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Making Knowledge and Making Drugs? Experimenting with University Innovation Capacity

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**MAKING KNOWLEDGE AND MAKING DRUGS?
EXPERIMENTING WITH UNIVERSITY INNOVATION
CAPACITY**

*Liza Vertinsky**

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INTRODUCTION

The innovation process for novel medical therapies needs repair.¹ The United States spends more than ever before on drug discovery without a

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¹ See, e.g., CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2006) (examining concerns about the productivity of the pharmaceutical industry, including escalating spending and declining trends in the number of new drugs approved); Francis S. Collins, Commentary, *Reengineering Translational Science: The Time Is Right*, SCI. TRANSLATIONAL MED., July 6, 2011, at 1. *But see* Iain M. Cockburn, *Is the Pharmaceutical Industry in a Productivity Crisis?*, 7 INNOVATION POL'Y & ECON. 1, 1 (2006) (suggesting that the productivity crisis may be overstated, but agreeing that changes are needed,

corresponding increase in new medical therapies.² Despite major advances in knowledge concerning the underlying mechanisms of disease and new technologies for drug discovery and design, there have been few significant changes in the treatment of disease.³ While this productivity crisis may be due in part to a move beyond low-hanging fruit and toward the pursuit of more complex and elusive therapies, inefficiencies inherent in the current system of pharmaceutical innovation are also to blame.⁴ The segmented, proprietary model of drug development that has dominated the pharmaceutical industry for decades is becoming not only increasingly undesirable, but also unsustainable.⁵ Federal and state governments are reluctant to devote their shrinking budgets to basic research without more and faster tangible returns, private investors are unwilling to absorb the cost and risk involved in moving from early-stage discovery to later development stages, and pharmaceutical companies are retrenching their development efforts in response to soaring costs and a dearth of new blockbuster drug candidates. Pharmaceutical companies miss opportunities to control costs and reduce error rates because of failures to share

particularly “[p]olicies that make ‘small’ markets more attractive, build capacity in translational medicine, reduce the cost, time, and uncertainty of regulatory review, maximize access to basic research, and encourage greater cooperation and collaborative research within the industry”). This Article focuses on the discovery and development of new drugs, but similar issues and opportunities arise in the discovery and development of other medical therapies, diagnostics, and medical devices.

² The U.S. Food and Drug Administration (FDA) approved approximately the same number of drugs in 2008 that were approved in 1950, while at the same time the cost of funding has continued to rise—some suggest by as much as 13.4% annually. See Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVS. DRUG DISCOVERY 959, 959, 962 (2009).

³ While there are about 4,500 conditions with defined molecular causes, for example, therapies now exist for only about 250 of them. *The National Institutes of Health—A Review of Its Reforms, Priorities, and Progress: Hearing Before the Health Subcomm. of the H. Energy & Commerce Comm.*, 112th Cong. 12 (2012) (statement of Francis S. Collins, Director, National Institutes of Health).

⁴ See, e.g., Huda Y. Zoghbi, *The Basics of Translation*, 339 SCIENCE 250 (2013) (suggesting that the failure to translate scientific discoveries into effective treatments is largely due to the “complexity of human physiology, and our limited understanding of how the vast majority of genes, proteins, and RNAs work”); see also Iain M. Cockburn, *The Changing Structure of the Pharmaceutical Industry*, HEALTH AFF., Jan./Feb. 2004, at 10; Collins, *supra* note 1; Praful Mehta & Sophia Walker, *Cardiovascular R&D Model—Increasing Innovation?*, IHS HEALTHCARE & PHARMA BLOG (Jan. 29, 2013), <http://healthcare.blogs.ih.com/2013/01/29/cardiovascular-rd-model-increasing-innovation/> (“In light of the high value-driven product development environment, the hard-coded blockbuster strategy has become completely futile with increasing probabilities of failure. . . . [I]t [is] not the technology or the markets that [are] to blame here, but the broader innovation strategy.”).

⁵ See, e.g., Fabio Pammolli et al., *The Productivity Crisis in Pharmaceutical R&D*, 10 NATURE REVS. DRUG DISCOVERY 428, 428 (2011) (discussing an empirical examination of the decline in pharmaceutical productivity and its determinants); Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceutical Industry’s Grand Challenge*, 9 NATURE REVS. DRUG DISCOVERY 203, 203 (2010) (describing the productivity crisis in the pharmaceutical industry and examining the contributions of each step in the R&D process to overall productivity).

costly and valuable information, such as toxicology results and other information about drug candidate failures.⁶ Inadequate investments in industry-wide process innovations, such as increasing data transparency and pooling discovery resources, lead to further missed opportunities to improve productivity. The promises that scientific advances in the understanding of disease offer for improving the treatment of disease seem increasingly out of reach, leading some members of Congress to question the significant investments being made in biomedical research.⁷

Nobody is happy with a situation in which the cost of drug discovery is increasing while the number of novel drugs approved for human use is flat or falling.⁸ In response, federal and even state government policy makers are scrambling to retool the innovation process for medical therapies in ways that will deliver faster, better, and more cost-effective results.⁹ They are focusing in particular on strategies for increasing the speed and effectiveness of translating scientific knowledge into new medical technologies.¹⁰ Pharmaceutical companies are joining in the search for new innovation models as expiring patents on blockbuster drugs and thinning drug pipelines threaten their existing business models.¹¹ In the pursuit of improved and cheaper ways to produce new drugs, both groups are turning to universities, traditionally the sources of early-stage drug discovery, to play an expanded role in the post-discovery drug

⁶ See, e.g., Julia Kollewe, *Pharmaceuticals Struggle to Find Next Blockbuster Drugs as R&D Costs Soar*, GUARDIAN (Nov. 20, 2011), <http://www.guardian.co.uk/business/2011/nov/21/pharmaceuticals-drug-research-costs-rise> (“[T]he pharmaceutical R&D sector can do more to work together, for example, sharing knowledge on the science behind failed molecules and studies will help improve success rates, and ultimately bring down the cost to develop new medicines.” (internal quotation marks omitted)).

⁷ See, e.g., JOHN F. SARGENT JR., CONG. RESEARCH SERV., R42410, FEDERAL RESEARCH AND DEVELOPMENT FUNDING: FY2013 (2012).

⁸ See, e.g., CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 3 (2006).

⁹ See Collins, *supra* note 1, at 1.

¹⁰ *Id.* Attention is focused in particular on what is often referred to as the “valley of death.” The valley of death refers to the part of the innovation process that begins with post-discovery development and moves through to later stages of product development. For a discussion of the valley of death in the drug discovery context, see Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL’Y L. & ETHICS 1 (2008), which offers a strategy for addressing the valley of death in drug discovery and development that separates upstream research on promising genes, proteins, and biological pathways from downstream drug candidates. While this Article focuses on the movement from biological research to the development of drugs, the ideas have broader application to other fields that involve a complex combination of research and development efforts and often risky and lengthy product development timelines, such as nanotechnology. See, e.g., Collins, *supra* note 1, at 1–2.

¹¹ See Daniel Cressey, *Traditional Drug-Discovery Model Ripe for Reform*, 471 NATURE 17, 17 (2011).

development process. As a result of financial pressures and the lure of new funding and research opportunities, many of the larger U.S. research universities are reconsidering the roles that they play in the innovation process and experimenting with new ways of moving into spaces traditionally reserved for commercial actors.¹² In doing so, they are pushing against implicit boundaries in the legal framework governing technology transfer and challenging traditional views of universities as sites for disinterested discovery and dissemination of public knowledge.

This Article begins with the challenges that face the pharmaceutical industry and the related pressures on universities and investigates two questions. First, the Article considers whether universities offer any advantages over firms and governments in managing not only drug discovery, but also post-discovery drug development. Second, this Article considers the implications of an expanded university role in drug development for the existing institutional framework governing university technology development and transfer. The Article uses an experiment with drug development capacity currently underway at Emory University as a case study with which to explore these questions. This experiment takes Emory much further along the path of drug development than most universities have ventured. It relies on Emory's ability to create and manage a number of separate but closely related public knowledge and proprietary development projects within a single organizational system. The case study illustrates the comparative advantages that the university, as a unique organizational form, might offer over firms and government labs in managing drug development. At the same time, the case study illustrates the challenges of protecting the public interest in access to and use of publicly funded research results without jeopardizing product development goals. The Article concludes that the governance structure of the university may offer certain advantages over both government and industry in managing the kinds of translational research and development activities that are becoming a critical part of downstream drug development.¹³ But realizing

¹² Fiscal challenges are forcing many, if not most, higher education institutions to rethink their purpose and modes of operation. The nature and direction of the changes taking place will, or at least should, vary tremendously based on existing institutional capabilities and strengths. This Article focuses on the shifts taking place in universities with well-established biomedical research capabilities, particularly those with existing experience in drug discovery. This limits the focus to a relatively small number of large U.S. research universities, primarily those with significant NIH and National Science Foundation (NSF) funding.

¹³ See, e.g., Julie Frearson & Paul Wyatt, *Drug Discovery in Academia: The Third Way?*, 5 EXPERT OPINION ON DRUG DISCOVERY 909 (2010) (suggesting opportunities that universities offer for creating new drug discovery paradigms). But see R. L. Juliano, *Pharmaceutical Innovation and Public Policy: The Case for*

the potential of these advantages may require changes in the legal and regulatory framework governing universities and their involvement in processes of innovation.¹⁴

In the current economic and political environment, it is highly likely that some of the largest research universities, which are also the recipients of the bulk of federal research funding,¹⁵ will continue to experiment with expanded roles in product development.¹⁶ This experimentation will exacerbate existing tensions between public science and private development interests in a way that merits a thoughtful policy response. Instead of leaving the regulation of development activities to an outdated technology transfer framework, the law should address the tensions between open science and proprietary development directly.¹⁷ Existing rules and regulations need to be sufficiently flexible to accommodate alternative models of university activity that permit at least some

a New Strategy for Drug Discovery and Development, 40 SCI. & PUB. POL'Y (forthcoming 2013) (suggesting creation of nonprofit drug development corporations as an alternative approach).

¹⁴ Throughout this Article I use the term *university* loosely to include both universities and academic medical centers, some of which are highly integrated into their affiliated universities and some of which remain fairly autonomous. Most academic medical centers are owned by their affiliated universities and have a reporting structure that involves oversight by the university. But the relationship between academic medical centers and the rest of the university is one that needs further exploration in the context of the changing university role and appropriate legal structure explored here. See generally Arthur S. Levine et al., *The Relationship Between the University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center—A Profile in Synergy*, 83 ACAD. MED. 816 (2008); Joseph V. Simone, *Understanding Academic Medical Centers: Simone's Maxims*, 5 CLINICAL CANCER RES. 2281 (1999) (illustrating, through a personal account of working within an academic medical center, the many different organizational challenges of an institution with combined goals of research, patient care, and revenue).

¹⁵ See, e.g., *NIH Awards by Location & Organization*, NIH RES. PORTFOLIO ONLINE REPORTING TOOLS, <http://report.nih.gov/award/index.cfm> (last updated Apr. 29, 2013); see also CHRISTINE M. MATTHEWS, CONG. RESEARCH SERV., R41895, FEDERAL SUPPORT FOR ACADEMIC RESEARCH (2012); Brandon Glenn, *Top NIH Grant Funding by Institutions, States for 2010*, MEDCITY NEWS (Mar. 7, 2011, 3:10 PM), <http://medcitynews.com/2011/03/top-nih-grant-funding-by-institutions-states-for-2010/>.

¹⁶ The combination of increasingly expansive industry–academic partnerships, funding pressures requiring public–academic–private collaborations, continued investment by policy makers in fostering translational research capacity at universities, and changing skill sets and research and development capabilities within the university make this a shift that is likely to continue for quite some time. See, e.g., Shreefal Mehta, Commentary, *The Emerging Role of Academia in Commercializing Innovation*, 22 NATURE BIOTECHNOLOGY 21 (2004).

¹⁷ As used in this paper, the “public knowledge” function of the university refers to the mission-driven roles of academic research universities to “create, preserve, teach, and apply knowledge” for the public good. See *University Mission Statement*, EMORY U., http://www.emory.edu/president/governance/mission_statement.html (last visited May 8, 2013). Both public and private research universities receive significant public support, including direct funding, special tax treatments, and philanthropic support, in return for their commitment to these public knowledge functions. For example, consider Emory University’s mission, which should be kept in mind when we discuss the Emory experiment in Part III of this Article: “Emory University’s mission is to create, preserve, teach, and apply knowledge in the service of humanity.” *Id.*

kinds of proprietary drug development activity. But they also need to provide for greater transparency, accountability, and responsibility on the part of the university in the use of public funds and the safeguard of public knowledge.¹⁸

The primary piece of legislation dealing directly with universities and their management of the fruits of federally funded research is the Bayh–Dole Act, passed in 1980 as an amendment to the U.S. Patent Act.¹⁹ The nonprofit tax status of research universities brings with it additional obligations on the management and use of university resources,²⁰ and publicly owned universities have still another layer of regulation.²¹ As a first step in adapting the legal framework to changing university roles, I suggest some modest changes to the Bayh–Dole Act and related tax rules that are designed to enhance the governance advantages of the university in mixed processes of scientific research and drug development. The patent-focused, technology-transfer-oriented mandate of the Bayh–Dole Act should be replaced with a broader mandate of managing and supporting innovation in the public interest. Flexibility in the types of income that can be earned and the ways in which Bayh–Dole funds can be used should be accompanied by university monitoring, disclosure, and reporting requirements designed to increase the transparency, accountability, and responsibility of universities in the management of drug development activities. Universities should have clear guidelines about how the funds they receive from drug development activities can be used and the volume of development-versus-research activities that they can engage in. Collective action problems among competing universities with a shared interest in open access to scientific knowledge should be addressed through limits on the use of patents in ways that impede competing research efforts.

¹⁸ The need for greater accountability in the management of federally funded research was highlighted in a recent National Academies report on university management of intellectual property. See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., *MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST* (Stephen A. Merrill & Anne-Marie Mazza eds., 2011); see also Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 *NATURE BIOTECHNOLOGY* 953 (2012) (finding underreporting of federal funding by universities).

¹⁹ See Bayh–Dole Act, Pub. L. No. 96-517, § 6, 94 Stat. 3015, 3018–27 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

²⁰ See I.R.C. § 501(c)(3) (2006).

²¹ Most public universities are founded and operated by state government entities, and they are subject to state-specific laws. For a list of major public and land-grant institutions and descriptions of issues specific to public universities, see ASS'N PUB. & LAND-GRANT U., <http://www.aplu.org> (last visited May 8, 2013).

Part I of this Article begins by describing the challenges facing modern drug development and the pressures that government and industry are placing on universities to expand their role in drug development. Part II explains why universities with existing drug discovery capabilities might have a comparative advantage in undertaking the kinds of mixed discovery and development efforts that are needed to reinvigorate pharmaceutical innovation. This advantage will be particularly large in areas of pharmaceutical innovation where the benefits to science and the satisfaction of unmet medical needs are not accompanied by expectations of a blockbuster drug. It goes on to examine some of the current experiments with expanding university innovation capacity. Part III investigates the shifting role of the university through the lens of an experiment in drug development currently underway at Emory University. This Part explores the intertwined organizational and legal structure and some of the motivating goals and assumptions underlying this project, and then considers the implications of this changing university role for the existing institutional framework governing universities and technology transfer. Part IV suggests potential directions of change in the legal framework designed to support and improve university governance of university-controlled drug development activities. While recognizing the opportunities that some universities may offer for advancing publicly beneficial drug development goals, this Article does not suggest that all universities should be experimenting with moving downstream into product development. Rather, it concludes that the relatively small number of universities that have strong capabilities in drug discovery and development may have comparative advantages in moving further downstream in drug development, and that the legal framework should respond directly to both the challenges and the opportunities that this changed university role might provide.

I. THE PRODUCTIVITY CRISIS IN THE PHARMACEUTICAL INDUSTRY

Consider two numbers: 800,000 and 21. The first is the number of medical papers that were published in 2008. The second is the number of new drugs that were approved by the Food and Drug Administration [in 2010].²²

The past 60 years have seen huge advances in many of the scientific, technological and managerial factors that should tend to raise the

²² David Bornstein, *Helping New Drugs out of Research's 'Valley of Death,'* N.Y. TIMES OPINIONATOR (May 2, 2011, 9:15 PM), <http://opinionator.blogs.nytimes.com/2011/05/02/helping-new-drugs-out-of-academias-valley-of-death>.

efficiency of commercial drug research and development (R&D). Yet the number of new drugs approved per billion US dollars spent on R&D has halved roughly every 9 years since 1950, falling around 80-fold in inflation-adjusted terms.²³

Few question the need for change in the pharmaceutical industry. What this change should look like, however, is a matter of debate. To understand the challenges facing the pharmaceutical industry and the role of U.S. research universities in helping to address these challenges, it is helpful to have some understanding of the traditional drug discovery and development process and the legal framework that helped to shape it.

A. *The Traditional Approach to Drug Development*

Creating a new drug is a complicated, iterative process, but at a basic and highly simplified level it can be understood as follows: Drug discovery typically begins with the identification of a drug target, such as a protein, that research has shown to play a role in disease.²⁴ Basic research into the underlying mechanisms of disease and the nature of disease pathways contributes to the discovery of new drug targets.²⁵ After identifying a promising drug target, investigators search for or create drug candidates that can block or activate that target.²⁶ Processes of drug discovery increasingly employ new technologies, such as high-throughput screening, to identify drug candidates.²⁷ Once promising drug candidates have been identified, next steps include synthesis, characterization, screening, and testing of the candidate to evaluate its therapeutic effectiveness.²⁸ The hoped-for result is a drug candidate that shows promise in addressing an unmet medical need. Drug development starts with the drug candidate and involves the steps required to seek transformation of the candidate into an approved drug. This involves

²³ Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REV. DRUG DISCOVERY 191, 191 (2012).

²⁴ For an accessible description and characterization of the drug development and discovery process, see Jens Eckstein, *Drug Discovery Tutorial*, ALZHEIMER RES. F., <http://www.alzforum.org/drg/tut/ISOATutorial.pdf> (last visited May 8, 2013).

²⁵ *Id.* at 3.

²⁶ *Id.* at 6.

²⁷ *See id.* at 7. An increasingly important way of finding promising drug candidates is to investigate how the target interacts with randomly chosen compounds, typically done through high-throughput screening (HTS) facilities with the use of compound libraries. *See id.* Hits, or compounds that show binding capacity to the target, become the subject of further study and refinement. *Id.* at 7–8, 11.

²⁸ *See Making a Drug*, BIG PICTURE, Jan. 2008, at 4, 4, available at http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_publishing_group/documents/web_document/wtx042416.pdf.

preclinical testing, primarily in microorganisms and animal models, followed by clinical testing in humans to determine the safety and efficacy of the proposed drug, and finally regulatory approval.²⁹

In the traditional model of drug discovery, private sector organizations rely on universities and publicly funded researchers, along with their own internal research efforts, to generate basic knowledge about disease mechanisms and to identify leads for new drug candidates. Biotechnology and pharmaceutical companies use this publicly funded knowledge to isolate promising drug candidates for further development work.³⁰ The traditional process of drug development has been a closed one, relying not just on legal mechanisms such as patents and data exclusivity, but also on organizational strategies such as internalizing core development activities to limit information sharing.³¹ Pharmaceutical companies look for exclusive intellectual property rights to promising drug candidates, and then engage in a closed, resource-intensive process of screening, testing, refining, and engaging in clinical trials for those drug candidates that have the potential to become approved drugs with significant economic markets.³² Universities have come to play a greater role in early phases of drug discovery over the past several decades because the lines between research and early-stage development have blurred and discovery tools, such as high-throughput screening, have become more accessible to academic researchers.³³ Yet the private sector has continued to dominate later phases of drug development.³⁴ Moreover, much of this

²⁹ See, e.g., *About Drug Discovery and Development*, PPD, <http://www.ppd.com/About/About-Drug-Discovery-and-Development.aspx> (last visited May 8, 2013); *Drug Development and Review Definitions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm176522.htm> (last updated Feb. 22, 2010). There is an additional complicated transition from regulatory approval to effective use by the patient with the unmet medical need. This second part of the translational medicine process is also an area in which universities can play an important role.

³⁰ See, e.g., B. Michael Silber, Commentary, *Driving Drug Discovery: The Fundamental Role of Academic Labs*, SCI. TRANSLATIONAL MED., May 5, 2010, at 1, 1.

³¹ See, e.g., Cressey, *supra* note 11, at 17.

³² See, e.g., KI Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 356 (2010).

³³ Silber, *supra* note 30, at 1, 3 (discussing the importance of academic labs in the development of innovative new medicines, particularly through discoveries arising from basic research).

³⁴ See, e.g., Cockburn, *supra* note 4 (describing changing industry structure but persistence of private sector in controlling downstream development).

development activity has been concentrated inside of a relatively small group of very large pharmaceutical companies.³⁵

This distribution of responsibilities between publicly funded research institutions and the private sector is largely a function of the U.S. legal and regulatory framework. Public funds are channeled through the National Institutes of Health (NIH) and other federal and state funding agencies, such as the National Science Foundation (NSF), to support scientific research.³⁶ These public funds support research on the underlying mechanisms of disease and potential targets for therapies, as well as discoveries in other areas with potential application to drug discovery and development.³⁷ This research is conducted mainly at universities, government laboratories, and other research institutions.³⁸ Large pharmaceutical companies and biotechnology companies pick up the resulting discoveries through licensing of underlying intellectual property rights.³⁹ These commercial entities engage in extensive drug

³⁵ For an example of an overview of pharmaceutical industry output based on different measures of concentration, see Joseph A. DiMasi, *New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms*, 34 *DRUG INFO. J.* 1169 (2000). See also LARRY DAVIDSON & GENNADIY GREBLOV, *THE PHARMACEUTICAL INDUSTRY IN THE GLOBAL ECONOMY* (2005) (examining major players in the pharmaceutical industry and industry trends).

³⁶ See SARGENT, *supra* note 7; see also *About NIH*, NAT'L INSTS. HEALTH, <http://www.nih.gov/about/> (last updated Feb. 6, 2013) (“NIH is the largest source of funding for medical research in the world . . .”).

³⁷ The mission of the NIH, for example, is to “seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.” *Mission*, NAT'L INSTS. HEALTH, <http://www.nih.gov/about/mission.htm> (last updated Mar. 3, 2011). It has grown into the single largest funder of biomedical research in the world. *About NIH*, *supra* note 36.

³⁸ See, e.g., MATTHEWS, *supra* note 15. This approach reflects a post-World War II vision of U.S. innovation in which public funding supports basic research at universities and other research institutions, which is later picked up and commercialized by the private sector. Universities are seen as the engines of innovation, generating public goods that serve as the inputs for private goods produced by the private sector. *Id.* at 1.

³⁹ See, e.g., Gary P. Pisano, *The Governance of Innovation: Vertical Integration and Collaborative Arrangements in the Biotechnology Industry*, 20 *RES. POL'Y* 237 (1991) (examining the evolution of the organizational structure of the biotechnology industry, highlighting governance choices as responding to the special nature and challenges of the technology, and noting the evolution of the biotechnology industry as a specialized R&D supply market). While a variety of other players have emerged in the pharmaceutical market alongside pharmaceutical companies, including biotechnology companies that venture downstream into drug development and contract research organizations that perform various phases of the development process, the characteristics of the process of concern here have remained largely unchanged. Drug development is still largely a proprietary process requiring significant scale economies, although outsourcing is increasing. See, e.g., Cockburn, *supra* note 4, at 13; David Maris, *What's Really Driving the Pharma M&A Frenzy*, *FORBES* (Apr. 27, 2012, 11:42 AM), <http://www.forbes.com/sites/davidmaris/2012/04/27/pharma-feeding-frenzy/> (discussing trend of consolidation in the pharmaceutical sector).

development efforts in the hope of finding and marketing a blockbuster drug.⁴⁰ They incur the significant cost of pushing promising drug candidates through the rigorous, time-consuming, and expensive process of clinical testing required by the Food and Drug Administration in order to obtain approval for new drugs.⁴¹

Two key pieces of legislation, the Bayh–Dole Act and the Stevenson–Wylder Technology Innovation Act, were enacted in 1980 to facilitate the transfer of federally funded inventions from university and government labs to the private sector for applied research and development.⁴² The Bayh–Dole Act, an amendment to the U.S. Patent Act, allows universities and other entities to elect title to inventions developed at least in part through the use of federal funds. If they elect title to the intellectual property rights in these inventions, these entities are then obligated to seek patent protection and engage in efforts to ensure the commercialization of the invention.⁴³ The Stevenson–Wylder Technology Innovation Act and the subsequent Federal Technology Transfer Act of 1986 granted new authority to federal laboratories, such as the NIH Intramural Research Program, to engage in technology transfer and partner with industry.⁴⁴ These Acts were designed with the key goal of facilitating the movement of ideas into the marketplace.⁴⁵ They leave the post-discovery piece of the innovation process largely to the private market. The Bayh–Dole Act in particular pays little attention to the innovation-related activities of the

⁴⁰ See Cressey, *supra* note 11, at 17.

⁴¹ For a description of the FDA drug approval process, see *Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm> (last updated Oct. 15, 2012); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). For critiques of the FDA process and its impact on drug costs, see for example, Gary S. Becker, *Get the FDA Out of the Way, and Drug Prices Will Drop*, BLOOMBERG BUSINESSWEEK (Sept. 15, 2002), <http://www.businessweek.com/stories/2002-09-15/get-the-fda-out-of-the-way-and-drug-prices-will-drop>; and Avik Roy, *How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials*, FORBES (Apr. 24, 2012, 5:19 PM), <http://www.forbes.com/sites/aroy/2012/04/24/how-the-fda-stifles-new-cures-part-i-the-rising-cost-of-clinical-trials/>, which reviewed a Manhattan report on FDA costs.

⁴² Stevenson–Wylder Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–3714 (2006)); Bayh–Dole Act, Pub. L. No. 96-517, § 6, 94 Stat. 3015, 3018–27 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)). The Stevenson–Wylder Act is codified in the U.S. Code under the heading “Technology Innovation.”

⁴³ See 35 U.S.C. § 202(c)(3) (2006) (amended 2011).

⁴⁴ For a summary of these major pieces of technology transfer legislation, see Howard Bremer, *U.S. Laws Affecting the Transfer of Intellectual Property*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 265, 266 (Anatole Krattiger et al. eds., 2007).

⁴⁵ David C. Mowery & Bhaven N. Sampat, *University Patents and Patent Policy Debates in the USA, 1925–1980*, 10 INDUS. & CORP. CHANGE 781, 796 (2001).

university beyond its initial disclosure, patenting, and minimal reporting requirements. While the Act includes march-in rights as a mechanism for ensuring that publicly funded inventions are not shelved, these march-in rights are poorly specified and have never been used.⁴⁶

Technology transfer legislation, along with significant public funds directed at research but not at development activities, has reinforced the existing distribution of drug discovery and development activities between research institutions and the private sector. The growth of technology transfer offices across most, if not all, of the major U.S. research universities has further entrenched this model of university technology transfer.⁴⁷ While additional federal programs have since been developed to support the private sector in moving early-stage technologies out of universities, these programs remain small in comparison to the amount of public funding directed at basic research.⁴⁸ Moreover, where public funds are targeted at development activities, they are directed primarily at commercial entities rather than at universities.⁴⁹

This model of proprietary drug development fueled by public biomedical research has dominated the biomedical industry for decades.⁵⁰ The apparent success of this model has served as the poster child for government policies supporting public funding of biomedical research and strong, privately owned patent rights on the fruits of this research.⁵¹ Against this background, a small group of large pharmaceutical companies has been able to retain its dominance in the pharmaceutical industry and has limited changes in downstream processes of drug development and distribution.⁵² The pharmaceutical industry

⁴⁶ See 35 U.S.C. § 203 (describing the march-in rights).

⁴⁷ See DAVID C. MOWERY ET AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* 144-47 (2004); Bhaven N. Sampat & Richard R. Nelson, *The Evolution of University Patenting and Licensing Procedures: An Empirical Study of Institutional Change*, in 19 *THE NEW INSTITUTIONALISM IN STRATEGIC MANAGEMENT* 135, 150-56 (Paul Ingram & Brian S. Silverman eds., 2002).

⁴⁸ See *Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs*, NAT'L INSTS. HEALTH OFF. EXTRAMURAL RES., http://grants.nih.gov/grants/funding/sbirsttr_programs.htm (last updated Mar. 6, 2013).

⁴⁹ See *id.* Both the SBIR and STTR programs involve seed funding to private companies—in the case of STTR, private companies working in partnership with research institutions. See *id.*

⁵⁰ See, e.g., *Making a Drug*, *supra* note 28, at 4.

⁵¹ Indeed, even Michele Boldrin and David Levine, in their arguments for abolishing the patent system, have suggested that patents may play a useful role in the pharmaceutical industry. MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY* (2008).

⁵² See DiMasi, *supra* note 35; see also DAVIDSON & GREBLOV, *supra* note 35 (examining major players in the pharmaceutical industry and industry trends).

is a highly regulated industry, and lack of change in the regulatory infrastructure may also have contributed to the lack of innovation in the process of making drugs. Despite the many advances that have taken place in the science and technology of drug discovery, the subsequent process of drug development has changed relatively little.⁵³ What has changed dramatically is the cost and risk of moving from an early-stage idea to a commercial drug candidate.⁵⁴

B. *The Need for Change*

Diverse commentators have expressed serious concerns about the sustainability of the current translational process. However, as can sometimes happen in the midst of crisis, this uncertainty is inspiring creative ideas among the various stakeholders and fueling quests for ground-breaking translational models.⁵⁵

– Francis Collins, Director of the NIH

Moving from early stages of the discovery process to late stages of development has become more and more expensive. The cost of developing a new drug is estimated to be in the hundreds of millions of dollars, commonly believed to be over \$800 million based on reported industry data, with some estimates at over \$1 billion.⁵⁶ Much of the expense arises in later stages of drug development, particularly during the preclinical studies and clinical trials

⁵³ See Collins, *supra* note 1, at 1 (discussing the need for innovation in the process of drug development, e.g., in how clinical trials are conducted).

⁵⁴ See Cockburn, *supra* note 1, at 2 (evaluating changes in productivity in the pharmaceutical industry).

⁵⁵ Collins, *supra* note 1, at 2.

⁵⁶ See, e.g., JORGE MESTRE-FERRANDIZ ET AL., OFFICE OF HEALTH ECON., THE R&D COST OF A NEW MEDICINE, at v (2012); Roger Collier, *Drug Development Cost Estimates Hard to Swallow*, 180 CMAJ 279, 279 (2009) (discussing Tufts Center of Drug Development figures of cost of drug discovery and development); DiMasi et al., *supra* note 41 (attempting to measure the total capitalized costs of sixty-eight randomly selected new drugs); John Carroll, *Economists Cite Soaring Costs Behind Average \$1.9B Price Tag on Drug R&D*, FIERCEBIOTECH (Dec. 3, 2012), <http://www.fiercebiotech.com/story/economists-cite-soaring-costs-behind-average-19b-price-tag-drug-rd/2012-12-03>. But see Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 46–47 (2011) (critiquing current reports on R&D costs for new drugs and seeking to show how much lower actual drug development costs may be and suggesting the true cost may be closer to \$43.4 million); James Love, *Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines 6–7* (Sept. 23, 2003) (unpublished manuscript), available at <http://www.cptech.org/ip/health/rnd/evidenceregardingrnd.pdf>; Timothy Noah, *The Make-Believe Billion*, SLATE (Mar. 3, 2011, 9:19 PM), http://www.slate.com/articles/business/the_customer/2011/03/the_makebelieve_billion.html (discussing studies critiquing high estimates of drug discovery and development costs).

needed to obtain regulatory approval of a new drug.⁵⁷ Fewer than one in ten medical therapies that move into human clinical trials succeed.⁵⁸ An estimated 82% of drugs fail phase II clinical trials,⁵⁹ only an estimated 50% of phase III studies are successful, and only about 60% of drugs submitted to the FDA get approved.⁶⁰ The high failure rate at these late stages of development produces massive financial losses for pharmaceutical companies engaged in drug development.⁶¹ Moreover, many of the drugs that end up failing in late-stage clinical trials fail due to lack of efficacy or safety based on issues that should have been discoverable long before phase III clinical testing.⁶² The high cost and risk of failure, along with average timelines from target discovery to new drug approval averaging thirteen years, deters the private sector from supporting many promising drug development projects. Those projects involving really new, and therefore risky, approaches to the treatment of disease are especially hard to finance.⁶³

The huge cost and time required to get a new molecular entity approved as a drug, coupled with the high number of late-stage failures and the increasing regulatory demand for more tailored therapeutics, has made drug development less profitable for pharmaceutical companies. These realities, combined with patent expirations of blockbuster drugs and thinning drug pipelines, have produced a cumulative loss of \$626 billion in the market capitalization of the

⁵⁷ See, e.g., Paul et al., *supra* note 5, at 206 fig.2; F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals* (Harvard Kennedy Sch. of Gov't, Faculty Research Working Paper No. 11-046, 2011). To obtain regulatory approval for a new drug in the United States, clinical testing is required to show safety and efficacy of the new drug. The process of regulatory approval by the FDA, the agency charged with approving new drugs, involves Phase 0, which involves testing the properties of the drug in a small number of individuals to study its properties, Phase I, which involves testing the drug in small numbers of people for safety, Phase II, which involves larger clinical trials to study efficacy and safety, and Phase III trials, which evaluate efficacy. Some drugs also go through Phase IV, post-approval studies. For a simple description of these phases, see *Clinical Trials: What You Need to Know*, AM. CANCER SOC'Y, <http://www.cancer.org/acs/groups/cid/documents/webcontent/003006-pdf.pdf> (last updated Sept. 21, 2012); *FDA's Drug Review Process: Continued*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm> (last updated Mar. 13, 2012).

⁵⁸ Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES, Mar. 12, 2012, at 38.

⁵⁹ John Arrowsmith, *Phase II Failures: 2008–2010*, 10 NATURE REV. DRUG DISCOVERY 328, 328 (2011).

⁶⁰ See Bernard Munos, *In Defense of the FDA*, FORBES (Dec. 19, 2012, 8:04 AM), www.forbes.com/sites/bernardmunos/2012/12/19/in-defense-of-fda/.

⁶¹ See Silber, *supra* note 30, at 1 (discussing financial impact of failed drugs).

⁶² See Munos, *supra* note 60 (reporting that the combined failure rate for phase III clinical trials and submission to the FDA is estimated to be 70%, and approximately “87% of these failures are due to lack of efficacy (66%) or safety (21%)”).

⁶³ See Collins, *supra* note 1, at 1.

pharmaceutical industry from 2001 to 2009 with further substantial losses expected ahead.⁶⁴ Between 2012 and 2015, for example, patents on drugs accounting for more than \$250 billion in annual sales will expire, and many of the largest pharmaceutical companies have already seen more than \$60 billion in lost annual sales due to competition from generics.⁶⁵

Barriers to the flow of knowledge and technology also help to explain why major advances in knowledge about the underlying mechanisms of disease, along with breakthroughs in technologies for molecular modeling, drug screening, and drug synthesis, have not produced corresponding breakthroughs in the treatment of disease.⁶⁶ Early-stage discoveries may be difficult to translate into downstream applications for a variety of reasons. Discoveries may be difficult to transfer across organizational boundaries due to both legal and cultural differences between university and industry, particularly where the transfer of tacit knowledge held by academic scientists is also needed to make sense of and implement early-stage discoveries.⁶⁷ In addition, discoveries may be difficult to attach to a particular drug development project because they illuminate general disease mechanisms rather than specific drug candidates, requiring translational work that is a combination of basic and applied research to narrow down promising next steps for developing a particular drug. As described by Francis Collins, the Director of the NIH:

⁶⁴ Kaitin, *supra* note 32, at 359.

⁶⁵ See, e.g., Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff,"* U.S. PHARMACIST, June 2012, at 12, 20.

⁶⁶ See Bornstein, *supra* note 22. As noted by David Bornstein:

Consider two numbers: 800,000 and 21.

The first is the number of medical research papers that were published in 2008. The second is the number of new drugs that were approved by the Food and Drug Administration last year.

That's an ocean of research producing treatments by the drop. Indeed, in recent decades, one of the most sobering realities in the field of biomedical research has been the fact that, despite significant increases in funding—as well as extraordinary advances in things like genomics, computerized molecular modeling, and drug screening and synthesization—the number of new treatments for illnesses that make it to market each year has flatlined at historically low levels.

Id.

⁶⁷ See, e.g., Ajay Agrawal, *University-to-Industry Knowledge Transfer: Literature Review and Unanswered Questions*, 3 INT'L J. MGMT. REVS. 285, 291–96 (2001); Lynne G. Zucker et al., *Commercializing Knowledge: University Science, Knowledge Capture, and Firm Performance in Biotechnology*, 48 MGMT. SCI. 138, 138–43, 149–51 (2002). See generally Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 BERKELEY TECH. L.J. 1009, 1012, 1014–16 (2008) (discussing tacit knowledge); Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2 (2010); Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503 (2012).

Scientific advances have moved us from an era in which most drug development was based on a short list of a few hundred targets with great depth of understanding to an era in which molecular technologies provide thousands of new potential drug targets but limited information about their mechanisms and potential “druggability.”⁶⁸

Advances in science may generate too many promising clinical avenues. They may challenge the existing medical taxonomy in ways that fit poorly with traditional disease-specific development paths.⁶⁹ Changes in the nature of the scientific knowledge reinforce the need for a changed model of drug discovery and development that includes a greater integration of research institutions into development processes.

Integrating research and development might improve upstream knowledge flows, but difficulties in managing and sharing information efficiently also plague downstream development efforts. A lack of data transparency at all stages of the drug development process contributes to a duplication of drug development efforts and wasted resources as firms pursue drug candidates that end in failure.⁷⁰ The challenge of moving a promising discovery from early-stage discovery to phase II clinical studies is often referred to with dread by stakeholders in drug discovery and development as moving across the “[v]alley of [d]eath.”⁷¹ Common themes emerging from the growing literature on translational research and technology transfer in biomedicine include inadequate private investment in drug development due to cost, duration, and risk of the development process; breakdowns in the flow of information between different entities in the innovation process; and underinvestment in

⁶⁸ Collins, *supra* note 1, at 1–2.

⁶⁹ *Id.* In discussing the challenges confronting translational research, Francis Collins has suggested that new research approaches “have revealed that diseases once considered quite distinct can share similar molecular pathways . . . suggest[ing] that the entire framework of medical taxonomy requires rethinking and that therapeutics of the future likely will be designed with cellular networks in mind, rather than being limited by historical designations of disease category.” *Id.* at 2.

⁷⁰ See, e.g., Michel Goldman et al., *Public-Private Partnerships as Driving Forces in the Quest for Innovative Medicines*, CLINICAL & TRANSLATIONAL MED. 2 (Jan. 15, 2013), <http://www.clintransmed.com/content/pdf/2001-1326-2-2.pdf> (discussing the importance of tackling knowledge fragmentation through public-private collaborations that foster areas of data sharing).

⁷¹ See, e.g., EWING MARION KAUFFMAN FOUND., *THE NEW ROLE OF ACADEMIA IN DRUG DEVELOPMENT* 7, 11 (2010), available at http://www.kauffman.org/uploadedfiles/town_hall_white_paper_12-10.pdf (discussing the valley of death and efforts to address it in a report based on town hall meetings with experts in the field); see also Rai et al., *supra* note 10, at 3–4, 8–9 (pointing out that big pharmaceutical companies tend to focus on a few hundred validated targets because they are safe and thus primarily produce “me-too” drugs instead of novel therapies).

and too little sharing of information that has a net public benefit due to limits on the private appropriation of value.

But cost, duration, risk, and barriers to the flow of information and knowledge are not the only problems facing the pharmaceutical industry. The dominance of the blockbuster-drug business model in the pharmaceutical industry has contributed to a growing disconnect between the therapeutic areas of concentrated industry focus and the types of treatments that are needed to address unmet medical needs.⁷² The prevalence of clusters of drugs that have only minor differences from an existing drug, known as “me-too” drugs, and the prevalence of expensive technologies with limited proven clinical effectiveness have prompted some health law scholars and advocates to propose interventions designed to tie the rewards of innovation more closely to health outcomes.⁷³

That this segmented, proprietary, blockbuster model of drug development is no longer either desirable or sustainable is increasingly well recognized and well documented.⁷⁴ “[T]he triple frustrations of long timelines, steep costs, and high failure rates bedevil the translational pathway” from dramatic advances in biomedical science to new drugs.⁷⁵ Stakeholders are coming to realize that a more radical change is needed. It is time to reengineer the drug development process.⁷⁶ These efforts must include increased interaction between different stages of discovery and development in support of a “fail earlier and more often and tell people about it” model of drug development involving greater collaboration, cooperation, and data sharing. Both government and research-

⁷² See, e.g., Carl Nathan, Commentary, *Aligning Pharmaceutical Innovation with Medical Need*, 13 NATURE MED. 304 (2007).

⁷³ See, e.g., THOMAS POGGE, AUSTL. NAT’L UNIV. DEV. POLICY CTR., *THE HEALTH IMPACT FUND: MORE JUSTICE AND EFFICIENCY IN GLOBAL HEALTH* (2011).

⁷⁴ See, e.g., Alex Kandybin & Vessela Genova, *Big Pharma’s Uncertain Future*, STRATEGY & BUS., Spring 2012, at 1, 3–4; see also Ben Hirschler, *Data Shows Declining Productivity in Drug R&D*, REUTERS, June 27, 2010, available at <http://www.reuters.com/article/2010/06/27/us-pharmaceuticals-rd-idUSTRE65Q3IM20100627> (“The 2010 Pharmaceutical R&D Factbook, compiled by CMR International . . . painted a gloomy picture of the global pharmaceuticals sector. New drugs launched within the last five years accounted for less than 7 percent of industry sales in 2009, down from 8 percent in 2008 . . .”).

⁷⁵ Collins, *supra* note 1, at 1.

⁷⁶ See Arti K. Rai, “*Open and Collaborative*” *Research: A New Model for Biomedicine*, in INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES: SOFTWARE AND BIOTECHNOLOGY 131 (Robert W. Hahn ed., 2005); Jeff Cohen et al., *Strategic Alternatives in the Pharmaceutical Industry*, KELLOGG SCH. MGMT., http://www.kellogg.northwestern.edu/biotech/faculty/articles/strategic_alternatives.pdf (last visited May 6, 2013).

based nonprofit organizations will play an important role in facilitating these efforts. As noted by the Director of the NIH:

[M]any of the most crucial challenges confronting translational science today are precompetitive ones. The development of systematic approaches for target validation, the reengineering of rate-limiting and failure-prone steps in the therapeutic development process, and the urgent need to increase the critical mass of well-trained individuals to drive innovations are among the various translational challenges that are ill-suited for solutions derived solely from the private sector.⁷⁷

C. *Public and Private Sector Responses Impacting University Roles*

The question for both public and private stakeholders in the pharmaceutical industry has thus become not whether but how to reconfigure the organization of pharmaceutical innovation. But despite the recognized need for change, new models of cost, risk, and information sharing have been slow to emerge. Entrenched organizational interests in the status quo often limit the kinds of shifts in development efforts between different stages of the innovation process that are needed to respond to the knowledge produced. This is especially true when the knowledge indicates that existing projects should be abandoned. Moreover, private sector competitors find it hard to open their labs and compound libraries to their competitors. Collective action problems among pharmaceutical firms may discourage the kind of transparency and information sharing needed to sustain new models of interactive discovery and development. Antitrust concerns may also discourage private sector competitors from collaborations amongst themselves.⁷⁸ Barriers to private sector restructuring combined with recognition of the collaborative capabilities that already exist in research universities explain why both the public and the private sectors are looking to universities to play an expanded role in drug development.⁷⁹

⁷⁷ Collins, *supra* note 1, at 2.

⁷⁸ See, e.g., Jason Clay, *Precompetitive Behaviour—Defining the Boundaries*, GUARDIAN (June 2, 2011, 6:46 PM), <http://www.guardian.co.uk/sustainable-business/precompetitive-behaviour-defining-boundaries> (discussing European Commission antitrust ruling that raises important questions about balance between precompetitive behavior and collusion). For an example of industry navigation of the antitrust rules, see for example, *Antitrust Policy and Guidelines*, BIOMARKERS CONSORTIUM, http://www.biomarkersconsortium.org/pdf/Antitrust_Policy.pdf (last modified Mar. 1, 2011).

⁷⁹ See, e.g., Cressey, *supra* note 11 (discussing emerging collaborative models of drug discovery and development involving greater university role).

Public sector views about what universities should be doing in the area of pharmaceutical innovation are by no means uniform, however.⁸⁰ Congressional responses to the perceived pharmaceutical productivity crisis and the valley of death have fallen largely into two silos. One response has been to question the amount of federal money currently being spent on biomedical research, with the suggestion that the rate of return is too low and the federal funding for this research should be cut.⁸¹ In other words, solve the “valley of death problem” by reducing the money spent on biomedical research.⁸² The second response has been to seek more support for translational science—the science of transforming knowledge about underlying mechanisms of disease into novel and effective medical therapies—as a way of bridging the gap between new ideas and economic returns.⁸³ This approach was reflected in the Obama Administration’s 2011 Strategy for American Innovation, which highlighted the goal of commercializing research performed at U.S. research universities.⁸⁴

⁸⁰ See, e.g., Steve Usdin, *Lost in Translation*, BIOCENTURY, Feb. 14, 2011, at A1 (describing the many competing views about federal spending on R&D).

⁸¹ The search for alternative forms of governance that will improve the system of biomedical innovation is driven in part by the beliefs of some members of Congress that the existing system of university technology transfer is broken, beliefs fueled by proponents of a more free-market, free-agency approach to technology transfer. See PRESIDENT’S COUNCIL ON JOBS & COMPETITIVENESS, TAKING ACTION, BUILDING CONFIDENCE: FIVE COMMON-SENSE INITIATIVES TO BOOST JOBS AND COMPETITIVENESS 21–22 (2011), available at http://files.jobs-council.com/jobscouncil/files/2011/10/Jobscouncil_InterimReport_Oct11.pdf (describing strategies for the private sector to foster entrepreneurship); Matt Erskine, *NACIE Promotes Innovative Lab-to-Market Strategies to Spur Economic Growth*, U.S. DEPARTMENT COM. (Mar. 13, 2012, 6:30 PM), <http://www.commerce.gov/blog/2012/03/13/nacie-promotes-innovative-lab-market-strategies-spur-economic-growth> (describing the National Advisory Council on Innovation and Entrepreneurship’s lab-to-market strategies). Of even more concern, perceived failures to translate public investments in biomedical science into tangible economic gains has fuelled pressures within Congress to alter, and even dramatically reduce, public spending on biomedical research even as costs for conducting biomedical research increase.

⁸² See, e.g., SARGENT, *supra* note 7; *Congress Shifting into FY2013 Spending Debate*, AM. ASS’N FOR CANCER RES. (Jan. 2012), <http://www.aacr.org/home/public--media/science-policy--government-affairs/aacr-cancer-policy-monitor/aacr-cancer-policy-monitor---january-2012/congress-shifting-into-fy2013-spending-debate.aspx> (discussing partisan stalemate that impacts spending on basic science); Jeffrey Mervis, *Making the Case for Science: Representative Randy Hultgren Sees Room for Improvement in Federal Role*, SCI. INSIDER (Nov. 13, 2012, 1:25 PM), <http://news.sciencemag.org/scienceinsider/2012/11/making-the-case-for-science-repr.html> (arguing against what some have called “luxury science” and advocating for the critical need to support science spending in Congress); see also T Randolph Beard et al., *A Valley of Death in the Innovation Sequence: An Economic Investigation*, 18 RES. EVALUATION 343 (2009) (suggesting that spending decisions that do not reflect later-stage investment patterns contribute to the valley of death).

⁸³ See Collins, *supra* note 1, at 3–5.

⁸⁴ See, e.g., Memorandum from Ass’n of Am. Univs. et al. to the Office of the Chief Economist, U.S. Dep’t of Commerce (Apr. 1, 2011), available at www.aau.edu/WorkArea/DownloadAsset.aspx?id=12038 (discussing models and strategies for university involvement in translational research and commercialization, including proof-of-concept centers, and highlighting the university position that the ownership provisions provided for under the Bayh–Dole Act should be maintained).

The result of these sometimes conflicting policy responses has been a moderate decline in the inflation-adjusted budget of the largest funder of biomedical research, the NIH, with looming threats of much larger cuts and a shift of existing NIH efforts and funding toward translational research projects, many of them involving universities.⁸⁵

The NIH has taken the lead among public policy makers in trying to reengineer the drug development process, and its views and actions have had a significant impact on the U.S. research university community. U.S. research universities with significant biomedical research capabilities watch NIH policy changes closely, since a substantial part of their research funding comes from the NIH and since their reputation is determined in part by the amount of NIH and NSF funds attracted by university investigators.⁸⁶ Expanding translational science capacity—the facilities, skills, and other resources needed to promote post-discovery efforts at pushing drug candidates through later-stage discovery, preclinical testing, and clinical testing—forms the core of the NIH's reengineering strategy.⁸⁷ In 2004 the NIH launched its Roadmap for Medical Research, making collaboration in the production, sharing, and application of knowledge its central theme.⁸⁸ This roadmap was the precursor to the NIH Common Fund, an institutional step toward creating translational science capacity by supporting crosscutting, trans-NIH programs targeted at specific, identified roadblocks in translational science.⁸⁹ The newest manifestation of

⁸⁵ See, e.g., MATTHEWS, *supra* note 15; SARGENT, *supra* note 7; Usdin, *supra* note 80. As part of the translational research efforts, there is also a push to increase the amount of work done by government agencies themselves in the development of medical therapies. See, e.g., *Cures Acceleration Network*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/funding-and-notice/can/can.html> (last visited May 8, 2013).

⁸⁶ See, e.g., *The Top American Research Universities*, CENTER FOR MEASURING U. PERFORMANCE, <http://mup.asu.edu/research.html> (last visited May 8, 2013) (noting the important role of federal research dollars in ranking); see also Joel Norris, *The Crisis in Extramural Funding*, ACADEME, Nov./Dec. 2011, at 28, 30–31 (suggesting “greater amounts of extramural funding appear to be associated with more prestige”); ASS'N AM. U., <http://www.aau.edu> (last visited May 8, 2013) (outlining organization of leading research universities where membership is by invitation and based largely on nature and amount of research funding).

⁸⁷ See, e.g., Collins, *supra* note 1, at 1; see also *Re-Engineering Translational Sciences*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/research/reengineering/reengineering.html> (last visited Sept. 29, 2012).

⁸⁸ See *About the NIH Common Fund*, NIH COMMON FUND, <http://commonfund.nih.gov/about.aspx> (last updated May 7, 2013). The roadmap was designed to “address roadblocks to research and to transform the way biomedical research is conducted by overcoming specific hurdles or filling defined knowledge gaps.” *Id.*

⁸⁹ See *id.* The Clinical and Translational Science Awards (CTSA) Consortium was initially created as a roadmap program, and the Molecular Libraries and Imaging Program is a current common fund program. These initiatives are designed to support and link a network of clinical and translational research centers, each of which is involved in public-private collaborations targeted at different parts of the drug development

these efforts at institutional reengineering is the National Center for Advancing Translational Science (NCATS).⁹⁰

NCATS was officially established in fiscal year 2012 with a budget of \$575 million, comprising programs and funds that were redirected from other units at NIH.⁹¹ In 2013 it will have an estimated budget of \$639 million, based on FY 2013 budget requests.⁹² NCATS includes both program support for institutions engaging in translational research and public facilities for pursuing different parts of the drug development process.⁹³ NCATS is now entering its second year and is focusing primarily on developing preclinical and clinical capabilities that can reduce the cost and risk of drug development for the private sector.⁹⁴ In some cases, the NIH provides translational research capacity directly, through creating facilities, compound libraries, or other resources that are open to the public.⁹⁵ In other cases, the NIH programs seek to build university capacity, either through funding university infrastructure or through opportunities for university investigators.⁹⁶ The intellectual property

process. See *About the CTSA Consortium*, CLINICAL & TRANSLATIONAL SCI. AWARDS, <https://www.ctsacentral.org/about-us/ctsa> (last visited May 8, 2013); *Molecular Libraries and Imaging*, NIH COMMON FUND, <https://commonfund.nih.gov/molecularlibraries/> (last updated Mar. 18, 2013).

⁹⁰ See NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/> (last visited May 7, 2013).

⁹¹ NCATS was created on December 23, 2011 by the Consolidated Appropriations Act, 2012, which amended the Public Health Service (PHS) Act to include NCATS. See Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, § 479, 125 Stat. 786, 1086-88 (codified as amended in scattered sections of 42 U.S.C.). The stated mission of NCATS is to "catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions." *Department of Health and Human Services National Institutes of Health Fiscal Year 2013 Budget Request: Hearing Before the S. Subcomm. on Labor-HHS-Educ. Appropriations*, 112th Cong. 8 (2012) (statement of Thomas R. Insel, Acting Director, National Center for Advancing Translational Sciences).

⁹² See *Budget*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/about/budget/budget.html> (last visited May 8, 2013).

⁹³ See *Research*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/research/research.html> (last visited May 8, 2013).

⁹⁴ See *id.* It is organized into a Division of Clinical Innovation that supports later stages of translational research, much of it done in academic medical centers, and a Division of Pre-Clinical Innovation with projects aimed at bridging gaps in investment in early development phases for new drugs that address unmet medical needs. The Division of Pre-Clinical Innovation includes the Therapeutics for Rare and Neglected Diseases (TRND) program and the Bridging Interventional Development Gaps (BRIDGs) program to assist both academic and private researchers and companies working on developing novel therapies for unmet medical needs. *Program Index*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/about/program-index/program-index.html> (last visited May 8, 2013).

⁹⁵ For a fact sheet, including a description of programs, see *NCATS Fact Sheet*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI. (Summer 2012), <http://www.ncats.nih.gov/files/factsheet.pdf>.

⁹⁶ *Id.*

structures supporting the different NCATS initiatives vary, but many of the infrastructure-based programs, such as developing open-source research tools, screening facilities, and compound libraries, seek to leave nongovernment parties in control of any inventions arising from contributions that they make.⁹⁷ These kinds of publicly funded and supported collaborations to develop drugs are already raising important questions about the fit of the existing legal structure governing federally funded research. The NIH is exploring special approaches to contracting and intellectual property ownership in the context of such programs in the hope of improving the governing structures for these projects.⁹⁸ Experiments such as the NIH pilot program on Discovering New Therapeutic Uses for Existing Molecules include proposed collaboration agreements designed to support project objectives, but these proposed agreements also include provisions that may run afoul of university norms and policies, such as broad development options to private sector developers.⁹⁹

The main NIH translational research efforts to date, which extend well beyond the domain of NCATS, are largely responses to the high costs, risks, and other barriers that deter drug discovery and development work. NIH responses have focused on providing public infrastructure for various aspects of the drug discovery and development process, such as government-owned screening facilities and compound libraries that are made publicly available,¹⁰⁰

⁹⁷ See, e.g., *Preclinical Drug Development Services for the NIH Center for Translational Therapeutics (NCTT)*, National Center for Advancing Translational Sciences (NCATS), FED. BUS. OPPORTUNITIES (May 2, 2012), https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=4c78cc3b9fd7d503ff94b9ff39c16812&_cvview=0. The proposed IP strategy for the NCATS Preclinical Drug Development Services program proposes to use the “Determination of Exceptional Circumstances” provided for under the Bayh–Dole Act to allow assignment of ownership to the private-party contributor. *Id.*

⁹⁸ For an NIH description of its Discovering New Therapeutic Use for Existing Molecules program and its use of template agreements and specific approaches to collaboration and intellectual property ownership, see *Discovering New Therapeutic Uses for Existing Molecules*, NAT’L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/therapeutic-uses.html> (last visited May 8, 2013). For concerns about this approach and responses to the NIH proposal for the preclinical programs, see for example, Letter from Anthony P. DeCrappeo, President, Council on Governmental Relations, to Nat’l Insts. of Health (June 1, 2012) [hereinafter Letter from Anthony P. DeCrappeo, June 1, 2012], available at www.cogr.edu/viewDoc.cfm?DocID=151925. See also Letter from Anthony DeCrappeo, President, Council on Governmental Relations, to Kelli T. Broda, Contracts Specialist, Office of Acquisitions (May 17, 2012), available at www.cogr.edu/viewDoc.cfm?DocID=151911 (expressing concerns with NIH efforts to use the “exceptional circumstances” provision in Bayh–Dole to reshape IP ownership rules for one of its programs).

⁹⁹ See, e.g., Letter from Anthony P. DeCrappeo, June 1, 2012, *supra* note 98 (expressing concerns with NIH dictating terms of contracts involved in the program that conflict with university policies).

¹⁰⁰ See, e.g., *Rescuing and Repurposing Drugs*, NAT’L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/rescue-repurpose.html> (last visited May 8, 2013). An example is the NCATS Drug Rescuing and Repurposing program that focuses on finding new uses

and encouraging partnerships between academic and industry players oriented around the movement from lab to market.¹⁰¹ Some of the newer NIH programs have focused on incentivizing the creation of public-private and public-academic-private collaborations, often referred to as PPPs, in targeted areas of drug discovery and early-stage development. These efforts have mainly taken the form of tailored grant opportunities and the creation of NIH-hosted drug discovery centers and consortiums.¹⁰² These initiatives have been supported by other key government players in the pharmaceutical industry, such as the FDA.¹⁰³

As noted above, universities are expected to play a central role in many of these translational science initiatives since they have the scientific capabilities and often the facilities and human capital needed to support earlier stage translational work. Moreover, pharmaceutical companies may be more willing to share their proprietary drug discovery and development resources with universities than with private firms because universities are not direct competitors. Universities provide a comparatively neutral site for what policy makers are optimistically referring to as precompetitive collaborations designed to share resources central to drug discovery efforts.¹⁰⁴ Even if

for existing medicines. As part of this repurposing program, NCATS has created the NCATS Pharmaceutical Collection, a publicly accessible database that includes 3,800 approved and investigational medicines available for screening to find new uses. *Id.*

¹⁰¹ See, e.g., Erskine, *supra* note 81 (suggesting using lab-to-market strategies to promote economic growth). These initiatives are designed to support cost and risk sharing, facilitate the transfer of knowledge among participants in the innovation process, and subsidize the production of socially valuable information. *Id.*

¹⁰² See, e.g., Lili M. Portilla & Barbara Alving, Commentary, *Reaping the Benefits of Biomedical Research: Partnerships Required*, SCI. TRANSLATIONAL MED., June 9, 2010, at 1 (noting the importance of academic collaboration among industry, academia, and government and the role of NIH in increasing the efficiency of the translational process through support of various partnerships).

¹⁰³ The FDA, another key government player in regulating the introduction of new drugs, outlined its own views in response to the problems experienced by the biomedical industry with the introduction of the Critical Path Initiative. The initiative was launched in March 2004, with the release of FDA's landmark report *Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*. See FDA's *Critical Path Initiative*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/ucm076689.htm> (last updated Dec. 28, 2012). This initiative was launched with the release of a report that diagnosed reasons for the translational valley of death and highlighted the need for collective action to modernize scientific and technical tools and harness information technology to help evaluate and predict the effectiveness and feasibility of medical products. The report "called for a national effort to identify specific activities all along the critical path of medical product development and use, which, if undertaken, would help transform the critical path sciences." *Id.* By encouraging collaborations between public and private players throughout the drug discovery and development process, both the FDA and NIH hope to increase the output of effective new medical therapies.

¹⁰⁴ See, e.g., INST. OF MED. OF THE NAT'L ACADS., *DIFFUSION AND USE OF GENOMIC INNOVATIONS IN HEALTH AND MEDICINE: WORKSHOP SUMMARY* (2008); INST. OF MED. OF THE NAT'L ACADS., *ESTABLISHING*

universities take on a bigger role in downstream drug development, they are likely to do so in partnership with pharmaceutical companies rather than in competition with them.

The NIH roadmap and the initiatives that followed in its wake have prompted experiments with university innovation capacity by universities with established biomedical research facilities that are eager to protect and even augment their NIH funding.¹⁰⁵ The push for new ways of organizing drug development processes that include expanded university roles comes not just from government, however, but also from industry. After decades of pursuing a highly centralized, proprietary approach to drug development, pharmaceutical companies are restructuring their own research and development activities in the face of unsustainable business models.¹⁰⁶ They are retrenching their drug discovery and development efforts and looking for alternative ways to fill their drug pipelines. Recognizing that new models of knowledge production and knowledge sharing are critical to solving the productivity crisis in the biomedical industry, they are radically changing their operations, moving away from centralized R&D, and instead relying on outsourcing, joint ventures, and other ways to decentralize the drug discovery and development process.¹⁰⁷ One way of reducing costs is to share development infrastructure wherever possible. This requires either collaboration or outsourcing of various steps in the development process.¹⁰⁸ Another way of reducing costs is to shift from a process in which there are late-stage drug development failures to a system in which there are frequent

PRECOMPETITIVE COLLABORATIONS TO STIMULATE GENOMICS-DRIVEN PRODUCT DEVELOPMENT: WORKSHOP SUMMARY (2011).

¹⁰⁵ All of the top U.S. research universities depend heavily on NIH and NSF funding to support their biomedical research efforts. *See, e.g.*, E. Ray Dorsey et al., *Funding of US Biomedical Research, 2003–2008*, 303 JAMA 137, 140 (2010) (“Federal sources remain the largest contributor to academic biomedical research expenditures, accounting for 65% of expenditures, followed by institutional funds (18% of expenditures).”). NIH and NSF funding also contributes heavily to the reputations of U.S. research universities, intensifying the interest of the top ranked schools in retaining and attracting new federal funds. *See, e.g.*, *The Top American Research Universities*, *supra* note 86; *see also* Margaret E. Blume-Kohout et al., *Federal Life Sciences Funding and University R&D* (Nat’l Bureau of Econ. Research, Working Paper No. 15146, 2009) (noting empirical evidence suggests that success in attracting federal funds may be interpreted as signal of recipient quality by nonfederal funders).

¹⁰⁶ *See* Pammolli et al., *supra* note 5, at 428 (discussing an empirical examination of the decline in pharmaceutical productivity and its determinants); Paul et al., *supra* note 5, at 203 (describing the productivity crisis in pharmaceutical industry and examining the contributions of each step in R&D process to overall productivity).

¹⁰⁷ *See, e.g.*, Cressey, *supra* note 11; *see also* Jackie Hunter, *Is Open Innovation the Way Forward for Big Pharma?*, 9 NATURE REVS. DRUG DISCOVERY 87, 87 (2010).

¹⁰⁸ *See, e.g.*, Hunter, *supra* note 107, at 87.

early failures.¹⁰⁹ This requires more interaction between different stages of the discovery and development process, such as more experimentation with a larger number of potential drug candidates at early stages of development.¹¹⁰

Pharmaceutical companies are pursuing both strategies, resulting in increased interaction between academic researchers and industry scientists and a closer integration of the scientific aspects of drug discovery with the commercial aspects of drug development.¹¹¹ The increasingly dual nature of many discoveries as both basic knowledge and commodities with commercial application further intertwines research and development efforts. University–industry partnering in different components of the drug discovery and development process is therefore expanding in frequency and scope.¹¹² While strategies have varied among pharmaceutical companies, most if not all of the larger ones have increased their proximity to and reliance on universities in some way.¹¹³ Sometimes this has involved outsourcing discrete tasks in the drug discovery and development process to universities or limited public–academic–private collaborations around a discrete research project.¹¹⁴ In other cases it has led to the creation of translational research centers involving

¹⁰⁹ Paul et al., *supra* note 5, at 211; *see also Failed Alzheimer’s Clinical Trial Data Made Public*, 9 NATURE REVS. DRUG DISCOVERY 505, 505 (2010).

¹¹⁰ *See, e.g.*, Eric Bonabeau et al., *A More Rational Approach to New Product Development*, HARV. BUS. REV., Mar. 2008, at 96 (discussing problem with focusing disproportionately on late-stage development and lack of adequate early-truth-seeking functions in drug development); Paul et al., *supra* note 5, at 211 (discussing quick-win, fast-fail models in contrast to traditional approaches to drug discovery and development).

¹¹¹ *See, e.g.*, Todd B. Sherer, *Money Without Collaboration Won’t Bring Cures*, 19 NATURE MED. 127 (2013).

¹¹² *See, e.g.*, Bethan Hughes, *Pharma Pursues Novel Models for Academic Collaboration*, 7 NATURE REVS. DRUG DISCOVERY 631 (2008) (discussing pharma’s search for new models of industry–academic collaboration); *see also* Jerry Thursby & Marie Thursby, *University–Industry Linkages in Nanotechnology and Biotechnology: Evidence on Collaborative Patterns for New Methods of Inventing*, 36 J. TECH. TRANSFER 605 (2011) (exploring emergence of new methods of collaborative inventing in nanotechnology and biotechnology).

¹¹³ *See* Goldie Blumenstyk, *Big Pharma Finds a Home on Campus*, CHRON. HIGHER EDUC. (D.C.), July 29, 2011, at A1 (examining the status and trends of pharmaceutical research in the United States in 2011, particularly highlighting the shift in project spending from large industries to research universities); Heidi Ledford, *Drug Buddies*, 474 NATURE 433 (2011) (discussing increasing ties between pharmaceutical industry and academia in an effort to speed up drug development).

¹¹⁴ *See, e.g.*, CHRISTOPHER-PAUL MILNE & ASHLEY MALINS, TUFTS CTR. FOR THE STUDY OF DRUG DEV., ACADEMIC–INDUSTRY PARTNERSHIPS FOR BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: ADVANCING MEDICAL SCIENCE IN THE U.S. (2012), *available at* http://csdd.tufts.edu/files/uploads/tuftscsdd_academic-industry.pdf (describing various types of university–industry partnerships and documenting recent trends).

varying degrees of joint research and development.¹¹⁵ New high-profile pharma-academic partnerships have sprouted at many if not all of the leading U.S. research universities.¹¹⁶ Pfizer, one of the world's largest pharmaceutical companies, has relocated many of its facilities next door to universities that have well-developed drug discovery capabilities and is seeking to create common campuses for collaborative work.¹¹⁷

In the search for new ways of reengineering the drug discovery and development process, pharmaceutical companies have been more willing to experiment with open-access models of academic collaboration.¹¹⁸ In some cases, pharmaceutical companies have partnered with universities to make preemptive investments in the public domain in efforts to preserve open access to research inputs.¹¹⁹ Merck's investment in the creation of the Merck Gene Index, developed in partnership with Washington University in St. Louis, provides an early example of this effort to preserve access to key inputs in drug development.¹²⁰ More recent efforts by both the private sector and the NIH

¹¹⁵ See, e.g., *id.*; see also Stewart Lyman, *Pharma-Academic Alliances: What the Numbers Don't Tell You*, XCONOMY (May 10, 2011), http://www.xconomy.com/seattle/2011/05/10/pharma-academic-alliances-what-the-numbers-dont-tell-you/?single_page=true (discussing changes in pharma-university partnerships, as well as concerns with trends toward broader umbrella arrangements between pharma and academia).

¹¹⁶ See *supra* notes 113, 114; see also Martin Lehr, *Pharma-Academic Partnerships & the Impact on Venture Funds*, OSAGE U. PARTNERS BLOG (Apr. 2, 2011), <http://www.blogoup.com/blog/2011/4/2/pharma-academic-partnerships-the-impact-on-venture-funds.html> (providing links to news stories covering recent high-profile university-industry collaborations); Alan Scher Zagier, *Drug Companies Partnering with Top Schools*, DRUG DISCOVERY & DEV. (Jan. 10, 2013, 2:54 PM), <http://www.ddmag.com/news/2013/01/drug-companies-partnering-top-schools>.

¹¹⁷ See *Pfizer: Creating a Biomedical Engine for Upstream Innovation*, PARTNERING NEWS (Aug. 29, 2011), <http://ebdgroup.com/partneringnews/2011/08/pfizer-creating-a-biomedical-engine-for-upstream-innovation/> (discussing Pfizer's new Centers for Therapeutic Innovation, which include new common campuses for collaborative work at highly ranked universities in San Francisco, Boston, San Diego, and New York, funding, access to its databases, and other resources, and in return Pfizer's first rights to license potential products coming out of the networks it has supported); see also Lisa M. Jarvis, *Pfizer's Academic Experiment*, CHEMICAL & ENGINEERING NEWS, Oct. 1, 2012, at 28, 28 (describing the Centers for Therapeutic Innovation that Pfizer has established as an experiment in "building a different R&D ecosystem," each center being a unit in the company that focuses on developing drug candidates through collaborations with academic partners through colocation of labs and broad collaboration arrangements).

¹¹⁸ See, e.g., B Munos, *Can Open-Source Drug R&D Repower Pharmaceutical Innovation?*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 534 (2010) (discussing proliferation of open-source R&D initiatives, including many public-private partnerships, but noting some challenges with this approach).

¹¹⁹ See, e.g., Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183, 188 (2004) (describing private efforts to protect the public domain).

¹²⁰ See, e.g., Press Release, Merck & Co., Inc., First Installment of Merck Gene Index Data Released to Public Databases: Cooperative Effort Promises to Speed Scientific Understanding of the Human Genome (Feb. 10, 1995), available at <http://www.bio.net/bionet/mm/bionews/1995-February/001794.html>. Concerns about patents on short snippets of the genetic code (SNPS), which were seen as important inputs in the development

have focused on identifying and supporting areas of precompetitive collaboration between academia and industry in which at least certain kinds of knowledge can be developed and shared more freely.¹²¹ Examples include the growth of compound libraries and high-throughput screening centers made available to academics on open-access terms, with the goal of spurring drug discovery and fueling pharmaceutical company product pipelines.¹²² Even broader experiments with open access are taking place in areas where proprietary commercial interests are low, such as the search for cures to neglected diseases. The Tropical Disease Initiative¹²³ and the open-access Malaria Box¹²⁴ are both examples of open-source drug development initiatives. In some cases pharmaceutical companies have taken the lead in promoting open-source initiatives. GlaxoSmithKline, for example, spearheaded formation of a patent pool for neglected diseases and made one of its facilities available to academic researchers interested in working on projects targeting neglected disease areas.¹²⁵ These open-source efforts remain focused on neglected disease areas, however, and are reliant on philanthropic and government support.

of diagnostics and drugs, prompted a pharmaceutical-company response led by Merck with the creation of the Merck Gene Index. *See* Merges, *supra* note 119, at 187–88. This was a collaboration with Washington University that involved the creation of a public database of gene sequences corresponding to expressed human genes. *See id.* at 188.

¹²¹ *See, e.g.,* About Us, BIOMARKERS CONSORTIUM, <http://www.biomarkersconsortium.org/about.php> (last visited May 8, 2013); *see also* BRETT M. FRISCHMANN, INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES (2012) (discussing the importance of public infrastructure in innovation processes); DISCOVERY PARTNERSHIPS WITH ACADEMIA, www.dpac.gsk.com (last visited May 8, 2013); OPEN INNOVATION DRUG DISCOVERY, <https://openinnovation.lilly.com/dd/> (last visited May 8, 2013).

¹²² *See, e.g.,* Anuradha Roy et al., *Open Access High Throughput Drug Discovery in the Public Domain: A Mount Everest in the Making*, 11 CURRENT PHARMACEUTICAL BIOTECHNOLOGY 764 (2010) (discussing emergence of high-throughput screening centers in the public domain, including the large Molecular Libraries Probe Centers Network Centers funded by the NIH roadmap initiative); *Bayer Supports Innovative Drug Discovery in Europe*, PHARMA NEWS.EU (Feb. 12, 2013), <http://www.pharmanews.eu/bayer/1213-bayer-supports-innovative-drug-discovery-in-europe> (reporting that Bayer initiated a pan-European consortium, European Lead Factory, to enhance early drug discovery through creation of small molecule library collection, with pharma contributions of at least 300,000 substances, supported by the Innovative Medicines Initiative, which is a large global public-private partnership focusing on improving pharmaceutical innovation in Europe through supporting academic-industry collaboration).

¹²³ *See, e.g.,* Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, PLOS MED. 183 (Dec. 2004), <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0010056>.

¹²⁴ *See, e.g.,* *Open Access Malaria Box*, MEDS. FOR MALARIA VENTURE, <http://www.mmv.org/malariabox> (last visited May 8, 2013) (describing the Malaria Box, which has 400 compounds with antimalarial activity available to researchers in return for publishing and placing resulting data in the public domain).

¹²⁵ *See, e.g.,* *Tres Cantos*, GLAXOSMITHKLINE, <http://www.gsk.com/partnerships/open-innovation/tres-cantos.html> (last updated Nov. 28, 2012) (describing the company's open lab at its Tres Cantos drug discovery and development facility).

While these various initiatives are promising ways of improving the productivity of pharmaceutical innovation, more change is needed. The push for new models of university involvement in drug development continues as resources remain scarce and concerns for the future of pharmaceutical innovation remain unabated.

II. EXPERIMENTING WITH UNIVERSITY INNOVATION CAPACITY

Universities are experiencing pressures from government and industry partners to move beyond their traditional sphere of producing knowledge about disease mechanisms and targets for new therapies and toward a more active role in transforming their ideas into tangible economic goods.¹²⁶ The combination of increasing costs in supporting biomedical research and more competitive and uncertain funding for such research has made this move attractive for even those research institutions with little prior interest in moving downstream into more applied development work. In response to these pressures and corresponding funding, partnering, and research opportunities, many leading U.S. research universities are actively experimenting with proof-of-concept centers, translational research centers, and other ways of broadening their involvement in drug discovery and development.¹²⁷ Although universities have collaborated with industry in drug discovery for decades, this kind of experimentation with post-discovery drug development is a relatively new phenomenon.¹²⁸

While these experiments are relatively small in comparison with the scale of more traditional academic biomedical research, they are paving the way for broader organizational changes. Indeed, undertaking many of these experiments has already required modifications to existing university intellectual property policies and the development of guidelines, contracting practices, and organizational structures to support multidisciplinary centers and different kinds of public–academic–private collaboration. Development-focused initiatives prompt not only administrative changes, but also norm

¹²⁶ See Anthony M. Boccanfuso, Commentary, *Why University–Industry Partnerships Matter*, SCI. TRANSLATIONAL MED., Sept. 29, 2010, at 1, 1; Blumenstyk, *supra* note 113; Jennifer A. Henderson & John J. Smith, *Academia, Industry, and the Bayh–Dole Act: An Implied Duty to Commercialize* 1 (Oct. 2002) (unpublished manuscript), available at http://www.cimit.org/news/regulatory/coi_part3.pdf.

¹²⁷ See Stephen Frye et al., *US Academic Drug Discovery*, 10 NATURE REV. DRUG DISCOVERY 409, 409 (2011); Joanne Kotz, *Small (Molecule) Thinking in Academia*, SciBX, June 2, 2011, at 1, 1.

¹²⁸ See, e.g., Frye et al., *supra* note 127, at 409 (analyzing small molecule drug discovery in academia and documenting a large jump in activity); Kotz, *supra* note 127, at 1 (examining potential impact of academic drug discovery and trends in academic involvement).

changes operating among researchers both inside and outside of academic medical centers, administrators, technology transfer professionals, and governing bodies engaged in oversight of university activities.¹²⁹ As research universities already involved in drug discovery become more engaged in development activities, beliefs among these constituencies concerning the ways in which knowledge should be produced and applied, the role of the university within the innovation process, and understandings of how academic productivity should be evaluated and rewarded are shifting to accommodate these activities. This raises concerns that universities may be shifting too much, and without appropriate safeguards on the public knowledge function of the university.

This Article suggests that there may be benefits to expanding the role of universities with established drug discovery capabilities in the pharmaceutical innovation process, provided that this expansion is managed carefully. These benefits stem from certain advantages that universities may have over firms and government labs in managing dual processes of producing knowledge and producing products. Since this expansion of the university role into the commercial domain of product development is not without significant costs and risks, it should not be taken lightly.¹³⁰ But where a university is already successfully involved in drug discovery, pushing the involvement of the university further into the development process may have advantages that are in the public interest. This is particularly true for areas of drug discovery and development that do not fit the blockbuster-drug profile and are therefore neglected by the industry. Section A of this Part describes the potential advantages of the university in managing drug discovery and development, and

¹²⁹ See generally Jeannette A. Colyvas & Walter W. Powell, *From Vulnerable to Venerated: The Institutionalization of Academic Entrepreneurship in the Life Sciences*, in THE SOCIOLOGY OF ENTREPRENEURSHIP 219, 220, 231, 255 (Martin Ruef & Michael Lounsbury eds., 2007) (studying the origins, acceptance, and spread of academic entrepreneurship in the biomedical field at Stanford); Toby E. Stuart & Waverly W. Ding, *When Do Scientists Become Entrepreneurs? The Social Structural Antecedents of Commercial Activity in the Academic Life Sciences*, 112 AM. J. SOC. 97, 98 (2006) (examining the conditions prompting university-employed life scientists to become entrepreneurs and finding evidence that the orientation toward commercial science of individuals' colleagues and coauthors, as well as a number of other workplace attributes, significantly influences transition to for-profit science).

¹³⁰ See, e.g., Zoghbi, *supra* note 4 (discussing concerns that the pressure to develop treatments and the bias in NIH funding toward practical outcomes will crowd out support for basic research that is critical to the future of biomedicine). "In recent years, however, the pressure to develop treatments at an ever more rapid pace has attenuated enthusiasm for deciphering the language of life. . . . [T]oday, many highly qualified basic scientists feel compelled to jump on the 'translational medicine' bandwagon." *Id.* at 250.

section B examines the directions that some universities are taking in experimenting with expanded innovation capacity.

A. *Comparative Advantages of Universities as Drug Developers*

As discussed above, the innovation process for new drugs needs to include greater interaction between discovery and development efforts; greater pooling and sharing of knowledge, data, materials, and facilities; and collaborative pathways for developing clusters of new drugs. This Article suggests that universities have certain organizational characteristics that may give them a comparative advantage over firms and government labs in managing the mixed research and development activities required of modern pharmaceutical innovation in ways that serve the public interest.¹³¹ These characteristics are (1) the ability of universities, as specialized entities with a public knowledge function, to sustain different systems of knowledge production with varying levels of openness; (2) the disciplining influence of multiple stakeholders in the knowledge production process on university decision making; and (3) the flexibility, varying levels of autonomy, and alternative incentive schemes that are available within the university's relatively decentralized governance structure.¹³²

This combination of characteristics is beneficial for mixed processes of scientific research and product development in at least two ways. First, the organizational structure allows for the creation of semiautonomous projects, or units, that can vary in terms of their level of openness and their end goals while

¹³¹ For a broader discussion of the organizational attributes employed in this paper, see Liza Vertinsky, *Universities as Guardians of Their Inventions*, 2012 UTAH L. REV. 1949. Nicholas Argyres and Julia Porter Liebeskind have put forward a different organizational perspective. See Nicholas S. Argyres & Julia Porter Liebeskind, *Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology*, 35 J. ECON. BEHAV. & ORG. 427, 429 (1998) (“[T]he standardization of universities’ governance arrangements, required by their social-contractual commitments to practice open science, limits their ability to maintain separate incentives and contracting policies for biotechnology on the one hand, and for the rest of the intellectual commons on the other.”). For contrasting views, see studies emphasizing the greater incentives, knowledge, and resources that industry scientists have to make cumulative discoveries and to push discoveries into development, such as Phillipe Aghion et al., *Academic Freedom, Private-Sector Focus, and the Process of Innovation*, 39 RAND J. ECON. 617 (2008); Zucker et al., *supra* note 67, at 138–43, 149–51. For a discussion of the tensions between the commercial and noncommercial aspects of university patenting, see Jacob H. Rooksby, *Innovation and Litigation: Tensions Between Universities and Patents and How to Fix Them*, 15 YALE J.L. & TECH. (forthcoming 2013).

¹³² These characteristics are discussed in Vertinsky, *supra* note 131, and this Article seeks to apply them to the context of drug discovery and development. In a subsequent paper, I explore the role of universities as innovators in agriculture, where universities have historically played an important role in downstream development of their discoveries.

remaining loosely connected as a single innovation process. These separable units can be restructured, or outsourced, without requiring major changes to the other units. This Article borrows from the organizational literature on modularity and asset partitioning to describe why this organizational capacity might be advantageous in managing drug development.¹³³ Second, these characteristics make universities comparatively good organizations for providing the kinds of semipublic infrastructure, such as drug discovery facilities and software tools, and the diversified intellectual capital needed to increase translational research capacity. Universities can harness a combination of public and private funds, they can take advantage of the mixed knowledge and development benefits of innovation activities, and industry players will be more willing to share their own resources with a university than with each other.

The first organizational advantage stems from the ability of the university to pursue a modularizing strategy in its organization of different tasks in drug discovery and development. Modularity, as used in the organizational literature, refers to the ability to decompose a production process into “components that are highly interdependent within sub-blocks, called modules, and largely independent across those sub-blocks.”¹³⁴ Within each module, elements of the system—which may be decisions, tasks, or components—are interdependent, and changing one will require changes in many others. Across modules, elements are more independent and changes in one element need not

¹³³ The growing literature on modularization, property, and intellectual property has a number of applications to this analysis. While a systematic application of the insights from this literature to analyze partitioning approaches within universities is beyond the scope of this Article, the discussion draws directly and indirectly on much of this literature. See, e.g., Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, 157 U. PA. L. REV. 2083 (2009) [hereinafter Smith, *Institutions and Indirectness*] (applying information cost theory to IP and explaining how difficulty in measuring inputs and identifying likely outputs creates advantages for placing a given activity within a module and giving control over local remodularization to private actors, with IP allowing for this modularization through the right to exclude); Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742 (2007) [hereinafter Smith, *Intellectual Property*] (applying information cost theory to explain how intellectual property works, albeit imperfectly, in addressing complex coordination problems of attributing outputs to inputs, and how exclusionary rights work by keeping entitlements over information modular); Carliss Y. Baldwin & Joachim Henkel, *The Impact of Modularity on Intellectual Property and Value Appropriation* (Harvard Bus. Sch., Working Paper No. 12-040, 2011), available at http://www.hbs.edu/faculty/Publication%20Files/12-040_895ee04c-1533-4cac-9a4a-69ffbf794edd.pdf; Carliss Y. Baldwin & Eric von Hippel, *Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation 7* (Harvard Bus. Sch., Working Paper No. 10-038, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1502864. For insights on asset partitioning as applied to patent law, see Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473, 480–84 (2005).

¹³⁴ Baldwin & Henkel, *supra* note 133, at 3.

be coordinated with changes in others.¹³⁵ This can reduce the complexity of a system and allow for greater flexibility of the system to adjust to changing circumstances by changing one part of the process rather than by reconfiguring the whole.¹³⁶ Organizations become increasingly modular when they start to replace hierarchical, integrated structures with more loosely connected forms of organization.¹³⁷ When a firm starts to outsource different parts of its product development process, for example, it is shifting to a more modular production system. The outsourced components are independent in the sense that they need not be modified when changes are made in other parts of the production process, and the firm can select from a range of alternative component suppliers to satisfy its outsourced needs. In more general terms, modularity involves breaking a process into separable blocks, referred to as modules, that have inputs and outputs that are sufficiently well-defined such that the modules can be “fit together and recombined into a complete process.”¹³⁸ This organizational strategy can be used to reduce complexity, allow for specialization, minimize the effects of changes in one part of a process on the other parts, and economize on the use of information within a production process.

While it has been used primarily to analyze the organizational structures and strategies of firms, modularity has also been applied to understand the changing organizational structures and functions of universities as they pursue different areas of focus within education and research.¹³⁹ Universities frequently create new projects, centers, interdisciplinary institutes, and sometimes even new departments to take advantage of changes in science, technology, or higher education.¹⁴⁰ Existing capabilities are grouped together in different ways as research goals change or new fields emerge. Similarly universities dissolve these units when their functions are no longer needed or the research or teaching is better performed elsewhere. Faculty members within universities form their own labs, research groups, collaborations, and

¹³⁵ *Id.* For an in-depth discussion of the concept of modularity and its application, see 1 CARLISS Y. BALDWIN & KIM B. CLARK, *DESIGN RULES: THE POWER OF MODULARITY* (2000).

¹³⁶ See Eric von Hippel, *Task Partitioning: An Innovation Process Variable*, 19 RES. POL'Y 407 (1990).

¹³⁷ See, e.g., Melissa A. Schilling & H. Kevin Steensma, *The Use of Modular Organizational Forms: An Industry-Level Analysis*, 44 ACAD. MGMT. J. 1149 (2001).

¹³⁸ Lloyd Armstrong, *Modularity in University Higher Education*, CHANGING HIGHER EDUC. (June 16, 2006), http://www.changinghighereducation.com/2006/06/modularity_in_u.html.

¹³⁹ See, e.g., Lloyd Armstrong, *Modularity in University Higher Education: Research*, CHANGING HIGHER EDUC. (June 16, 2006), http://www.changinghighereducation.com/2006/06/modularity_in_u_1.html.

¹⁴⁰ See *id.*

other arrangements in response to changing opportunities and the needs of the problems they are working on.

This Article uses the concept here to illustrate how universities can rearrange and partition their activities in ways that can support dual processes of scientific discovery and drug development.¹⁴¹ Some aspects of drug discovery and development may be conducive to open systems of innovation; others may be more conducive to proprietary, hierarchically managed development.¹⁴² Different funding sources will have different requirements attached, with private investors requiring at least some forms of proprietary development and public funders more open to alternative development modes and goals. The nature of universities as specialized entities with knowledge production and dissemination functions, combined with their decentralized structure, can sustain divergent governance approaches for different kinds of projects while leaving in place some level of shared oversight and imposing limits on the proprietary nature of project results.¹⁴³ A single innovation process can be organized into separate projects, each project with its own membership and rules of access to the results generated. Where the projects are nested within a single organization, the costs of sharing information and resources between these projects will be lower than it would be with an

¹⁴¹ Although beyond the scope of this paper, the ways in which universities generate and manage intellectual property for very different purposes has interesting implications for the types of distributed innovation systems that can be sustained. Joachim Henkel, Carliss Baldwin, and Willy Shih argue that “managing a system’s modular structure in conjunction with its IP . . . can reconcile opportunities for distributed innovation with . . . value [capture].” See Joachim Henkel et al., *IP Modularity: Profiting from Innovation by Aligning Product Architecture with Intellectual Property* 1 (Harvard Bus. Sch., Working Paper No. 13-012, 2012), available at <http://dash.harvard.edu/bitstream/handle/1/9369296/13-012.pdf?sequence=1>. This Article suggests that perhaps the university can capture and retain value in different ways and can worry less about the appropriability of the intellectual assets of different projects where the projects take place under the organizational umbrella of the university.

¹⁴² Differences in the innovation process may be a factor of different funding models (e.g., drug with commercial potential funded by private sector versus drug project that is largely supported by public funders), different starting points in the drug development process (e.g., repurposing drugs versus starting with a new drug candidate), and different technologies.

¹⁴³ This touches on a related and very relevant literature on intellectual property and the boundaries of the firm, including work by Robert Merges, Dan Burk, Joe Miller, Scott Kieff, Paul Heald, and many others. See, e.g., Dan L. Burk & Brett H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575 (examining the role of IP in balancing resource allocation needs within the firm and between firms); Joseph Scott Miller, *Standard Setting, Patents, and Access Lock-In: RAND Licensing and the Theory of the Firm*, 40 IND. L. REV. 351 (2007) (discussing the role of IP in allowing access lock-in to facilitate the joint development and use of standards).

outsourcing approach, and the projects can be more readily reconfigured as dictated by the needs of the innovation process.¹⁴⁴

This flexibility allows for the possibility of reengineering the drug discovery and development process in ways that protect both the development of knowledge and the development of drugs. Information and discoveries may have applications for both further research and narrower drug development objectives, and these different uses can be simultaneously pursued by different units within the university. “[S]eparate modules can be worked on independently and in parallel” without costly communication across modules.¹⁴⁵ Where knowledge is sticky—costly and difficult to move between locations—efforts can be made to shift the locus of innovation to where the knowledge is the stickiest by designing the different modules in light of this constraint.¹⁴⁶ Where the research opportunities offered by a particular project are reduced, or the project requires capabilities that the university does not have, the university can collaborate with a third party or outsource the project without having to revisit and reorganize the structure of other connecting projects. Moreover, the university can adapt the modules and the boundaries between the modules in ways that reflect both commercial and public knowledge production processes.¹⁴⁷ Intellectual property licensing, rules governing access to and sharing of information created within a module, and flexibilities in the design of incentive structures and working spaces characterizing different modules provide important tools for adjusting these boundaries.

¹⁴⁴ This is not to say that reorganization of activities within the university is either easy or costless, and universities exhibit institutional inertia just as private firms do—in some ways even more inertia than private firms. But where we think of innovation processes that take advantage of existing institutional structures, such as research facilities and a development facility, it may be relatively easier to break up a larger project into pieces that occur within the university rather than to divide them between different entities. Moreover, universities have some institutional competence to support fluid research projects and research portfolios.

¹⁴⁵ Baldwin & von Hippel, *supra* note 133, at 7.

¹⁴⁶ See Eric von Hippel, “*Sticky Information*” and the Locus of Problem Solving: Implications for Innovation, 40 MGMT. SCI. 429 (1994).

¹⁴⁷ By focusing on the innovation process as a process of knowledge production and sharing, we can take advantage of the insights from a growing literature on knowledge commons. From this literature we get ideas of why universities might offer comparative advantages as organizations for conducting drug development in a process that is increasingly focused on new ways of producing and sharing knowledge. See, e.g., Elinor Ostrom & Charlotte Hess, *A Framework for Analyzing the Knowledge Commons*, in UNDERSTANDING KNOWLEDGE AS A COMMONS: FROM THEORY TO PRACTICE 41 (Charlotte Hess & Elinor Ostrom eds., 2007). Universities can also incorporate public interest terms into the conditions that they impose on downstream developers of their technologies. See, e.g., Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKLEY TECH. L.J. 1031, 1039 (2005) (proposing that public-sector institutions adopt equitable access principles when licensing medical technologies).

If we take seriously the increasingly dual nature of the knowledge generated in drug development as socially and commercially valuable, then regarding drug development as not just a commercial process but also a science—a “translational science”—makes sense. In this case, the university—as knowledge commons, knowledge curator, knowledge producer, and industry partner—becomes a natural site for locating translational science.¹⁴⁸ As translational science becomes more established and accepted as an academic pursuit, we can imagine ways of judging the results of processes that have both scientific and commercial applications in new ways. Efforts at expanding tenure standards to reward patents and start-up activities is only one way, and perhaps not the best way, of adapting incentive schemes to reflect the dual nature of activities in translational spaces.¹⁴⁹ By clearly identifying activities as falling in the translational space, perhaps universities will also be better able to protect spaces for research directed solely at adding to the body of foundational knowledge. As research projects change, the ways in which they are governed can also change, allowing for shifts between different kinds of basic and applied research and development.

In addition to advantages in managing the needs of dual-natured activities, universities may be better placed than firms and the government to make decisions about how to handle the results of such activities, particularly where they are involved in both discovery and development. They have the potential to make more balanced decisions about patenting, licensing, and preserving access than private firms and government. This advantage stems from the fact that universities can and must reconcile competing interests in financial sustainability, practicality, and future research interests when managing each

¹⁴⁸ The idea of translational research as a science has been a centerpiece of the NIH vision of modern drug discovery and development. See Collins, *supra* note 1, at 2. For the notion of university as knowledge curator, see Michael J. Madison, *Knowledge Curation*, 86 NOTRE DAME L. REV. 1957 (2011) [hereinafter Madison, *Knowledge Curation*]. For the notion of university as cultural or knowledge commons, see Michael J. Madison et al., *The University as Constructed Cultural Commons*, 30 WASH. U. J.L. & POL’Y 365 (2009). For the role of universities in creating infrastructure critical in science and technology policies, see Brett M. Frischmann, *Commercializing University Research Systems in Economic Perspective: A View from the Demand Side*, in UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 155 (Gary D. Libecap ed., 2005).

¹⁴⁹ Texas A&M University became one of the first public universities in the United States to formally incorporate commercialization factors into its tenure process. *Commercialization Added to Tenure Criteria, Boosts Flow of Inventions*, TECH. TRANSFER TACTICS, Oct. 2007, at 82. The University of Maryland also recently adapted its tenure criteria to include reflections of patenting. See *Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act: Hearing Before the H. Subcomm. on Tech. & Innovation of the H. Comm. on Sci., Space, & Tech.*, 112th Cong. 7–8 (2012) (statement of Robert A. Rosenbaum, President & Executive Director, Maryland Technology Development Corporation).

stage of the discovery and development process.¹⁵⁰ They can use organizational strategies to manage tensions between these competing interests and to protect core knowledge production processes. The university's ability to pursue separate operations with different orientations under a single umbrella can be harnessed, for example, to balance the needs and demands of both open science and proprietary drug development by choosing the least restrictive knowledge management practices necessary to preserve development opportunities.

Given the range of funding sources and the mix of monetary and nonmonetary benefits that universities have available, they may also be able to pursue research and development activities that are focused more on unmet medical needs and less on commercial market size.¹⁵¹ To the extent that the governing mission can remain directed at knowledge production rather than profit maximization, project decision making can and will diverge from that of a private firm. The university and its principal investigators will benefit from nonmonetary by-products, such as a paper in a top peer-reviewed journal about a path-breaking advance in treating malaria, in a way that commercial firms do not. Publication of a new scientific advancement can count for more in the university than in either government or the private sector, making risk taking in markets with limited commercial potential more feasible. Other forms of nonmonetary benefits, including intrinsic benefits to principal investigators motivated to pursue humanitarian goals and scientific interests, can offset lower economic rewards.

Even with the best of intentions, requiring development activities to be financially self-sustainable will inevitably slant project selection toward more lucrative projects. The bias toward money-making ventures in a time of shrinking university budgets may dominate unless significant philanthropic or government money is provided and sufficient mechanisms for policing and rewarding efforts to pursue projects with high social returns, but potentially low or lower commercial returns, are put in place. While economic concerns will be impossible to escape, universities nevertheless remain good places to experiment with alternative ways of pursuing and funding development for

¹⁵⁰ Peter Lee, *Interface: The Push and Pull of Patents*, 77 *FORDHAM L. REV.* 2225, 2230–31 (2009) (exploring the ways in which the unique institutional contexts of universities can inform their patenting and technology transfer practices in ways that can reflect a “push” of nonmarket goals).

¹⁵¹ The role of philanthropic funding will be particularly important in supporting this avenue of development. See Fiona Murray, *Evaluating the Role of Science Philanthropy in American Research Universities*, 13 *INNOVATION POL'Y & ECON.* 23 (2013).

those drugs with limited economic returns but high social welfare payoffs. Their public knowledge function, combined with their flexibility to pursue focused development projects, will make universities attractive to funders providing the kinds of socially oriented funding needed to support socially important projects.

This is not to say that universities will get the balance between public and private interests in drug discovery and development right, and indeed what balance is the “right” one is itself a contested subject. This Article’s claim is only that the organizational structure of the university provides opportunities for decision making that is more informed by the interest of balancing financial sustainability, socially beneficial project choice, and public access than the same decisions would be if made by firms, government entities, or even existing forms of public–academic–private collaborations.¹⁵²

The second advantage conferred by the combination of characteristics discussed above is that the distinctive characteristics of universities give them the capability to be good at creating and providing access to the kinds of public infrastructure— inventions and other kinds of knowledge, data, and physical resources and facilities—needed to increase translational research capacity.¹⁵³ Images of paths, roads, and bridges—traditional sources of public infrastructure—pervade the recent roadmaps of government agencies charged with seeking ways to improve the outlook of the biomedical industry.¹⁵⁴ This is no surprise, as many of the government efforts currently underway to support drug development are essentially investments in public infrastructure, construed broadly to encompass not just physical facilities but also intangibles that are inputs into research and development processes. The NIH Chemical Genomics Center—with its assay development, high-throughput screening, and chemistry technologies—and the NCATS Pharmaceutical Collection—a publicly accessible database of small-molecule compounds useful in

¹⁵² Interesting parallels can be drawn to the considerations that inform university enforcement of their intellectual property rights. See, e.g., Jacob H. Rooksby, *When Tigers Bare Teeth: A Qualitative Study of University Patent Enforcement*, 46 AKRON L. REV. (forthcoming 2013).

¹⁵³ See generally Brett M. Frischmann, *The Pull of Patents*, 77 FORDHAM L. REV. 2143, 2167 (2009) (exploring how “university science and technology research systems perform economically as infrastructural capital”); Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 WASH. L. REV. 39 (2008) (exploring the concept of intellectual infrastructure in IP law and suggesting IP laws can be used to provide access to productivity-enabling intellectual infrastructure).

¹⁵⁴ See NAT’L ECON. COUNCIL ET AL., A STRATEGY FOR AMERICAN INNOVATION: SECURING OUR ECONOMIC GROWTH AND PROSPERITY 3 (2011) (describing a national innovation strategy based on public investments in physical and human capital as “infrastructure” to support innovation).

repurposing strategies—provide important examples of this kind of public infrastructure.¹⁵⁵ In many ways universities are themselves public infrastructure.¹⁵⁶ They produce and disseminate knowledge that forms the foundation for both further knowledge creation and the development of new products. They develop research facilities that the private sector can take advantage of through sponsored research, collaborations, or other forms of formal and informal academic–industry partnerships and networking. They train students who go on to become part of the workforce.

The case for public support of traditional kinds of public infrastructure, such as roads and bridges, and to a lesser degree newer forms of intangible public infrastructure, such as basic scientific research, is well understood.¹⁵⁷ Federal government involvement in research and development stems largely from the policy view that technological innovation is a key determinant of economic growth and that some of the inputs into technological innovation are public goods that will be undersupplied by the private market.¹⁵⁸ The U.S. government is estimated to have invested \$147.4 billion for research and development in 2010, excluding American Recovery and Reinvestment Act funding.¹⁵⁹ This funding is used not just for specified missions of federal departments, such as defense, public health, and environmental quality, but also to support work in areas where there is an identified need for research and development that is not being performed by the private sector.¹⁶⁰ Providing the capacity to move certain kinds of inventions through the innovation process, particularly those with significant public benefit but inadequate private returns, is increasingly viewed as having a public-good component. But finding publicly acceptable and socially efficient ways of supporting the existing, primarily private, drug development process has proven difficult. Many policy

¹⁵⁵ See generally *NCATS Pharmaceutical Collection*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., <http://www.ncats.nih.gov/research/tools/preclinical/npc/pharmaceutical-collection.html> (last visited May 8, 2013); *NIH Chemical Genomics Center*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., www.ncats.nih.gov/research/reengineering/ngc/ngc.html (last visited May 8, 2013).

¹⁵⁶ Frischmann, *supra* note 153.

¹⁵⁷ See generally FRISCHMANN, *supra* note 121.

¹⁵⁸ See, e.g., U.S. DEP'T OF COMMERCE IN CONSULTATION WITH NAT'L ECON. COUNCIL, *THE COMPETITIVENESS AND INNOVATIVE CAPACITY OF THE UNITED STATES*, at v (2012), available at http://www.commerce.gov/sites/default/files/documents/2012/january/competes_010511_0.pdf.

¹⁵⁹ See, e.g., SARGENT, *supra* note 7; WENDY H. SCHACHT, CONG. RESEARCH SERV., RL32324, *FEDERAL R&D, DRUG DISCOVERY, AND PRICING: INSIGHTS FROM THE NIH-UNIVERSITY-INDUSTRY RELATIONSHIP 2* (2011).

¹⁶⁰ WENDY H. SCHACHT, CONG. RESEARCH SERV., RL33528, *INDUSTRIAL COMPETITIVENESS AND TECHNOLOGICAL ADVANCEMENT: DEBATE OVER GOVERNMENT POLICY 1–2* (2009).

makers and their taxpaying constituents object to injections of public money into a process that will yield private drugs owned and sold by private companies.¹⁶¹ While taxpayers have become accustomed to paying for university research, even when the university is able to retain rights to resulting discoveries and license them to private companies, they are less comfortable with subsidizing the development costs for a pharmaceutical company pursuing a new drug.¹⁶²

Efforts to subsidize private development costs have therefore taken the more subtle form of public support for university and government development capacity that is made available for private use. The NIH has focused its translational research efforts on the development of NIH-supported public infrastructure. A good example is the NIH Common Fund's Molecular Libraries and Imaging program.¹⁶³ This program provides biomedical researchers with access to large-scale screening facilities needed to identify small molecules that can be refined and used as chemical probes to study the functions of genes, cells, and other aspects of disease pathways.¹⁶⁴ The facilities can also be used by public- and private-sector researchers to validate new drug targets.¹⁶⁵ Universities, with their nonprofit status and public knowledge mission, are palatable sites for this kind of public investment in development infrastructure. In some cases, it is private actors that are taking the lead in building their own shared resources.¹⁶⁶ But in many cases research

¹⁶¹ Indeed, this view that publicly funded research should remain open and available to the public was one of the biggest hurdles to the passage of the Bayh-Dole Act in 1980. *See* Mowery & Sampat, *supra* note 45. The same sentiment has supported proposals for payback provisions in federal funding legislation and proposals to limit the prices of prescription drugs that were developed using federal funds. Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 96 (2004).

¹⁶² *See, e.g.*, Scott J. Wallsten, *The R&D Boondoggle*, REGULATION, Winter 2000, at 12; *see also Taxpayer Access to Research*, ALLIANCE FOR TAXPAYER ACCESS, <http://www.taxpayeraccess.org/issues/access/index.shtml> (last visited May 8, 2013).

¹⁶³ *See Molecular Libraries and Imaging*, NIH COMMON FUND, www.commonfund.nih.gov/molecularlibraries (last updated Mar. 18, 2013) (describing the NIH Common Fund Molecular Libraries and Imaging program).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ Examples include pharmaceutical company collaborations to share information about failures in clinical testing as a way of allowing all of the companies to identify their own failures earlier in the development process, as well as "precompetitive" collaborations such as the Biomarkers Consortium. The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the NIH. This consortium is designed to develop and qualify biomarkers that will be useful in diagnosing and treating disease. The results of the project are to be made broadly available to the entire scientific community. *See, e.g.*, JA Wagner et al., *The Biomarkers Consortium: Practice and Pitfalls of Open-Source Precompetitive Collaboration*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 539 (2010) (evaluating Biomarkers

collaborations involve universities because industry players are more comfortable sharing their data with a university than with a competitor, or because universities provide the complementary skills that other industry partners do not. Moreover, the public investments made in such university projects can be justified in terms of dual contributions to research and to development, and the costs of such investments can be spread over many different projects.¹⁶⁷ This role of universities as neutral sites for industry collaboration contributes to the drug development infrastructure.

B. University Experiments with Changing Roles in Pharmaceutical Innovation

While many U.S. research universities are experiencing pressures and exploring opportunities to move beyond traditional roles, there is significant variation in the nature and scope of their responses.¹⁶⁸ The experiments that universities undertake are determined largely by their existing resources and areas of expertise, although their institutional histories and cultures also play a determinative role. Most, if not all, of the significant experiments in drug development are being undertaken by a relatively small number of large research universities. While a survey and categorization of all the university experiments in drug discovery and development currently taking place is beyond the scope of this Article, this section briefly canvasses some of the initiatives to illustrate the ways in which universities are experimenting with innovation capacity.

This section loosely categorizes these experiments in terms of levels of ownership in, control over, and financial commitment to the drug development process as a way of illustrating the degree of departure from traditional university roles.¹⁶⁹ The first level simply extends the research capabilities that

Consortium as an example of precompetitive collaboration among pharmaceutical companies); RL Woosley et al., Commentary, *The Critical Path Institute's Approach to Precompetitive Sharing and Advancing Regulatory Science*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 530 (2010) (discussing shift among pharmaceutical companies toward data sharing).

¹⁶⁷ This relates to the notion of university investments in systems of technology development and transfer as public infrastructure. See Frischmann, *supra* note 148.

¹⁶⁸ Research universities vary significantly in terms of how they approach and engage in post-discovery development initiatives. See, e.g., Argyres & Liebeskind, *supra* note 131; Rosa Grimaldi et al., *30 Years After Bayh-Dole: Reassessing Academic Entrepreneurship*, 40 RES. POL'Y 1045 (2011) (examining aspects of academic entrepreneurship).

¹⁶⁹ There are many different ways in which university experiments with drug discovery and development capacity could be organized, and alternative schematics for understanding university-industry involvement have been provided in the literature. See Bronwyn H. Hall, *University-Industry Research Partnerships in the*

universities already have to explore some low-hanging fruit in drug discovery. It involves relatively little ownership of, control over, or financial responsibility for the post-discovery development process on the part of the university, and applications to drug development are largely byproducts rather than project goals. The second level involves some form of cost sharing and risk sharing for projects which have a development focus and some level of decision making, particularly in the early stages of post-discovery development. But ownership and control of the development process are still largely managed outside the university. The third level of experiments takes the university into a position of financial and managerial responsibility for, and governance of, development projects, although this position may be shared with other actors. Along with the greater control and financial responsibility come opportunities for a larger share of the returns from products that succeed. Expansion of university control over development projects, as well as university discretion in selecting which projects to push downstream, is in many cases limited by the need to retain industry interest in the projects being undertaken. Some universities are engaged at multiple levels, often focusing on one or two disease areas at a deeper development level while engaging in applied research and developing certain drug discovery and development capabilities more generally across other areas. This section describes a small sample of university initiatives here to illustrate the different levels of university governance of drug development and the opportunities and limits of these different levels.¹⁷⁰

The first and most common level of involvement is investment in specific types of discovery capacity that expand on the university's underlying research strengths. Where a university has strengths in medicinal and synthetic chemistry, for example, developing facilities that support hit-to-lead chemistry

United States 5–6 (Feb. 2004) (unpublished manuscript), *available at* http://elsa.berkeley.edu/~bhall/papers/BHH04_Kansai.pdf (exploring recent U.S. experience with the various types of university–industry research relationships, including reasons they have increased, the evidence on their performance, and the tensions that have emerged between public and private interests in the academic research process, focusing in particular on tensions between appropriating and diffusing knowledge). The levels of involvement discussed here are designed to correlate with the degree of financial investment and control that the university has in the drug development process.

¹⁷⁰ The framework used here is based on how much development activity the university assumes and controls, but there are many other ways of categorizing and comparing universities and their development roles. Universities may be effective at creating start-up companies, for example, or at generating entrepreneurs. *See, e.g.,* MILNE & MALINS, *supra* note 114 (categorizing landscape of academic–industry partnerships).

is a natural investment with payoffs for both research and development.¹⁷¹ Where the university has strengths in computational chemistry, molecular modeling capacity may be a natural extension.¹⁷² Increased availability and familiarity and reduced cost of certain technologies, such as high-throughput screening, have bridged the gap between drug research and drug discovery and spurred university investments in discovery capacity.¹⁷³ Screening centers for small molecules, many of which include a variety of expensive screening and computational design facilities and corresponding capabilities, have been developed in a number of the major U.S. research universities.¹⁷⁴ The Penn Center for Molecular Discovery at the University of Pennsylvania is one such example.¹⁷⁵ These facilities are used by researchers from the University of Pennsylvania to further drug-discovery-related research. The center draws on and contributes to a large public domain database, PubChem, where interactions between an NIH small-molecule repository and thousands of biological candidates can be data mined. Northwestern University has developed ChemCore, an equipment-intensive shared facility that provides medicinal and synthetic chemistry, molecular modeling, and compound purification services to research investigators both within Northwestern

¹⁷¹ Hit-to-lead chemistry refers to the move from finding chemical compounds that modify a particular target relevant to a disease process (hits) to selecting and refining the most promising compound in the hopes of turning it into a drug. *See, e.g., Hit-to-Lead Chemistry*, SMALL MOLECULE DISCOVERY CENTER, <https://smdc.ucsf.edu/chemistry/hit.htm> (last visited May 8, 2013) (describing hit-to-lead chemistry by the Small Molecule Discovery Center at the University of California San Francisco (UCSF)).

¹⁷² *See, e.g.,* Gerald M. Maggiora, *Is There a Future for Computational Chemistry in Drug Research?*, 26 J. COMPUTER-AIDED MOLECULAR DESIGN 87 (2012).

¹⁷³ *See, e.g.,* Ricardo Macarron et al., *Impact of High-Throughput Screening in Biomedical Research*, 10 NATURE REVIEWS DRUG DISCOVERY 188, 194 (2011) (noting high-throughput screening uses for experimental as well as purely commercial purposes and the role of university facilities). The shift of knowledge from industry into universities has contributed to the expansion of academic drug discovery capacity. *See* Kotz, *supra* note 127; Macarron et al., *supra*, at 193, “‘The expertise in small molecule drug discovery that has traditionally resided in industry is being integrated into academia. The result is that you’ve brought what industry is good at and juxtaposed it with innovative targets and disease-specific knowledge,’ both of which are areas of strength for academia,” according to Stephen Frye, previously the worldwide vice president of discovery medicinal chemistry at GlaxoSmithKline PLC and now director of the Center of Integrative Chemical Biology and Drug Discovery at the University of North Carolina Eshelman School of Pharmacy. *See* Kotz, *supra* note 127, at 1.

¹⁷⁴ *See, e.g.,* Kotz, *supra* note 127, at 1 (discussing study done by Stephen Frye); *High-Throughput Screening*, JP SULZBERGER COLUM. GENOME CENTER, <http://genomecenter.columbia.edu/index.php?q=node/20> (last visited May 8, 2013); *High Throughput Screening (HTS)*, SCRIPPS RES. INST., www.scripps.edu/florida/technologies/hts/index.html (last visited May 8, 2013); *High Throughput Screening Laboratory*, U. KAN., www.hts.ku.edu (last visited May 8, 2013); *Penn Center for Molecular Discovery*, U. PA., www.seas.upenn.edu/~pcmd/ (last visited May 8, 2013).

¹⁷⁵ *See Penn Center for Molecular Discovery*, *supra* note 174.

University and externally.¹⁷⁶ Many of the facilities and capabilities that are developed are supported in part by government and philanthropic organizations, and many are made available to users outside of the university on a fee-for-service basis.¹⁷⁷ In these kinds of experiments with drug discovery capacity, the university ultimately ends up with relatively little control over and stake in the downstream drug development process.

Experiments at this first level can be successful at reducing the costs of certain activities by taking advantage of scale economies in facilities that can be used for more than one research program. Universities can also support facilities that have high research value combined with practical product development value, addressing problems of private sector undersupply. By increasing the physical proximity of different users of a facility to each other and by reducing organizational barriers to their interaction, these initiatives may foster greater information sharing and can be used as the basis for collaborations between entities with complementary skills. Ultimately, however, experiments at this level are unlikely to do much to move drug candidates past the early discovery stage. They are limited in scope to specific parts of the drug discovery process—often those parts that are in closest proximity to traditional university research functions. They do not fundamentally change the cost and risk profiles of drug development. Moreover, they do not address the challenges of incentivizing and promoting information production and transfer in later stages of development where research benefits are more limited and departures from traditional university research activities are more significant.

¹⁷⁶ *ChemCore*, CENTER FOR MOLECULAR INNOVATION & DRUG DISCOVERY, <http://www.cmidd.northwestern.edu/chemcore> (last visited May 8, 2013).

¹⁷⁷ See, e.g., MILNE & MALINS, *supra* note 114 (categorizing landscape of academic–industry partnerships). Although the focus of the discussion in this Article is on discovering new therapeutics, universities can and do play interesting roles in other aspects of drug innovation. As one example, approximately five universities have been able to leverage their capabilities in industrial and physical pharmacy in university-affiliated pharmaceutical facilities. These include the Chao Center for Industrial Pharmacy and Contract Manufacturing, linked to Purdue University, and the University of Iowa Pharmaceuticals Development Consortium. See *Chao Center for Industrial Pharmacy and Contract Manufacturing, United States of America*, PHARMACEUTICAL-TECHNOLOGY.COM, <http://www.pharmaceutical-technology.com/projects/chao> (last visited May 8, 2013); *UI Development Consortium Develops Drugs, Dosages for Clinical Studies*, INST. FOR CLINICAL & TRANSLATIONAL SCI. U. IOWA (May 7, 2009, 2:58 PM), <http://www.icts.uiowa.edu/content/ui-development-consortium-develops-drugs-dosages-clinical-studies>. As processes of drug discovery and development change, these kinds of downstream university involvement are likely to expand as well.

In the second category are universities that have moved beyond investment in facilities to support research and academic–industry collaborations, and have invested in establishing and financially supporting one or more central locations for drug discovery and development. The creation of academic drug discovery and development centers within universities is a relatively new and emerging phenomenon, and much of our knowledge about these initiatives takes the form of anecdotal data.¹⁷⁸ A web search reveals that 92 out of the top 114 U.S. research universities claim to have some kind of translational research initiative.¹⁷⁹ Many of these claims, however, simply reflect a relabeling or recharacterization of existing research projects. About 37 of these universities have a drug discovery or development center that has its own administrative staff, faculty, and a concerted drug discovery and development strategy.¹⁸⁰ These centers generally involve, at a minimum, bringing together in a common space a group of university employees who are engaged in different aspects of drug discovery and development. The University of Pittsburg (Pitt), currently the sixth-ranked NIH-funded institution, was a relatively early mover.¹⁸¹ It created a Drug Discovery Institute in 2006 that draws on multiple schools and departments within the university as well as its affiliated academic medical center to generate the capacity to translate basic research into clinical practice.¹⁸² The institute provides a centralized facility and core staff with a combination of academic and industrial experience that are designed to help both academic and industry collaborators translate promising ideas from basic science into a form useful for more focused drug

¹⁷⁸ This is starting to change. A recent survey of seventy-five such entities provided some interesting insights into these organizations and how they are funded, how they operate, and other aspects of their drug discovery efforts. See Frye et al., *supra* note 127, at 409.

¹⁷⁹ The 114 institutions are selected based on data collected by the Center for Measuring University Performance. See CENTER FOR MEASURING U. PERFORMANCE, <http://mup.asu.edu> (last visited May 8, 2013). These rough numbers are calculated based on whether the university web site includes a drug discovery initiative, either in the form of an institute or a center. See Frye et al., *supra* note 127, at 409–10 (noting study done at the University of North Carolina analyzing status of small molecule drug discovery in academia).

¹⁸⁰ This is an approximate measure based on information provided by the 114 institutions on their web sites. The Drug Discovery Institute at the University of Pittsburgh provides one such example. It has its own space, a range of facilities, and an administrative and lab staff focused on drug discovery capabilities. See U. PITT. DRUG DISCOVERY INST., <http://www.upddi.pitt.edu> (last visited May 8, 2013).

¹⁸¹ UNIV. OF PITTSBURGH SCH. OF MED., UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE 2011/12 FACT BOOK 3 (2011).

¹⁸² See *About UPDDI*, U. PITT. DRUG DISCOVERY INST., <http://www.upddi.pitt.edu/index.php?page=overview2> (last visited May 8, 2013).

discovery.¹⁸³ In addition to this collaboration function, the core staff also supports experiments with drug development through projects such as developing and applying technologies in the design and synthesis of drugs.¹⁸⁴ Intellectual property generated by university participants is managed by the university office of technology management according to regular university policy.¹⁸⁵ Vanderbilt University's activities with drug development provide another example of efforts to provide the kind of drug development infrastructure traditionally found only in pharmaceutical companies.¹⁸⁶ Most of the academic drug discovery centers, such as the Center for Integrative Chemical Biology and Drug Discovery at the University of North Carolina (UNC), stop at earlier stages of the discovery process.¹⁸⁷

As the private business model of drug development shifts to a fail-early-and-often model, one that is more discovery intensive and experimental, the overlap between the facilities important in research and facilities important to

¹⁸³ Shannon Barnes, *Spotlight on Research: Top-Notch Researchers Propel Pitt's Drug Discovery Institute*, PITTCHRONICLE (July 18, 2011), <http://chronicle2.pitt.edu/?p=8922> ("Over the years, DDI has expanded to a high-production facility, capable of holding as many as five million chemical compounds and equipped with more than 10 robots for automated assay plating, giving researchers virtually infinite drug-screening opportunities. Its faculty members hail primarily from three Pitt schools—the School of Arts and Sciences, the School of Medicine, and the School of Pharmacy—and create a unique mosaic of scientists, from organic chemists to clinical scientists, who work along the continuum of drug discovery.").

¹⁸⁴ See U. PITT. DRUG DISCOVERY INST., *supra* note 180.

¹⁸⁵ *Intellectual Property*, U. PITT. DRUG DISCOVERY INST., <http://www.upddi.pitt.edu/index.php?page=ip> (last visited May 8, 2013).

¹⁸⁶ Vanderbilt's efforts include the Vanderbilt Center for Neuroscience Drug Discovery (VCNDD) and the Vanderbilt Clinical and Translational Research Center (VICTR). See *Clinical Research Center Overview*, VAND. U. MED. CENTER, <http://www.mc.vanderbilt.edu/crc/> (last visited May 8, 2013); VAND. CENTER FOR NEUROSCIENCE DRUG DISCOVERY, <http://www.vcndd.com> (last visited May 8, 2013) (describing the center as a "new model for neuroscience drug discovery"). VCNDD's stated mission is to "promote translation of advances in basic science to novel therapeutics by [de-risking] efforts focused on novel approaches for treatment of serious brain disorders." P. Jeffrey Conn, *Translation of Research Across Disciplines to Impact Patient Care*, VAND. CENTER FOR NEUROSCIENCE DRUG DISCOVERY, <http://www.vcndd.com/presentations/Translationofresearchacrossdisciplinestoimpactpatientcare.pdf> (last visited May 8, 2013). This center has 100 full-time employees and investment in drug development infrastructure traditionally found only in pharmaceutical companies. It draws on Vanderbilt's other research capabilities, including a number of centers that are relevant to different aspects of drug development. Its funding is predominantly from NIH but also includes major private and philanthropic funding. The VICTR, which is funded in part by the NIH CTSA program, is a virtual home for Vanderbilt's clinical and translational research—in other words, it is not a physical space, but a coordinating mechanism for linking together relevant Vanderbilt projects and facilities.

¹⁸⁷ See *Center for Integrative Chemical Biology and Drug Discovery*, UNC ESHELMAN SCH. PHARMACY, <http://www.pharmacy.unc.edu/research/centers/center-for-integrative-chemical-biology-and-drug-discovery/> (last visited May 8, 2013). The capabilities of this center include assay development, medicinal chemistry, computational chemistry, and compound screening. Target proposals seeking use of these capabilities come from the UNC faculty. *Id.*

more commercially focused drug discovery and development increases. As a result, drug discovery research collaborations between the university and pharmaceutical companies have increased in size and scope.¹⁸⁸ Some of these academic–industry collaborations have raised concerns among stakeholders in public science because of the expansive intellectual property rights that are sometimes conferred on industry partners.¹⁸⁹ An interesting question for further exploration is whether the conflicts between public knowledge and private knowledge are larger or smaller when the university is itself in control of development rather than only the recipient of funding and shared resources in exchange for broad option rights. Another question for further exploration is whether a change in the university’s role in commercial activities will negatively impact its relationship with industry partners that currently view them as noncompetitors.

In contrast to the more limited experiments at the first level of involvement, these broader initiatives begin to address challenges of cost and risk sharing by supporting later stages of drug discovery using a mix of public, private, and university resources. The creation of a university-governed or joint university–industry-governed center focused on biomedical translational research, if done properly, can be used to reduce both geographical and organizational barriers to the translation of knowledge into products and to take advantage of the organizational capabilities that universities have in managing mixed processes of public and private knowledge creation.¹⁹⁰ Collaborative structures that deal effectively with intellectual property ownership and use rights at the start of the collaboration may be able to create joint research spaces that foster greater sharing of information while also ensuring that investments in the

¹⁸⁸ See, e.g., Frye et al., *supra* note 127, at 409–10 (noting study done at University of North Carolina analyzing status of small molecule drug discovery in academia); Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 *NEW ENG. J. MED.* 535 (2011) (examining expanded role of public sector in applied research phase of drug discovery).

¹⁸⁹ See, e.g., Josephine Johnston, *Conflict of Interest in Biomedical Research*, in *FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS* 31, 31–34 (Mary Crowley ed., 2008); Richard S. Saver, *Is It Really All About the Money? Reconsidering Non-Financial Interests in Medical Research*, 40 *J.L. MED. & ETHICS* 467 (2012) (discussing both financial and nonfinancial conflicts of interest in medical research); see also Lyman, *supra* note 115 (discussing the dangers inherent in trends toward broader umbrella arrangements between pharma and academia, including pharma–university department alliances).

¹⁹⁰ See, e.g., Donna M. Huryn, *Drug Discovery in an Academic Setting: Playing to the Strengths*, 4 *ACS MEDICINAL CHEMISTRY LETTERS* 313 (2013) (highlighting the unique ability of universities to engage in drug discovery because of their ability to engage in risky projects and to bring deep expertise to bear, but expressing caution about universities simply recreating the pharma model inside the university).

collaboration can be captured and allocated more easily.¹⁹¹ Development-oriented research centers can provide mechanisms for rewarding continued participation by both university investigators and industry participants.

Despite the promise of these collaborative models, however, disconnects between the ultimate interests of the university and its researchers and the interests of the commercial partners often remain.¹⁹² While organizational barriers to the sharing and transfer of information may be reduced through collaborative structures, they are difficult to remove completely. Differences in incentive structures, motivations, and cultures between academic and industry participants reinforce these barriers.¹⁹³ These problems make many university–industry collaborations difficult to sustain and challenging to expand beyond focused areas in which research and development interests are substantially aligned. Finally, these kinds of collaborations do not adequately address the tensions between appropriability of knowledge and disclosure of knowledge, and in many cases the private development interests in appropriability of knowledge win out over the more diffuse, and in many cases unidentified, public interests in disclosure.¹⁹⁴ Moreover, the agenda for research and development will still be largely determined by the industry partner, since the university has to attract and retain the industry partner.

In the third category are the very small number of universities that are trying to internalize the financial and managerial aspects of moving from

¹⁹¹ See, e.g., Sherer, *supra* note 111 (noting the critical role of collaboration between stakeholders, including industry and academic researchers, at every stage of therapeutic development in enabling translational research and development). Greater sharing of information between universities and their industry partners may also create risks, however, particularly if research results are treated as proprietary and access is limited. How the collaborations are structured becomes critical in determining whether the collaboration enhances or detracts from the university's public knowledge mission. See LAWRENCE BUSCH ET AL., INST. FOR FOOD & AGRIC. STANDARDS, EXTERNAL REVIEW OF THE COLLABORATIVE RESEARCH AGREEMENT BETWEEN NOVARTIS AGRICULTURAL DISCOVERY INSTITUTE, INC. AND THE REGENTS OF THE UNIVERSITY OF CALIFORNIA 50, 142–43 (2004) (using a controversial collaboration between Novartis Agricultural Discovery Institute and the University of California, Berkeley to examine broader challenges of university–industry collaboration and the need to protect the core principles of the university, identified as creativity, autonomy, and diversity, when engaging in such collaborations).

¹⁹² See, e.g., Michael Rosenblatt, *How Academia and the Pharmaceutical Industry Can Work Together*, 10 ANNALS AM. THORACIC SOC'Y 31 (2013) (discussing some of the barriers to academic–industry collaboration from an industry perspective); John Hudson & Hanan F. Khazragui, *Into the Valley of Death: Research to Innovation*, 18 DRUG DISCOVERY TODAY (forthcoming 2013) (noting the challenges of academic–industry collaboration).

¹⁹³ See Rosenblatt, *supra* note 192; see also Huryrn, *supra* note 190 (noting that culture in academia that encourages and rewards individual accomplishments makes collaboration challenging and conflicting views of goals, priorities, and credit often difficult to resolve).

¹⁹⁴ See Merges, *supra* note 119, at 183.

discovery through development. These efforts are most pronounced in public universities that work in cooperation with, and experience more pressures from, local and state governments as part of a concerted economic development plan. One example of this more holistic approach to moving from discovery to market through collaborative support structures is the Maryland Drug Discovery and Development Network and its member institutions, which include Johns Hopkins University and the University of Maryland.¹⁹⁵ The network pieces together and provides support for various activities involved in drug development. Member institutions such as the University of Maryland also offer incubator lab and office space and other business-related support services.¹⁹⁶ Similarly, the Georgia Institute of Technology has adopted a comparatively holistic approach toward translational research. Its efforts include proof-of-concept centers and incubator spaces designed to move promising discoveries to a point where they are more attractive to private investors.¹⁹⁷

The University of California San Francisco (UCSF) goes further than most other research institutions in its involvement in the entire drug discovery and development process.¹⁹⁸ UCSF's Institute for Neurodegenerative Diseases in

¹⁹⁵ See *The Maryland Drug Discovery and Development Network*, MD. BIOTECHNOLOGY CENTER, <http://marylandbiocenter.org/businessdevelopment/Pages/marylanddrugdiscoverynetwork.aspx> (last visited May 8, 2013).

¹⁹⁶ *Id.*

¹⁹⁷ See, e.g., *Translational Research*, GA. TECH. C. ENGINEERING, <http://www.coe.gatech.edu/content/translational-research> (last visited May 8, 2013). Georgia Tech has a number of initiatives geared toward the development of medical devices and medical therapies, many of them involving collaborations with Emory University and other local medical centers. These initiatives include the Georgia Tech Translational Research Institute for Biomedical Engineering and Science (TRIBES). TRIBES is a collaborative entity that has as its focus the provision of early-stage engineering, product development expertise, and other support services targeted at developing and implementing engineering solutions needed to move medical technology into clinical practice. See *id.*

¹⁹⁸ See *About Us*, CTSI UCSF, <http://ind.ucsf.edu/ind/aboutus> (last visited May 8, 2013). UCSF branches out into multiple aspects of drug discovery and development. See, e.g., *About CDDS*, CENTER FOR DRUG DEV. SCI., <http://bts.ucsf.edu/cdds/about/> (last updated Mar. 21, 2007) ("The overall mission of the center is to establish clinical drug development science as a rigorous academic discipline for advancing new scientific methodologies, to contribute to the education of scientists engaged in clinical evaluation of drugs, and to provide solutions to real-world drug development problems."); Kristen Bole, *UCSF Enters Drug Discovery Agreement with Genentech*, UCSF (Feb. 18, 2010), <http://www.ucsf.edu/news/2010/02/4369/ucsf-enters-drug-discovery-agreement-genentech> (noting collaboration between UCSF and Genentech with intent of generating drug candidates, different from traditional licensing and collaboration arrangements); Jeffrey Norris, *UCSF Scientists Play Key Role in Success of Yervoy, a New Cancer Drug*, UCSF (May 5, 2011), <http://www.ucsf.edu/news/2011/05/9803/ucsf-scientists-play-key-role-success-yervoy-new-cancer-drug>; *Research Excellence I*, UCSF, <http://www.ucsf.edu/research/research-excellence> (last visited May 8, 2013).

particular focuses on the entire drug discovery process.¹⁹⁹ The institute aims to discover new medicines for neurodegenerative diseases by performing steps from the hypothesis-generation stage of drug discovery to phase II clinical trials.²⁰⁰ UCSF has also fashioned new joint departments, such as its Department of Bioengineering and Therapeutic Sciences, with a focus on the issues that arise along the full continuum of the drug development process.²⁰¹ This redesign of disciplines in light of both research and development objectives is a hallmark of those universities most actively engaged in expanding their downstream capabilities in biomedicine.

This last level of involvement takes the university farthest along the drug development path. Universities assume some level of ownership, control, responsibility, and risk for selecting which projects to pursue and for directing at least some parts of the post-discovery drug development process. In return, universities have greater control over the intellectual property generated and also reap a larger share of the rewards from the development of successful medical therapies. Rather than a university-directed initiative, however, most involve collaboration with and decision-making input from government and industry partners.²⁰² Multiple players with divergent interests and incentives share the decision making about which projects to support at early stages of innovation, and once in the commercial pipeline, private interests are likely to dominate. Moreover, the processes of academic research and commercial development are still largely divided between different organizations, and the boundaries around projects are established at least in part as a result of the different organizations and their cultures, norms, and interests rather than as a result of the characteristics of the innovation process. Breakdowns in information transfer and inadequate incentives to engage in incremental improvements are difficult to avoid in collaborative models of production because of challenges in appropriating the benefits from nonpatentable data. Moreover, the goal underlying this approach often remains to push university developments into the hands of the private sector, simply at later stages of the development process. Where it is the private sector that is selecting and directing development projects, even indirectly, the result is likely to be underinvestment in projects that have a large net public benefit but lack the

¹⁹⁹ See *About Us*, *supra* note 198.

²⁰⁰ *Id.*

²⁰¹ *Drug Development Sciences*, U.C.S.F. DEPARTMENT BIOENGINEERING & THERAPEUTIC SCI., <http://bts.ucsf.edu/research/drug-development-sciences/> (last visited May 8, 2013).

²⁰² MILNE & MALINS, *supra* note 114.

promise of blockbuster profits. Moreover, there is likely to be less experimentation with alternative ways of developing drugs, such as open-source drug development initiatives.

As universities develop innovation capabilities, their interests in setting the drug development agenda, controlling the development process, and sharing in the rewards of development are also changing. A few universities are now experimenting with different ways to control a larger piece of the drug development process. It is one such approach that is the subject of the case study examined in Part III. This case study gives us the opportunity to explore whether some universities may indeed offer any advantages over firms and governments in managing post-discovery drug development and, if so, how they need to change in order to do so. The implications of such an expanded university role for the legal framework are explored in Part IV.

III. A CASE STUDY: EMORY UNIVERSITY AS DRUG DEVELOPER

Emory University has been actively engaged in academic drug discovery and its efforts have resulted in a relatively high number of drug candidates.²⁰³ Part of its success is attributable to principal investigators on its faculty who have both interest and experience in drug discovery.²⁰⁴ These investigators, along with other members of the university community, are interested in leveraging Emory's expertise in drug and vaccine development to move promising drug and vaccine candidates successfully through relatively late stages of drug development.²⁰⁵ They want to move the university into areas of the innovation process previously reserved for the private sector.²⁰⁶ They also hope to attract a combination of public and private resources to push forward innovations in important but neglected areas, such as finding cures for

²⁰³ See Stevens et al., *supra* note 188, at 539. A study published in the *New England Journal of Medicine* in 2011 found that Emory University was the fourth largest contributor in the United States to the discovery of new drugs and vaccines by public sector research institutions. This ranking was based on a comparison with federally funded universities, research hospitals, and federal laboratories. *Id.*

²⁰⁴ See, e.g., Mary J. Loftus, *The Dream Team*, EMORY MAG. (Spring 2005), http://www.emory.edu/EMORY_MAGAZINE/spring_2005/aids_sidebar.htm. The importance of role models for engaging in academic entrepreneurship has been the subject of interest for a number of organizational scholars. See Janet Bercovitz & Maryann Feldman, *Academic Entrepreneurs: Organizational Change at the Individual Level*, 19 ORG. SCI. 69, 70 (2008); Janet Bercovitz & Maryann Feldman, *Entrepreneurial Universities and Technology Transfer: A Conceptual Framework for Understanding Knowledge-Based Economic Development*, 31 J. TECH. TRANSFER 175, 180 (2006).

²⁰⁵ See Mike King, *Molecular Match Game*, EMORY HEALTH, Spring 2011, at 2, 4 (describing the motivations and goals of the Emory Institute for Drug Development).

²⁰⁶ See, e.g., Huryn, *supra* note 190.

neglected diseases.²⁰⁷ This interest in neglected diseases is motivated both by existing research capacity and by a desire to solve public-interest-oriented problems in drug development.²⁰⁸ This group has spearheaded and helped to fund the initiative described below, which for ease of reference is referred to as the “Project.”²⁰⁹

The Project clearly falls in the third category of experiments discussed above, involving university selection and ownership of, control over, and responsibility for managing the post-discovery development process. While various stakeholders may disagree on what “success” ultimately entails, the Project must at a minimum achieve financial self-sustainability. It must also advance medical therapies with an expected net public benefit in a way that is consistent with the university’s public knowledge mission. If successful in meeting these requirements, the approach to university innovation capacity embodied in this Project could mark a new model for university-driven drug development. If not successful, we can at least learn more about the nature and source of the barriers that impede the transition of university discoveries into products and move on to alternative strategies. The Project thus offers an excellent pilot study from which to extrapolate ideas about how the organizational structure of universities, as supported or impeded by the legal framework, may be harnessed to expand innovation capacity.

This Part begins with a detailed description of the corporate and intellectual property structures underlying the Project, with the goal of uncovering the ways in which the characteristics of the university can support or impede development activities. It then analyzes the potential of this approach as an effective way of improving pharmaceutical innovation.²¹⁰

²⁰⁷ See, e.g., *Emory Institute for Drug Development Is Awarded the Global Health Primer*, EMORY NEWS CENTER (Nov. 7, 2012), http://news.emory.edu/stories/2012/11/global_health_primer/ (noting award of “unique on-line resource that tracks drug, vaccine and diagnostic products for 25 of the world’s most devastating yet neglected tropical diseases” to be managed and expanded by EIDD and to be used to facilitate Emory’s “direct engagement with pharmaceutical companies, academic institutions, foundations and others pursuing preventives, diagnostics and therapeutics for neglected diseases worldwide”).

²⁰⁸ *Id.*

²⁰⁹ The description of the Project is based on a combination of internal documents such as the Project’s business plan, presentations made to the Emory University trustees, and descriptions of the Project provided by its management and leadership team.

²¹⁰ The description of the legal and corporate structure of the Project is drawn from the DRIVE business plan, the organizational documents governing DRIVE and the Emory Institute for Drug Discovery, and presentations prepared for the board of directors of Emory in May 2012.

A. *The Organizational Framework*

Motivated by a key faculty member, Dr. Dennis C. Liotta, the governing body of Emory University approved a plan for a self-sustaining, not-for-profit operating model to translate scientific discoveries into global health solutions in the spring of 2012.²¹¹ The stated goal of this plan was to discover and develop therapeutic agents to treat infectious diseases, particularly viral diseases, building on existing research interests and capabilities.²¹² The proposal that Emory's board of directors approved provides for the development of three entities designed to work together to create a sustainable, not-for-profit operating model for drug discovery and development. These entities are wholly owned by Emory University, which is a 501(c)(3) nonprofit organization, and the rules attaching to Emory pursuant to its 501(c)(3) status cover the actions of Emory's subsidiaries.²¹³ But these subsidiaries have their own distinct governance structures and supporting intellectual property policies. Emory Innovations Incorporated, Drug Innovation Ventures, and the Emory Institute for Drug Development were all developed using Bayh–Dole funds generated from past successes with drug discovery.²¹⁴ This funding approach opens up interesting questions about whether the entities are now also constrained by Bayh–Dole Act provisions, and if so, what these

²¹¹ Professor Dennis C. Liotta is the Samuel Candler Dobbs Professor of Chemistry at Emory University. He has been a coinventor of a number of drugs, including Emtricitabine, which is a breakthrough HIV drug marketed under the name Emtriva, widely used as part of the treatment for HIV-positive patients. Dr. Liotta, along with other Emory faculty such as Dr. Raymond Schinazi, have helped to create a number of commercial spin-off companies to further the development of their discoveries. Recognizing the considerable resources that Emory University has in certain areas of drug discovery and development, Dr. Liotta has been pivotal in pushing forward and providing start-up funds for the Project. See *Dennis C. Liotta, Jim P. Synder*, EMORY U. DEPARTMENT CHEMISTRY, <http://www.chemistry.emory.edu/faculty/liotta/> (last visited May 8, 2013).

²¹² See *Emory Institute for Drug Development Is Awarded the Global Health Primer*, *supra* note 207.

²¹³ Emory University is a 501(c)(3) organization—an American tax-exempt nonprofit organization as defined under the U.S. Internal Revenue Code. See I.R.C. § 501(c)(3) (2006). This tax-exempt status is accompanied by certain obligations, such as limits on the activities of the organization, reporting requirements, and limits on how its assets are transferred. See IRS, PUB. 557, TAX-EXEMPT STATUS FOR YOUR ORGANIZATION (2011), available at <http://www.irs.gov/pub/irs-pdf/p557.pdf>.

²¹⁴ Pursuant to the Bayh–Dole Act, universities must share with the inventor(s) a portion of any revenue received from licensing an invention developed using federal funds. 35 U.S.C. § 202(c)(7)(B) (2006). Any remaining revenue, after expenses, must be used to support scientific research or education. *Id.* § 202(c)(7)(C). Emory University has an intellectual property policy that provides for a distribution of funds received from an invention between the inventor(s), the department, the school, and the general university funds. The inventor(s) have some discretion over how a portion of the department's share is used. See EMORY UNIV., POLICY 7.6: INTELLECTUAL PROPERTY POLICY § 7.6.05 (2011), available at http://policies.emory.edu/policy/index_pdf.php?policy_number=7.6.

constraints would mean in operational terms.²¹⁵ The entities must become financially self-sustainable before their seed funds run out.

The first entity, Emory Innovations, Inc., is a wholly owned subsidiary company of Emory University.²¹⁶ It operates as a holding company for a single-member limited liability company called Drug Innovation Ventures at Emory (DRIVE) and for what could be many future portfolio companies, each directed toward a different innovation goal.²¹⁷

The second entity is a single-member limited liability company called Drug Innovation Ventures at Emory that has Emory Innovations, Inc. as its single member. DRIVE operates as the business arm of the drug development system and is organized like a virtual drug development company, with no internal development facilities of its own. It has a management team drawn largely from industry, with a chief executive officer experienced in commercial drug development. It has an advisory board drawn primarily from industry, its own employment objectives, and its own intellectual property policies, modeled largely on standard commercial practices. The entity has full control over its budget, but is also solely responsible for becoming self-sustaining once its initial seed funding is exhausted. It will retain 80% of any net intellectual property revenues earned up to \$10 million and 60% of any net intellectual property revenues earned beyond \$10 million, such revenue to be used in the continuing operations of the company in accordance with its mission. The remaining percentage of revenue will go back to the university. This structure marks a departure from the revenue-sharing model governing the university's mainstream research activities, a model that has its roots in the Bayh–Dole

²¹⁵ See, e.g., 35 U.S.C. § 202(c)(7)(C) (creating “a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) . . . be utilized for the support of scientific research or education”). Part IV suggests ways in which the legal framework should be clearer about the ability of universities to conduct drug development activities such as those explored here.

²¹⁶ Holding companies, sometimes created as subsidiaries and sometimes as separate affiliates, have been used by many research universities to manage their intellectual property. See David C. Mowery & Bhaven N. Sampat, *Patenting and Licensing University Inventions: Lessons from the History of the Research Corporation*, 10 INDUS. & CORP. CHANGE 317, 318 (2001); see also Sampat & Nelson, *supra* note 47, at 148, 151.

²¹⁷ The use of holding companies, with separate projects run in subsidiaries of the holding company, is a commonly used structure in many types of business activities. Reasons for this structure include tax advantages, limiting overall liability of risky projects, and protecting core assets in the event of individual project failures. See Phillip I. Blumberg, *The Transformation of Modern Corporation Law: The Law of Corporate Groups*, 37 CONN. L. REV. 605 (2005).

Act.²¹⁸ It allows for a much larger reinvestment of any proceeds made from successful drug development back into drug development than would occur under the university's general intellectual property policies.²¹⁹

DRIVE negotiates to obtain the development rights for early-stage discoveries from Emory and from outside of Emory. It manages the drug development process that starts with the discovery of a drug candidate and moves from refining and optimizing this candidate through to Phase II clinical testing. The business plan for DRIVE is to license potential drug candidates from Emory University or from other academic or private institutions. DRIVE will then contract with the Emory Institute for Drug Development and other Emory-affiliated or third-party institutions or companies for drug development services, and license out the resulting drug candidate to third parties such as pharmaceutical companies once favorable clinical results have been generated. In other words, DRIVE would push the drug candidate through the drug development process until late-stage clinical testing and then move it into the hands of commercial drug developers.

While DRIVE has a number of characteristics that resemble a private drug development company, it diverges from an industry counterpart in important ways. It is the wholly owned subsidiary of Emory University, a nonprofit organization, and its decision-making structure gives weight to the research and educational missions at Emory.²²⁰ While DRIVE is designed to operate as a drug development business, because of its nature as a nonprofit organization it is not constrained to focus only on profitable development opportunities. It must become financially self-sustaining, but need not select projects based only on their economic value.²²¹ The company is expected to reinvest earnings

²¹⁸ Under the Bayh-Dole Act, the university is required to share royalties from inventions developed through the use of federal funds with its inventors. 35 U.S.C. § 202(c)(7)(B).

²¹⁹ See EMORY UNIV., *supra* note 214, § 7.6.05. Under Emory's intellectual property policy, any proceeds from licensing are shared between the inventor(s), department, school, and general university funds. For proceeds \$4 million and above, the shares are 25% to the inventor, 33% to the department, 17% to the school, and 25% to the university. See *id.* Up to 50% of the department share or a maximum of \$500,000 per year may be held in a discretionary account to support the inventor(s) lab expenses. See *id.* § 7.6.05(B).

²²⁰ See *supra* note 211.

²²¹ While making a profit is not the mission of the unit, earning revenue is an undeniable part of its continued existence and operation. The ability of this unit to balance concerns about revenue with the relative social merits of alternative projects will depend largely on the resources it is able to attract and the management decisions made by the entity's CEO as influenced by the entity's board of advisors and constrained by the oversight of Emory's board of directors. As a pragmatic matter, project choice will also be influenced by the types of projects that present themselves and the types of investors that this Project is able to attract.

from out-licensing or sale of assets into new development opportunities that are selected by its chief executive officer with advice from the advisory board.²²² The focus of DRIVE is thus on financial self-sustainability rather than profit maximization. In addition, it is physically located in Emory and has a governance structure that includes Emory personnel responsible to Emory University as a whole. This physical and organizational proximity reinforces the role of the university's public knowledge mission in constraining and even guiding project decisions made at DRIVE. It does so by increasing the likelihood and ease of oversight over DRIVE activities by the university's governing body, and by reducing the contractual, intellectual property, physical, and cultural barriers between DRIVE, the Emory Institute for Drug Development, and the other parts of the university.

The third entity, the Emory Institute for Drug Development (EIDD) established in 2009, has drug development capabilities designed to carry out the kinds of tests and reporting needed to progress from an interesting drug candidate into serious drug development.²²³ EIDD's stated mission is to "promote and support drug discovery research at Emory University, translate promising technological advances from the bench-top to the bedside and train future generations of pharmaceutical scientists by leveraging in-house drug discovery and development expertise."²²⁴ More specifically, EIDD is intended to focus on the early-stage development of therapeutic agents to treat infectious diseases, particularly viral diseases, which occur in populations throughout the developed and developing world.²²⁵ This encompasses treatments that do not have commercially viable markets, with the idea that given the lower margins needed for this kind of model, funding might be attracted from public and charitable sources. The focus of this institute is on small molecule therapeutics,

²²² The selection of projects will be an area in which the tensions between public health and public knowledge interests and private commercial interests become evident. While the university retains general oversight, the board and other members of the university administration are not expected to intervene in daily management and project decisions. Key researchers from Emory, particularly those instrumental to the formation of the Project, will doubtless play an important role in project selection. Moreover, the selection will depend on the opportunities made available both within and outside of Emory.

²²³ The EIDD has the capabilities to design and conduct nonhuman clinical testing needed to examine the efficacy, toxicology, and other important properties of a drug candidate. It has significant physical and human resources devoted to the preclinical studies needed to ascertain whether a drug candidate is ready for testing in humans. *Laboratory Capabilities*, EMORY INST. FOR DRUG DEV., <http://eidd.emory.edu/laboratory-capabilities> (last visited May 8, 2013).

²²⁴ *Mission Statement*, EMORY INST. FOR DRUG DEV., <http://eidd.emory.edu/mission-statement> (last visited May 8, 2013).

²²⁵ *World Health and Neglected Diseases*, EMORY INST. FOR DRUG DEV., <http://eidd.emory.edu/world-health-and-neglected-diseases> (last visited May 8, 2013).

and its lab spaces are scattered across the Emory campus to utilize both Emory's specialized resources and available space. The growth of this project will take place in a pragmatic way, taking advantage of existing resources within the university.

EIDD is technically organized as a department within Emory University, but it is structured and operated in a manner closer to a private drug development contract research organization than a traditional academic department. It has the lab space, equipment, and personnel needed to conduct preclinical activities that move from target identification through preclinical activities. It does not have the capability to conduct clinical trials, however. EIDD will not be funded in the way that traditional university biomedical research activities are funded, which is largely through the use of NIH grants, but rather will be funded on a fee-for-service type model. DRIVE contracts with EIDD and other academic and commercial parties for drug development services, and EIDD in turn can contract with third parties to provide drug development services. Unlike other departments of Emory University, employees of EIDD are not—at least according to the proposal for the Project—governed by Emory intellectual property policies. They are hired as non-tenure-track employees who assign their intellectual property rights to the University without retaining a percentage share of any revenues generated by their inventions.

EIDD retains important differences from its industry contract research organization counterpart, however. As a department of Emory University, it is subject to Emory's general university policies, with the proposed exception of Emory's standard intellectual property policies. It is located on the university campus in proximity to Emory's research facilities and is integrated with the Emory research and development community. Its leadership team is headed by an Emory professor, and it is structured in a way that facilitates, and relies on, collaboration with members of the Emory research community. Although EIDD in its current form is unlikely to generate inventions, those that do emerge would be owned by Emory University and managed by Emory's Office of Technology Transfer. This ensures that the university retains control over, and responsibility for, the knowledge-intensive byproducts of development work.

There are at least two distinctive features of this four-part structure (Emory University, Emory Innovations, Inc., DRIVE, and EIDD), which differentiate it from a private drug development company. The first feature is the governance

structure, which tries to balance general university oversight with some degree of autonomy for project-focused decision makers. University oversight of drug development activities is provided at the board level. Emory Innovations, Inc. has a board of directors appointed by the president of Emory that includes the university's three executive vice presidents. The board is required to include a minimum of three and a maximum of seven members, with additional members drawn from the university trustees and the Emory community. All of the existing Emory University board governance parameters apply to the Emory Innovations board. In addition, the operations of the entity and its disposition of assets are subject to the restrictions imposed on its parent company, Emory University, by virtue of its tax-exempt status as an educational entity.²²⁶ What this means is that Emory University has ultimate control over, and responsibility for, the activities of Emory Innovations, Inc. and its subsidiary, DRIVE. Autonomy is preserved, however, by leaving operations and management decisions to a chief executive officer and staff for DRIVE and each additional subsidiary, with personnel drawn primarily from industry. Practical decisions about innovation projects are made by the chief executive officer with advice from an advisory board that is also drawn primarily from industry. This distances decisions about project choice and management from the central university decision-making structure. As a contract research organization designed to pay its own way, EIDD is also somewhat removed from the normal systems of academic governance and central administration control despite its organizational status as a department of Emory University.

Ideally, this governance structure means that the activities of Emory Innovations, Inc. and its subsidiaries and the activities of EIDD will be consistent with and supportive of the public knowledge mandate of the university while also supporting efficient commercial development. The autonomy left to the individual subsidiaries, however, combined with the management focus on achieving financial self-sustainability, leaves open the potential for project choices and project management decisions that reflect localized profit interests rather than generalized public knowledge and public health interests. Moreover, if the subsidiaries are successful in attracting significant funds, this could influence how the university thinks about resource

²²⁶ These restrictions include limits on unrelated business income, limits on the amount of space that can be devoted to commercial activities, and a requirement to run the entity's operations in accordance with its stated nonprofit mission. *See* I.R.C. § 501(c)(3) (2006).

allocation and intellectual property management. Discretion in this context is a double-edged sword.

A second important feature of this structure is the way it partitions assets, including intellectual property rights and projects. The partitioning of assets and decision making may allow for the financing and operation of economically valuable ventures that would not be feasible within the existing organizational structure of the university. The creation of semiautonomous management units may facilitate nimble decision making about specific commercialization projects. Decisions about the drug development path can be made faster, and with the focused goal of drug development in mind, when the entity is operated and controlled by its own industry-trained chief executive officer. Making decisions through the normal university channels, by contrast, could be slow, cumbersome, and encumbered with conflicting interests and incentives that are likely to interfere with effective development strategies. Moreover, potential investors would be reluctant to invest in the development process without some security that decisions would be made with their development projects foremost in mind. Centralizing intellectual property rights and management decisions necessary to post-discovery drug development within such an entity will make this an attractive vehicle for private investors, nonprofit funders with drug development objectives, and collaborators.

This partitioning also has the effect of separating development resources and decisions from the university's central administration of funds and intellectual property. In its current set up, Emory Innovations and its subsidiaries will not be financed by general university funds. They are supported with seed funds—albeit seed funds that are proceeds from the licensing of Bayh–Dole-supported inventions—and must adopt a strategy to become financially self-sustaining. Moreover, this plan involves a clean break between the intellectual property policies that apply to discoveries made by Emory researchers and those that apply to work performed at EIDD and other entities that DRIVE contracts with as part of a drug development program. DRIVE negotiates with the Emory Office of Technology Transfer for Emory's intellectual property rights based on discoveries made by Emory inventors, and this license is negotiated by Emory in the same way a license with a private party would be. Emory's Office of Technology Transfer retains control over decisions concerning the patenting and licensing of inventions emerging from its faculty. Early-stage patenting decisions are thus, at least in theory, informed by a broader range of both commercial and noncommercial concerns, rather

than being driven by a single-product focus. DRIVE can also enter into licenses and contract for drug development services with third parties, and EIDD can perform drug discovery and development services for third parties.

This type of structure works by simultaneously partitioning and connecting activities in the drug discovery and development process. By locating DRIVE and EIDD within the university and making these entities a part of Emory, this approach could not only facilitate interactions between drug discovery and development personnel, but also lower the transaction costs of collaboration with other parts of the university, as well as with other academic collaborators. Physical and cultural proximity will help keep informal costs low and organizational proximity will help keep legal costs low. Indeed, it is DRIVE's relationships with EIDD and the relationship of both DRIVE and EIDD with other groups within the Emory University "family" that help to differentiate DRIVE from a non-Emory virtual development company and EIDD from its industry contract research organization counterparts. DRIVE and EIDD benefit from their organizational and contractual ties to within-Emory collaborators, such as the Emory Chemical Biology High-Throughput Screening Center,²²⁷ the Emory Vaccine Center,²²⁸ the Winship Cancer Institute and its Phase I Clinical Trials Unit,²²⁹ the Atlanta Clinical and Translational Science Institute,²³⁰ and the Yerkes National Primate Research Center.²³¹ The comparative advantage of universities over other private and public organizations lies in part in the programs and facilities they can bring together in this way under a connected and loosely coordinated umbrella.

²²⁷ See generally EMORY CHEMICAL BIOLOGY DISCOVERY CENTER, <http://www.pharm.emory.edu/ECBDC> (last visited May 8, 2013).

²²⁸ See generally *Mission Statement*, EMORY VACCINE CENTER, <http://www.vaccines.emory.edu/mission/mission.shtml> (last visited May 8, 2013) (describing the Emory Vaccine Center, established in 1996 and one of the largest academic vaccine centers in the world).

²²⁹ The Winship Cancer Institute provides a cancer research center for investigators from thirty-one departments at Emory, as well as outside collaborators such as the CDC, to focus on basic and translational research into cancer treatments. It includes clinical testing capacity. *Winship Cancer Institute of Emory University*, EMORY WOODRUFF HEALTH SCI. CENTER, <http://whsc.emory.edu/home/about/components-and-figures/Winship-cancer-inst.html> (last visited May 8, 2013) (describing the Winship Cancer Institute and its clinical trials unit).

²³⁰ See generally *About ACTSI*, ATLANTA CLINICAL & TRANSLATIONAL SCI. INST., www.actsi.org/about/index.html (last visited May 8, 2013) (describing the Atlanta Clinical and Translational Science Institute). This is a collaboration between the Morehouse School of Medicine, the Georgia Institute of Technology, and Emory funded as part of the NIH CTSA program designed to integrate resources to pursue translational research projects. *Id.*

²³¹ See generally *About*, EMORY YERKES NAT'L PRIMATE RES. CENTER, www.yerkes.emory.edu/about/index.html (last visited May 8, 2013) (describing the Yerkes National Primate Research Center, which conducts both basic and translational research).

B. *Analysis of This Approach*

This Project diverges from mainstream approaches to university involvement in drug discovery and development by extending the university role to encompass financing and managing the drug development process through the valley of death.²³² Part II of this Article explained how universities have organizational characteristics that may give them comparative advantages over private firms in the dual process of creating knowledge and creating drugs.²³³ These advantages included the ability to support a modular structure that can accommodate different kinds of intellectual production and the ability to provide the kinds of semipublic infrastructure, such as drug discovery facilities, and the diversified human capital needed to increase translational R&D capacity. The case study above gives us a more concrete idea of how the organizational advantages of the university could be combined with existing university drug-discovery capabilities to reach two related goals. The first goal is to support socially valuable drug development efforts that private firms are either unable or unwilling to engage in. The second goal is to produce a drug development process that differentiates more effectively than private firms between public knowledge aspects of drug development, which are made publicly accessible, and private proprietary aspects of drug development, with an emphasis on narrowing what is proprietary and how proprietary it really has to be.

In the Project, the unique characteristics of the university, along with a combination of organizational law and intellectual property law, are used to design semiautonomous projects with their own governance structures that together create a university-controlled process of distributed pharmaceutical innovation.²³⁴ This design is essentially a “modularizing” or “partitioning”

²³² Here the “valley of death” refers to the movement from selecting the most promising drug candidate and refining the properties of that candidate through to Phase II of clinical testing. See MILNE & MALINS, *supra* note 114.

²³³ These characteristics were described as: the ability of universities, as specialized entities with a public knowledge function, to sustain different systems of knowledge production with varying levels of openness; the disciplining influence of multiple stakeholders in the knowledge production process on university decision making; and the flexibility, varying levels of autonomy, and alternative incentive schemes that are available within the university’s relatively decentralized governance structure.

²³⁴ Eric von Hippel used the term *distributed innovation* to describe a system in which innovation emanates not just from a central producer but from many sources including users and rivals. ERIC VON HIPPEL, *THE SOURCES OF INNOVATION* 5 (1988). Scholars such as Carliss Baldwin have explored the consequences of modularity for distributed innovation. See Carliss Y. Baldwin, *Organization Design for Distributed Innovation* (Harvard Bus. Sch., Working Paper No. 12-100, 2012). Concepts such as task partitioning also provide a useful conceptual framework on which to base an analysis of university-based innovation strategies. See von

approach to the governance of mixed processes of drug discovery research and drug development activities.²³⁵ Boundaries between the different entities in the innovation process are based on the separable nature of different activities and the need for varying degrees of openness and autonomy. The Project uses this structure to: (1) pursue new funding strategies that include mixed public and private funding; (2) minimize breakdowns in and restrictions on technology and knowledge transfer; (3) respond to incentive problems that impede middle stages of drug development and support reinforcing norms and cultures of innovation; and (4) minimize the impact of commercialization activities on the traditional research functions of the university.

To tackle the challenge of funding drug development, along with its own operations, the Project creates separate entities with distinct project-management and intellectual-property-ownership structures as vehicles for creating attractive investment opportunities.²³⁶ There is a clean break in the intellectual property rights and policies that apply to the university as a whole and the intellectual property rights and policies that apply once intellectual property has been in-licensed by DRIVE, the drug development company. The idea is to partition those university assets, primarily relevant intellectual property rights, which are essential to developing a portfolio of drugs.²³⁷ The

Hippel, *supra* note 136 (analyzing how the ways in which projects are partitioned into smaller tasks affects innovation outcomes). A related concept is the use of patents to partition assets in ways that facilitate the governance of private firms. Heald, *supra* note 133, at 480–84 (showing how patents may act as affirmative asset partitions and resolve team production problems within firms).

²³⁵ The growing literature on modularization, property, and intellectual property has a number of applications to this analysis. While a systematic application of the insights from this literature to analyze partitioning approaches within universities is beyond the scope of this Article, the discussion here draws directly and indirectly on much of this literature. *See, e.g.*, Smith, *Institutions and Indirectness*, *supra* note 133 (applying information cost theory to IP and explaining how difficulty in measuring inputs and identifying likely outputs creates advantages for placing a given activity within a module and giving control over local modularization to private actors, with IP allowing for this modularization through the right to exclude); Smith, *Intellectual Property*, *supra* note 133 (applying information cost theory to explain how intellectual property works, albeit imperfectly, in addressing complex coordination problems of attributing outputs to inputs); Baldwin & Henkel, *supra* note 133 (focusing on the link between modularity and value appropriation, and the role of IP in this process); Baldwin & von Hippel, *supra* note 133.

²³⁶ This touches on a related and very relevant literature on intellectual property and the boundaries of the firm, including work by Robert Merges, Dan Burk, Joe Miller, Scott Kieff, Paul Heald, and many others. *See, e.g.*, Burk & McDonnell, *supra* note 143 (examining the role of IP in balancing resource allocation needs within the firm and between firms); Miller, *supra* note 143 (discussing the role of IP in allowing access lock-in to facilitate the joint development and use of standards).

²³⁷ *See, e.g.*, Henry E. Smith, *Toward an Economic Theory of Property in Information*, in RESEARCH HANDBOOK ON THE ECONOMICS OF PROPERTY LAW 104 (Kenneth Ayotte & Henry E. Smith eds., 2011) (discussing the asset partitioning function of intellectual property and other roles it plays in modular exclusion strategies). Intellectual property law provides a modular platform for the interactions of parties, especially

intellectual property license from the university to its development entity can define the assets over which the development entity has control, using patent rights as proxies for a cluster of information relevant to the development of a particular drug or portfolio of drugs. This approach allows investors to identify the boundaries of the projects they invest in and secures their investments even when the inputs into the process are difficult to monitor and the outputs are diffuse.²³⁸

Depending on the nature of the investors, which may include a mix of industry investors, venture capitalists, philanthropists, and government funders, the investors may be anticipating first rights to license any resulting drug candidates, monetary returns, or in the case of nonprofit organizations or government funding sources, progress of a drug candidate to meet targeted health needs. The dual benefits of certain activities as both knowledge creating and commodity creating can attract a combination of different kinds of funding. Investors with diverging, noncompeting interests may be able to pool their investments to mutual advantage, and they can invest in a portfolio of project opportunities rather than basing investments on a single promising drug candidate. The ways in which investments are made can be tailored to the needs of different investors, although the ability of DRIVE to facilitate different investor interests will be constrained by the existing legal framework. Intellectual property rights not essential to securing investment in drug development can be made available for broader public use.

Second, the Project can minimize breakdowns in and restrictions on technology and knowledge transfer by tailoring the governance of internal activities within each module or project to reflect the nature of the activities and the nature of the knowledge being produced. Some activities will be well suited to an open-commons or open-access research model, for example.²³⁹

when it comes to commercialization. Although exclusive rights have their costs—and because of the nonrivalness of information itself these costs are more apparent in intellectual property than in property—the modular bundling in intellectual property can serve to manage the complexity of coordinating rival inputs to commercialization; the same basic architecture of defining a modular thing and using on/off exclusion rights as a starting point, supplemented with rules of proper use, can be discerned even in IP.

²³⁸ For a discussion of the role of intellectual property rights in facilitating asset partitioning in ways that support productive activity, see Heald, *supra* note 133, at 480–84, which suggests that just like organizational law, intellectual property has an asset partitioning function.

²³⁹ See, for example, the proposed Archipelago to Proof of Clinical Mechanism (Arch2POCM) initiative supported by the Structural Genomics Consortium and Sage Bionetworks, which aims to generate and disseminate data about targets for cancer/immunology and schizophrenia/autism in a way that is IP-free with the goal of improving the efficiency of drug development processes. See Stephen Friend, Sage Bionetworks, Arch2POCM: A Drug Development Approach from Disease Targets to Their Clinical Validation (Nov. 2011),

Other activities will require secrecy, again requiring accommodations at the institutional level of the university. Boundaries between different activities, or projects, can and should be designed to limit barriers to the flow of information where it is useful, but also to create barriers to the flow of information where proprietary uses dominate and public knowledge aspects are limited.²⁴⁰ We care more about open access to early discoveries that reveal information about disease mechanisms, for example, than we do about the toxicology results of a particular drug candidate, although we may also care about the latter. Boundaries can also be used to define tasks in a way that minimizes the problem-solving interdependencies between the tasks and minimizes the costs of cross-boundary problem solving where possible.²⁴¹ This will be particularly useful as drug discovery shifts from single-disease pathways to exploring the molecular basis for groups of diseases.²⁴² Organizing the innovation process in this way may help to minimize breakdowns in the movement of knowledge across different stages of development and can reduce costs in the creation and flow of necessary information and technology along the drug development path. It also allows the university to outsource those aspects of the drug development process that do not draw on the university's comparative strengths.

Third, the governance of separate projects can be designed in ways that respond to different incentive problems, such as eliciting effort levels in team production processes and ensuring the right amount of information sharing both within and across connected projects.²⁴³ Research-oriented projects must

available at <http://www.slideshare.net/sagebio/stephen-friend-institute-of-development-aging-and-cancer-20111129>.

²⁴⁰ The use of IP rights to create and navigate boundaries between different kinds of activities suggests a distinction between what goes on within creative groups and between creative groups. For an exploration of these ideas, see Katherine J. Strandburg, Intellectual Property at the Boundary (unpublished manuscript), available at <http://www.bc.edu/content/dam/files/schools/law/doc/patconpapers/Strandburg%20Paper20Draft.docx>.

²⁴¹ See generally von Hippel, *supra* note 137 (exploring the link between how an innovation project is divided into tasks ("task partitioning") and the efficiency and effectiveness of the project; suggesting the location of task boundaries may impact both the efficiency of task performance and project outcomes due to associated changes in problem-solving interdependence among tasks).

²⁴² See Collins, *supra* note 1, at 2 (noting that "diseases once considered quite distinct can share similar molecular pathways," which suggests future approaches based on cellular networks rather than individual disease categories); Andrew L. Hopkins, *Network Pharmacology: The Next Paradigm in Drug Discovery*, 4 NATURE CHEMICAL BIOLOGY 682 (2008).

²⁴³ Various scholars have discussed the implications of different ownership structures. See, e.g., Burk & McDonnell, *supra* note 143 (examining the effects of intellectual property rights on allocation of resources within the firm, including allocation of rights between employers and employees and effects on specialization versus integration of activities); Erika Färnstrand Damsgaard & Marie C. Thursby, *University*

allow for peer review, publication, and replication by other members of the scientific community. But more routine tasks generating results specific to a particular drug candidate will need alternative review and monitoring structures and may require restrictions on the publication of results. Using varying incentive structures may also facilitate positive selection effects among university employees.²⁴⁴ In the Project, different intellectual property policies—including both ownership, benefit sharing, and disclosure rights—apply to different units within the drug discovery and development system based on the nature of the activities undertaken and the types of contributions expected from these employees. General university intellectual property policies favor inventors, rewarding them for breakthrough discoveries. This may make sense for early-stage discovery efforts, but not for efforts directed at making incremental contributions to the drug development process. Moreover, it may impede the kind of immediate and free flow of information between collaborating parties that is essential to efficient drug discovery.²⁴⁵ The employer ownership model featured by DRIVE and EIDD, in contrast, divorces the return to employees from their inventorship contributions, if any. Employees have a bonus system that can be used to reward the production of incremental improvements and to support team production efforts.

Along with individual incentive structures, norms and institutional culture are also important in the success or failure of experiments like the Project. The creation of separate entities contained within the university is intended to create enclaves dominated by a more business-oriented culture. The norms and institutional practices of academic research are different from the norms and practices of industry research.²⁴⁶ The focus on and resources devoted to

Entrepreneurship and Professor Privilege, 22 *INDUS. & CORP. CHANGE* 183 (2013) (analyzing how differences in institutional regimes regarding ownership of faculty inventions affect university entrepreneurship); Robert P. Merges, *The Law and Economics of Employee Inventions*, 13 *HARV. J.L. & TECH.* 1 (1999).

²⁴⁴ See, e.g., Xuhong Su, *Academic Faculty Affiliated with University Research Centers: Selection Dynamics* 3–4 (Apr. 1, 2012) (unpublished manuscript), available at <http://ssrn.com/abstract=2032787> (describing how recruitment of faculty typically involves providing incentives to encourage voluntary participation).

²⁴⁵ See, e.g., Michaël Bikard, *Is Academic Science Trapped Inside the Ivory Tower? Universities and Science-Based Cumulative Invention* (Apr. 2012) (unpublished manuscript), available at http://druid8.sit.aau.dk/acc_papers/9hdupx4qjhr1kbrde7hfg7dsved.pdf. Using a novel empirical strategy, Michaël Bikard tested the relative impact of the academic and corporate environments on follow-on cumulative invention. *Id.* He found that firms are a more prolific source of science-based inventions and that industry discoverers generate three times as many cumulative patents as academic counterparts. *Id.* He also found that nondiscoverer inventors draw scientific knowledge more from industry than academia. *Id.*

²⁴⁶ See, e.g., Fiona Murray, *The Oncomouse That Roared: Hybrid Exchange Strategies as a Source of Distinction at the Boundary of Overlapping Institutions*, 116 *AM. J. SOC.* 341 (2010) (examining collision

technological development, as well as linkages to innovation networks, vary between academic and industry groups.²⁴⁷ Moreover, the individual incentives of researchers within the university diverge from their industry counterparts.²⁴⁸ The university has deliberately created separate, self-contained systems in order to create a more business-focused culture. Development entities such as DRIVE are hierarchical, they have a focused leadership, employees are selected in part based on their connection to a broader industry network and their past experience as employees of pharmaceutical companies, and they have clear product-focused objectives. Employment schemes and intellectual property policies reinforce the business-oriented, technological-development-focused culture. DRIVE in particular is geared to the needs of a commercial drug development process. Its officers are drawn from industry and its advisory board is composed primarily of industry experts. EIDD is similarly staffed with individuals that have industry experience in drug development. They are hired not as faculty inventors, but as staff scientists engaged in moving a drug candidate along the drug development path.

But while seeking to foster a distinct, product-development-focused culture within the university, the design of the Project also seeks to limit the scope and impact of the cultural divide. The cultural differences are constrained, and are meant to be constrained, by the not-for-profit nature of DRIVE and EIDD and the deliberate proximity and intentionally designed close interaction between research and discovery personnel. EIDD includes both development employees and researchers with Emory University faculty appointments, for example, and DRIVE will rely on and bring together the resources of the Emory research community around different development projects. In turn, the proximity of academic scientists to development-focused projects might foster more interest

between academic and commercial science as exacerbated by patenting); Henry Sauermann & Paula E. Stephan, *Twins or Strangers? Differences and Similarities Between Industrial and Academic Science* (Nat'l Bureau of Econ. Research, Working Paper No. 16113, 2010) (developing a framework to compare and contrast academic and industrial science).

²⁴⁷ See, e.g., Bikard, *supra* note 245, at 6–7 (discussing the “ivory tower” view of universities, which emphasizes that industry scientists have stronger incentives to develop new technologies based on the scientific knowledge that they create, that the effectiveness of firm limits on dissemination of knowledge is limited and that knowledge often flows between firms, that universities often occupy peripheral positions in networks of innovative organizations, and that inventor collaboration networks are similarly distinct).

²⁴⁸ Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240 (2001) (suggesting that while academic institutions have dissemination of knowledge as their mission, individual researchers often lack the resources and incentives to develop their ideas beyond very early stages of discovery). There are also pressures on individual research scientists to protect their research tools and early results in order to give them a comparative advantage in being the first to publish on advances in the area.

in, and desire to become involved in, pushing scientific discoveries into more accessible forms. Ideally, the fact that these entities are owned by the university and located within the university leads to greater balancing of public access with private development incentives and lower organizational, cultural, and legal barriers in the movement of knowledge between research and development activities.

A fourth advantage of segmenting the different discovery and development activities is to minimize the impact of commercialization activities on the traditional research functions of the university.²⁴⁹ All of the activities take place under the umbrella of Emory University, and the success of the Project will require continuing collaboration with centers and departments within the university as well as with its external academic collaborators. This interaction must take place in a way that protects and supports the university's public knowledge mission. The hope is that the modularizing approach, pursued within an overarching organization that retains oversight and responsibility for the process as a whole, will provide an adequate balance of the public knowledge and private development interests. Information can, at least in theory, pass more easily between discovery and development entities due to reduced organizational barriers, and intellectual property policies can be used as a means of partitioning assets into commercial and noncommercial uses in ways that can balance public knowledge and private development needs.²⁵⁰ Moreover, because the discovery and development activities take place within a single organization, the university can make choices about when not to protect information through the use of intellectual property rights as well as making choices about the scope and nature of intellectual property rights that it does obtain.²⁵¹ Ideally, internalizing proprietary development and public

²⁴⁹ See generally Damsgaard & Thursby, *supra* note 243 (discussing the implications of institutional choice including income sharing, investment in reputation, and ability to attract commercial partners); Jerry Thursby & Marie Thursby, *University Licensing: Harnessing or Tarnishing Faculty Research*, in 10 INNOVATION POLICY AND THE ECONOMY 159, 166–67 (Josh Lerner & Scott Stern eds., 2010) (discussing trade-off between harnessing tacit knowledge of faculty for development and diverting faculty from more basic duties at the university).

²⁵⁰ This idea of using a modularizing architecture to strategically manage barriers and balance access and appropriation interests in processes of innovation is drawn from a very different context—the strategic use of modularity by entrepreneurial firms. See Carliss Y. Baldwin, *When Open Architecture Beats Closed: The Entrepreneurial Use of Architectural Knowledge* 1 (Harvard Bus. Sch., Working Paper No. 10-063, 2010) (describing how entrepreneurial firms can use superior architectural knowledge to open up a technical system to gain strategic advantage, identifying and modularizing and supplying key bottlenecks while outsourcing supply of nonbottleneck components).

²⁵¹ For the challenges inherent in managing information for the public good and the importance of responsible knowledge management, see for example, Madison, *Knowledge Curation*, *supra* note 148.

knowledge processes within a single organization, one that has a public knowledge mission, will also reduce current industry problems of underinvestment in information and undersharing of information that has a net public benefit. The university does not have to worry as much about value appropriation when designing the innovation process. This is because it at least partially internalizes the public knowledge benefits and is at least partially subsidized in its development activities. The university can select and engage in socially beneficial projects and pursue knowledge-sharing strategies for projects in ways that might not be attractive or available to private firms.²⁵² Ultimately, the activities remain subject to the university's oversight, constrained by its overriding interest in ensuring that the public knowledge mission of the university, along with its not-for-profit tax-exempt status and valuable academic reputation, is not compromised by development activities.²⁵³

Despite these notes of optimism about balancing public and private interests to make both knowledge and drugs, the tension between public knowledge and private development interests as universities pursue development roles is a very real one. Managing the balance between sometimes competing interests in public knowledge and product development and preserving a strong foundation of disinterested, curiosity-driven science remain the biggest challenges in pursuing a shifting university role in the innovation process.²⁵⁴ The framework in its current form leaves open key areas

²⁵² Universities may be better able to take advantage of modularity to create value because they do not have to worry as much about appropriating the commercial value from collaborative activities, although the ability to appropriate value still plays an important role in the optimal design of the system. Carliss Baldwin and Joachim Henkel have discussed the relationship between creation and appropriation of value and the use of IP to facilitate this process. See Joachim Henkel & Carliss Y. Baldwin, *Modularity for Value Appropriation—How to Draw the Boundaries of Intellectual Property 2* (Harvard Bus. Sch., Working Paper No. 11-054, 2010) (“[I]n a modular system, a firm must simultaneously decide on the technical boundaries of the modules and the IP deployed in each one. Controlling too much of the system’s IP is problematic if it deters innovation by others. But controlling too little—or the wrong parts—may prevent the focal firm from capturing value for itself.”).

²⁵³ Analogies can be drawn between the organizational strategies and objectives discussed here and efforts to create a hybrid organization for social entrepreneurship goals. I suspect that efforts to use the L3C may run into more problems than efforts at modularizing innovation within a university, but both approaches involve inherent challenges as well as opportunities. For a critical evaluation of the L3C, see Rachel Culley & Jill R. Horwitz, *Profits v. Purpose: Hybrid Companies and the Charitable Dollar* (Univ. of Mich. Law Sch. Pub. Law & Legal Theory Working Paper Series, Working Paper No. 272, 2012), available at http://papers.ssm.com/sol3/papers.cfm?abstract_id=2055368.

²⁵⁴ Concerns about university involvement in money-making initiatives are not new. For influential work highlighting the tensions between academic and commercial science more generally, see DEREK BOK, *UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION* (2003), which

of discretion in how the balance between competing public and private interests is maintained, particularly in project selection choice and university decisions about how to structure license terms with DRIVE, but also in broader decisions about where to target growth in research capabilities.

IV. LEGAL RESPONSES TO A CHANGING UNIVERSITY ROLE

The challenges of making universities attractive sites for proprietary drug development while also protecting their core public knowledge functions are evident.²⁵⁵ Universities must seek to sustain and balance different cultures in a way that promotes the health and vitality of both research and development groups.²⁵⁶ They must wear a business hat while preserving their commitment to a mission of public knowledge and education. They will have a growing stake in commercial outcomes while seeking to preserve curiosity-driven science.²⁵⁷ They will be conflicted in their approach to the disclosure and

examined whether everything in the university is for sale and argued that universities must be vigilant to avoid compromising the primary mission and purpose of an academic institution. *See also* JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF AMERICAN HIGHER EDUCATION (2005) (arguing that universities are selling out to corporate sponsorship and intellectual property is being transferred too readily to industry). For a thoughtful review of the tensions between public and private interests in university science, see STEPHEN M. MAURER, PROMOTING AND DISSEMINATING KNOWLEDGE: THE PUBLIC/PRIVATE INTERFACE (2002). For a discussion of the tension that patenting may create with the university mission, see for example, Geertrui Van Overwalle, *Reconciling Patent Policies with the University Mission*, 13 ETHICAL PERSP. 231 (2006), which examined how to reconcile the traditional academic mission of knowledge production and science sharing with the current trend in universities toward knowledge protection and appropriation through patenting and suggested mechanisms designed to provide oversight of conflicts and modifications to patenting to respect public interests.

²⁵⁵ Concerns about the commercialization of academic institutions have been highlighted by scholars such as Derek Bok. *See* BOK, *supra* note 254.

²⁵⁶ *See, e.g.,* Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223, 225 (Rochelle Cooper Dreyfuss et al. eds., 2001). Other scholars have a different view of the role of patents and industry partnerships on the dissemination and use of biomedical discoveries, suggesting that patent rights may actually increase the sharing and use of research results and support norms important to basic science. *See* F. Scott Kieff, Forum, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 694 (2001) (suggesting that patents may actually improve rather than dampen norms supporting basic research, contrasting it with the imperfect operation of the market for “kudos,” and discussing the positive effects of patents on encouraging more and broader forms of funding for scientific research); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001) [hereinafter Kieff, *Property Rights and Property Rules*] (noting the role of patents as property rights in supporting commercialization of inventions by encouraging coordination and bargaining to achieve efficient investment in and use of discoveries); *see also* Lee, *supra* note 67.

²⁵⁷ *See, e.g.,* Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer*, in UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL

sharing of information and the management of early-stage patenting and licensing because of their involvement as licensees and developers of these same inventions.²⁵⁸ I have suggested that for some universities, those with well-developed drug discovery capabilities, the social benefits of pursuing these dual activities may sometimes outweigh the costs. But to achieve these benefits without jeopardizing the integrity and autonomy of academic science, policy makers need to respond simultaneously to the frequently conflicting needs of product-driven and curiosity-driven science. This concluding Part of this Article suggests a few ways in which policy makers could use the legal framework governing universities and their technology development and transfer activities to respond more directly to the opportunities and challenges of universities that expand their role in processes of innovation.

Concerns about the harm that commercial technology transfer activities may have on the public knowledge functions of universities are not new.²⁵⁹ The existing literature includes detailed proposals for protecting the public knowledge function of universities through patent law change. These proposals advocate creating robust research-use or fair-use defenses,²⁶⁰ increasing control

PROPERTY, *supra* note 148, at 93, 97–122 (suggesting the importance of funding for curiosity-driven science and the need to preclude researchers from using patenting to control follow-on research).

²⁵⁸ See, e.g., Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, LAW & CONTEMP. PROBS., Winter/Spring 2003, at 289 (expressing concerns with the erosion of open science and the increasingly proprietary character of university biomedical research and suggesting that federal funding agencies should have more discretion in determining when to require that publicly funded research discoveries be dedicated to the public domain).

²⁵⁹ See, e.g., MAURER, *supra* note 254 (noting the need for intervention to protect the public interest in academic science, including a survey of activities by universities and governments that impact the public domain); Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601 (2005); Rai & Eisenberg, *supra* note 258, at 289, 313 (expressing concerns about inadequate motivation of universities to take social costs of patenting decisions into account); Strandburg, *supra* note 257, at 97–122 (noting the importance of preserving adequate funding for curiosity-driven research); Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 FORDHAM L. REV. 2237 (2009) (exploring the implications of convergence of academic research with commercial interests and the implications for norms of sharing research tools and materials and suggesting need for policies to enhance sharing). Changes that diminish the public knowledge orientation of universities could interfere with core organizational principles such as autonomy, creativity, and diversity that are essential to the university's public knowledge functions. See, e.g., BUSCH ET AL., *supra* note 191, at 16 ("There are arguably three central principles and associated practices that must stand at the core of any university that is worthy of the title: creativity, autonomy, and diversity.").

²⁶⁰ Numerous scholars have put forward detailed and carefully tailored proposals for research-use and, even more broadly, fair-use defenses. See, e.g., Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 464 (2004); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) (proposing research-use defense that distinguishes between situations requiring payment and those not requiring payment, with a focus on protecting robust domain for basic research uses); Donna M.

by funding agencies over patenting decisions by universities,²⁶¹ protecting the disclosure of research results in the face of proprietary interests in restricting disclosure,²⁶² and limiting early-stage patenting and restrictive licensing practices.²⁶³ The problems that these measures seek to address become even bigger in a world in which university innovation capacity expands. But in reconsidering the need for measures such as these, we also need to consider whether they will impede or even foreclose potentially beneficial university development roles.²⁶⁴ It may be difficult to encourage more private investment in university development activities while also introducing a broad research-use exemption for universities into patent law, for example. Moreover, the

Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1684–90 (2001); Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17 (2001); Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 130–46 (proposing a research-use exemption based on characteristics of the invention and distinguishing between experimenting on a patented invention and experimenting with the patented invention).

²⁶¹ Rai & Eisenberg, *supra* note 258 (advocating for greater NIH control over patenting decisions for federally funded research).

²⁶² See, e.g., Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 217 (2006) (proposing protections to disclosure norms by creating “an opt-in extended grace period that would provide more time for academic researchers to publish and present early-stage research before having to file a patent application,” combined with early application publication); Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 TEX. L. REV. 1363, 1363–404 (1988).

²⁶³ Various scholars have put forward proposals for requiring or encouraging open-access licensing and supporting other modes of open science by universities. See, e.g., Yochai Benkler, *Commons-Based Strategies and the Problems of Patents*, 305 SCIENCE 1110, 1110–11 (2004); Kapczynski et al., *supra* note 147, at 1090–1109; Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917 (addressing the role of public institutions in supporting distributed commons through ownership stakes and leverage from funding); Lemley, *supra* note 259 (noting concerns that university interests may not align with optimal use of building block inventions in nanotechnology); Van Overwalle, *supra* note 254 (suggesting mechanisms such as public patents, open patents, and two-tiered licensing strategies as mechanisms for balancing ethos of sharing and profit maximization in universities).

²⁶⁴ One set of arguments against public law interventions is that private actions may be sufficient to protect public policy objectives. See, e.g., Peter Lee, *Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 889, 898–99 (2009) (suggesting that the increasing use of conditional research support by government and nonprofit funders can be used to contractually construct a biomedical research commons and reflecting the use of consideration-based contracting to effectuate policy goals). Another set of arguments is that public law interventions such as fair use will introduce uncertainty, be costly to implement, and will lower incentive costs and thus dampen innovation. See, e.g., Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 950–51 (2006); Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2176–85 (1991); see also Kieff, *Property Rights and Property Rules*, *supra* note 256 (emphasizing the importance of property rights in encouraging commercialization of inventions).

organizational innovations behind university experiments complicate the application of rules that rely on clear boundary drawing between commercial and research activities. This is one of the main problems with the existing legal framework—it works through boundary drawing instead of responding to the governance challenges created by the dual nature of university research and development activities.

As Emory University is discovering during the course of its experiment with drug development capacity, there are a number of internal and external rules and policies that create difficulties for funding university-driven drug development. In addition, organizational strategies designed to support drug development activities create new areas of tension within the university between competing public and private interests and even between competing public interests. This Article's contribution to the policy debate is to focus attention on ways in which the legal framework can improve university governance of commercial activities rather than preclude them. While a comprehensive blueprint for legal and regulatory change is beyond the scope of this Article, it suggests some modest changes to the Bayh–Dole Act and to tax rules impacting university-managed innovation that are designed to enhance the governance advantages of the university in mixed processes of research and drug development. This Part focuses in particular on changes in existing rules that limit university strategies for financially supporting their development activities, changes that can reduce tensions between pursuing academic science and pursuing proprietary drug development, and collective action problems among competing universities that may harm collective innovation outcomes. Part IV looks first at whether the Bayh–Dole Act, in its current form, might interfere with strategies for self-sustainable drug development within the university.

The funding structure and legal rules governing university activities are geared primarily toward supporting traditional forms of scientific research.²⁶⁵ The NIH and other federal funding agencies provide significant research funding to universities, much of it in the form of grants made to principal investigators for scientific projects that are selected through peer review by other scientists.²⁶⁶ This system tends to reinforce existing patterns of research

²⁶⁵ See, e.g., MATTHEWS, *supra* note 15.

²⁶⁶ See, e.g., JUDITH A. JOHNSON & PAMELA W. SMITH, CONG. RESEARCH SERV., R41705, THE NATIONAL INSTITUTES OF HEALTH (NIH): ORGANIZATION, FUNDING, AND CONGRESSIONAL ISSUES 6–7 (2011) (noting more than 80% of NIH funds are spent on extramural awards and more than 75% of this amount goes to researchers in higher education institutions, particularly the 131 U.S. medical schools).

funding.²⁶⁷ Discoveries made at least in part using these federal funds are subject to the requirements of the Bayh–Dole Act, which governs how universities manage inventions that are developed at least partly through the use of federal funds.²⁶⁸ As previously discussed, the Bayh–Dole Act was designed to support the transition from publicly funded, publicly available research into privately funded, proprietary research and development based on a linear model of technology transfer.²⁶⁹ Universities could decide to elect title to federally funded inventions provided that they took subsequent efforts to patent and commercialize these inventions, typically through licensing to industry.²⁷⁰ The Bayh–Dole Act avoided dealing directly with the tension between public knowledge and private commercial development by presuming that product development would occur in the private sector.²⁷¹ Where the university instead retains and begins to develop its federally funded inventions, as intended in the Project, certain clarifications and modifications to the Bayh–Dole Act such as those suggested below may be needed.

The Bayh–Dole Act requires that the university share funds from any subject inventions with inventors, with the remaining funds to be used for scientific research and education.²⁷² It focuses on rewarding inventions, to the neglect of valuable but nonpatentable improvements. As the Project suggests, university proceeds from the licensing of inventions subject to the Act may provide a natural source of funds for drug development. But it is unclear

²⁶⁷ See, e.g., Pierre Azoulay et al., *NIH Peer Review: Challenges and Avenues for Reform* (Nat'l Bureau of Econ. Research, Working Paper No. 18116, 2012), available at http://www.nber.org/papers/w18116.pdf?new_window=1.

²⁶⁸ 35 U.S.C. §§ 200–211 (2006). For an extensive overview and review of the Bayh–Dole Act and its implementing regulations, see SEAN O'CONNOR ET AL., *LEGAL CONTEXT OF UNIVERSITY INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER* (2010).

²⁶⁹ One of the most significant legal measures is the Bayh–Dole Act, a 1980 amendment to the Patent Act that allows research institutions to elect title to inventions that are produced using federal funds. Pub. L. No. 96-517, § 6, 94 Stat. 3015, 3018–27 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

²⁷⁰ See 35 U.S.C. § 202(c) (amended 2011). For a discussion of patenting and technology transfer activities by universities, see Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503 (2012).

²⁷¹ See, for example, NIH discussions of preserving access to research tools in ways consistent with the Bayh–Dole Act. The discussions focus on concerns with how universities will license research tools to the private sector, and provides principles and guidelines to govern how universities make research tools broadly available to the research community. See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090 (Dec. 23, 1999); see also *NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources*, NAT'L INSTS. HEALTH OFF. EXTRAMURAL RES., <http://grants.nih.gov/grants/sharing.htm> (last updated Mar. 5, 2013).

²⁷² See 35 U.S.C. § 202(c)(7)(B)–(C).

whether drug development activities are encompassed within the statutory meaning of scientific or educational purposes. In addition, the Bayh–Dole Act in its current form may restrict the ability of the university to differentiate between the revenue-sharing policies covering initial drug discovery, made using federal funds and subject to the requirements of the Act, and those covering later-stage incremental improvements on the same initial discovery. Where research and development activities mix, and facilities, equipment, and knowledge are shared between different projects, inventions made within a proprietary–development-focused project may be considered “subject inventions” and fall within the ambit of the Act.²⁷³ Even when research and development activities are distinct, the continued development of a subject invention may bring with it the continuation of Bayh–Dole obligations, including its restrictions on how revenue is distributed and used. These concerns about what is covered by the Act and how it impacts revenue flows may limit the types of funding strategies that universities have available for supporting drug development efforts, particularly efforts to secure private investment in post-discovery development activities.

The Bayh–Dole Act also includes reserved rights to subject inventions for government use.²⁷⁴ For any subject invention that the university elects title to, the federal agency that provided the relevant funding “shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”²⁷⁵ The role of the government as a consumer of pharmaceuticals through programs such as Medicare and Medicaid raises interesting questions about the consequences of the Act for university-developed drugs. If the university develops a drug, and the government is the primary purchaser of the drug, can the government use its reserved rights under Bayh–Dole to argue that it should not have to pay as much for the drug? Or at least should the government be able to have a generic form of the drug made by a government contractor? Where the government, through federal agencies such as the NIH, is financially supporting research leading to the discovery of drugs, particularly

²⁷³ See *id.* § 201(e). The Bayh–Dole Act applies to “subject inventions” as defined in § 201(e), encompassing “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” *Id.* Where the university continues to work on a discovery that is made using federal funds, and where the university mixes research that is federally funded with development work that is not, questions may arise as to whether the results of the development activities are subject to the requirements of the Act.

²⁷⁴ See *id.* § 202(c)(4).

²⁷⁵ *Id.*

drugs that satisfy a critical health need, pressures arise on the government to make the resulting drugs accessible and affordable, with or without the cooperation of patent owners.²⁷⁶ The reserved rights for government use provided in the Act are supplemented at the international level by provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a key international intellectual property agreement, that allow for compulsory licensing to meet public health needs.²⁷⁷ While reserved rights for government use may indeed be important to protect public interests in access to the fruits of federally funded research, the ways in which government use rights can and should be exercised in the context of academic drug development need to be further clarified.

This Article suggests that in order to harness the organizational advantages of the university to solve problems of developing socially desirable drugs, the Bayh–Dole Act should allow for the use of Bayh–Dole funds to support university-managed drug development activities. Moreover, the university should be able to draw a reasonable line between research activities covered by the Act and development activities that are not subject to the requirements of the Act unless the development activities are themselves publicly funded. Where public funds are used for development activities, in contrast, these activities should fall under the provisions of the Act. This would facilitate different intellectual property policies and investment strategies for the development entities in the Project, for example. In addition, clear guidelines about how government use rights can be exercised should be developed with the goal of balancing needs to attract private capital and needs to ensure access to the resulting knowledge and drugs. These guidelines should be designed to manage competing objectives, and they should be informed by accurate data about the costs and benefits of alternative drug development processes and the consequences of government use rights.

In addition to the Bayh–Dole Act, federal tax laws may limit university strategies to fund their own drug development efforts.²⁷⁸ The federal tax code

²⁷⁶ See, e.g., Colin Macilwain, *NIH Urged to Cap Profits Made on Publicly Funded Research*, 406 NATURE 5 (2000); *Taxpayers May Be Paying Twice for Some Drugs*, N.Y. TIMES, July 12, 1994, at C3.

²⁷⁷ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. Article 31 of TRIPS addresses compulsory licensing.

²⁷⁸ For a general discussion of the problems inherent in the way that tax laws handle commercial activities by nonprofit organizations, see John D. Colombo, *Commercial Activity and Charitable Tax Exemption*, 44 WM. & MARY L. REV. 487, 491 (2002). Issues discussed include how engaging in commercial activities may impact the tax-exempt status of the organization, whether the income from these activities is taxable, and

includes restrictions on the ability of universities, as nonprofit institutions, to engage in commercial activities based on their nonprofit tax status.²⁷⁹ Even when permissible, revenue from such activities may be treated as taxable income.²⁸⁰ There are also other tax provisions specific to nonprofit organizations, such as those accompanying the financing of university buildings using tax-exempt bonds, which restrict the types of activities that universities may engage in. Universities can issue tax-exempt bonds that yield advantageous tax-exempt interest for bond purchasers. But the university must use the funds and facilities financed by the funds in ways that are consistent with Internal Revenue Service regulations in order to retain the tax-exempt status of the bonds. This imposes significant restrictions on the private business use of the university's property.²⁸¹ How drug development activities will be treated and private interests measured when universities manage innovation processes will be important in determining how much existing tax rules restrict university innovation strategies. Matters become even more complicated when the university wants to attract angel and venture capital investors, who demand premiums on their investments, to fund drug development efforts. Universities will likely need to be able to offer commercially attractive returns to at least some private parties in order to attract needed private capital for drug development projects. Philanthropic capital may be increased if entrepreneurial donors can also participate financially in the results of a university's portfolio of drug prospects—a part-gift, part-investment strategy that may attract donations from entrepreneurial alumni. But the tax laws governing nonprofit organizations limit both compensation schemes and the ways in which the assets of the nonprofit may

whether commercial activities by some entities within a complex organizational structure are imputed to other entities within that structure. Colombo concludes that the laws governing these issues are a mess and need to be fixed.

²⁷⁹ See I.R.C. § 501(c)(3).

²⁸⁰ The tax code includes a definition of unrelated business income, which is income from activities regularly carried on by the organization that are not substantially related to furthering the exempt purpose of the organization. See *id.* §§ 512(a), 513(a).

²⁸¹ See, e.g., *id.* § 145; see also IRS, PUB. 5005, YOUR RESPONSIBILITIES AS A CONDUIT ISSUER OF TAX-EXEMPT BONDS (2012), available at <http://www.irs.gov/pub/irs-pdf/p5005.pdf>. Federal tax law generally requires that property that is financed by a nonprofit organization using tax-exempt bonds must be owned by the nonprofit organization and must be used to further the charitable, educational, or other exempt purpose of the nonprofit organization. Only an insubstantial use (generally less than three percent) of the property may be for non-exempt or private business purposes. See, e.g., TAX-EXEMPT BOND PRIVATE USE MONITORING PROCEDURES 1 (2010), available at https://www.finance.emory.edu/home/accounting_svcs/Fiscal%20Accountability/FINAL%20PBU%20Monitoring%20Procedures.pdf.

be transferred or disposed of.²⁸² As this and other forms of public-private partnerships become increasingly common and new financial models are required to sustain them, tax laws that impede these models may need to be revisited.

Overall, the tax rules that govern both the ability of universities to engage in and the tax treatment of commercial activities need to be reevaluated in light of their consequences for promising models of supporting university innovation. In some cases the rules may need to be revised to ensure that the university has the flexibility it needs to engage in financially self-sustainable development work. This may include defining the purpose of the university as encompassing drug development activity and careful consideration of whether income from drug development activities that is reinvested in drug development should be taxable. In other cases the rules may simply need to be clarified to guide the university in its handling of different activities. While there are costs associated with any such change to the tax code, at the very least tax laws should be examined to determine their impact on university product development and to assess whether the cost of change is worth undertaking. Just how to get the balance of public and private concerns right in adjusting, or not adjusting, these kinds of tax regulations remains a question for further study.

In addition to difficulties in financing development activities, universities also run into challenges in balancing the needs of academic science with the needs of proprietary drug development. While protecting open access to and use of scientific knowledge, the university also needs the ability to keep certain kinds of information private and to restrict the use of certain uses of intellectual property in order to secure the funding needed to push forward drug development. While supporting autonomous, curiosity-driven scientific research, universities also need to pursue more focused and centrally controlled development approaches for promising drug candidates. The organizational strategies discussed earlier in this Article seek to manage this tension through the use of a modularizing or partitioning strategy. Projects will be separately grouped and managed based on whether the interests of academic science predominate, and rules of access and use will be devised accordingly. But there are changes in the law that could go further in reducing the tension between

²⁸² See, e.g., IRS, PUB. 4221, COMPLIANCE GUIDE FOR 501(C)(3) PUBLIC CHARITIES (2009), available at <http://www.irs.gov/pub/irs-pdf/p4221pc.pdf> (discussing restrictions on private benefit and inurement and other restrictions on how public charity assets are transferred and distributed).

academic science and proprietary drug development. Avenues of change in patent law suggested in the existing literature include giving longer grace periods for inventions published in academic journals and later patented to allow for publication.²⁸³ Changes such as this could be incorporated into the Bayh–Dole Act for inventions produced using federal funding, since these are the kinds of discoveries that are most likely to be the subject of academic publications and the most in need of early disclosure and dissemination. Research-use exemptions and other ways of protecting access to and use of scientific knowledge may also help to maintain this balance, as discussed further below, although the cost of such measures on drug development efforts needs to inform the scope and implementation of any such measures.

The changes suggested above will provide universities with more discretion and more flexibility in how they structure their drug development activities. But increases in discretion and flexibility should be accompanied by increased university accountability and responsibility for protecting the public interest when managing development activities. As a start, universities should clearly articulate their missions in the context of expanding innovation capacity and should work together to establish best practices for university-driven innovation.²⁸⁴ As part of this process, universities should work in collaboration with their stakeholders, including members from the public and private sector and from different constituencies within the university, to identify acceptable experiments with university innovation capacity and to adopt guidelines for engaging in development. They should find ways of building socially beneficial innovation practices into traditional metrics used to evaluate university performance. This governance-focused approach to managing an expanded university role in development builds on recommendations made in a recent report by the National Academies on universities and technology transfer. The report emphasized the need for universities to place “IP-based technology transfer squarely within the university’s core mission to advance discovery and learning and to contribute to the well-being of society.”²⁸⁵ This

²⁸³ See, e.g., Bagley, *supra* note 262, at 217, 254 (proposing protections to disclosure norms by creating “an opt-in extended grace period that would provide more time for academic researchers to publish and present early-stage research before having to file a patent application,” combined with early application publication).

²⁸⁴ Analogies can be drawn to efforts by university technology transfer managers to establish best practices for university technology transfer in the form of *In the Public Interest: Nine Points to Consider in Licensing University Technology*. See, e.g., CAL. INST. OF TECH. ET AL., *IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY* (2007), available at http://www.autm.net/Nine_Points_to_Consider1.htm. *In the Public Interest* is endorsed by a number of leading U.S. research universities and provides principles to guide technology transfer decisions with the public interest and social benefit in mind.

²⁸⁵ See NAT’L RESEARCH COUNCIL OF THE NAT’L ACADS., *supra* note 18, at 4.

report went on to articulate the need for university accountability to ensure compliance with this mission.²⁸⁶

Allowing universities to expand their role in commercial product development activities should not be taken lightly. The idea behind these proposed changes is not to encourage all universities to move into drug development, but rather to allow for development activities by those universities that may have a comparative advantage in socially beneficial drug development, and to allow it only when they undertake the investments required to manage the process in ways that protect the public interest. Investment by both universities and policy makers in a system that will oversee this balancing of public and private interests is an essential part of expanded university innovation capacity.

Policy makers should therefore accompany increased flexibility to pursue development activities with expanded monitoring and reporting requirements for universities to ensure compliance with existing rules and with socially beneficial goals. Both universities and policy makers should also explore additional measures designed to increase the transparency and accountability of the university as it engages in product-focused activities such as drug development. The Bayh–Dole Act provides a natural place to begin instituting more comprehensive and meaningful systems of reporting and monitoring drug development activity. Current reporting requirements under the Act are tied mainly to disclosure of subject inventions and brief summaries of how patented inventions are being developed.²⁸⁷ These reporting requirements should be expanded both in detail and in scope. Where substantial development activities are undertaken, for example, reports should include a showing of how this expanded role will further the university’s mission. Reports should include details about how the development activities are financed and how they are expected to progress. Where public funds support development activities, such as the building of a high-throughput screening facility, reporting requirements should extend to the management and use of these facilities. In addition, some kind of meaningful review of university reports and university compliance with their responsibilities should be implemented both within the university and by an independent government regulator. Universities should have an internal review process for new drug development projects and modifications of existing projects that is transparent to stakeholders in the university. There

²⁸⁶ See NAT’L RESEARCH COUNCIL OF THE NAT’L ACADS., *supra* note 18.

²⁸⁷ See 35 U.S.C. § 202(c) (2006) (amended 2011).

should be a public component to their reporting process. There should be established lines of authority and accountability within the university to ensure that university activities are consistent with the university mission and performed in compliance with rules and regulations. University activities should also be reviewed periodically by some kind of external, independent committee, perhaps one comprised of members from public funding agencies like the NIH, along with representatives from some of the main research university associations.

The changes discussed above relate to the individual governance issues of each university. This Article concludes with some ways in which the law can address collective action problems that impede the sharing of research tools and data. The competitive pressures on universities engaged in drug development may discourage the kinds of industry-wide collaborations needed to improve drug development efforts. Proposals for research-use exemptions are worth revisiting in this area, at least in a limited way. I suggest that the reserved rights for federal use of subject inventions provided in § 202 of the Bayh–Dole Act could be amended to include not just government use, but use by any research institutions for research use.²⁸⁸ Guidelines for what constitutes “research use” should be established based on input from both public and private stakeholders. This exemption would ensure a certain level of openness to inventions useful in follow-on innovation even along proprietary development paths. It would also address collective action problems faced by the university community in making research tools and other discoveries with broad applicability to further innovation available to the research community.²⁸⁹ Critiques of expanding research-use exemptions highlight the negative effects of such changes on private incentives to invent and invest in commercialization, problems of over-inclusiveness, and the cost and feasibility of making such changes to the patent system through either legislation or common law.²⁹⁰ While these remain important concerns, it seems unlikely that

²⁸⁸ 35 U.S.C. § 202(c)(4) provides that “[w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”

²⁸⁹ Interesting questions arise as to the effect of such a change on the use of patented inventions for research on U.S. entities versus non-U.S. entities.

²⁹⁰ See, e.g., O’Rourke, *supra* note 260 (discussing and evaluating objections to patent fair use); Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, in [2 PATENTS AND TRADE SECRETS] *INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE* 107 (Peter K. Yu ed., 2007) (discussing some of the concerns with different kinds of research-use exemptions as part of argument in support of a research-use exemption).

the costs would outweigh the benefits for the following reasons. Many university researchers already act as if there is a broad research-use exemption,²⁹¹ and as research and development activities merge, clear guidelines clarifying what is and is not permissible might have a positive rather than a negative effect on private incentives. Moreover, private actors are themselves increasingly interested in sharing costs by collaborating in the creation and use of research tools and in some cases contribute the results of their research efforts to the public domain.²⁹² As invention and innovation become more collaborative and alternative open systems of innovation emerge, a carefully tailored exemption may be favored by the private as well as the public sector. Starting with a research-use exemption that is limited to inventions developed with the use of federal funding would also provide an opportunity to learn about how lines between research and nonresearch use could be drawn and how such an exemption might function more broadly in the law.

As the recent passage of the Leahy–Smith America Invents Act demonstrates, legal change is inevitably accompanied by uncertainties and costs and often falls far short of the problems motivating the legal change.²⁹³ But this Article argues that these costs and uncertainties may be well worth undertaking to bring the legal framework more in line with the modern organizational challenges and opportunities facing research universities. This Article has suggested some preliminary ideas for adjusting the legal and regulatory framework to allow for changing innovation capacity in some of the U.S. research universities while preserving their core public knowledge functions. The adjustments proposed are relatively modest in scope, and deal largely with ways of enhancing the characteristics that may make universities comparatively good at managing at least some downstream stages of pharmaceutical innovation.

²⁹¹ See, e.g., Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19.

²⁹² See *supra* Part II.

²⁹³ See generally Leahy–Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.). The Act was a result of years of congressional deliberations and is now the subject of scrutiny and discussion by multiple constituencies trying to understand how the new rules impact them. See, e.g., Dan L. Burk, *Patent Reform in the United States: Lessons Learned*, REGULATION, Winter 2012–2013, at 20 (discussing limits of America Invents Act).

CONCLUSION

U.S. research universities with biomedical research capabilities are reconsidering the roles that they play in drug development as they both reach for and are pushed further downstream in the pharmaceutical innovation process. They are being pushed by funding needs and pulled by scientific opportunities into experiments with university innovation capacity. They are moving slowly and cautiously, interested to be among the leaders in attracting new funds and prestige for innovative translational research models, but also anxious to remain among the followers in deviating from traditional university functions. In many cases, they have antiquated administrative structures and a set of academic norms that are resistant to change. While the pace of change is not rapid, organizational innovation in some of the larger U.S. research universities is nevertheless outpacing innovation in the legal framework that governs the role of universities in processes of innovation. To the extent that universities are making changes in how they engage in technology development and transfer, they are doing so against the backdrop of a legal landscape that has remained relatively unchanged for the past thirty years.

This Article has suggested the importance of revisiting this legal framework as universities expand their roles in the innovation process. The case study of Emory University's foray into a domain once reserved for pharmaceutical companies illustrates the kinds of organizational changes that such a move requires and highlights the tensions that may emerge in balancing research and development activities and interests. Although universities may offer unique advantages in supporting the kinds of knowledge production and sharing that are critical to revitalizing pharmaceutical innovation, harnessing these advantages in a financially sustainable, yet also socially productive way, is challenging. Expanding the role of universities in product development carries with it both costs and potential benefits. For the small number of universities with established drug discovery capabilities who are already heading in the direction of drug development, the benefits may outweigh the costs if properly managed. The law should assist rather than impede these universities in managing the balance of public interests and private requirements implicated in making knowledge while also making drugs.