*, NAT'L INSTITUTES HEALTH, <https://commonfund.nih.gov/regulatoryscience> (last updated Jan. 18, 2018) (summarizing projects that have been studied to date, including the Tissue Chip program); *Tissue Chip for Drug Screening*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIENCES, <http://www.ncats.nih.gov/tissuechip> (last updated Mar. 20, 2018).

⁴⁵ *RePORTER: Project Information: Accelerating Drug and Device Evaluation Through Innovative Clinical Trial Design*, NAT'L INSTITUTES HEALTH, https://projectreporter.nih.gov/project_description.cfm?projectnumber=1U01NS073476-01 (last visited May 18, 2018).

⁴⁶ Scholars have recognized the potential benefits of pull mechanisms like prizes. See, e.g., Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Michael Polanyi, *Patent Reform*, 11 REV. ECON. STUD. 61 (1944); Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1013 (2014); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983); Kremer, *supra* note 17, at 83; see also Steven Shavell & Tanguy Van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 528 (2001) (cataloging the literature).

⁴⁷ *NIH Single Cell Analysis Challenge: Follow That Cell*, INNOCENTIVE (Aug. 15, 2014), <https://www.innocentive.com/ar/challenge/9933618>.

⁴⁸ Press Release, Nat'l Insts. of Health, NIH Announces Winners of Public-Private Undergraduate Biomedical Engineering Design Competition (Aug. 23, 2016), <https://www.nih.gov/news-events/news-releases/nih-announces-winners-public-private-undergraduate-biomedical-engineering-design-competition>.

⁴⁹ Press Release, Nat'l Insts. of Health, Federal Prize Competition Seeks Innovative Ideas to Combat Antimicrobial Resistance (Sept. 8, 2016), <https://www.nih.gov/news-events/news-releases/federal-prize-competition-seeks-innovative-ideas-combat-antimicrobial-resistance>.

⁵⁰ Pub. L. No. 114-255, 130 Stat. 1033 (2016).

“Eureka prize” competitions,⁵¹ and so we can expect the NIH’s actions in this area to increase with time.

The NIH’s influence on research funding goes beyond the already large amount it disburses each year. The NIH in particular, and the federal government in general, have enormous soft power to set the agenda for the types of research that will be prioritized and engaged in by universities, foundations, and the private sector. Recently announced governmental programs like the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the Precision Medicine Initiative, and the Cancer Moonshot provide helpful examples. These programs have marshaled substantial non-governmental funds in pursuit of their goals. For instance, non-governmental entities have contributed over \$500 million to date to pursue the goals set forth by the BRAIN Initiative,⁵² bolstering the \$300 million devoted by the government in 2016 to the project.⁵³ Non-governmental projects related to the Precision Medicine Initiative may exceed the \$200 million allotted by the government for that program, with institutions from hospital systems and universities to technology companies like Intel, IBM, and Microsoft all devoting resources to precision medicine projects.⁵⁴

The NIH has decades of experience administering grants to promote innovation in the life sciences all along the spectrum of health technologies, from basic research to post-approval studies. Yet scholars (of science and law alike) do and should ask questions about how the NIH allocates funding among many competing priorities.⁵⁵ The appropriate mix of funding between basic and applied research is an open question, as is how closely NIH funding should track disease burden.⁵⁶ Problematically, these questions are often asked from a

⁵¹ 42 U.S.C. § 283q (2012).

⁵² OFFICE OF SCI. & TECH. POL’Y, EXEC. OFFICE OF THE PRESIDENT, OBAMA ADMINISTRATION PROPOSES OVER \$300 MILLION IN FUNDING FOR THE BRAIN INITIATIVE 1 (Feb. 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/brain_initiative_fy16_fact_sheet_ostp.pdf.

⁵³ *Id.*

⁵⁴ Press Release, White House Office of the Press Sec’y, FACT SHEET: Obama Administration Announces Key Actions to Accelerate Precision Medicine Initiative (Feb. 25, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/02/25/fact-sheet-obama-administration-announces-key-actions-accelerate>.

⁵⁵ Congress does put some limits on how the NIH can allocate its funding, often by earmarking funds for particular projects or particular institutes. However, within those limits the NIH has a great deal of flexibility to allocate grants. Further, to the extent that the NIH has some amount of discretionary, fungible funding, NIH leadership should have some ability to balance a skewed Congressional allocation. *See generally* Bhaven N. Sampat, *Mission-Oriented Biomedical Research at the NIH*, 41 RES. POL’Y 1729 (2012).

⁵⁶ Michael S. Lauer, David Gordon & Michelle Olive, *Matching Taxpayer Funding to Population Health Needs: Not So Simple*, 116 CIRCULATION RES. 1301 (2015); Hamilton Moses et al., *The Anatomy of Medical Research: US and International Comparisons*, 313 JAMA 174 (2015); *see also* *Funding: Report on NIH Funding vs. Global Burden of Disease*, NAT’L INSTITUTES HEALTH, https://report.nih.gov/info_disease_burden.aspx (last updated Aug. 12,

viewpoint that assumes the NIH is the sole funder of research in the United States.

Instead, discussions about the appropriate balance of NIH funding (both by research type and disease area) ought to begin by recognizing that the NIH, at least in some cases, complements research funded by other parties.⁵⁷ In the area of basic research, the NIH may well be the primary funder by a large margin. But when considering translational research or regulatory science work, scholars ought to ask how the NIH might augment work being performed both in the private sector⁵⁸ and, more generally, in the executive branch. The NIH's work in regulatory science in particular may have a multiplicative quality. The development of new clinical trial models or of new methods for conducting preclinical research may reduce development costs not just for one but for a wide range of companies. Asking how the NIH might best use its limited funds to support projects with broad-based impact, as opposed to projects that would benefit one or a few private companies, is a key area of further policy discussion.

B. Food and Drug Administration

The FDA is too often criticized as an entity whose *raison d'être* is to impede innovation by imposing onerous, expensive requirements on companies seeking to bring new products to market. This view is grossly oversimplified.⁵⁹ In actuality, the FDA may be the most powerful innovation-promoting agency in the federal government when it comes to life sciences inventions, more important even than the PTO. The FDA promotes innovation in two types of ways: it forces information production through its role as regulator of drug and device approvals, and it encourages the development of particular types of socially valuable products through its administration of a series of finely specified innovation incentives.

First, the process of drug and device regulation overseen and administered by the FDA is indeed expensive and lengthy,⁶⁰ although

2017); Thomas Insel, *Post by Former NIMH Director Thomas Insel: Transparency*, NAT'L INST. MENTAL HEALTH (Mar. 13, 2015), <http://www.nimh.nih.gov/about/director/2015/transparency.shtml> (considering, within NIMH, existing investments based on public health need and whether other criteria ought to matter).

⁵⁷ See, e.g., COMM. ON THE NIH RESEARCH PRIORITY-SETTING PROCESS, INSTITUTE OF MEDICINE, SCIENTIFIC OPPORTUNITIES AND PUBLIC NEEDS: IMPROVING PRIORITY SETTING AND PUBLIC INPUT AT THE NATIONAL INSTITUTES OF HEALTH 16 (1998).

⁵⁸ See, e.g., Budish, Roin & Williams, *supra* note 20, at 2081–82 (providing examples of important research projects that received public support); Kapczynski & Syed, *supra* note 16, at 1907–08.

⁵⁹ See generally Eisenberg, *supra* note 22.

⁶⁰ The typical cost of developing a new drug is hotly contested. The Tufts Center for the

the cost and time vary widely by drug and risk level.⁶¹ However, inherent in the FDA's authority to oversee this process is the ability to shape the kinds of information that companies produce through the drug approval process.⁶² More specifically, the role of the FDA as pharmaceutical regulator is to ensure pharmaceuticals and devices that companies seek to bring to market are safe and effective for their intended use. In fulfilling this role, the FDA requires companies to undertake clinical trials and produce information about their products. Professor Becky Eisenberg has reframed this role as "motivat[ing] drug sponsors to generate valuable information about their drugs."⁶³

This information—about which drugs and devices are useful for which patients at which doses or using which methods, or about whether any harmful side effects may arise, etc.—is useful, not only to

Study of Drug Development recently estimated the cost at \$2.6 billion, a significant increase from their 2003 estimate of \$802 million. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (estimating pre-approval costs to be \$802 million); Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) (estimating pre-approval costs to be \$2558 million). Studies like these have been heavily criticized by public interest advocates, who report far lower numbers. See, e.g., Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 47 (2011) (concluding "that R&D costs companies a median of \$43.4 million per new drug"). For my purposes, though, there is sufficient agreement that drugs are among the most costly technological goods to develop. See Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 426, 448–57 (2014).

⁶¹ One survey of device manufacturers found that the average cost to develop a high-risk device requiring premarket approval was \$94 million, while the average cost to develop a device requiring only 510(k) approval was \$31 million. JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 28 (2010).

⁶² Problematically, the FDA's ability to force the production of information through the clinical trials process has waned in recent years. In particular, the FDA has recently lost a series of court cases involving off-label promotion of drugs in which companies seek to promote their drugs for uses that have not received FDA approval. Courts have begun to side with companies on First Amendment grounds, permitting them to make health claims about their products that have not been vetted by the FDA. See, e.g., *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). Most scholars have roundly criticized these opinions, arguing that they rely on erroneous interpretations of First Amendment doctrine or that they will undermine the FDA's ability to police the safety and efficacy of products on the market today. See Amy Kapczynski, *Free Speech and Pharmaceutical Regulation—Fishy Business*, 176 JAMA INTERNAL MED. 295 (2016); Aaron S. Kesselheim & Michelle M. Mello, *Health Care Decisions in the New Era of Health Care Reform: Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, 92 N.C. L. REV. 1539 (2014); Christopher Robertson, *When Truth Cannot Be Presumed: The Regulation of Drug Promotion Under an Expanding First Amendment*, 94 B.U. L. REV. 545, 551–52 (2014); see also Stephanie M. Greene & Lars Noah, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. ONLINE 239 (2014). Fewer scholars have noted the innovation-related impacts of these decisions. If the FDA cannot force a company interested in marketing its drug for a second use to conduct clinical trials for that use, the FDA cannot fulfill this information-producing role. Its authority as a gatekeeper on the front end remains absolute, but its ability to police successive indications is lower than it has been previously.

⁶³ Eisenberg, *supra* note 22, at 370.

the FDA and the individual company seeking FDA approval, but also far more broadly to scientists, policymakers, physicians, patients, and other companies. The company's reward for producing information about the safety and efficacy of a particular drug or device is the ability to monetize the product itself. But the social value of that product also lies in the information produced through the clinical trial process, not just in the approved drug or device.⁶⁴

The second set of ways in which the FDA promotes innovation is not inherent in its role as pharmaceutical regulator. However, Congress has nonetheless given the FDA the authority to administer a number of policy levers that provide incentives for companies seeking to develop pharmaceutical products.⁶⁵ The primary goal of these mechanisms is to promote innovation incentives, unlike the information-producing role of the FDA, which has an incidental (but strong) innovation function but whose purpose is first and foremost the production of data to inform the agency's safety and efficacy evaluations.⁶⁶

As in the case of the NIH, the innovation policy levers administered by the FDA can be divided into push and pull mechanisms, some of which help decrease the costs of development and others of which provide rewards for successful approvals of particular types of products. In the push column, the FDA primarily administers a series of four expedited approval pathways.⁶⁷ These programs—priority review, accelerated approval, fast-track designation, and breakthrough therapy designation—are designed to shorten the regulatory review process for companies seeking approval for drugs of various types.⁶⁸ Shortening the review process enables companies to bring their products to market sooner, saving time and money and likely preserving more time remaining on their patent term. Some of the programs

⁶⁴ *Id.* at 347; see also, e.g., Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 198–99 (2005). This is true for small molecule drugs, but the information-producing function of approval may be less true for biologics. W. Nicholson Price II & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars?: Regulations for Approving Biologic Drugs Thwart the Market for Would-be Competitors*, 348 SCI. 188 (2015).

⁶⁵ By contrast, there are far fewer special innovation incentives for companies seeking to make medical devices or diagnostics. See, e.g., Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *New FDA Breakthrough-Drug Category—Implications for Patients*, 370 NEW ENG. J. MED. 1252, 1253–54 (2014).

⁶⁶ Eisenberg, *supra* note 22, at 372–73.

⁶⁷ For an overview and comparison of these four programs, see FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS—DRUGS AND BIOLOGICS 7–8 (2014) [hereinafter GUIDANCE], <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>.

⁶⁸ *Id.* at 1, 7–8. Some studies have shown that these programs may lead to increased safety signals among the drugs ultimately approved through these pathways. See Darrow, Avorn & Kesselheim, *supra* note 65, at 1253–54.

shorten the review process directly, as with priority review, which cuts the amount of time the FDA has to review evidence from clinical trials from ten months to six.⁶⁹ Others shorten it indirectly, as with accelerated approval, which permits approval on the basis of a surrogate endpoint rather than a true clinical endpoint.⁷⁰ Breakthrough therapy and fast-track designation shorten the review period in the process sense in that these designations entitle their grantees to frequent meetings with FDA officials on the progress of their drugs through the clinical trial process, ensuring there are no surprises in terms of the FDA's demands come review time.⁷¹ Companies will often stack two or more of these expedited programs, combining their benefits.⁷²

These programs are only available to companies producing drugs that meet two main criteria. First, they all require as a threshold matter that the drug in question be intended to treat a "serious condition."⁷³ Second, each program essentially requires the submission of evidence that the drug in question provides a significant improvement over and above existing therapies.⁷⁴ The substance of this second criterion is worded differently across each program, yet they are phrased similarly enough that drugs will commonly meet several of them.⁷⁵ For instance,

⁶⁹ GUIDANCE, *supra* note 67, at 8.

⁷⁰ 21 U.S.C. § 356(c)(1)(A) (2012). A surrogate endpoint is a "laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions, or survives." Robert J. Temple, *A Regulatory Authority's Opinion About Surrogate Endpoints*, in CLINICAL MEASUREMENT IN DRUG EVALUATION 3, 4 (Walter Nimmo & Geoffrey Tucker eds., 1995); see also 21 C.F.R. § 314.500 (2018). A classic example is cholesterol. Drugs may be tested based on their ability to lower a patient's level of cholesterol, a surrogate endpoint, rather than on their ability to decrease the risk of death from heart disease, the true endpoint. Katalin Bogner et al., *The Role of Imperfect Surrogate Endpoint Information in Drug Approval and Reimbursement Decisions*, 51 J. HEALTH ECON. 1, 2 (2017). Clinical trials of interventions whose efficacy can be tested using a surrogate endpoint tend to be shorter and to require fewer patients than those using a true endpoint. See, e.g., Thomas R. Fleming, *Surrogate Endpoints and FDA's Accelerated Approval Process*, 24 HEALTH AFF. 67, 67 (2005).

⁷¹ 21 U.S.C. § 356(a)-(b).

⁷² See, e.g., CTR. FOR HEALTH POL'Y, BROOKINGS, BREAKTHROUGH THERAPY DESIGNATION: EXPLORING THE QUALIFYING CRITERIA: DISCUSSION GUIDE 3 (2015), http://www.brookings.edu/wp-content/uploads/2015/03/Breakthrough-Therapy-Designation_final.pdf.

⁷³ 21 U.S.C. § 356(a)-(c); CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., POLICY AND PROCEDURES: OFFICE OF NEW DRUGS (2013), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM447165.pdf>.

⁷⁴ 21 U.S.C. § 356(a)(1). These criteria guide the FDA in administering these expedited programs, but they do not meaningfully restrict the benefits of expedited review to drugs for particular categories of disease. Mental health conditions, cancer, Alzheimer's disease, communicable diseases—these are all serious conditions with large unmet medical needs. New therapies for any of them might qualify for one or more expedited pathways.

⁷⁵ Admittedly, the *process* considerations behind this second criterion do differ by program. For instance, fast-track designation permits the submission of clinical or non-clinical evidence to demonstrate the drug's potential, while breakthrough therapy requires clinical evidence. And of course, the accelerated approval program requires the availability of a validated surrogate

the priority review program is triggered when a drug would provide a “significant improvement in safety or effectiveness” relative to current therapies,⁷⁶ while accelerated approval is triggered upon a showing of “meaningful therapeutic benefit . . . over existing treatments”⁷⁷

Most of the innovation policy levers administered by the FDA fall into the category of pull mechanisms. Two such levers in particular—exclusivity periods and priority review vouchers—are worth discussing in some detail, the first for its breadth and power and the second for its specificity and purposiveness.⁷⁸ First, a number of statutes empower⁷⁹ the FDA to award periods of regulatory exclusivity for approved drugs. In contrast to the uniform twenty-year term of patent protection,⁸⁰ these periods vary in duration and in the set of drugs to which they apply. But they all serve the same function: to provide innovative drug manufacturers with sufficient incentives to carry new products through the extensive clinical trial process.

The Hatch-Waxman Act of 1984 and the Biologics Price Competition and Innovation Act, created as part of the Affordable Care Act in 2010, create data exclusivity periods for small-molecule and biologic drugs, respectively. Hatch-Waxman provides innovator small-molecule drug companies with five years of exclusivity, during which the FDA may not accept for filing an application for a generic product that uses the innovator company’s clinical trial data.⁸¹ The Biologics Act functions similarly but provides innovator biologic drug companies with twelve years of data exclusivity from the approval of the innovator

endpoint.

⁷⁶ GUIDANCE, *supra* note 67, at 24.

⁷⁷ 21 C.F.R. § 314.500 (2018); *see* GUIDANCE, *supra* note 67, at 16. Relatedly, fast-track is triggered upon a showing of “potential to address unmet medical needs” and breakthrough therapy upon a showing of “substantial improvement over existing therapies” 21 U.S.C. § 356(a)(1), (b)(1).

⁷⁸ There are other pull mechanisms where the FDA plays at least some role, most notably patent term restoration. As noted above, the drug approval process is lengthy and expensive, and a significant portion of the patent term on most drugs runs before the drug may be legally sold. *See, e.g.,* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330–31 (2012); Eisenberg, *supra* note 22, at 352 (providing an example of the antidepressant drug, Paxil, which did not reach the market until the original patent had expired). As such, the 1984 Hatch-Waxman Act rewarded companies bringing drugs to market with the ability to restore at least part of the time lost in the FDA review process. The FDA and PTO must share information to extend the patent term, with the FDA determining a product’s eligibility for the restoration and providing information to the PTO on how long the product spent under review. *See* Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD, DRUG & COSM. L.J. 269, 304 (1985).

⁷⁹ Or even require—the FDA may not have the legal authority to refuse the grant of such an exclusivity period. *See, e.g.,* *Depomed, Inc. v. U.S. Dep’t of Health & Human Servs.*, 66 F. Supp. 3d 217, 233 (D.D.C. 2014).

⁸⁰ 35 U.S.C. § 154(a)(2) (2012).

⁸¹ 21 U.S.C. § 355(j)(5)(F)(ii) (2012).

product to the approval of the biosimilar.⁸² The appropriate length of the biologics exclusivity period was hotly contested,⁸³ but in general there is agreement that exclusivity periods like these are useful in promoting long-term investment in drugs.

The Orphan Drug Act of 1983 is a closely related example. The Act provides special incentives to companies bringing to market drugs for FDA-designated orphan diseases, those affecting relatively small populations in the United States.⁸⁴ Companies bringing such drugs through the approval process receive seven years of market exclusivity, during which the FDA may not approve a new or generic drug application for the same product and indication.⁸⁵ Because the size of the patient market for orphan drugs is by definition small, the argument is that a period of exclusivity longer than Hatch-Waxman's five-year period for new small-molecule drugs may be needed to assure pharmaceutical companies that they can recoup their investments.⁸⁶

These exclusivity periods function in some ways like patents, and indeed they run concurrently for at least some period of time with any patent life remaining after a drug is approved.⁸⁷ However, there are several key differences between the two. Exclusivity periods are automatically enforced by the FDA in its role as pharmaceutical gatekeeper, meaning that companies do not need to expend time and money searching for potential violators and then enforcing their patents against them, as they do in most technological fields. Additionally, exclusivity periods are nearly impossible to challenge in court, while patents are challenged by competitors and invalidated on a semi-regular

⁸² 42 U.S.C. § 262(k)(7)(A) (2012).

⁸³ *Compare, e.g.*, FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 4-5 (2009) (suggesting that having no exclusivity period would be sufficient to promote innovation), *with* BIOTECHNOLOGY INDUS. ORG., A FOLLOW-ON BIOLOGICS REGIME WITHOUT STRONG DATA EXCLUSIVITY WILL STIFLE THE DEVELOPMENT OF NEW MEDICINES 1, 4 (2007) (arguing for a minimum of fourteen years of exclusivity). *See also* Heled, *supra* note 22, at 423 n.5.

⁸⁴ 21 U.S.C. § 360bb(a)(2). Although data exclusivity is legally more limited than market exclusivity; functionally, for FDA purposes, data and market exclusivity are often interchangeable. In addition to the period of regulatory exclusivity awarded upon approval of a drug with an orphan designation, companies working under the Act are eligible to claim a fifty percent tax credit of their clinical trial expenses, which may be thought of as a push mechanism. Hemel & Ouellette, *supra* note 8, at 379. However, the 2017 tax reform in Congress notably reduced the Orphan Drug clinical trial tax credit to twenty-five percent. Amendment of Internal Revenue Code of 1986, Pub. L. No. 115-97, § 13401, 131 Stat. 2054, 2133-34 (2017) (modification of Orphan Drug Credit).

⁸⁵ 21 U.S.C. § 360cc(a) (Orphan Drug Act, conferring seven years of market exclusivity).

⁸⁶ However, commentators have begun to question this conventional wisdom. *See, e.g.*, Carolyn Y. Johnson, *High Prices Make Once-Neglected 'Orphan' Drugs a Booming Business*, WASH. POST (Aug. 4, 2016), https://www.washingtonpost.com/business/economy/high-prices-make-once-neglected-orphan-drugs-a-booming-business/2016/08/04/539d0968-1e10-11e6-9c81-4be1c14fb8c8_story.html.

⁸⁷ Heled, *supra* note 22, at 423-24.

basis. Finally, and perhaps most obviously, the exclusivity period is tied in scope to the marketed drug and its approved indication.⁸⁸ Patents, by contrast, may be both broader than an individual drug (covering a class of compounds) and narrower than that same drug (covering only its method of production).⁸⁹

The Priority Review Voucher (PRV) is a second pull mechanism administered by the FDA. A company receiving FDA approval for a treatment for any of a specified set of neglected tropical diseases⁹⁰ receives a transferable voucher, which, when presented to the FDA, entitles its bearer to an expedited review process for a different product.⁹¹ The value of a voucher may be considerable, with two recent vouchers selling for \$350 million and \$245 million.⁹² Companies have used vouchers not only to come to market earlier, potentially having more patent-protected time on the market and saving costs, but also to leapfrog competitors and lock up market share earlier.⁹³ Importantly, the voucher has been subject to several instances of gaming, in which companies merely shepherded existing drugs through the clinical trial process rather than developing entirely new compounds,⁹⁴ but the

⁸⁸ *Id.* at 459–60.

⁸⁹ See, e.g., Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make a Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 300 (2010).

⁹⁰ The voucher program has more recently been expanded to cover rare pediatric conditions, Creating Hope Act of 2011, H.R. 3059, 112th Cong. § 2 (2011), as well as “agents that present national security threats.” 21st Century Cures Act, Pub. L. No. 114–255, § 565A, 130 Stat. 1033, 1144–47 (2016).

⁹¹ 21 U.S.C. § 360n (2012). The primary value of the voucher comes not necessarily from its benefits to the organization receiving it, but from its transferability. Importantly, the voucher does not apply only to the neglected tropical diseases as defined by the World Health Organization (WHO). It also applies to malaria and tuberculosis, *id.* at (a)(3)(A)–(B), and in 2014, it was updated to include filoviruses, a class that includes Ebola. *Id.* at (a)(3)(Q); see also Adding Ebola to the FDA Priority Review Voucher Program Act, Pub. L. No. 113–233, § 2, 128 Stat. 2127, 2127–28 (2014).

⁹² Alexander Gaffney, Michael Mezher & Zachary Brennan, *Regulatory Explainer: Everything You Need to Know About FDA’s Priority Review Vouchers*, REGULAT. AFF. PROFESSIONALS SOC’Y (Apr. 30, 2018), <http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers>.

⁹³ John Carroll, *AbbVie Hands United a Record \$350M Payoff for a Speedy FDA Review Voucher*, FIERCEBIOTECH (Aug. 19, 2015, 6:26 AM), <http://www.fiercebiotech.com/regulatory/abbvie-hands-united-a-record-350m-payoff-for-a-speedy-fda-review-voucher>.

⁹⁴ The recent grant of a voucher to Knight Pharmaceuticals for its approval of miltefosine for the treatment of leishmaniasis, came under fire from the access to medicines community. The drug’s utility in treating leishmaniasis had been studied in clinical trials as early as the 1990s, and Knight spent just \$10 million to complete the clinical trial process with the FDA in 2014. It then sold the voucher for \$125 million. Bernard Pécoul & Manica Balasegaram, *FDA Voucher for Leishmaniasis Treatment: Can Both Patients and Companies Win?*, PLOS: BLOGS (Jan. 20, 2015), <http://blogs.plos.org/speakingofmedicine/2015/01/20/fda-voucher-leishmaniasis-treatment-can-patients-companies-win>. Advocates have also expressed concern about the voucher granted for Coartem, an antimalarial drug. *Id.* The Food & Drug Administration Reauthorization Act of 2017 aimed to close some of these loopholes, but its

central idea has economic merit.⁹⁵

What is most interesting about the voucher is the list of diseases to which it applies and the FDA's authority over that list of diseases. When first established, the list of conditions meriting a voucher overlapped largely but incompletely with the World Health Organization's list of neglected tropical diseases.⁹⁶ Importantly, Congress foresaw the possibility that the FDA might wish to add diseases to the PRV list, and it authorized the FDA to designate by regulation "[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations" as deserving of a voucher.⁹⁷ The FDA has since exercised this authority, issuing in 2015 an order adding Chagas disease and neurocysticercosis to the list of designated tropical diseases such that manufacturers of drugs approved for these conditions may be awarded a voucher.⁹⁸ In its order, the FDA both specified the factors it intends to consider in interpreting the terms of the statute and applied those factors to the two diseases at issue.⁹⁹ The FDA's experience fielding applications to add diseases to the PRV list and giving reasons in its adjudication thereof help demonstrate its expertise as an administrator of innovation incentives.¹⁰⁰

Importantly, all of the above innovation incentives are largely limited to drug approvals. The vast majority of medical devices and diagnostics requiring FDA approval are not entitled to any exclusivity periods post-approval,¹⁰¹ and there is no analogous PRV program. Some medical devices may be entitled to expedited approval pathways similar

impact remains to be seen. FDA Reauthorization Act of 2017, Pub. L. No. 115-52, § 611, 131 Stat. 1005, 1054 (2017); see also 21 U.S.C. § 360n(a)(4).

⁹⁵ Compare David B. Ridley et al., *Developing Drugs for Developing Countries*, 25 HEALTH AFF. 313 (2006), with Rebecca S. Eisenberg, *Intellectual Property and Public Health*, in THE OXFORD HANDBOOK OF INTELLECTUAL PROPERTY LAW 933, 944-45 (Rochelle C. Dreyfuss & Justine Plina Eds., 2018).

⁹⁶ The FDA's list did not originally include conditions like Chagas disease and cysticercosis, which are on the WHO list. Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act, 80 Fed. Reg. 50,559, 50,562-63 (2015).

⁹⁷ 21 U.S.C. § 360n(a)(3)(S).

⁹⁸ Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act, 80 Fed. Reg. at 50,559.

⁹⁹ *Id.* at 50,560-62.

¹⁰⁰ However, it is relevant to note that the FDA does not like the Priority Review Voucher program and has expressed its dislike for the system in strong terms (for the FDA, at least). Michael McCaughan, *FDA's "Concerns" with PRVs*, PINK SHEET (Oct. 9, 2015), <https://pink.pharmaintelligence.informa.com/PS079786/FDAs-Concerns-With-PRVs>.

¹⁰¹ Class III devices, approved through the Premarket Approval (PMA) program, receive six years of data exclusivity. 21 U.S.C. § 360j(h)(4)(A). However, PMA devices make up a small percentage of overall device approvals. See, e.g., Jeffrey N. Gibbs, Allyson B. Mullen & Melissa Walker, *510(k) Statistical Patterns: Applying Moneyball-Style Statistical Analysis to FDA Data Yields Important Insights About the Most Common Pathway to Market for Medical Devices*, MDDI ONLINE (Dec. 2, 2014), <https://www.mddionline.com/510k-statistical-patterns> ("In 2013, FDA cleared approximately 140 510(k)s for every original PMA application approved.").

to those existing in the pharmaceutical context, but the device programs are newer, smaller, and their impact remains unclear.¹⁰² This pharmaceutical exceptionalism is likely because pharmaceuticals are generally thought to be far more expensive, time-consuming, and risky to develop than almost any other product, including other health technologies. Policymakers have repeatedly been convinced of the need to create special pathways to benefit pharmaceutical companies for fear of decreased innovation.¹⁰³

As a whole, many of the innovation incentives administered by the FDA are intended to bolster private incentives to invest in drugs either for which incentives would otherwise be too low or which may have a particularly high social value. The Orphan Drug Act and Priority Review Voucher program for neglected diseases are facially designed to support incentives for companies to engage in research on diseases affecting small, poor, or otherwise marginalized populations. The expedited approval pathways are designed to push companies toward products making truly significant treatment advances or meeting unmet medical needs, rather than the stereotypical “me-too” drugs which may add little, if anything, to the arsenal of drugs already available for a given condition.

C. Centers for Medicare and Medicaid Services

Unlike the NIH or FDA, CMS is rarely discussed in the literature as an innovation agency. Yet CMS has an important role to play in innovation policy, primarily through the enormous amount of money it brings to bear on the system. Specifically, CMS’s role as insurance company for over 100 million Americans through Medicare and Medicaid¹⁰⁴ means that it makes countless decisions about which health care services and products to purchase and at what prices. Scholars studying CMS have therefore generally understood it as a tool for

¹⁰² See 21st Century Cures Act, Pub. L. No. 114–255, § 3051, 130 Stat. 1033, 1121 (2016); FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., EXPEDITED ACCESS FOR PREMARKET APPROVAL AND DE NOVO MEDICAL DEVICES INTENDED FOR UNMET MEDICAL NEED FOR LIFE THREATENING OR IRREVERSIBLY DEBILITATING DISEASES OR CONDITIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015), <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393978.pdf>.

¹⁰³ Importantly, though, for those devices and diagnostics requiring FDA approval, the FDA’s gatekeeper function still serves as a barrier to entry for follow-on companies. As will be explained *infra* text accompanying notes 152–56, the FDA has for many years declined to regulate a large number of diagnostic tests.

¹⁰⁴ See DEP’T OF HEALTH & HUMAN SERVS., CTNS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2016: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 109–10 (2015) [hereinafter FY 2016: JUSTIFICATION OF ESTIMATES], <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2016-CJ-Final.pdf>.

promoting access to existing medications. However, those reimbursement decisions also give CMS great power to influence ex ante the kinds of technologies that are developed.¹⁰⁵ Further, CMS also has a secondary role to play in the innovation process by virtue of its possession of an enormous amount of health care information.

Most importantly, prescription drug insurance administered through CMS strongly resembles a prize system¹⁰⁶ or pull mechanism rewarding innovator drug companies, much like those administered by the FDA. By law, Medicare and Medicaid are required to cover most (and for some classes of patients or diseases, all)¹⁰⁷ FDA-approved drugs, meaning that companies know there is at least a partially guaranteed market for their drug. The size of the reward obtained is still uncertain, depending on things like the number of patients with a given condition, the distribution of those patients across the insurance system,¹⁰⁸ and the number of drugs competing in a particular class.¹⁰⁹ But the availability and size of the reimbursement pool is a key factor underlying pharmaceutical companies' decisions to invest in drugs for different classes of diseases.

Medicare Part D is the clearest example of this phenomenon in the health insurance context. Although the broader Medicare program has existed since 1965, Medicare largely¹¹⁰ did not cover prescription drugs until 2006 when Medicare Part D went into effect.¹¹¹ Medicare Part D provided a prescription drug benefit to Medicare enrollees, and as a

¹⁰⁵ See Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1013 (2014); Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613, 645–55 (2010); Arti K. Rai, *The Ends of Intellectual Property: Health as a Case Study*, 70 LAW & CONTEMP. PROBS. 125, 128–29 (2007); Sachs, *supra* note 18, at 193; William Fisher, *Intellectual Property and Innovation: Theoretical, Empirical, and Historical Perspectives*, in 37 INDUSTRIAL PROPERTY, INNOVATION, AND THE KNOWLEDGE-BASED ECONOMY, BELEIDSSTUDIES TECHNOLOGIE ECONOMIE 12 (2001), <https://cyber.law.harvard.edu/people/tfisher/Innovation.pdf>.

¹⁰⁶ Sachs, *supra* note 18, at 178.

¹⁰⁷ Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w835 (2009).

¹⁰⁸ Medicaid is entitled by law to rebates off of the private market price of prescription drugs. See 42 U.S.C. §§ 1396r-8(c)(1)(B)(i)(VI), (c)(3)(B)(iii) (2012) (meaning that companies can expect to make less money from drugs targeted at Medicaid-eligible populations).

¹⁰⁹ If a drug is the only FDA-approved product for a particular indication, it will be relatively more likely to enjoy market power and be priced accordingly, than in a situation where there are multiple products available for a particular indication; and at least some insurers can use the pressure of formularies in which some drugs are given preferred positions and others are deprioritized or even excluded altogether.

¹¹⁰ Some drugs, such as anesthetics used in surgery, are covered under Medicare Parts A and B as incidental to hospital or physician services. See *Your Medicare Coverage: Anesthesia*, MEDICARE.GOV (2015), <https://www.medicare.gov/coverage/anesthesia.html> (last visited May 21, 2018).

¹¹¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, § 1860D-1(2), 117 Stat. 2066, 2072 (codified in scattered sections of 26 and 42 U.S.C.).

result it both expanded the population of seniors with access to prescription drug coverage¹¹² and increased the prices pharmaceutical companies could expect to recoup for many drugs sold to senior citizens who had previously been eligible only for Medicaid.¹¹³ The passage of Medicare Part D has been empirically associated with increased pharmaceutical investment in drug classes with higher consumption among the Medicare population.¹¹⁴ Medicare Part D is not the only example of this phenomenon, with other analyses examining the effects of individual coverage mandates or of population shifts.¹¹⁵

It would be a mistake to view the innovation-related effects of Medicare Part D merely as an accidental side benefit of its publicly stated goal to promote access to pharmaceuticals for Medicare enrollees. Public health insurance schemes exist to instantiate a series of policy choices about which populations deserve coverage and which technologies and services will be covered. Even if consumers value and are willing to pay for cosmetic drugs (such as injections that reduce the appearance of facial wrinkles or under-eye bags), governments may choose to manipulate the insurance system to disfavor these or other categories of drugs. Governments (including the United States) often make decisions to *favor* certain socially valuable categories as well, such as when the Affordable Care Act mandated that preventive technologies like routine vaccinations be covered without cost-sharing.¹¹⁶

A more purposeful example of CMS's potential as an innovation agency comes through its implementation of the new technology add-on payment (NTAP) system in Medicare. Essentially, policymakers had

¹¹² KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS 5 (May 2010), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/3057-08.pdf> ("Prior to January 1, 2006, . . . about one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003."); see also Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, HEALTH AFF. (Apr. 19, 2005), https://www.researchgate.net/publication/7896125_Prescription_Drug_Coverage_And_Seniors_Findings_From_A_2003_National_Survey.

¹¹³ Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 HEALTH AFF. 33, 34, 36–37 (2008).

¹¹⁴ Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327 (2013); see also David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* 2–3, 6–7 (Nat'l Bureau of Econ. Research, Working Paper No. 20212, 2014) (qualifying the findings of Blume-Kohout and Sood by noting that truly innovative activity takes longer to emerge).

¹¹⁵ Professor Amy Finkelstein has discovered that several policies designed to increase the uptake of vaccines (including Medicare's 1993 decision to cover the flu vaccine) resulted in an increase in clinical trials for new vaccines. Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 556–57 (2004); Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1084 (2004) ("[A] 1 percent increase in the potential market size for a drug category leads to approximately a 4 percent growth in the entry of new nongeneric drugs and new molecular entities.").

¹¹⁶ See 42 U.S.C. § 300gg-13 (2012).

become concerned that Medicare's system of paying for hospital services did not sufficiently reward the development of new technologies and their incorporation into medical practice. As a result, Congress directed CMS to create a procedure for identifying new medical technologies and providing additional payments for their use.¹¹⁷

Although the NTAP statute is highly general, CMS has created finely specified procedures for implementing the program. By regulation, CMS has established criteria for determining which medical technologies are eligible for the add-on payments, created an annual application system for interested companies, and developed a formula for calculating the size of the payments.¹¹⁸ As the FDA has cultivated its expertise over time in administering expedited approval programs and the PRV system, the expertise CMS has developed in implementing the NTAP program could be brought to bear more generally to encourage innovation into needed medical technologies.

Beyond its role as the largest payor for health technologies in the country, CMS also possesses enormous amounts of information about the health needs of the American people in its capacity as their health insurer. Medicare and Medicaid have information about what the primary health care needs of their beneficiaries are, what diseases are imposing the largest financial drains on our system, and relatedly, where health innovation can provide the greatest benefit to the many Americans under CMS's care.

Scholars have paid attention to the ways in which the NIH, FDA, and CMS individually play significant roles in promoting health innovation in the United States. They are in charge of administering different policy levers and working at different stages along the value chain of innovation, from funding basic research to shepherding products through the approval process, to paying for the results of investment and innovation. Yet scholars have paid comparatively less attention to the ways in which these agencies sometimes work together to promote health innovation.

This lack of focus on agency collaboration is puzzling particularly in light of the fact that each of these agencies is formally a sub-agency within the Department of Health and Human Services (HHS). As such, scholars and policymakers ought to consider not only the potential innovation-related goals to be achieved if each agency acts alone. They also ought to consider the potential for coordination across agencies under the auspices of HHS. This next Part takes up that idea.

¹¹⁷ See *id.* § 1395ww(d)(5)(K); see also Alexandra T. Clyde et al., *Experience with Medicare's New Technology Add-on Payment Program*, 27 HEALTH AFF. 1632, 1633 (2008).

¹¹⁸ See 42 C.F.R. §§ 412.87, 412.88 (2018).

II. INTERAGENCY COORDINATION AND COLLABORATION IN PRACTICE

This Part aims first to construct a taxonomy of the ways that the NIH, FDA, and CMS work together at present to promote health innovation. Secondly, though, this Part argues that such coordination is often limited, non-public, and tenuous. Sometimes such relationships seem to be ad hoc. In other cases, public clashes exist to balance out the examples of coordination.

Before constructing the taxonomy, a word about terminology is in order. Much of the leading administrative law scholarship on interagency relationships speaks in terms of *coordination*,¹¹⁹ where the primary goal in situations involving agencies with interacting jurisdictional assignments (like the NIH, FDA, and CMS) is to minimize inconsistency.¹²⁰ But it is worth distinguishing mere *coordination* from a relationship that rises further to the level of *collaboration*, in which agencies actively work together, exchanging information and resources, to achieve shared goals. To be sure, the literature itself (rather than just the terminology it applies) is concerned with both. Requirements for interagency consultation frequently fall into the coordination category while joint rulemakings are often closer to collaboration, and there are also particular instances of true collaboration.¹²¹ My focus going forward is on this category of true collaboration, although the personal and institutional relationships supporting relationships of mere coordination are often a key precondition for collaboration.

In constructing the taxonomy of forms of interagency collaboration, this Article is comparatively free from a problem that has affected most of the scholarship focusing on interagency relationships: the problem of agency non-disclosure. That is, agencies are often not required and often do not choose to disclose the many different types of relationships they have with other agencies.¹²² Some individual relationships can be discerned from particular statutes requiring consultation or public actions taken jointly,¹²³ but in general, transparency is not the norm.

By contrast, the NIH and FDA are generally very forthcoming on the collaborations they have with other federal agencies. Since 2006, the

¹¹⁹ See generally, e.g., Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131 (2012); Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421 (2015); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 21 (2008) (noting that “government agencies often fail to coordinate innovation policy, resulting in incoherence and perhaps bald inconsistency”).

¹²⁰ Freeman & Rossi, *supra* note 119, at 1146–48.

¹²¹ *Id.* at 1157, 1163, 1166.

¹²² *Id.* at 1161, 1189–91.

¹²³ See, e.g., *id.* at 1165–68 (discussing instances of joint rulemaking).

NIH has been required by statute to publish an annual report identifying, categorizing, and analyzing every relationship it formally enters into with other administrative agencies.¹²⁴ And although seemingly not required by law, the FDA publishes a list of all formal memoranda of understanding it has with other federal agencies.¹²⁵ CMS is comparatively less forthcoming, but information about CMS's collaborations with the NIH and FDA, in particular, may of course be backed out of those agencies' lists. This is not to say that these lists are exhaustive—indeed, as I go on to argue in this Part, I suspect additional relationships are operating behind the scenes. Further, much of the publicly available information about these collaborations is quite sparse. However, these lists are a start and provide a window into the size and scope of interagency collaboration in this space.

In general, the NIH, FDA, and CMS collaborate in different combinations and ways to serve different functions. These functions can loosely be grouped into three main categories: information-sharing, research, and decision-making and product approval.¹²⁶

A. *Information-Sharing*

More than two hundred collaborations devoted primarily to information-sharing purposes have proliferated among these agencies, and these types of collaborations are more prevalent than any other type of relationship between these agencies.¹²⁷ These information-sharing initiatives sometimes seem to go by as many different names as there are collaborations—working groups, advisory committees, coordinating committees, leadership councils, etc.—but they all: (1) bring together representatives from more than one agency; (2) for the purpose of sharing information between them.

Although they have the same basic function, these groups differ from each other in a host of ways. Substantively, they span most of the health technology space, considering topics from pediatric drugs¹²⁸ to

¹²⁴ 42 U.S.C. § 283(a) (2012).

¹²⁵ *About FDA: Domestic MOUs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm> (last updated May 9, 2018).

¹²⁶ This is an amalgamation of the taxonomy developed by Freeman & Rossi, *supra* note 119, and the taxonomy used by the NIH in its annual reporting of its collaborations.

¹²⁷ *NIH Collaborations with Other HHS Agencies: Intra-Agency Collaborations Reporting System (CRS)*, NIH, <https://report.nih.gov/crs/ViewCollaborations.aspx?TID=19&Title=Committee,%20Advisory%20Group,%20or%20Work%20Group&AG=F&FY=2016> (last updated July 11, 2017).

¹²⁸ *Collaboration Details: American Academy of Pediatrics (AAP) Committee on Drugs*, NIH, <https://report.nih.gov/crs/View.aspx?Id=4032&FY=2015> (last visited May 22, 2018).

nanotechnology¹²⁹ to blood products.¹³⁰ Structurally and procedurally, these groups differ along at least five key dimensions. First, they exist at different stages within the leadership hierarchy. Second, they exist at different levels of generality. Third, they were constituted through different types of procedural mechanisms. Fourth, they engage in varying levels of transparency about their activities. Fifth and finally, they use the information shared through the group for different purposes. That is, sometimes information-sharing serves to set priorities for further research. In other cases, information-sharing is used to revise existing agency processes. To illustrate these differences, consider the following two examples.

The NIH-FDA Joint Leadership Council brings together the heads of the FDA and NIH and senior leadership from both agencies¹³¹ to engage in broad-based consideration of the ways in which information-sharing can support the activities of each agency. Specifically, the Council aims to ensure both that “regulatory considerations form an integral component of biomedical research planning,” and that “the latest science is integrated into the regulatory review process.”¹³² Since the Council meets only at the request of the Chairs, each of whom is a busy agency head, it is difficult to say how productive the Council has been thus far. But it represents one possible information-sharing model. The Council exists at the highest levels of the leadership hierarchy, has a broad scope of interest, is not very transparent, and aims to use the information shared with the group to inform and improve both research priority-setting and regulatory processes.

A very different example is the Interagency Pain Research Coordinating Committee (IPRCC). The Committee’s creation was mandated by the Affordable Care Act, which not only instructed the Secretary of HHS to establish the committee “to coordinate all efforts within [HHS] that relate to pain research”¹³³ but also finely specified the membership, meeting schedule, and duties of the committee.¹³⁴ The Committee’s leadership is less senior than the Council’s and its focus is

¹²⁹ *Collaboration Details: National Nanotechnology Initiative (NNI) Nanotechnology Signature Initiative on Nanotechnology for Sensors and Sensors for Nanotechnology: Improving and Protecting Health, Safety, and the Environment*, NIH, <https://report.nih.gov/crs/View.aspx?Id=3839&FY=2015> (last visited May 22, 2018).

¹³⁰ *Collaboration Details: FDA Blood Product Advisory Committee*, NIH, <https://report.nih.gov/crs/View.aspx?Id=3601&FY=2015> (last visited May 22, 2018).

¹³¹ FOOD & DRUG ADMIN. & NAT’L INSTITUTES HEALTH, NIH-FDA JOINT LEADERSHIP COUNCIL ROSTER (Jan. 25, 2016), <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM484666.pdf>.

¹³² *Science & Research: FDA-NIH Joint Leadership Council Charter*, FDA, <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm201654.htm> (last updated Mar. 30, 2018).

¹³³ 42 U.S.C. § 284q(b)(1) (2012); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 409J(b), 124 Stat. 119, 585-86 (2010).

¹³⁴ 42 U.S.C. § 284q(b)(2)-(5).

narrowed to pain research. And although within that focus the Committee aims to achieve different goals (including both prevention and treatment, for instance), it is primarily focused on bolstering research, rather than altering the regulatory environment for pain-related products.¹³⁵ The Committee is also highly transparent about its activities. The Committee announces its public meetings in the Federal Register, streams the meetings online, and provides the public with access to the presentations and minutes.¹³⁶ It also publicly outlines its strategic plan for pain research and solicits feedback on ways in which it can be improved.

B. *Research*

In some cases, the information-sharing conducted through various collaborations, as considered in Section II.A, will then be used by individual agencies in their sponsorship of different research or regulatory activities. But in other cases, the collaboration between the agencies is based around the research itself, rather than information underpinning that research. These research initiatives are diverse in their subject areas, focusing on everything from rheumatoid arthritis¹³⁷ to robotics¹³⁸ to women's health.¹³⁹

Although there was great structural and procedural diversity in the types of collaborations occurring in the information-sharing context, there is somewhat less variety in these research collaborations. Some of the homogeneity stems from the nature of research, which relies on the efforts of individual scientists asking specific questions, not agency heads promulgating vague directives. Therefore, these research initiatives are generally situated lower in the agency hierarchies and initiated with greater specificity than are some of the information-sharing collaborations. Further, because the vast majority of these

¹³⁵ Interestingly, the Committee does have as one area of focus: "service delivery and payment," INTERAGENCY PAIN RESEARCH COORDINATING COMM., NAT'L INSTS. OF HEALTH, NATIONAL PAIN STRATEGY OBJECTIVES AND UPDATES 34–40 (2016), https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf, yet CMS is not one of the HHS agencies involved in the Committee. *Membership & Agency Representation*, NAT'L INSTITUTES HEALTH, <https://iprcc.nih.gov/About/Membership-Agency-Representation> (last updated Sept. 27, 2017).

¹³⁶ See, e.g., *IPRCC Meeting—12/03/2015*, NAT'L INSTITUTES HEALTH, <https://iprcc.nih.gov/Meetings-Events/IPRCC-Meetings/2015/IPRCC-Meeting-12032015> (last updated Apr. 9, 2018).

¹³⁷ *Collaboration Details: Accelerating Medicines Partnership in Rheumatoid Arthritis and Lupus*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/View.aspx?Id=3940&FY=2015> (last visited May 22, 2018).

¹³⁸ *Collaboration Details: National Robotics Initiative*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/View.aspx?Id=3667&FY=2015> (last visited May 22, 2018).

¹³⁹ *Collaboration Details: Cancer and Women's Health Interagency Agreement*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/View.aspx?Id=3829&FY=2015> (last visited May 22, 2018).

collaborations exist between the NIH and the FDA (with CMS contributing only to a small handful), there is relative homogeneity in the type of research being conducted. Most of these collaborations involve regulatory science rather than active product development. To illustrate, consider two examples.

First, the Tobacco Regulatory Science Program (TRSP), as discussed in Section I.A, directs research into tobacco products that then supports the FDA's regulatory activities. The TRSP was developed internally to HHS by the NIH and the FDA, rather than formally imposed externally by the President or Congress. Research supported by the TRSP can help the FDA set its regulatory priorities, decide whether to regulate a product at all, and decide how to regulate it. For instance, one of the TRSP's areas of focus is e-cigarettes.¹⁴⁰ Research into e-cigarettes, including their health risks, use by minors, and chemical characteristics, may support these aspects of the FDA's decision. Although the FDA's regulatory decisions may influence the direction that private industry takes in developing new tobacco products, the primary point of the TRSP is not to accelerate such innovation, but to choose how to regulate it.

Second, the BRAIN Initiative is an effort to “support[] the development and application of innovative technologies that can create a dynamic understanding of brain function.”¹⁴¹ Much like the Precision Medicine Initiative or the Cancer Moonshot, the BRAIN Initiative emerged from and is driven by the White House as one of its key priorities in biomedical innovation, rather than emerging from internal HHS discussions as the TRSP did.¹⁴² This allows the Initiative to bring together agencies within HHS (NIH and FDA) as well as other agencies outside of HHS, including the National Science Foundation and the Defense Advanced Projects Research Agency.¹⁴³ The proximate goal of the BRAIN Initiative is not to develop treatments for brain-related conditions like Alzheimer's disease or depression that exact an enormous toll on our health care system.¹⁴⁴ The BRAIN Initiative seeks

¹⁴⁰ *Research Priorities: FDA Center for Tobacco Products Research Interest Areas*, NAT'L INSTITUTES HEALTH, <https://prevention.nih.gov/tobacco-regulatory-science-program/research-priorities> (last updated Mar. 13, 2017).

¹⁴¹ *The BRAIN Initiative*, WHITE HOUSE, <https://obamawhitehouse.archives.gov/node/300741> (last visited May 22, 2018).

¹⁴² *Id.*

¹⁴³ *Why Is The BRAIN Initiative Needed?*, NAT'L INSTITUTES HEALTH, <https://www.braininitiative.nih.gov/about/index.htm> (last updated July 14, 2017).

¹⁴⁴ See *infra* text accompanying notes 178–85. Unfortunately, pharmaceutical companies have tried and failed repeatedly to develop therapies for Alzheimer's disease, Greg Miller, *Is Pharma Running out of Brainy Ideas?*, 329 SCI. 502, 502 (2010), and they have been shutting down their mental health pipelines after recent failures there. Dennis W. Choi et al., *Medicines for the Mind: Policy-Based “Pull” Incentives for Creating Breakthrough CNS Drugs*, 84 NEURON 554, 554–55 (2014).

instead to develop tools and information about these diseases that can be used both by these companies and by regulatory agencies going forward.

C. *Decision-Making and Product Approval*

Far less common than either information-sharing collaborations or research initiatives are efforts to engage in collaborative decision-making and product approval. The NIH seemingly does not engage in collaborative activities that are directly related to the approval of individual products, but the FDA and CMS have recently developed two such collaborative programs in the context of medical devices and diagnostics. By statute, the FDA and CMS have shared jurisdiction over devices and diagnostics,¹⁴⁵ in which the FDA is in charge of approval and CMS is in charge of reimbursement. The idea behind these collaborative programs is to harmonize, where possible, the often divergent standards employed by these agencies in making those decisions and to reduce uncertainty for companies bringing new products to market.¹⁴⁶

Historically, medical device companies have had to navigate two separate regulatory systems: they must both obtain FDA approval and proceed through CMS's national coverage determination process to secure Medicare reimbursement for their device. But the two agencies apply different legal standards to those determinations¹⁴⁷ and are concerned with different aspects of the device, resulting in substantial uncertainty about whether the information generated in the FDA

¹⁴⁵ This is a slightly different regulatory situation than the situation of interacting jurisdictional assignments I describe in the rest of this Article. This particular delegation more accurately fits into the overlapping agency situation described by Freeman & Rossi, *supra* note 119, at 1146.

¹⁴⁶ Although this Article focuses on parallel review as a collaboration between the FDA and CMS, CMS itself has on occasion chosen to invoke a program designed to decrease this uncertainty: coverage with evidence development (CED). Unlike parallel review, CED preserves the separation in time between FDA and CMS review. Instead, CMS provides temporary reimbursement for the device in question while the manufacturer carries out clinical trials to produce the information sought by CMS. The CED program has been around since 1995, but only one product has successfully made it through CED: a form of an imaging test used to scan for a range of oncology indications. LIZ RICHARDSON, HEALTH AFFAIRS, HEALTH POLICY BRIEF: ALIGNING FDA AND CMS REVIEW 2–3 (2015).

¹⁴⁷ The FDA ensures that devices are “safe and effective . . .” 21 U.S.C. § 360e(c)(1)(A) (2012) (providing that applicants for medical device premarket approval must show “whether or not such device is safe and effective”). CMS covers products that are “reasonable and necessary.” 42 U.S.C. § 1395y(a)(1)(A) (2012) (providing that “no payment may be made . . . for any expenses incurred for items or services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”); *see also* 21 U.S.C. § 393(b)(2)(B) (describing part of the FDA’s mission as “ensuring that . . . human and veterinary drugs are safe and effective”).

approval process is sufficient to support a coverage determination.¹⁴⁸ Even where a company has produced sufficient information, the additional time required to go through the CMS coverage determination process after FDA approval is costly both for the company and for patients who may want to access the device in question.

As a result, the FDA and CMS have developed a collaborative decision-making program operating in the medical device space: parallel review. The Parallel Review pilot program, first created in 2011, allows product sponsors to request that CMS begin the coverage determination process while the product is still under review by the FDA. The idea is to collapse the two review timelines, at least partially, and permit product sponsors to anticipate and develop the data needed by both agencies. The program was formally made permanent in 2016,¹⁴⁹ although in its five years of operation, just two devices have been approved through the program—Cologuard, a non-invasive colorectal cancer screening test,¹⁵⁰ and a next generation tumor sequencing test from Foundation Medicine.¹⁵¹

The other collaborative effort between CMS and the FDA involves diagnostic tests. Although the FDA is typically viewed by the public as the chief regulator of medical technologies, CMS actually plays a far more prominent role in the area of diagnostic tests. Until 2014, the FDA essentially exercised no regulatory authority over a large class of diagnostics known as “laboratory developed tests” or LDTs, those which are “designed, manufactured and used within a single laboratory.”¹⁵² Instead, these tests were primarily regulated by CMS through the

¹⁴⁸ RICHARDSON, *supra* note 146, at 2 (“This can lead to cases in which the FDA approves a product that is subsequently denied Medicare coverage because the evidence collected in pivotal clinical trials does not meet the ‘reasonable and necessary’ bar.”).

¹⁴⁹ Program for Parallel Review of Medical Devices, 81 Fed. Reg. 73,113 (Oct. 24, 2016).

¹⁵⁰ RICHARDSON, *supra* note 146, at 4. It is worth noting that at least one other product (from Medtronic) failed to demonstrate efficacy in its Phase III trial and thus did not complete the program. *Id.*

¹⁵¹ Press Release, Ctr. for Medicare & Medicaid Servs., FDA Announces Approval, CMS Proposes Coverage of First Breakthrough-Designated Test to Detect Extensive Number of Cancer Biomarkers (Nov. 30, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-30-2.html>.

¹⁵² FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., DRAFT GUIDANCE FOR INDUSTRY, FOOD AND DRUG ADMINISTRATION STAFF, AND CLINICAL LABORATORIES: FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTs) 5 (2014) [hereinafter LDT DRAFT GUIDANCE], <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf>. Importantly, this does not mean that only one laboratory in the country performs a given test. Many of the most widely available tests are LDTs, precisely because they are simple for every lab to develop and perform independently. Routine laboratory tests like a complete blood count or Pap smear typically qualify as LDTs for this reason. These tests are performed in hundreds or even thousands of labs around the country, but they can still qualify as LDTs as long as there is no test manufacturer who sells a diagnostic product to other labs.

Clinical Laboratory Improvement Amendments of 1988 (CLIA),¹⁵³ which requires laboratories and the diagnostics they perform to meet certain analytical validity benchmarks.¹⁵⁴ The FDA always took the position that it had the authority to regulate LDTs, but it chose to exercise its enforcement discretion, meaning that diagnostic testing companies faced only a single federal regulator.¹⁵⁵ In 2014, however, the FDA announced its intention to begin regulating LDTs. The FDA's plan was to require companies to produce a different type of data about their diagnostics—data about their clinical validity.¹⁵⁶

Although the FDA has decided not to finalize this particular regulatory framework, the FDA and CMS have nevertheless created a task force on LDT quality requirements.¹⁵⁷ The goal is for the agencies to collaborate in modernizing their regulatory requirements, taking care to delineate the respective duties of each agency¹⁵⁸ and to minimize duplicative efforts by the agencies.¹⁵⁹ From the agencies' public statements, it seems as if CMS's role through CLIA would be altered slightly to focus more on the labs themselves, while the FDA would focus on determining each test's analytical and clinical validity.

As will be apparent from the preceding descriptions, when agencies choose to collaborate, there are benefits and drawbacks to choosing different collaborative mechanisms that may make them more or less attractive as a means of promoting innovation into health technologies. Information-sharing initiatives are relatively low-cost and the agencies devote little if any formal resources to them other than the time involved to collect existing information and gather officials for meetings. Of course, these personnel resources may be more or less scarce. The "cost" to convene a meeting of the NIH-FDA Joint Leadership Council, bringing together not only the heads of two

¹⁵³ Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a (2012)).

¹⁵⁴ 42 C.F.R. §§ 493.1253(b)(1)–(2) (2018).

¹⁵⁵ There are additional regulators involved in the system. Perhaps most notably, New York state's regulatory system oversees roughly seventy-five percent of all genetic and cytogenetic specimens tested in the United States. U.S. DEP'T OF HEALTH & HUMAN SERVS., U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY 3, 8 (2008).

¹⁵⁶ Framework for Regulatory Oversight of Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Availability, 79 Fed. Reg. 59,776, 59,776 (Oct. 3, 2014).

¹⁵⁷ Jeffrey Shuren & Patrick H. Conway, *FDA and CMS Form Task Force on LDT Quality Requirements*, FDA: FDA VOICE (Apr. 16, 2015), <http://blogs.fda.gov/fdavoiced/index.php/2015/04/fda-and-cms-form-task-force-on-ldt-quality-requirements>.

¹⁵⁸ For instance, CLIA does not require adverse event reporting or even the removal of unsafe diagnostics from the market, while the FDA has the power to take both of these actions. LDT DRAFT GUIDANCE, *supra* note 152, at 9.

¹⁵⁹ Food & Drug Admin., Discussion Paper on Laboratory Developed Tests (LDTs) 8–9 (Jan. 13, 2017) (unpublished paper), <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf>.

agencies but over a dozen senior officials, may be quite high. But the on-budget cost of these initiatives may still be zero, meaning that institutional commitment is the primary barrier to their establishment. However, information-sharing initiatives may be comparatively less likely to actually lead to the development of new technologies, since they are so early-stage.

With research initiatives, the primary question is the availability of financial resources for the program. Higher-level support within HHS, or even external support (such as from the President), may be needed to convince agencies to spend scarce resources on particular topics rather than others. When the collaboration is adequately resourced and staffed by committed agency members, it may be more likely to lead to productive research.

In some ways, product approval collaborations face both kinds of difficulties. They may not require direct additional expenditures of money as do research initiatives, and they therefore depend more on institutional commitment for their functioning. However, they do result in the agencies spending time, resources, and expertise on areas that they might not otherwise have to pursue. For instance, when CMS begins the national coverage determination process for a medical device that the FDA later declines to approve, that time is taken away from other potential CMS projects.¹⁶⁰

Relevantly, nearly all of the FDA-CMS collaborations noted above emerged in the last few years of President Obama's Administration, under the leadership of Commissioners Robert Califf (FDA) and Andy Slavitt (CMS). Commissioners Califf and Slavitt have repeatedly and publicly emphasized the importance of agency collaboration in these areas.¹⁶¹ Under their leadership, a CMS-FDA-NIH Trilateral Council was formed, to "provide[] a forum for agency leaders to . . . determine appropriate interfaces and collaborations . . ."¹⁶² The many programs resulting from their collaboration are evidence of the potential power committed agency heads can wield in promoting innovation.

The NIH, FDA, and CMS clearly do engage in at least some amount of collaboration to promote innovation, broadly conceived. However, orderly, transparent collaboration may be the exception, not the rule. As noted above, these collaborations are often restricted to particular types of products or information. Further, not all collaboration is public, although the best explanation for an agency's

¹⁶⁰ See, e.g., Cass R. Sunstein & Adrian Vermeule, *The Law of "Not Now": When Agencies Defer Decisions*, 103 GEO. L.J. 158, 160–61 (2014).

¹⁶¹ Robert M. Califf, Rachel E. Sherman & Andrew Slavitt, *Knowing When and How to Use Medical Products: A Shared Responsibility for the FDA and CMS*, 316 JAMA 2485 (2016).

¹⁶² *Collaboration Details: CMS-FDA-NIH Trilateral Counsel*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/ViewCollaborations.aspx?TID=19&Title=Committee%2c+Advisory+Group%2c+or+Work+Group&AG=F&FY=2016> (last updated May 22, 2018).

action may be that collaboration or at least coordination exists behind the scenes. Consider as an example a grant made by the NIH for the study of FDA regulation of microbiota transplants. This grant was made under the Human Microbiome Project, which is fully housed at the NIH and does not formally include the FDA.¹⁶³ Yet it seems that the FDA has at least knowledge of, if not input into, the grant. The grant itself is intended to provide information to the FDA, and FDA observers attend meetings of the working group.¹⁶⁴ But the FDA has taken several regulatory steps that would seem to contravene the existence of this grant.¹⁶⁵

Perhaps more importantly, the agencies not only do not always collaborate, but in some cases they do not even agree about issues and may clash publicly over them. A recent clash between CMS and the FDA is perhaps the most obvious example of this in recent years. In 2012, the FDA and CMS began a very public battle over medical devices. The battle concerned Unique Device Identifiers (UDIs), particular identifiers given to medical devices. The goal of the UDI system is to improve patient safety by enhancing the ability of providers and the FDA to track and report adverse events, to more speedily identify problematic clusters of events, and to facilitate the process for recalling unsafe devices.

Congress enacted the UDI concept into law in the 2007 FDA Amendments Act,¹⁶⁶ and by 2012 the FDA had developed plans to incorporate UDIs into data from medical claims to enable them to reap the benefits of the UDI system.¹⁶⁷ There was just one problem: CMS objected to the inclusion of UDIs in claims data, on the grounds that it was both technically difficult and expensive.¹⁶⁸ The agencies feuded publicly for years, and only in the summer of 2016 did they settle their dispute in the FDA's favor.¹⁶⁹

This feud should not have spilled over into public view. It is true

¹⁶³ *Human Microbiome Project: Overview*, NAT'L INSTITUTES HEALTH, <https://commonfund.nih.gov/hmp/overview> (last updated Mar. 20, 2017).

¹⁶⁴ *NIH Microbiota Transplantation Project Working Group List* (Dec. 2015), https://www.law.umaryland.edu/programs/health/events/microbiota/documents/WG1_members.pdf.

¹⁶⁵ Rachel E. Sachs & Carolyn A. Edelstein, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, 2 J.L. & BIOSCIENCES 396, 398 (2015).

¹⁶⁶ Pub L. No. 110-85, § 360i, 121 Stat. 823, 854 (2007) (codified as amended at 21 U.S.C.).

¹⁶⁷ Unique Device Identification System, 77 Fed. Reg. 40,736 (proposed July 10, 2012).

¹⁶⁸ Thomas M. Burton, *Medical Device ID Effort Hits Snag*, WALL ST. J. (Mar. 10, 2015, 6:44 PM), <http://www.wsj.com/articles/medical-device-id-effort-is-stalled-1426027440>.

¹⁶⁹ Letter from Andrew M. Slavitt, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs. & Robert M. Califf, Comm'r, U.S. Food & Drug Admin., to Gary Beatty, Chair, Accredited Standards Comm. X12 (July 13, 2016), <http://www.modernhealthcare.com/assets/pdf/CH106132714.PDF>. See *infra* text accompanying notes 172-74 for possible explanations for the resolution. *But see* Jessica Davis, *CMS May Reverse Agency Support on Unique Device Identifier Requirements*, HEALTHCARE IT NEWS (Oct. 2, 2017, 1:25 PM), <http://www.healthcareitnews.com/news/cms-may-reverse-agency-support-unique-device-identifier-requirements>.

that agency competition over substantive issues can serve a range of laudable goals.¹⁷⁰ Vociferous advocacy for both sides of the issue can help the administration as a whole reach the best policy outcome. But when policy disagreements are aired publicly, it may harm the relevant actors in the regulated industry. Actors on the device side (medical device manufacturers and labelers) as well as on the provider side (payers and claims management organizations) need to trust the agencies setting forth the relevant policies. If payers know that CMS is not committed to implementing UDI policy, they may drag their feet or otherwise attempt to delay its implementation.

The public airing of the UDI feud may be attributed to at least two potential failures. First, although the FDA and CMS are separate agencies with separate leadership, they are both formally sub-agencies within HHS. The existence of a strong agency head should have prevented conflicts between sub-agencies from reaching the public. Of course, this conflict took place at a time of turnover in the office¹⁷¹ and while HHS was focused on implementing the complex provisions of the Affordable Care Act, many of which began to go into effect during this period.

Second, the FDA and CMS had failed to reach a compromise decision on the UDI question. The FDA and CMS are agencies concerned with the very same types of questions involving the very same types of technologies. How can we encourage scientists and industry to develop new medical technologies that improve human health? How can we bring these products through our approval process and how will we pay for them? Their positioning as sub-agencies within HHS should have highlighted their overlapping missions, not pitted them against each other.

The reasons why CMS eventually came to agree with the FDA are not publicly known, but there are several potential explanations. CMS may have been swayed by recent scandals involving medical device adverse events, such as Olympus Corporation's duodenoscope that caused an outbreak of antibiotic-resistant bacteria, infecting hundreds of patients and possibly killing several.¹⁷² CMS may have had an eye toward the potential cost savings from UDIs as it considers its push for

¹⁷⁰ See, e.g., Daniel A. Farber & Anne Joseph O'Connell, *Agencies as Adversaries*, 105 CALIF. L. REV. 1375, 1384–85 (2017); Freeman & Rossi, *supra* note 119, at 1151; Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 212.

¹⁷¹ After serving as HHS Secretary for five years, in mid-2014 Secretary Kathleen Sebelius resigned and Secretary Sylvia Mathews Burwell was appointed. Michael D. Shear, *Sebelius Resigns After Troubles over Health Site*, N.Y. TIMES (Apr. 10, 2014), <https://www.nytimes.com/2014/04/11/us/politics/sebelius-resigning-as-health-secretary.html>.

¹⁷² HEALTH, EDUC., LABOR & PENSIONS COMM., U.S. SENATE, PREVENTABLE TRAGEDIES: SUPERBUGS AND HOW INEFFECTIVE MONITORING OF MEDICAL DEVICE SAFETY FAILS PATIENTS: MINORITY STAFF REPORT i (2016), <https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf>.

value-based payments, which often penalize physicians and hospital systems for preventable adverse events. The collaborative relationship between Commissioners Califf and Slavitt may have catalyzed the agreement.¹⁷³ Alternatively, the Secretary of Health and Human Services may have mediated the dispute between them.¹⁷⁴ A strong HHS Secretary may have the power to defuse intra-agency battles,¹⁷⁵ achieving coordination if not collaboration.

III. TOWARD A PURPOSIVE SYSTEM OF INTERAGENCY COLLABORATION FOR INNOVATION

Having considered in Part II the ways in which collaboration *is* happening between these agencies, this Part moves to consider the ways in which collaboration *can* and *should* occur but is not happening. The goal is to view the NIH, FDA, and CMS as agencies with particular core competencies and expertise and envision them in complementary situations. In doing so, this Part theorizes potential collaborations to fill the negative spaces in the existing collaborative landscape. Further, it argues that by working together, these agencies can achieve two unique types of goals: First, these agencies can accomplish goals together that they cannot accomplish apart. And second, by working together these agencies can accomplish goals synergistically, in the sense that their combined contributions are greater than the sum of any particular part.

The essential question asked in this Part is simple: to the extent that these agencies working together can more effectively promote innovation incentives than agencies acting alone, when should these agencies work together and in what capacities? I propose four categories which represent different modes of collaborations between these agencies. Importantly, the collaborations described in Part II fall largely into the second and third category, suggesting that although there is surely work to be done in those areas, large swathes of collaboration remain nearly unexplored.

¹⁷³ See text accompanying note 161.

¹⁷⁴ During Secretary Sylvia Burwell's confirmation hearing in 2014 she appeared to come out on the FDA's side on the UDI issue, stating that the FDA's system for detecting device adverse events would "benefit . . . by incorporating UDIs into its claims data sources." Letter from Elizabeth Warren, U.S. Senator & Charles E. Grassley, U.S. Senator, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs. (Dec. 22, 2014), <http://www.pewtrusts.org/~media/assets/2014/12/lettertotavennerreudi.pdf?la=en>.

¹⁷⁵ See generally Nou, *supra* note 119.

A. *Enhancing NIH Priority-Setting for Basic Research with CMS Data*

The first category of collaboration brings together the NIH and CMS to engage in information-sharing and priority-setting activities. The central idea here is that when the NIH makes decisions about how to allocate funding between or within institutes, it ought to do so on the basis of data. To be sure, reasonable people can disagree about what types of data will be most important,¹⁷⁶ how much weight the data should have in funding decisions, and about how to trade off different pieces of information against each other, a topic to which I will soon turn. But in general, the more information the NIH possesses, the better and more informed its allocation of resources will be.

Helpfully, CMS is in possession of an enormous amount of data that is relevant to the NIH in this area. In its role as health insurer to over 100 million Americans,¹⁷⁷ CMS and its contractors have information about disease burdens, about what types of drugs and interventions exist for a particular disease, and therefore by extension about which disease areas are currently underserved by medical technologies. But there is also information that CMS may want but does not have. For instance, where there is more than one intervention available for a given disease, CMS may be uncertain about the relative value of those interventions.

Information-sharing between CMS and the NIH can better enable the agencies to accomplish two primary goals. First, the NIH may improve its ability to set its funding priorities if it has an increased understanding of the unmet disease burden faced by the many Americans on public health insurance. Second, CMS may be able to make more informed decisions about relative reimbursement rates if it has information from the NIH on cost-effectiveness and value.

Each of these potential goals may be illustrated with a single example: mental health conditions. Mental health and other neuropsychiatric disorders are now responsible for the loss of more disability-adjusted life years worldwide than any other set of conditions.¹⁷⁸ Mental health disorders are responsible for at least \$300

¹⁷⁶ For instance, in addition to the kinds of demand-side data that CMS may contribute to the deliberation process, it might be reasonable for the NIH to consider supply-side questions about whether a sufficient number of scientists will be interested in a particular area or about whether a particular area is ripe for a scientific breakthrough. Of course, these questions are interrelated, and a NIH announcement about increased funding in an underserved area might well encourage new scientific interest in that area. *See supra* text accompanying notes 55–58.

¹⁷⁷ *See* FY 2016: JUSTIFICATION OF ESTIMATES, *supra* note 104, at 109.

¹⁷⁸ WORLD ECON. FORUM, HARV. SCH. OF PUBLIC HEALTH, THE GLOBAL ECONOMIC BURDEN OF NON-COMMUNICABLE DISEASES 26 (2011), http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf; *see also* Steven E.

billion in costs annually in the United States alone, when the cost of direct health care expenditures is added to the (far larger) related lost income and disability expenses.¹⁷⁹ Much of these costs are traceable to major depression, which affects approximately fifteen million Americans.¹⁸⁰

Fortunately, the NIH already recognizes the high disease burden due to mental health conditions and devotes significant resources towards these conditions, devoting funding roughly in proportion to disease burden¹⁸¹ and devoting institutional resources in the form of the National Institute for Mental Health. Yet these investments have yet to lead to real, effective treatments for many patients with these conditions.¹⁸² The Director of the National Institute of Mental Health has argued that the new generation of antidepressants is no more effective than the medications available in the 1980s.¹⁸³ We simply lack an understanding of neurobiology that can be translated into effective treatments,¹⁸⁴ and these scientific difficulties have even led many large pharmaceutical companies to shutter their neuroscience divisions entirely.¹⁸⁵

As discussed both in Parts I and II, the White House's leadership of the BRAIN Initiative is an attempt to solve some of these problems, focusing on increasing our understanding of neurobiology and the development of tools that can eventually be used to create and evaluate new treatments. And without the White House's leadership, it is

Hyman, *The Unconscionable Gap Between What We Know and What We Do*, 6 SCI. TRANSLATIONAL MED. 253 (2014); Thomas R. Insel & Story C. Landis, *Twenty-Five Years of Progress: The View from NIMH and NINDS*, 80 NEURON 561, 562–63 (2013). The global costs attributable to these diseases, already at \$2.5 trillion annually, are likely to grow as high as \$6 trillion annually by 2030, given current treatment capabilities. WORLD ECON. FORUM, *supra* note 178, at 27.

¹⁷⁹ Thomas R. Insel, Editorial, *Assessing the Economic Costs of Serious Mental Illness*, 165 AM. J. PSYCHIATRY 663, 664 (2008).

¹⁸⁰ NAT'L ALL. ON MENTAL ILLNESS, MENTAL ILLNESS FACTS AND NUMBERS 1 (2013), http://bhsarkansas.org/pdf/facts_and_stats.pdf.

¹⁸¹ See *Funding: Report on NIH Funding vs. Global Burden of Disease*, *supra* note 56.

¹⁸² To date, no clinical trial has demonstrated success in the treatment of mild depression. Silvana Borges et al., *Review of Maintenance Trials for Major Depressive Disorder: A 25-Year Perspective from the US Food and Drug Administration*, 75 J. CLINICAL PSYCHIATRY 205, 205 (2014). And clinical trials performed on individuals with severe depression typically show only modest success rates for the studied treatment. Ni A. Khin et al., *Exploratory Analyses of Efficacy Data from Major Depressive Disorder Trials Submitted to the US Food and Drug Administration in Support of New Drug Applications*, 72 J. CLINICAL PSYCHIATRY 464, 470 (2011). Large meta-analyses have confirmed these results. See, e.g., Jay C. Fournier et al., *Antidepressant Drug Effects and Depression Severity: A Patient-Level Meta-Analysis*, 303 JAMA 47, 47 (2010); Irving Kirsch et al., *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLOS MED. 0260, 0260 (2008).

¹⁸³ Insel & Landis, *supra* note 178, at 563–64.

¹⁸⁴ *Id.* at 564–65; see also Nicholas Kozauer & Russell Katz, *Regulatory Innovation and Drug Development for Early-Stage Alzheimer's Disease*, 368 NEW ENG. J. MED. 1169, 1170 (2013).

¹⁸⁵ See Choi et al., *supra* note 144, at 554. See generally, e.g., Miller, *supra* note 144.

difficult to say whether NIH would have reoriented its funding around these foci. But CMS is not involved in the BRAIN Initiative, at least not publicly.¹⁸⁶ Instead, the FDA plays a prominent role in the Initiative.¹⁸⁷ This may reflect the Administration's view that pharmaceuticals are likely to be a fruitful avenue for treating mental health conditions—and it is surely right about that. But this is also a narrow view of medical interventions, one that CMS's involvement would broaden.

To be more specific, there are interventions, such as pharmaceuticals and medical devices, where the private sector has historically played the dominant role in product development, manufacturing, and sales. Scholars typically argue that the incentive system we have developed around medical technologies—patents, exclusivity periods, and the like—is necessary to encourage private companies to invest in these types of products, because these exclusive rights permit companies to prevent others from making and selling their inventions.¹⁸⁸ The system may not always be sufficient, though, and where the basic science is as uncertain as it is in the area of mental health conditions, additional early-stage research may well be warranted.

However, patents and other exclusive rights have a tendency to “predictably and systematically distort private investment decisions . . . by overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones.”¹⁸⁹ And there are a range of nonexcludable technologies with the potential to mitigate the symptoms of mental health conditions, technologies in which the private sector has displayed little interest to date. Consider talk therapy, which may be prescribed for the treatment of a broad range of mental health conditions. Yet there are few rigorous clinical trials examining the practice, including the ways in which it might be optimized for particular maladies.¹⁹⁰ Even further along the continuum of nonexcludability, consider that studies have demonstrated the efficacy of exercise for the treatment of moderate depression, finding it

¹⁸⁶ *Why Is The BRAIN Initiative Needed?*, *supra* note 143.

¹⁸⁷ *Id.*

¹⁸⁸ *See, e.g.*, Burk & Lemley, *supra* note 11, at 1617–18. In general, pharmaceuticals are highly excludable in the economic sense, meaning that it is possible to prevent consumers from accessing drugs they have not paid for. However, the information leading to their development is often nonexcludable, such that it is far more difficult to prevent its consumption once it exists in public. The result is to bias innovative activity away from the collection of information about existing drugs, discouraging the production of both positive and negative information.

¹⁸⁹ Kapczynski & Syed, *supra* note 16, at 1907.

¹⁹⁰ *See* Richard A. Friedman, *To Treat Depression, Drugs or Therapy?*, N.Y. TIMES: WELL (Jan. 8, 2015, 8:00 AM), <https://well.blogs.nytimes.com/2015/01/08/to-treat-depression-drugs-or-therapy>. *See generally, e.g.*, Callie L. McGrath et al., *Toward a Neuroimaging Treatment Selection Biomarker for Major Depressive Disorder*, 70 JAMA PSYCHIATRY 821 (2013); Charles B. Nemeroff et al., *Differential Responses to Psychotherapy Versus Pharmacotherapy in Patients with Chronic Forms of Major Depression and Childhood Trauma*, 100 PNAS 14293 (2003).

as or more effective than existing pharmacological interventions.¹⁹¹

Not only is private industry largely uninterested in pursuing such nonexcludable technologies, but the FDA does not “see” interventions like these, as they do not fit within its purview of regulating and approving medical products. The FDA by law does not regulate the practice of medicine itself.¹⁹² But in some ways, CMS does. CMS is formally agnostic as between whether a decrease in disease burden is achieved through a drug or through a medical treatment,¹⁹³ and CMS involvement in the BRAIN Initiative specifically or NIH decision-making more broadly may be valuable in raising the profile of interventions like these within the funding process.¹⁹⁴

A CMS-NIH partnership may be able to go further in the area of pricing, enabling CMS to make more informed decisions about relative reimbursement rates for interventions based on cost-effectiveness and value. New pharmaceuticals are often evaluated against a placebo or only a single other treatment, and scholars have long recognized the dearth of quality research on the comparative effectiveness of different kinds of drugs.¹⁹⁵ But CMS may not only be interested in comparing drugs to each other. CMS may also want to compare drugs to non-pharmaceutical interventions or explore combinations of pharmaceutical and non-pharmaceutical care. Just as there is little private investment in non-pharmaceutical interventions now, there is

¹⁹¹ See, e.g., Leandro Z. Agudelo et al., *Skeletal Muscle PGC-1 α 1 Modulates Kynurenine Metabolism and Mediates Resilience to Stress-Induced Depression*, 159 CELL 33 (2014); Madhukar H. Trivedi et al., *Exercise as an Augmentation Treatment for Nonremitted Major Depressive Disorder: A Randomized, Parallel Dose Comparison*, 72 J. CLINICAL PSYCHIATRY 677 (2011).

¹⁹² W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1061 (2016).

¹⁹³ However, there are certainly procedural factors that go into this decision. Drugs and services may be reimbursed through different sections of Medicare. For instance, Medicare Part B covers physician services in the outpatient setting, 42 U.S.C. § 1395k(a)(2) (2012), but in doing so it covers prescription drugs that are administered in those settings. *Id.* § 1395u(o)(1). Medicare Part D only covers prescription drugs, by contrast. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.). CMS has had more ability to control and set the prices it pays for services than it does for pharmaceuticals. See, e.g., Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: The Engines of True Health Reform*, 13 YALE J. HEALTH POL'Y, L. & ETHICS 253, 266-68 (2013).

¹⁹⁴ It is difficult to figure out if formal collaboration of this type is actually happening. NIH's thorough database of its interagency collaborations lists only a “CMS-NIH Data Access Committee” whose description resembles the above suggestions. However, very little else about the Committee is public (how often it meets, what is discussed, how its priorities are set, etc.). Transparency may be desirable here. *Collaboration Details: Centers for Medicare and Medicaid Services (CMS)-NIH Data Access Committee*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/ViewCollaborations.aspx?TID=19&Title=Committee%2c+Advisory+Group%2c+or+Work+Group&AG=F&FY=2016> (last updated May 22, 2018).

¹⁹⁵ See, e.g., Richard S. Saver, *Health Care Reform's Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research*, 159 U. PA. L. REV. 2147, 2150 (2011).

similarly little to no investment in the comparison of pharmaceutical and non-pharmaceutical interventions. Yet this information would benefit CMS as it sets reimbursement rates and makes coverage decisions.¹⁹⁶

CMS may also work with NIH to ensure it obtains preferential rates for drugs or other technologies developed with the assistance of federal funds. Scholars and policymakers have often asked why the public “pay[s] twice” for some drugs, first by subsidizing their development and then again by paying monopoly prices for the resulting product.¹⁹⁷ More recently, at least two Senators have introduced bills which would require companies to offer reasonable prices on technologies developed with taxpayer money more generally, not only to public payers.¹⁹⁸ But as CMS has an interest not only in the development of new technologies for those Americans it insures but also the procurement of those technologies at prices that make them widely available, it would be fruitful to see CMS and NIH work together to ensure reasonable pricing terms at least for public payers.

B. *Improving FDA Regulatory Processes Through NIH Involvement*

The second set of collaborations would bring together the NIH and the FDA for two purposes that are similar to those expressed in the previous subpart. Specifically, the two agencies should first engage in information-sharing and priority-setting activities. The FDA is an expert on its regulatory process, but it also knows the ways in which that process could be improved. Sharing information with the NIH about difficulties with the current system and asking questions about the ways in which it can be improved would aid the NIH’s funding allocations in

¹⁹⁶ If generalized, this type of research comes close to the work carried out by the Agency for Healthcare Research & Quality, or AHRQ. Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 651 (2001). AHRQ was created as a sub-agency of HHS (like NIH and CMS) in 1989 to conduct health care services research rather than house these functions within the existing NIH or CMS. It is not obvious why Congress desired to create a separate agency to conduct process-oriented research of this type, rather than cultivate such expertise within an existing agency. AHRQ’s provenance and its relationships with other HHS agencies are beyond the scope of this Article, as it is small relative to NIH and administers no other innovation policy levers.

¹⁹⁷ See, e.g., Colin Macilwain, *NIH Urged to Cap Profits Made on Publicly Funded Research*, NATURE, July 6, 2010, at 5.

¹⁹⁸ See, e.g., Alexander C. Kaufman, *Bernie Sanders to Propose New Rule Requiring Fair Prices for Taxpayer-Funded Drugs*, HUFFINGTON POST (July 31, 2017, 12:12 PM), http://www.huffingtonpost.com/entry/bernie-sanders-drug-prices_us_597f4546e4b0da64e87aaebf; Ed Silverman, *A Proposal Would Limit Prices on Meds Developed with Defense Department Dollars*, STAT (July 6, 2017), <https://www.statnews.com/pharmalot/2017/07/06/xtandi-zika-king-amendment-defense>.

the area of regulatory science and would redound to the benefit not only of the FDA and the regulated industry but also the public, if medical products can be approved more efficiently and with greater accuracy. Second and relatedly, the two agencies should focus their efforts in terms of translational and regulatory science research on the particular areas of research that would help improve the regulatory process or at least gather information about that process.

These will not be new suggestions, given Part II of this Article. Unlike NIH and CMS, NIH and the FDA are already actively collaborating with each other across several dimensions. The NIH-FDA Joint Leadership Council creates space for high-level NIH and FDA officials to share information and communicate about joint goals, while the Interagency Pain Research Coordinating Committee (IPRCC) provided just one example of the ways in which these agencies can share information in a more concrete way.¹⁹⁹ Further, the agencies are already engaged in different regulatory science research activities. The TRSP and the BRAIN Initiative are examples of the different ways in which research can support the FDA's regulatory processes—in the first case, by supplying information that enables the agency to promulgate regulations and set priorities, and in the second case, by developing tools to be used in the process itself.²⁰⁰

However, there may still be two main areas of improvement for these NIH-FDA collaborations: purposiveness and transparency. First, the set of NIH-FDA collaborations that currently exists is not clearly driven by a high-level, systematic view of the areas in which these agencies ought to collaborate. Instead, NIH-FDA collaborations often develop in an ad hoc, externally-driven way. The IPRCC and BRAIN Initiative are examples of this—recall that the IPRCC was created and given specific charges by Congress and that the BRAIN Initiative is largely driven by the White House, rather than HHS.²⁰¹ Although the NIH and the FDA may agree that these are worthy areas for them to invest time and resources, if left to their own devices they may have focused on other areas of collaboration.²⁰²

Instead, a higher-level strategy driven by HHS or at least by the heads of the NIH and the FDA would be more effective in achieving innovation policy goals. Conversations among leadership in which these agencies prioritized areas of information-sharing and research are essential to creating the most valuable data-driven, purposive

¹⁹⁹ See *supra* text accompanying notes 131–36.

²⁰⁰ See *supra* text accompanying notes 42–43, 140–44.

²⁰¹ See *supra* text accompanying notes 133–36, 141–44.

²⁰² As a result, in some ways these externally driven projects take up valuable time and mental energy of these agency officials. But in other ways, the fungibility of their funding can be useful. If the BRAIN Initiative provides additional funding for NIH to develop research tools, that frees up NIH money that may have otherwise been spent in this area.

collaborations for innovation in health technologies. Importantly, such conversations may already be taking place. The NIH-FDA Joint Leadership Council, bringing together the heads of the FDA and NIH and senior leadership from both agencies,²⁰³ seems perfectly positioned to have exactly these kinds of conversations. However, the main problem with the Leadership Council is its total opacity.

In addition to improving their purposiveness, the current set of NIH-FDA collaborations can be improved by increasing their transparency and public accountability. It is not a matter of public record when the Leadership Council meets—or even if it has *ever* met—and if it does meet, what the Council has discussed. Nor are there reports, annual or otherwise, detailing the Council's areas of focus, particular projects, or research investments. Most of the publicly listed collaborations are closer to the Leadership Council's level of transparency than to the IPRCC's, and as argued in Part II, there are at least some instances of coordination which are not even publicly listed.²⁰⁴

There are good reasons to make these and other categories of intra-HHS collaborations more transparent, although these reasons may suggest different levels of transparency. First, transparency both about goals and about methodologies—such as whether these collaborations prioritize certain types of diseases over others, and if so, why—is important to ensure public accountability. These agencies already issue guidance documents and rulemakings for public comment for similar reasons. Issuing yearly reports or even documents listing the areas the collaborations hope to focus on going forward, as the FDA does each year,²⁰⁵ would be a step in the right direction.

Second and possibly more importantly, transparency about areas of collaborative focus helps academic scientists and companies plan for the future. The primary point of these collaborations is to improve both regulatory priority-setting and the regulatory process itself, and many of these collaborations may lead to disease or field-specific process improvements. Scientists and companies who have previously avoided particular disease areas or are considering exiting them due to regulatory barriers may reevaluate those decisions on the basis of new information about agency priorities and investment in these areas. In some ways, this is an exercise of the government's agenda-setting power.

²⁰³ NIH-FDA JOINT LEADERSHIP COUNCIL ROSTER, *supra* note 131.

²⁰⁴ See *supra* text accompanying notes 163–65.

²⁰⁵ See *infra* text accompanying notes 245–46.

C. *Reducing Uncertainty for Product Sponsors Through FDA-CMS Collaboration*

A third set of collaborations unites the FDA and CMS to engage in activities that simplify and speed the two regulatory hurdles that companies aiming to produce innovative health technologies must typically surmount: approval and reimbursement. Companies approach each of these regulatory processes at different times in a product's lifecycle and with different amounts and types of information about the product in question. But the separation of the regulatory hurdles adds time, cost, and uncertainty to the innovation process.²⁰⁶ The FDA and CMS have recognized the burden this additional time and uncertainty may place on innovative medical technology companies and have begun some collaborations in this area.²⁰⁷ Those collaborations themselves leave something to be desired.²⁰⁸ Even more problematic, though, is that the existing collaborations leave open broad areas in which the FDA and CMS could fruitfully collaborate but have not yet chosen to.

As detailed in Part II, in the medical device space, the FDA and CMS have entered into a set of collaborations designed to decrease the burden on companies from surmounting two separate regulatory hurdles with distinct evidentiary requirements.²⁰⁹ Specifically, their Parallel Review pilot program for medical devices aims to collapse the approval and reimbursement processes, providing earlier information to companies about what types of evidence will be required in both situations.²¹⁰ And although their task force on LDT quality requirements is focused only on the approval part of the process, it seeks to harmonize and clarify the duties of both agencies in the review and approval of diagnostic tests, minimizing administrative and regulatory burdens for diagnostic companies.²¹¹

The Parallel Review program was finalized in late 2016,²¹² even though just two products have successfully been approved in the program's five years of operation. It is difficult to say why the program has not yet been more successful. Perhaps industry was less interested in parallel review than they claimed to be publicly.²¹³ Perhaps the program

²⁰⁶ Because the two agencies apply different legal standards at different times, *see supra* note 147, there is often substantial uncertainty about whether the information generated in the FDA approval process is sufficient to support a coverage determination, beyond the additional time required to complete the reimbursement process. RICHARDSON, *supra* note 146, at 2.

²⁰⁷ *See supra* text accompanying notes 146–51.

²⁰⁸ *See supra* text accompanying notes 149–51.

²⁰⁹ *See supra* Part II.

²¹⁰ *See supra* text accompanying notes 149–51.

²¹¹ *See supra* text accompanying notes 157–59.

²¹² Program for Parallel Review of Medical Devices, 81 Fed. Reg. 73,113 (Oct. 24, 2016).

²¹³ A recent industry report supported by AdvaMed, the trade association for medical device

was inefficient, given the cost and rarity of national coverage determinations. More pessimistically, perhaps the agencies chose not to invest enough in the program to make it worthwhile. Or perhaps the FDA-CMS battle over the Unique Device Identifier question bled more deeply into the device sides of the agencies, making it difficult to work together. The lack of transparency over the program makes it impossible to learn from this experience. I reserve judgment on the LDT task force, as it is much newer. But it may be subject to these same concerns.

The FDA and CMS have at least attempted collaborations in the medical device and diagnostic areas. No such collaboration has taken place in the pharmaceutical context, at least not publicly. However, collaboration between these agencies in the drug context may have greater societal benefits than collaboration in the device or diagnostic space. The high cost of developing drugs and related failure rates have been widely publicized, and any collaboration with the potential to reduce those costs might be extremely socially valuable.

To be clear, there are plausible reasons why no comprehensive collaboration has yet been developed in the drug approval area. First, CMS is often statutorily required to cover particular FDA-approved drugs.²¹⁴ As such, if companies view the CMS coverage determination as largely pro forma, with the primary uncertainty lying only in the FDA context, they may be even less interested in parallel review here. Second, because most drugs fail at some point in the regulatory process,²¹⁵ it may not be an efficient use of CMS's time to involve itself in the clinical trials process.

Yet there may be particular areas where consultations between the FDA and CMS might be useful. Three examples are illustrative. First, recall that the FDA administers a set of four expedited approval pathways, whose goal is to shorten the regulatory review process for companies seeking approval for drugs.²¹⁶ The criteria for acceptance into these expedited pathways involves medical determinations that can be bolstered with evidence from CMS. Most importantly, each pathway requires the submission of evidence that the drug in question provides a

companies, repeatedly complained about the problems inherent in a divided regulatory system but referred to the parallel review process obliquely, stating only that it “has limitations.” MATTHEW GARDNER & IAN HATHAWAY, INNOVATION COUNSELORS LLC, A FUTURE AT RISK: ECONOMIC PERFORMANCE, ENTREPRENEURSHIP, AND VENTURE CAPITAL IN THE U.S. MEDICAL TECHNOLOGY SECTOR 25 (2016), <https://www.cmdt.org.nz/edit/library/docs/Advamed2016Afuturatrisk.pdf>.

²¹⁴ See 42 U.S.C. § 1396r-8(d)(2) (2012) (requiring states to cover essentially all FDA-approved drugs under the Medicaid program); Outterson & Kesselheim, *supra* note 107, at w835-36 (describing the formulary design of Medicare Part D programs).

²¹⁵ Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40 (2014).

²¹⁶ See *supra* text accompanying notes 67-77.

significant improvement over and above existing therapies.²¹⁷ Although each program words this requirement slightly differently,²¹⁸ CMS is well-positioned to help the FDA make each of these determinations.

Second, although CMS is often statutorily required to cover FDA-approved drugs, in some cases CMS has a choice of which drugs to cover.²¹⁹ In addition, even where CMS must cover a particular drug, that drug may receive a disfavored placement on a formulary and therefore be accessible to fewer patients.²²⁰ Companies who foresee that their drugs may fall into these categories may desire CMS's input into the FDA regulatory process. CMS may provide feedback on whether the evidence required by the FDA for approval is sufficient to ensure the company a preferred formulary placement, or on what evidence would be required to demonstrate a drug's cost-effectiveness relative to other products.

Third, CMS could assist the FDA in carrying out post-market reviews of approved drugs. Increasingly, as discussed in Part I, drugs approved by the FDA are using accelerated approval pathways that result in approvals based on surrogate endpoints.²²¹ These drugs must be monitored post-approval to be sure that they are eventually proven safe and effective for the true endpoint they aim to cure—to be sure that the cancer patient whose tumors have shrunk will actually live longer, or the patient with heart disease whose cholesterol is lowered actually has a reduced risk of heart attacks. CMS, with its possession of and access to vast databases of patient data, can assist both industry and the FDA in making these determinations more efficiently.

D. *Building Capacity and Lowering Costs with Tripartite Agreements*

The final set of collaborations would unite all three agencies—the NIH, FDA, and CMS—to pursue a more advanced, more involved set of innovation goals. Together, these agencies have the capacity essentially to serve as a product development partnership, in which they set priorities in underserved areas of medicine, conduct research or make grants in those areas, and shepherd products through the FDA approval process. The end goal is to approve products which are then marketed at relatively low prices²²² for unmet medical needs.

²¹⁷ See sources cited *supra* note 73.

²¹⁸ See *supra* text accompanying notes 73–77.

²¹⁹ 42 C.F.R. § 423.120(b)(2)(i) (2018).

²²⁰ 42 U.S.C. § 1396r-8(d)(1)(A) (2012).

²²¹ See *supra* text accompanying note 70.

²²² Although I will explore this issue in more detail, *infra* text accompanying note 237, for now I should say that I am formally agnostic as between government production of these

Collaboration at this level is not merely aspirational. The agencies are already engaged in partnerships that embody these ideals. One representative example is the Clinical Islet Transplantation Consortium,²²³ a network of clinical centers started in 2004 devoted to improving the safety and success of transplanting islet cells, the pancreatic cells that produce insulin, for those with Type I diabetes. Type I diabetes is typically diagnosed in children and young adults, and affects more than one million Americans.²²⁴ Although Type I diabetes is far less prevalent than Type II diabetes, which is typically diagnosed in adulthood and affects more than thirty million Americans,²²⁵ it still significantly burdens our health care system. The Juvenile Diabetes Research Foundation estimates that Type I-associated health care costs in the United States may be as high as fourteen billion dollars annually,²²⁶ and for the approximately 200,000 children and adolescents²²⁷ who cannot lead normal lives and who must either inject themselves with insulin several times each day or wear an insulin pump connected to their body, the psychological burden may be quite large as well.

Pharmaceutical companies, enticed by the large markets and daily needs of the diabetes population, have developed a range of pharmaceutical therapies for both Type I and Type II diabetes patients.²²⁸ But these therapies are often costly. Indeed, both scholars²²⁹ and the popular press²³⁰ have recently noted the skyrocketing cost of insulin. Further, adherence may be difficult to sustain, especially for children. And these therapies are just that—therapies, requiring patients to maintain these regimens as long as they live. Such therapies are intensely profitable for pharmaceutical companies but impose financial and other burdens on patients. Physicians and patients would prefer a

products and a competitive bidding process.

²²³ *Collaboration Details: Clinical Islet Transplantation Consortium*, NAT'L INSTITUTES HEALTH, <https://report.nih.gov/crs/View.aspx?Id=3738&FY=2015> (last visited May 23, 2018).

²²⁴ *Medical Encyclopedia: Type 1 Diabetes*, MEDLINEPLUS, <https://medlineplus.gov/ency/article/000305.htm> (last updated Apr. 30, 2018) (“It is most often diagnosed in children, adolescents, or young adults.”).

²²⁵ CTRS. FOR DISEASE CONTROL, U.S. DEP'T HEALTH & HUMAN SERVS., NATIONAL DIABETES STATISTICS REPORT 1–6 (2017), <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

²²⁶ See source cited *supra* note 224.

²²⁷ NATIONAL DIABETES STATISTICS REPORT, *supra* note 225, at 3.

²²⁸ Jing Luo, Jerry Avorn & Aaron S. Kesselheim, *Trends in Medicaid Reimbursements for Insulin from 1991 Through 2014*, 175 JAMA INTERNAL MED. 1681, 1682 (2015) (examining a selection of sixteen insulin products that are available in the United States); Ed Silverman, *Insulin Prices Have Skyrocketed, Putting Drug Makers on the Defensive*, STAT (Apr. 5, 2016), <https://www.statnews.com/pharmalot/2016/04/05/insulin-prices-skyrocketed-putting-drug-makers-defensive>.

²²⁹ See Luo, Avorn & Kesselheim, *supra* note 228.

²³⁰ Silverman, *supra* note 228.

cure.²³¹

Islet cell transplantation may be such a cure. Type I diabetes patients' bodies turn on and destroy their own islet cells. Successful islet cell transplants could enable these patients to avoid multiple insulin injections every day.²³² Islet cell transplantation would not be a worry-free cure—at least for the foreseeable future, patients would still need to take immunosuppressive drugs as with other transplantation procedures—but it could be an improvement over current therapies.

Yet private industry is unlikely to devote significant resources to developing safe, effective methods for islet cell transplantation. Recall the discussion in Section I.A about pharmaceutical incentives to invest in new drugs rather than investing in the development of information about new drugs.²³³ Pharmaceuticals are excludable goods in the sense that they can be manufactured and sold to particular patients. Surgical methods are largely non-excludable in the sense that it is difficult to prevent the dissemination of information about how to perform a given surgical procedure once that information has been developed.²³⁴ As a result, it is difficult for private companies to monetize such information and they will be reticent to invest in its development.²³⁵ This is a classic situation in which public investment may be needed to drive the development of new medical procedures, and the NIH, CMS, and the FDA have come together for that purpose.

This example can be generalized to three broad areas in which these agencies might collaborate in a way that complements existing private sector investment for the purpose of developing products with high social value. First, the agencies might focus on developing diagnostics and drugs for conditions primarily affecting poor Americans, where CMS and state governments bear the primary burden of care but where pharmaceutical companies underinvest relative to the disease burden. Some of this work might focus on tweaking existing drugs or drug protocols with an eye toward improving adherence, for instance, but some of it might focus on the development of entirely new therapies.

Second, the agencies ought to focus on products whose development can be expected to be particularly lengthy. They might

²³¹ Carolyn Y. Johnson, *Why Treating Diabetes Keeps Getting More Expensive*, WASH. POST (Oct. 31, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/?utm_term=.5cb9e8281321.

²³² *What Is Diabetes?*, CLINICAL ISLET TRANSPLANTATION CONSORTIUM, <http://www.citiletstudy.org/diabetes.html> (last visited May 23, 2018).

²³³ See *supra* text accompanying notes 27–28.

²³⁴ Kapczynski & Syed, *supra* note 16, at 1935–36. Such patents may also be unenforceable under 35 U.S.C. § 287(c)(1) (2012), which prevents patentholders from enforcing patents on surgical methods against physicians performing those methods. Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1197 (2000).

²³⁵ Kapczynski & Syed, *supra* note 16, at 1923–28.

focus on preventive interventions for diseases like cancer or Alzheimer's, where any study will need to be extremely large and possibly last for decades. Private actors are typically thought to be disincentivized from funding and performing such studies because any patent rights they may have in the product at issue may expire before the product comes to market, impairing their ability to recoup their investment in the technology.²³⁶ Yet these interventions may be highly socially valuable and deserving of research dollars.

Third and relatedly, the agencies ought to focus on investments in nonexcludable technologies, to the extent that they would implicate the FDA in some fashion. I have already argued earlier that CMS and the NIH should collaborate to direct research toward nonexcludable technologies that may prove valuable, particularly to CMS as an insurer. The Clinical Islet Transplantation Consortium described above is one such technology, but because it involves the transplantation of human tissue it necessarily implicates the FDA's jurisdiction.

I am relatively agnostic about the methods the agencies use to form and carry out these collaborations. That is, one option would be for the government to essentially become a pharmaceutical manufacturer, developing the capacity to produce and sell any technology it develops in the above categories. Another option would be for the government to form partnerships with generic manufacturers and pay them to produce these therapies still at relatively low cost.²³⁷ Which route to pursue depends on a range of empirical factors including the economics of the situation as well as political priors about the role of government in general.

IV. FACILITATING INTERAGENCY COLLABORATION

Given that there are tremendous unexplored opportunities for collaboration among these agencies, why have they not taken full advantage of these possibilities? This Part first considers existing barriers to collaboration. Are they practical, legal, or both? In light of such obstacles, how should we determine when collaboration is worthwhile? This Part then turns to procedural facilitation of such collaboration, presenting a menu of possible procedural approaches at different levels of hierarchy both within the executive branch and

²³⁶ See, e.g., Budish, Roin & Williams, *supra* note 20, at 2074.

²³⁷ Gilead's Access Program is structured in this way, through a network of partnerships. *Access Partnerships*, GILEAD, <http://www.gilead.com/responsibility/developing-world-access/access%20partnerships> (last visited May 23, 2018); see also MOLLY McDONOUGH & EBBA MARK, GLOB. ACCESS IN ACTION, WORKSHOP REPORT: PRACTICAL STRATEGIES TO EXPAND ACCESS TO MEDICINE AND PROMOTE INNOVATION 4 (2016), <http://www.globalaccessinaction.org/files/2016/07/FinalWorkshopReport.pdf>.

outside of the executive branch.

A. *Legal and Practical Barriers to Collaboration*

There are at least three potential barriers to interagency collaboration for the promotion of health innovation. The first is legal, the second practical, and the third a combination of the two. First, a number of laws constrain agency jurisdictions or agency information-sharing in a way that may impede collaboration. For instance, the FDA is not permitted to consider costs in the drug approval process,²³⁸ which may restrict its ability to engage in collaborations with that explicit purpose.²³⁹ Perhaps more problematically, the Trade Secrets Act²⁴⁰ and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule²⁴¹ may limit the information agencies are able to share with each other about potential products under development or about American health care needs.

A second set of barriers to interagency collaboration is practical. Interagency collaboration is difficult. It requires support from senior officials within the agency, scarce personnel resources, and (often) even scarcer financial resources. As considered previously, it may not be “worth” CMS’s time to help the FDA adjudicate applications for expedited approval as most drugs will fail before reaching the market. Relatedly, agencies may need to invest great time and energy in testing and improving collaborative systems as with the CMS-FDA Parallel Review program, which existed in pilot form for five years before it was made permanent.

Collaboration may be difficult for agencies who want to retain decision-making authority in their core competencies. The NIH understandably may not want to cede priority-setting authority to the

²³⁸ Julie Steenhuysen, *FDA Cancer Chief Says ‘Escalating’ Drug Prices Can’t Continue*, REUTERS (June 1, 2014, 2:15 AM), <https://www.reuters.com/article/us-health-cancer-fda/fda-cancer-chief-says-escalating-drug-prices-cant-continue-idUSKBN0EC13W20140601> (“By law, Dr. Richard Pazdur, the U.S. Food and Drug Administration’s cancer drug czar, is not allowed to consider the cost of treatments his agency reviews, only whether they are safe and effective.”); *see also* 21 U.S.C. § 355(b)(1) (2012).

²³⁹ Of course, the FDA may be free to engage in collaborations where this is one of many goals. Congress has often been of two minds on this. Although Congress has not permitted the FDA to consider costs in approving new drugs, FDA officials are often summoned to congressional hearings when it is perceived that the FDA is not approving generic drugs (and thus lowering prices) quickly enough. *See, e.g.*, Katie Thomas, *Mylan’s Chief Is Chastised by Lawmakers Questioning EpiPen Pricing*, N.Y. TIMES (Sept. 21, 2016), <https://www.nytimes.com/2016/09/22/business/mylan-chief-to-insist-epipen-is-priced-fairly-at-house-hearing.html> (“[S]everal lawmakers criticized the [FDA] and said it had dragged its feet in approving alternatives and providing help to smaller companies that wanted to enter the market.”).

²⁴⁰ 18 U.S.C. § 1905 (2012).

²⁴¹ 45 C.F.R. § 160.101–.552, 164.102–.106, 164.500–.534 (2018).

FDA and CMS, especially when it faces so many continuing disbursement obligations. Political considerations may come into play here as well. To the extent that collaborations not only require buy-in from the highest levels of the agency, but require *sustained* buy-in over a period of time that may span administrations, new political appointees eager to make their mark on an agency may choose to jettison existing programs.

More problematically, collaboration may even require agencies to make trade-offs against their own core interests. Recall the fight between CMS and the FDA over Unique Device Identifiers, considered above. Although the Identifiers might help the FDA improve patient safety, in the short run they would only add costs to CMS, which must now alter insurance claim forms to include that field. The FDA may be forced to make similar trade-offs. Recall the various expedited approval pathways administered by the FDA, considered above. Some methods of shortening the FDA's review period may result in the production of less information about the products in question, working against the FDA's public health mission.

A third set of potential barriers may result from the interaction of legal and practical considerations. Note that the legal barriers raised above do not explicitly prevent the agencies from working together. Indeed, Congress's requirement that the NIH both engage in and report on its efforts²⁴² suggests that Congress would prefer more, rather than less, collaboration. Instead, the legal barriers merely make it more difficult procedurally for the agencies to work together. Memoranda of understanding signed between the various agencies recognize that some information, including information subject to trade secret protection or HIPAA, must be "protected from unauthorized disclosure,"²⁴³ and that "[s]afeguards are needed"²⁴⁴ for this purpose.

Collaboration is not an unalloyed good to be pursued at all costs. Whether any particular collaboration is desirable depends on an assessment of its potential benefits as well as of its potential costs to the system. We may well decide that an agency head who does not want to cede authority to other agencies should not be able to derail a meaningful collaboration. At the same time, we ought to tread carefully

²⁴² 42 U.S.C. § 283a(a) (2012).

²⁴³ CTRS. FOR MEDICARE & MEDICAID SERVS. & FOOD & DRUG ADMIN., MOU 225-10-0010, MEMORANDUM OF UNDERSTANDING BETWEEN UNITED STATES FOOD AND DRUG ADMINISTRATION AND CENTERS FOR MEDICARE AND MEDICAID SERVICES (2015), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm>.

²⁴⁴ NAT'L INSTS. OF HEALTH & FOOD & DRUG ADMIN., MOU 225-13-023, MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND THE NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (2015), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm446756.htm>.

before requiring agencies to do work that is likely to be wasted when a drug fails in the clinical trial process. But it is surely not the case that we have arrived at the proper level of collaboration through trial and error. More can and should be done.

B. *Procedural Approaches to Encourage Collaboration*

To the extent that significant practical barriers must be overcome in order to encourage interagency collaboration, I now turn to policy options that would break down those barriers. These options primarily differ in terms of their location within the government and the range of actions they have the potential to address.

1. Procedural Approaches Internal to HHS

On its own, HHS could select among a number of procedural options that would promote substantive interagency collaborations. These options exist at different levels of formality and require different levels of involvement from HHS. However, they also have the potential to achieve different levels of success, as a result. Perhaps most importantly, though, options like these are not mutually exclusive—HHS might decide to select more than one such option.

First, the HHS Secretary might require each agency to set priorities for interagency collaboration and to report on those priorities regularly, perhaps annually. Each agency would need to identify particular areas in which it hopes to make progress and with whom it will work on those goals. This idea combines elements of other existing reporting obligations. As considered above, the NIH is required by statute to report each year on the collaborations it engaged in the previous year.²⁴⁵ This analysis is retrospective, but its existence does force the NIH to report out certain statistics about its collaborations. The FDA, by contrast, has developed expertise in setting strategic priorities for years in the future and publicly reporting on those at different levels of generality, from publishing broad five-year plans²⁴⁶ to making public lists of specific rules they hope to promulgate and benchmarks they hope to meet in the next year.²⁴⁷

²⁴⁵ 42 U.S.C. § 283a(a); see also *Report on NIH Collaborations with Other HHS Agencies for Fiscal Year 2015*, NIH, <https://report.nih.gov/crs/default.aspx?FY=2015> (last updated May 22, 2018).

²⁴⁶ FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA STRATEGIC PRIORITIES 2014–2018 (2014), <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf>.

²⁴⁷ Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, CDER 2016 Priorities (2015)

Second, the Secretary might appoint a staff member—perhaps under the position of Chief Innovation Officer—whose sole responsibility is to identify potential avenues of collaboration within sub-agencies of HHS and is given the authority to summon representatives from those different agencies to meet and consider those issues. This idea draws inspiration from a proposal by Professors Arti Rai and Stuart Benjamin, who suggest the creation of a similar entity within the executive branch.²⁴⁸ My proposal does not necessarily conflict substantively²⁴⁹ with the Rai and Benjamin proposal.²⁵⁰ Their proposal, if implemented, might well contemplate the appointment of individual officers with subject-matter expertise in particular areas. If so, my proposal might be viewed as fleshing out the duties of the health innovation officer. More generally, it is important to reaffirm the importance of developing deep subject matter expertise in health innovation in a way that a more general member of the executive branch might not inherently possess.

A third, more reactive option would be for the Secretary to simply monitor and manage or adjudicate disagreements between sub-agencies as they arise. Consider the public dispute between CMS and the FDA over the use of Unique Device Identifiers, as explored in Part II as one such example. This dispute is not only unproductive and time-consuming for the regulated agencies, but it is also problematic for the regulated industry. Rather than allowing these disputes to fester for years, the Secretary could take a more active, top-down role in settling these debates before they become larger problems.

2. Procedural Approaches Internal to the Executive Branch

A second set of procedural approaches could be implemented within the executive branch but external to HHS. Many initiatives in health innovation policy are run through the White House rather than through HHS, such as the above-described examples of the BRAIN Initiative, Personalized Medicine Initiative, and Cancer Moonshot. The President obviously has an interest in the success of these initiatives, and that interest may extend to associated collaborations between the

(unpublished Powerpoint slides), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM477299.pdf>; see also Erica Cribbs, Gretchen E. Harper & April E. Schweitzer, *The FDA's Priority List for 2016*, LAW360 (Jan. 29, 2016, 11:03 AM), <http://www.law360.com/articles/751420/the-fda-s-priority-list-for-2016> (summarizing CDER's priorities).

²⁴⁸ Benjamin & Rai, *supra* note 119, at 6; see also Narechania, *supra* note 14, at 1523–26.

²⁴⁹ I take up the procedural conflicts *infra* Section IV.B.

²⁵⁰ And indeed we have almost identical goals: to analyze “how government institutions as a whole should be structured in order to advance innovation.” Benjamin & Rai, *supra* note 119, at 6.

agencies in question.

First, it is worth returning to the Rai and Benjamin proposal to establish an entity within the executive branch to promote innovation.²⁵¹ Importantly, the Rai and Benjamin proposal is primarily directed at encouraging agency coordination, but it can easily be extended to encourage agency collaboration of the type I propose here. They consider the advantages of centralizing an innovation office and housing it within the executive branch, arguing quite rightly that the decentralization we observe at present is precisely the problem from an innovation perspective.²⁵² Interestingly, in keeping with many of my arguments in Part III, Rai and Benjamin would create a regulator with both “an obligation and an incentive to operate transparently.”²⁵³

Rai and Benjamin would house their innovation regulator within the executive branch generally, rather than within a particular administrative agency.²⁵⁴ However, I have just suggested creating an officer for these purposes within HHS. In my view, my proposal may strike a middle-ground between complete centralization and complete decentralization. As compared to housing separate innovation officers within the NIH, FDA, and CMS or within the Executive Branch generally, housing an officer within HHS but giving them control over the collaborative activities of the subsidiary agencies is a compromise. This situation may allow the officer to develop deeper, more personal connections with the material than would housing them within the executive branch,²⁵⁵ while at the same time minimizing some of the difficulties of decentralization.

Second, the executive branch as a whole already has a system for requiring interagency consultation in particular cases: through the Office of Information and Regulatory Affairs (OIRA). OIRA is responsible for reviewing “significant regulatory action[s]” under development by administrative agencies,²⁵⁶ and in the course of that review, OIRA often facilitates interagency consultations. Professor Cass Sunstein, who was the OIRA Administrator under President Obama from 2009 to 2012, subsequently wrote that

[t]he governing idea is that relevant agencies have information and expertise, and the rulemaking agency should benefit from their

²⁵¹ Benjamin & Rai, *supra* note 119, at 6; *see also* Narechania, *supra* note 14, at 1523–26.

²⁵² Benjamin & Rai, *supra* note 119, at 57.

²⁵³ *Id.* at 78.

²⁵⁴ *Id.* at 58.

²⁵⁵ *Id.*

²⁵⁶ Exec Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), *reprinted as amended in* 5 U.S.C. § 601 app. at 86–91 (2012). The Executive Order defines this term to include rules that may, to simplify, “[h]ave an annual effect on the economy of \$100 million or more or . . . [c]reate a serious inconsistency . . . with an action taken or planned by another agency,” among other criteria. *Id.*

perspectives before finalizing or even proposing rules. A central goal of the OIRA process is to ensure that rulemaking agencies have access to the wide variety of perspectives that can be found throughout the executive branch.²⁵⁷

When OIRA reviews agency regulations that implicate healthcare innovation, it might formalize this process of interagency consultation, although that may fall short of active collaboration.

Unfortunately, OIRA review will only capture a small subset of actions that are important for healthcare innovation. Much of the NIH's priority-setting and grant-making activities would not qualify as "significant regulatory action[s]" warranting OIRA review. The FDA certainly makes rules, but more commonly it issues guidance documents that are not always²⁵⁸ subjected to OIRA review.²⁵⁹ To the extent that it is CMS's possession of information rather than its rulemaking ability that contributes to much of the above discussion, that would not obviously implicate OIRA review either.

3. Procedural Approaches External to the Executive Branch

A third and final set of procedural options exists outside of the executive branch. Specifically, an interested Congress may choose to play a greater role in the development of innovation policy. This Article has considered a number of examples of congressional involvement in this area including the passage of 42 U.S.C. § 283a, requiring the NIH Director each year to report on the NIH's collaboration with other HHS agencies²⁶⁰ and the creation of the Interagency Pain Research Coordinating Committee (IPRCC) and specification of its duties by statute.²⁶¹ The executive branch has real institutional advantages in terms of flexibility and expertise, but Congress has tremendous power to force collaboration itself, require the transparency of that collaboration, and fund the collaboration.

The first and most obvious way for Congress to involve itself in

²⁵⁷ Cass R. Sunstein, *The Office of Information and Regulatory Affairs: Myths and Realities*, 126 HARV. L. REV. 1838, 1855 (2013) (footnote omitted).

²⁵⁸ Daniel A. Farber & Anne Joseph O'Connell, *The Lost World of Administrative Law*, 92 TEX. L. REV. 1137, 1162 (2014) (explaining that significant guidance documents may still be subject to OIRA review).

²⁵⁹ Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 821–22 (2010). As a result, Congress sought to limit some of these practices. See 21 U.S.C. § 371(h) (2012). For a more general treatment of these issues, see Jennifer Nou, *Agency Self-Insulation Under Presidential Review*, 126 HARV. L. REV. 1755, 1783–86 (2013).

²⁶⁰ 42 U.S.C. § 283a(a) (2012); see also *Report on NIH Collaborations with Other HHS Agencies for Fiscal Year 2015*, *supra* note 245.

²⁶¹ 42 U.S.C. § 284q(b)(1).

health innovation policy would simply be to codify a number of the approaches suggested above. Such statutes could remain process-oriented in the IPRCC mold, sticking to specifying goals, committee composition, regularity of meetings, and reporting obligations, while avoiding substantive issues that would be worked out by the collaborations themselves. Congressional involvement might be particularly useful for collaborations requiring additional resources, as Congress can appropriate funds for projects it wants to foster.

But a second and potentially more generative solution may be to develop a non-partisan, independent organization along the lines of MedPAC, the Medicare Payment Advisory Commission.²⁶² MedPAC is composed of independent experts who advise Congress on potential reforms to Medicare, broadly speaking.²⁶³ These experts are drawn primarily from academia, health care providers, and the health care industry more generally.²⁶⁴ Such a commission could not only review the individual actions of the NIH, FDA, and CMS as they relate to innovation policy, but it could also review the ways in which these agencies relate to each other.

This idea is not merely speculative. An early draft of the 21st Century Cures Act would have created a national Medical Product Innovation Advisory Commission based on MedPAC. The proposed Commission would “analyze medical product innovation in the United States and recommend policies to accelerate the discovery, development, and delivery of new medical products.”²⁶⁵ As such, the Commission would not only be specifically tasked with reviewing policies of the NIH (discovery), FDA (development), and CMS (delivery), but would also be tasked with “review[ing] the interaction of Federal agencies with respect to the discovery, development, and delivery of new medical products and how such interactions influence medical product innovation.”²⁶⁶ Unfortunately, this provision was removed from all subsequent drafts.

²⁶² See *About MedPAC*, MEDPAC, <http://www.medpac.gov/-about-medpac-> (last visited May 23, 2018).

²⁶³ See, e.g., MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY (2016), <http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf>.

²⁶⁴ Cf. Benjamin & Rai, *supra* note 119, at 54 (“[A]n innovation regulator that improved congressional decisionmaking would appear quite attractive.”).

²⁶⁵ 114TH CONG., 21ST CENTURY CURES ACT § 229A (discussion document 2015), <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/Cures/20150127-Cures-Discussion-Document.pdf>.

²⁶⁶ *Id.* § 229A(b)(2)(B).

CONCLUSION

In this Article I have argued that scholars and policymakers ought to look beyond the capacities of administrative agencies like the NIH, FDA, and CMS individually to contribute to health innovation policy, and instead ought to focus on the potential for collaboration across agencies. Critically, there are important areas of collaboration which are almost entirely unexplored, and we ought to consider procedural options for encouraging or requiring such collaboration. The ultimate point of this Article, though, is broader. It presents a view of these agencies, which have distinct missions regarding overlapping subject matter, that is coherent and provides a way forward for innovation policy law and scholarship.