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REPLACING PATENT AWARDS WITH GOVERNMENT-FUNDED PRIZES FOR BIOPHARMACEUTICAL INNOVATION: AN ECONOMIC ASSESSMENT

Henry Grabowski and Genia Long***

I. Introduction

In recent years, there have been various proposals, some of which have been incorporated into proposed legislation, to replace the current market-based system that relies on intellectual property (IP) incentives to spur private sector investment in biopharmaceutical research and development (R&D) with an administrative system of government contracts[1], patent buyouts[2], or prize awards for the successful discovery and development of new medicines.[3] These proposed policy changes would replace, modify or supplement the system of intellectual property (IP) protections that operate through a combination of general and targeted legislative market exclusivity provisions, and limited periods of patent protection as provided for in the Constitution and U.S. patent law. Because prize approaches have received recent attention, we focus most of our discussion on them, but all would to some degree substitute a government administrative system for the current system that relies on IP rights to drive R&D resource allocation decisions.

While historically the government has allocated resources for basic research based on expert judgement, as reflected in the peer-reviewed grant system, by far the majority of drug development resource allocation decisions are made by individual private sector firms. Firms make

** Professor Emeritus of Economics, Duke University.*
*** Principal, Genia Long Consulting.*

[1] For example, The Free-Market Drug Act of 2004, H.R.5155,108th Congress. This proposal would have created several public research corporations to conduct both the discovery and development of new medicines through FDA approval. See also, STAN FINKELSTEIN AND PETER TEMIN, REASONABLE RX: SOLVING THE DRUG PRICE CRISIS (2008). The authors propose creating an intermediary "independent, public, nonprofit Drug Development Corporation (DDC)" that would pay development companies to license approved drugs and then auction these rights to competing distribution companies.

[2] For example, see Michael Kremer, *Patent buyouts: A mechanism for encouraging innovation*, 113 Q. J. Econ. 1137 (1998).

[3] See, for example Joseph E. Stiglitz, *Scrooge and intellectual property rights*, 333 BMJ 1279 (2006). , and ; Joseph E. Stiglitz, *Prizes, Not Patents*, Project Syndicate (Mar. 6, 2007), https://www.project-syndicate.org/commentary/prizes--not-patents. ; and James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 Annals Health L. 155 (2009).

these decisions based on expected economic returns in the competitive market, including the value of patents awarded for inventive activity and their eligibility for various forms of legislative exclusivity.

Advocates of replacing this IP-driven, market-based system for R&D investment allocation view an administrative system of expert judgment and prize awards as superior, and the aim of these proposals generally is to accelerate the approval and marketing of generic drugs, or otherwise to achieve sooner the lower average prices paid after generic drug entry -- potentially as early as the time of initial U.S. drug approval. At the same time, these proposals raise several issues including practical obstacles to and the transaction costs of implementation, the substantial upfront costs to government and taxpayers that would be necessary to maintain current levels of investment and innovation, efficiency concerns associated with the government replacement of private sector R&D, and adequate incentives for continued innovation.

In this chapter, we describe the current system of IP incentives that drive competitive investment decisions for new drug development by individual firms and consider the economic implications of proposals to replace private IP rights-based private investment incentives in biopharmaceutical R&D with administrative public government funding approaches. Currently, private sector R&D expenditures are much larger than those of the historical NIH budget (even prior to proposed reduced funding levels for 2026), so to maintain the same level of historical total investment these proposals would imply a substantial increase in upfront government funding for biomedical research. We review recent estimates of these additional government costs, along with various efficiency issues and challenges associated with replacement of private investment with government funding. Regarding prizes specifically, the "hold-up" or time inconsistency problem, with the prospect that government will reduce expected rewards after private firms have incurred considerable sunk costs is a primary efficiency concern. Information challenges, including adequate *ex ante* specifications of criteria for prize awards, also have been discussed extensively in the literature. Because prizes would be awarded by a centralized government decision-making body applying some form of expert judgment, concerns about political influence and rent-seeking would apply. Finally, there are concerns about reduced incentives for follow-on innovation.

II. The Biopharmaceutical Research and Development Ecosystem and Current IP-Based Incentives for New Drug Development Investment

A. The Complementary Roles of Public and Private Biomedical Research

Government support of research at universities and nonprofit research institutes has a long history in the United States and its societal benefits are well-documented.[4] While historically the NIH has been the world's largest public sector funder of biopharmaceutical research, most of this budget is dedicated to basic research, defined as the "…systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind…"[5] This can involve understanding the biology of a disease as well as the identification of targets (proteins, receptors or enzymes) for potential therapeutic intervention. For instance, in 2018, an estimated 48% of the NIH budget was devoted to basic research.[6] In comparison, an estimated 15% went to clinical investigations of interventions of all kinds, about half of which (8%), went to clinical investigation of drugs, either pre- or post-approval. Post-approval investigation includes the investigation of uses of generic drugs for different uses, which would otherwise be subject to limited investment incentives.[7]

Researchers have generally found that the public and private sectors play complementary roles in the biopharmaceutical innovation ecosystem, with government typically providing essential support for basic research on disease mechanisms and biologic pathways, and private

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[4] See, for instance: David M. Cutler, Amy B. Rosen & Sandeep Vijan, *The Value of Medical Spending in the United States, 1960–2000*, 355 NEW ENG. J. MED. 920 (2006); Frank R. Lichtenberg, *Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-Income Countries, 2000-2009*, 3 Health Pol'y & Tech. 36 (2014); and Danielle Li, Pierre Azoulay & Bhaven N. Sampat, *The Applied Value of Public Investments in Biomedical Research*, 356 SCIENCE 78 (2017). For an analysis and review of the positive impacts of government R&D spending on US productivity across non-defense sectors, see Andrew J. Fieldhouse and Karel Mertens, *The Returns to Government R&D: Evidence from U.S. Appropriations Shocks* (Federal Reserve Bank of Dallas, Working Paper 2305, December 2023).

[5] U.S. Nat'l Sci. Found., *NCSES 22-209, Definitions of Research and Development: An Annotated Compilation of Official Sources* (2022).

[6] Pharm. Rsch. & Mfrs. of Am., *Chart Pack: Biopharmaceuticals in Perspective, Fall 2020* 5 (2020) (showing PhRMA estimates for 2018 National Institutes of Health budget obligations). Available at: https://cdn.aglty.io/phrma/global/resources/import/pdfs/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf.

[7] Ernst R. Berndt, Rena M. Conti & Stephen J. Murphy, *The Landscape of US Generic Prescription Drug Markets, 2004–2016* (Nat'l Bureau of Econ. Research, Working Paper No. 23640, 2017).

sector firms generally focusing on the development of new drugs.[8] For example, Toole (2007) and Azoulay *et al.* (2008) find a significant lagged relationship between public R&D in biopharmaceuticals and subsequent private sector R&D investments and patents.[9] Researchers have also conducted qualitative case study reviews of specific sets of drugs.[10] Others have explored indicators of public sector participation in drug discovery and development through quantitative analyses of patent information.[11] Sampat and Lichtenberg (2011) calculated that 9.0% of the 379 NMEs approved between 1988 and 2005 having at least one patent reflected in the Orange Book[12] had either a Bayh-Dole disclosure of government funding or had a US government agency as the first-named patent assignee (or both).[13] Applying the same method to updated data, Long (2019) confirmed these findings and similarly found that for 2013-2017 top-selling drugs, 8.6% had at least one patent with a Bayh-Dole disclosure of government interest, 1.5% had at least one U.S. government agency assignee, and 10.2% met either criterion.[14]

B. The Market for Innovation, The Cost of Drug Development and the Importance of IP Incentives

The translation of upstream basic research into new FDA-approved medicines available to patients is primarily done by private sector startups and established biopharmaceutical companies. Private sector companies also engage in basic research activities, which may be research into

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[8] R. Chakravarthy *et al*., *Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy*, 50 Ther. Innovation & Regul. Sci. 759 (2016).

[9] Andrew A. Toole, *Does Public Scientific Research Complement Private Investment in Research and Development in the Pharmaceutical Industry?* 50 J.L. & Econ. 81 (2007); Azoulay P, Li D, Zivin JSG, & Sampat BN, *Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules*, 86 Rev. Econ. Stud. 117 (2019).

[10] See, for instance, the differing conclusions of two sets of researchers about the same set of drugs: Benjamin Zycher *et al.*, *Private sector contributions to pharmaceutical science: thirty-five summary case histories*, 17 Am. J. Ther. 101 (2010); and Aaron S. Kesselheim, Yongtian Tina Tan & Jerry Avorn, *The Roles of Academic, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs*, 34 Health Aff. 286 (2015).

[11] Under the University and Small Business Patent Procedures Act of 1980 (the Bayh-Dole Act), universities and other recipients of federal funds (e.g., teaching hospitals, non-profit research institutes) may retain title to and license to others the right to apply patents arising directly from their federally-sponsored research activities, but they must meet certain procedural requirements, including disclosing the government's interest in the form of Government Interest Statements in those patents (called "Bayh-Dole disclosures").

[12] The Orange Book is an FDA listing of patents reported by approved drugs required by the Hatch-Waxman Act to be made available to facilitate the generic manufacturer ANDA filing process.

[13] Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 Health Aff. (Millwood) 332, 332–39 (2011).

[14] Genia Long, *Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs*, 22 J. Med. Econ. 1261 (2019).

platform biological mechanisms and therapeutic areas of continuing commercial interest, with the aim of discovering a new medicine or set of commercial applications.

The growing importance of risk-based capital in the form of venture-funded companies, often spinoffs from NIH-supported research in universities, has been highlighted in several studies. These startup companies are particularly active in the discovery process and early research stages. They then frequently partner with, or license their intellectual property to, larger established firms for ongoing development and regulatory approval. For instance, a recent study found that 65% of the new drugs approved between 2015 and 2021 originated from licensing and M&A deals between such companies and larger integrated pharmaceutical companies.[15] Some of these smaller firms also participate in later-stage development, sometimes up through FDA approval.[16]

IP protections are viewed as essential to attract and fund investments in new drug development. This is particularly true for early-stage firms, which only have IP assets and expectations with which to attract investment capital to fund continued development and to support their valuations. They are also essential for established companies that plow back earnings into R&D investments for future new medicines. Without IP protections, there would be few incentives for investors and companies to fund the years-long, costly and risky R&D process from discovery to FDA approval.

New drug candidates must undergo extensive preclinical and clinical testing to assemble evidence on safety and efficacy for FDA submission. Research teams across scientific specialties are assembled to focus on the discovery and synthesis of potential new medical therapies for targeted diseases. Promising product candidates are tested in preclinical assays and animal models. Human testing of lead compounds follows which requires an investigational new drug (IND) FDA license. Clinical trials generally proceed through three successive phases in which a drug is investigated in human studies involving an increasing number of subjects to evaluate its safety and efficacy, with "go-or-no-go" decisions after each key development. If the drug candidate passes

[15] Alexander Schuhmacher *et al*., Investigating the origins of recent pharmaceutical innovation, 22 Nature Rev. Drug Disc. 781 (2023).
[16] In 2021, emerging firms were linked to 42% of all active pre-registration drugs filed with the FDA. IQVIA, Emerging Biopharma's Contribution to Innovation (2022), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation.

successfully through each phase, applicants submit the evidence as a New Drug Application (NDA) or Biologic License Application (BLA) to obtain FDA approval for U.S. marketing.[17]

The economics of the biopharmaceutical R&D process have been studied extensively. While estimates of the cost, risk and duration of drug development vary depending on the period and cohort of medicines studied, the sampling methodology employed, and the specific assumptions (such as the discount rate) used, there is consensus that pharmaceutical R&D is a long, costly and risky process. It generally takes more than a decade for a compound to successfully proceed from initial molecule synthesis through FDA approval. Moreover, only a small fraction of compounds entering clinical trials pass all testing to eventually become approved new medicines.[18] Given the inherent risks, potential medicines can fail in any of the discovery, development and clinical testing phases due to safety, efficacy or commercial viability issues. Success rates, measured from the start of human trials to approval, range between 5% and 15% and vary by therapeutic area and other characteristics. Two oft-cited studies of R&D costs by Dimasi *et al.* and Wouters *et al*. have estimated average capitalized R&D costs per new drug approval at $2.3 billion (in 2013 $) and $1.6 billion (in 2018 $), respectively.[19] This contrasts with the much lower cost and risk of generic drug imitators, which can be marketed rapidly after patents and any legislative exclusivity protections expire.

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[17] An NDA is required for drugs subject to the drug approval provisions of the Federal Food, Drug and Cosmetic Act of 1938 (generally small molecule or chemically synthesized drugs, with some exceptions), and a BLA is required for biological products subject to licensure under the Public Health Services Act of 1944 (generally biologics such as vaccines, blood and blood products, cellular and gene therapies, and other products derived from living organisms). See, U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.

[18] When using the term "new medicines" or "new drug," analysts are often referring to New Molecular Entities (NMEs). An NME "contains no active moiety that has been previously approved by the Agency in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States." See, *Manual of Policies and Procedures, Center for Drug Evaluation and Research, NDA Classification Codes* (Food & Drug Admin. MAPP 5018.2, effective Nov. 4, 2015).

[19] For instance, see: Joseph A. DiMasi *et al*., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20 (2016); Olivier J. Wouters, Martin McKee & Jeroen Luyten, Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018, 323 JAMA 844 (2020);. For comparison, these estimates include only pre-approval expenditures since post-approval R&D was not estimated by Wouters. R&D costs are capitalized at a risk-adjusted cost of capital of 10.5%. The studies are somewhat complementary in terms of data samples. The DiMasi *et al.* study is based on audited data from larger, well-established pharmaceutical firms. The Wouters *et al.* study is drawn from a sample of accessible public data filings. It mainly consists of smaller firms with above-average numbers of orphan drugs, first-in-class drugs and FDA accelerated approvals. Pre-clinical data is missing in many firms in the Wouters *et al.* sample. When an adjustment was made to account for this, mean R&D costs per approval increased to $2.1 billion. See also Wong, CH, Siah KW, Lo AW. *Estimation of clinical trial success rates and related parameters*. Biostatistics, 20(2): 273-286 (2019).

C. Patents and Incentives for Drug Innovation and Generic Competition Under the Hatch-Waxman Act

Property rights in the form of patents are the main incentive to encourage investment in lengthy, costly and risky biopharmaceutical R&D. Patents confer the right to exclude competitors for a limited time, within the scope defined by patent claims.[20] However, they do not guarantee demand, and they do not prevent therapeutic competition, or competition from nonidentical drugs that treat the same diseases through mechanisms that fall outside the scope of the patent protections for a particular approved drug. Through the required public disclosure function, patents disseminate information supporting future innovation and subsequent improvements. They also provide important market signals of value and provide the basis for markets to emerge for new technologies and early-stage, pre-sale firms.

While statutory patent life is twenty years in the U.S., the actual average period of protection experienced by marketed drugs is much less. This is because companies generally apply for patents on new drug candidates when sufficient evidence exists to satisfy the fundamental U.S. Patent and Trademark Office (USPTO) requirements that the application is for a useful, novel and non-obvious invention. However, generally this will be several years before large-scale human trials are completed and data are submitted to the FDA as part of the approval process. This resulting lost patent time, when the "patent clock" is running but the drug is years away from being on-market, adversely impacts R&D investment incentives.

Congress addressed this issue in the Hatch-Waxman Act (formally the Drug Price Competition and Patent Term Restoration Act of 1984)[21], which also eased the way for generic drug approval. On the one hand, Congress encouraged the development of the generic drug industry by creating an accelerated pathway for market entry in which generic drugs must show only that they are bioequivalent to the reference drug. Generic drug companies were also provided with incentives to challenge patents in the form of a six-month market exclusivity period for a

[20] The basis for patent protection is found in the U.S. Constitution, which provides that Congress shall have the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. It is described further in U.S. patent law. 35 U.S.C. §1-390 (2018).

[21] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

successful challenge.[22] On the other hand, Congress provided positive incentives for innovative drug developers by allowing some of the patent time lost during the long regulatory IND and NDA application periods to be restored, subject to a maximum cap of a14-year exclusivity period after patent restoration.[23]

In addition to patents, various types of legislative exclusivity protection may apply. Hatch-Waxman provides a minimum base period of exclusivity protection of five years for new molecular entities[24]. Drugs also may be eligible for various targeted legislative exclusivity protections designed to enhance incentives in areas of market underinvestment. These include pediatric studies (six-month extension to a drug's marketing exclusivity for FDA-requested pediatric studies); orphan drug indications (seven-year exclusivity for FDA-approved rare disease drug indications)[25]; and antibiotics (five years of additional exclusivity in the case of approved new antibiotics)[26]. Congress has also authorized the FDA to award a transferable Priority Review Voucher for treatment advances in the case of neglected tropical diseases and rare pediatric diseases that entitle the voucher holder to obtain priority review for another medicine that would otherwise not be eligible for one. [27]

In a series of studies, we have examined the impacts on U.S. competition between brand-name and generic drugs over time. We have observed that average market exclusivity periods

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[22] Generic companies can challenge the validity of innovators' patents (which must be listed with the FDA) after five years (via a "Paragraph IV challenge"). An automatic stay of 30 months is imposed before a generic drug can enter the market unless there is a patent validity ruling prior to the end of this time. As a result, patent challenges have substantially increased, and the six-month period of first-generic exclusivity has become a major profit consideration for generic manufacturers, as during this period the exclusive generic manufacturer can charge higher prices than when there are many competing generics. We found that for NMEs experiencing first generic competition in 2017-19, more than 80% experienced at least one patent challenge, and there were an average of 6.8 challenges per NME. Challenges occurred on average 6 years after brand launch. Henry Grabowski *et al.*, *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Med. Econ. 908 (2021).

[23] One of the innovator's drug patents is eligible for partial patent term restoration, based on the patent time lost during FDA review and one-half of the time lost during clinical development, capped at five years. The extended patent term cannot exceed fourteen years from FDA approval, including restoration. 35 U.S.C. §156 (2018).

[24] This new drug exclusivity runs concurrently with patent protection. Generic manufacturers can submit ANDAs only after the five-year period (four years in the case of a patent challenge).

[25] Rare diseases are those affecting fewer than 200,000 people in the U.S. each year. FDA may not approve an application for the same drug for the same orphan indication for seven years. Manufacturers may also be eligible for certain other benefits, namely tax credits of up to 50% of qualified clinical development spending, exemption from certain FDA fees, government grants, and access to special FDA technical advice. Orphan Drug Act, 21 U.S.C. § 360cc(a) (2018).

[26] Generating Antibiotic Incentives Now (GAIN) Act of Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, 21 U.S.C. § 355e (2018). Drugs are also eligible for FDA Fast Track and Priority Review.

[27] 21 U.S.C. § 360ff(a)(2). Legislative authorization for the FDA's Rare Pediatric Disease Priority Review program expired in December 2024 and renewal is subject to action by Congress. 21 U.S.C. § 360ff(b)(5).

(MEPs, or the time between a branded drug's launch and its first generic equivalent entry) for new molecular entities has changed relatively little between1995 and 2019. They ranged between 12.2 and 14.6 years for all NMEs and between 10.1 and 13.7 years for NMEs with sales greater than $250 million (in 2008 dollars) in the year prior to generic entry. For the most recent period examined (2017-19) these larger-selling NMEs had an average MEP of 13.0 years, while all NMEs averaged 14.1 years.[28] A year after generic entry, the brands' average unit market share had rapidly eroded to 18% for the higher-sales NMEs, and 23% for all NMEs. The Hatch-Waxman Act applies to small molecule drugs. Regulatory requirements for and the nature of competition between biosimilars and innovative biologics are still evolving.[29]

The Hatch-Waxman framework aimed to provide strong incentives for both drug innovation and for generic drug savings. The lifecycle of drugs therefore includes a limited period of time when branded drugs compete with one another (that is, therapeutic competition), followed by generic entry, when average prices fall dramatically for individual drug entities as generic substitution dominates due to managed care contracted formularies and state automatic state substitution laws requiring or encouraging generic use.

With regard to drug innovation, studies have documented large gains in health benefits[30] and societal welfare[31] from new drug introductions. The U.S. also has experienced an increasing

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[28] NMEs with sales of $250 million or more (in 2008 dollars) in the year prior to generic entry represent 42 percent of all drugs and 92 percent of sales for all drugs in our data set experiencing generic entry. Grabowski *et al.*, *supra* note 22.

[29] As part of the Affordable Care Act, Congress adopted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an accelerated pathway for biosimilars to biological drugs. Pub. L. No. 111-148, § 7002. The BPCIA established a 12-year exclusivity period for biologics, versus 5 years (plus 30-month stay with patent challenge) for small molecule drugs. Given the greater manufacturing complexity of biologics, the FDA has required some clinical safety and efficacy testing to establish biosimilarity. In most instances, they are not approved as interchangeable with the reference biologic as with generic drugs but rather are considered close therapeutic substitutes.

[30] See for example, David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?*, 20 Health Aff. 11 (2001); Frank R. Lichtenberg, Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS, 20 Health Aff. 241 (2001); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medicinal Expenditure, 1990-2003: Evidence from Longitudinal, Disease-Level Data*, 97 Am. Econ. Rev. 438 (2007).

[31] With regard to the allocation of welfare benefits, Philipson and Jena found that for HIV drugs, innovators captured only 5% of the social surplus. Tomas J. Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs*, 9 Forum Health Econ. & Pol'y 1, 1–33 (2006). Later, in a review of results in a large registry of cost-effectiveness analyses, Hult and Philipson found that if patients value health improvements at $150,000 per QALY, the median percentage of total value allocated to manufacturers for pharmaceuticals was 18%. K.J. Hult & T.J. Philipson, *The Value of Medical Innovation Versus Industry Rewards*, 26 Value Health 320 (2023). Finally, Garrison *et al.* find that "the manufacturers of all-oral DAAs received approximately 6.5% of the economic value that was created for HCV patients treated with DAAs over the period 2015 to 2019." Louis P. Garrison Jr. *et al.*, *Estimating the Allocation of*

number of innovative new drug approvals in recent years. A Congressional Budget Office (CBO) report found that between 2010 and 2019, the number of NME approvals increased by 60% and industry R&D expenditure more than doubled.[32] Others have noted a high and increasing proportion of approvals classified as first-in-class or advance-in-class.[33] At the same time, with regard to generic drug savings, over 90% of all prescriptions dispensed in the U.S. are for generics[34], up from 18.6% in 1984[35], and the FDA reports that through 2022 more than 32,000 generic drugs had been approved.[36]

III. Replacing the Current IP-Based R&D Incentive System with Public Sector Administrative Approaches

Some have proposed alternatives that would completely replace the current system of private IP incentives and investment with government financing. Among three types of proposals (direct government provision of R&D, grants and contracts, and prizes), prizes have received most of the recent attention. Generally, proposals have avoided proposing direct government R&D production in government facilities with government employees, to retain as much as possible current private sector infrastructure and expertise in the execution of biopharmaceutical R&D.

It is also generally recognized that government contracts like those typically found in "cost-plus" defense project procurement face major efficiency issues. Applying this approach to drug development would likely lead to higher costs, greater uncertainty, and longer delays in an already long and risky process. Long-term contracts between government and private companies face the

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the Economic Value Generated by Utilization of All-Oral Direct-Acting Antivirals for Hepatitis C in the United States, 2015 to 2019, 27 Value Health 1021 (2024).

[32] Congressional Budget Office, Research and Development in the Pharmaceutical Industry (2021).

[33] Advance-in-class drugs are defined as those that are not designated by FDA as first-in-class approvals, but that receive an FDA priority review designation. Categories defined in Michael Lanthier *et al*., *An Improved Approach to Measuring Drug Innovation Finds Steady Rates of First-In-Class Pharmaceuticals, 1987–2011*, 32 Health Aff. 1433 (2013). Between 2018 and 2022, the FDA approved an average of 49.4 drugs a year, including 31.2 that were classified as first-in-class or advance-in-class (63% of approvals), whereas they represented just under half of all NMEs in an analysis spanning 1987-2002. David Proudman *et al*., *Public Sector Replacement of Privately Funded Pharmaceutical R&D: Cost and Efficiency Considerations*, 27 J. Med. Econ. 1253 (2024). Also referencing results of Ranjana Chakravarthy *et al.*, *Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy*, 50 Ther. Innov. Regul. Sci. 759 (2016).

[34] IQVIA Inst. for Hum. Data Sci., *Understanding the Use of Medicines in the U.S. 2025: Evolving Standards of Care, Patient Access, and Spending* (2025).

[35] Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 Int'l J. Econ. Bus. 177, 201 (2011).

[36] U.S. Food & Drug Admin., *Office of Generic Drugs 2022 Annual Report* (2022).

challenge that high-stakes contracting can have high transaction costs. This is because "once investments have been sunk and the parties have become locked-in to each other"[37] while theoretically contractual provisions can spell out how to resolve disagreements, it may not be possible or may be very expensive (have high transaction costs) to anticipate, describe and resolve all issues in advance. As a result, contracts are likely to be incomplete and therefore provide either reduced incentives for investment or large cost overruns, relative to current market-based decisions and outcomes.

In comparison to contracts, prizes have the potential advantage of rewarding outcomes rather than funding cost inputs. They may also attract a wider set of proposals and participants, as compared to centralized government contracting.[38] The stated aim of prize proposals to replace patents and other forms of IP is to balance two objectives: providing adequate economic incentives to encourage innovation (through prizes that maintain incentives for costly and risky upfront R&D investments), while avoiding the economic inefficiency associated with pricing above marginal cost during the period before generic competition ("reward(ing) innovators while making the fruits of the innovation public"[39]). In principle, they could be designed to provide the highest rewards to new medicines that provide the greatest expected health benefits for patients, subject to the information challenges and political influences discussed below.

Among recent prize proposals (and their close relatives "patent buyouts"), are bills proposing "delinking research and development incentives from product prices." One recent proposal would eliminate the current system of patents and legislative exclusivity incentives and instead fund drug innovation through a compulsory and comprehensive system of prize awards.[40]

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[37] Oliver Hart & John Moore, *Incomplete Contracts and Renegotiation*, 56 Econometrica 755 (1988).

[38] See, for instance, discussion in NAS committee workshop proceedings, noting "the ability of prize competitions to include more diverse 'solvers' when compared to other funding mechanisms—as prize participants don't necessarily need a specific technical skill or knowledge expertise to contribute to the innovation process, which in turn, helps build a larger community of practice." Nat'l Acads. of Scis., Eng'g, & Med., *The Role of Inducement Prizes: Proceedings of a Workshop–in Brief* (2020).

[39] Daron Acemoglu *et al.*, *Prizes and Patents: Using Market Signals to Provide Incentives for Innovations* (Fed. Reserve Bank of Minneapolis, Working Paper No. 673, 2008).

[40] Senator Sanders has been the lead sponsor of a series of bills that would delink drug innovation and drug supply through prize awards instead of patents and statutory exclusivities. For instance, the Medical Innovation Prize Fund Act introduced in March 2017 would establish an annual prize fund equal to 0.55% of U.S. GDP administered by a board and six advisory committees. S.495, 115th Cong. (2017). Prizes would be based on the assessed health benefits of a drug, with priority for neglected global diseases, orphan drugs and global infectious diseases. This legislative proposal builds on the proposals of Love and Hubbard and others. See, for instance, James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 Annals Health L. 155 (2009).

Patents would only function to secure eligibility for funding rather than create exclusivity rights and all legislative programs providing incentives for drug development through the award of exclusive marketing periods would be eliminated. This would include exclusivity under Hatch-Waxman, and special targeted incentives such as pediatric and orphan drug exclusivity, although these areas could remain as priorities for government prizes. Firms would be eligible to receive payments from a revolving "Fund for Medical Innovation Prizes," with the amount determined by a Board, paid for a period of "not more than 10 fiscal years, regardless of the term of any related patents."[41]

Below, we review estimates of the upfront cost to government and taxpayers if the public sector were to become responsible for direct R&D financing for new medicines, as provided for in this or similar proposals. In addition, we highlight some conceptual efficiency challenges in substituting upfront government funding for private sector IP rights incentives. We then consider voluntary prizes as alternatives to mandatory ones, as well as targeted policy approaches in situations where market incentives may be insufficient to achieve desired levels of innovation investment.

A. Estimated Costs of Replacing Private Sector R&D with Government Upfront Funding and Impact on NIH Budget

There have been several recent estimates of the replacement cost of a government-financed system that maintains the same level of NME approvals. Chakravarthy *et al*. estimated the upfront government R&D replacement costs that would be necessary to maintain the same level of FDA-approved NMEs during the 2003 to 2011 period at $41.2 billion per year for all new therapeutic approvals ($23.6 billion for the drugs rated as first-in-class or advance-in-class by the FDA).[42] They found this exceeded the annual total NIH budget during this period ($25.9 billion) by 59%, noting that only a small percentage of the NIH budget is devoted to applied research on drug development. Government funding for health care research therefore would have to increase to 2.5 times the NIH budget to maintain the same number of NMEs during this period, and nearly double to maintain the same number of first-in-class or advance-in-class drugs. The estimates excluded

[41] S. 495, 115th Cong. (2017), Section 9(d)(3).
[42] Chakravarthy *et al*., *supra* note 33.

non-R&D costs such as manufacturing, distribution, and other operational and administration-related costs.

Building on this approach and updating it to include more recent periods and key assumption values, Proudman *et al*. estimate the replacement cost to maintain the same number of annual NME approvals during the 2018-2022 period (an average of 49 NME approvals per year).[43] They estimate the uncapitalized costs to replace private-sector R&D funding for one year of FDA approvals was $139.6 billion, or 302% of the total NIH budget for 2022 ($46.2 billion), or approximately 25 times the estimated $5.6 billion dedicated to clinical trials for pharmaceuticals.[44]

Several factors account for the increase in the estimated replacement cost of public for private investment between the Chakravarthy *et al.* and Proudman *et al.* estimates. First, there has been a substantial increase in both NME approvals and private sector R&D spending since the earlier study. The average annual number of NME approvals in the 2018-2022 period of 49.4 was more than double the figure of 24 in the prior 2003-2011 analysis. Second, the proportion of NMEs classified as first-in-class or advance-in-class has also increased. While they represented just under half of NMEs in an analysis spanning 1987-2002, they represented 63% of approvals for 2018-2022. Replacement costs would therefore be higher than those observed in the earlier analysis, both in absolute terms and when compared to the NIH budget, which has grown more modestly.

Another important driver is a riskier R&D process. Several studies have found a significant downward trend in the probability of success for new drug candidates[45], which leads to a corresponding upward trend in average R&D costs per approved NME. These developments result in a challenging environment from a budgetary standpoint for the introduction of a government funding approach that would replace the current IP-based system.

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[43] They multiply estimates of the out-of-pocket costs at each clinical trial stage by the probability of moving to succeeding stages and eventually securing FDA marketing approval. Pre-clinical and post-clinical costs are then added to obtain an estimate of average out-of-pocket costs per approved NME. Calculations reflect R&D clinical costs based on Wouthers *et al*., success probabilities on IQVIA, and preclinical and post-clinical costs on DiMasi *et al*.

[44] Proudman *et al*., *supra* note 33.

[45] For a summary, see, Global Health Ctr., Graduate Inst. of Int'l & Dev. Stud., *Research Synthesis: Time and Success Rates of Pharmaceutical R&D* (2020), [, https://www.knowledgeportalia.org/r-d-time-and-success-rate]; Also, see BIO, Informa Pharma Intelligence & QLS Advisors, *Clinical Development Success Rates and Contributing Factors 2011–2020* (2021).[https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020].

In addition, the earlier Chakravarty *et al.* study does not include any risk-adjusted return on investment required for private firms to undertake R&D under a government-funded prize approach. By excluding any opportunity cost, it underestimates the prize level necessary to attract private investment. To provide a return that is risk-adjusted for alternative competing investments, Proudman *et al.* incorporate a cost of capital for pharmaceutical companies, based on the baseline value of 10.5% employed in recent R&D cost analyses.[46] The addition of the capitalized cost component increases upfront government funding replacement costs to $209 billion, or more than 400% of the total 2022 NIH budget.

Finally, these estimates do not include any costs for program administration, or post-approval distribution and education. Generic drugs compete primarily on price and do not have an incentive to invest in promotion or educational activities, given low-cost free entry by rivals. To maintain these investments, these costs would also have to be government-funded.

There would be some offsets to the increases in government spending in the form of lower average drug prices in government-provided health care programs (from even higher rates of generic-level utilization), indeed that is an objective of such proposals. However, lower prices also would be expected to stimulate increased usage of prescription drugs, so it is difficult to estimate what the net effect on government spending would be.

B. Economic Efficiency Challenges

Beyond the practical obstacle of the substantial upfront government spending that would be required to implement a replacement for the billions of dollars in privately funded investment under the current system, there are a number of other implementation challenges that would need to be overcome.

Information Barriers and Asymmetry**.** Under a reward or prize system, to establish the optimal prize amount, the prize awarder needs information about the social value of the innovation, which may not be available to it. Private firms are likely to be better positioned to track evolving information about scientific opportunities, markets, and patient needs, which they use to modify development path investment decisions. For instance, if pre-determined performance targets for prizes set years in advance of drug approval and launch do not reflect later scientific advances or

[46] See for instance, DiMasi *et al., supra* note 19; Wouters *et al., supra* note 19.

evolving clinical knowledge, firms may adopt overly narrow or inflexible approaches, leading to suboptimal societal value.

Transaction Costs. The cost to administer a comprehensive prize system, including the cost of resolving disputes over whether projects have achieved specified objectives, needs to be considered. Due to efficiency losses, costs to achieve the same outcomes would be expected to be higher than under currently dispersed private decision-making, which has the benefit of greater decision flexibility. In a historical review of prize schemes and technology policy in multiple countries, Khan concludes, "A systematic assessment of the role of incentives for innovation in the nineteenth century highlights the advantages of market-oriented policies which economize on information, especially in the decentralized determination of prize, value and winners. Market mechanisms also bypassed many of the high transaction costs attendant on negotiating, monitoring and contracting with applicants and winners."[47] Spulber (2015) observes that"(p)rize advocates tend to assume the government would expend no resources in administering the prize fund, including managing contests, selecting winners and allocating inventions…The government could not replace the entire patent system with contests and awards in every area of science and technology by the patent system without incurring astronomical administrative costs."[48]

The "Hold-Up" Problem. Even if the information concerning the social value of a new medicine could be reasonably estimated (either *ex ante* before development, at drug approval/launch, or post-launch, as relevant under the prize structure), there may be incentives to undercut the expected reward value below that justified by the evidence. This so-called "hold-up" or "time inconsistency problem" is particularly an issue in the case of projects with lengthy development timelines, where firms invest substantial sunk costs on the basis of *ex ante* expectations of the prize amount (or agreed-upon contract value). Their relative negotiating power is therefore much diminished by the time the prize is awarded, with the government purchaser able to extract terms that if offered *ex ante* would be insufficient to justify the investment.[49] When faced

[47] B. Zorina Khan, *Inventing Prizes: A historical Perspective on Innovation Awards and Technology Policy* (Nat'l. Bureau of Econ. Research, Working Paper No. 21375, 2015).
[48] Daniel F. Spulber, *Public Prizes versus Market Prices: Should Contests Replace Patents?*, 97 J. Pat. & Trademark Off. Soc'y 690 (2015).
[49] Researchers have documented impacts in a number of fields, including vaccines, incentives for reduced quality in prison contracts, agriculture, and telecommunications utilities. See, for instance: Michael Kremer, Jonathan Levin & Christopher M. Snyder, *Advance Market Commitments: Insights from Theory and Experience*, 110 AEA Papers & Proc. 269 (2020); Oliver Hart, Andrei Shleifer & Robert W. Vishny, *The Proper Scope of Government: Theory and*

with even much-reduced prize values, firms would have little alternative to accepting the reduced amount, as then nearly all of their costs would be sunk. In addition, government budgetary pressures years later could result in arbitrary reductions in prize value. The potential for actual prize awards below anticipated values would lead to higher uncertainty and reduced risk-taking by innovators.

A historical example of this phenomenon of reduced *post hoc* government-set prize value versus licensing values set by the private market can be found in atomic energy programs after World War II. The U.S. Atomic Energy Act of 1946 established a Patent Compensation Board (PCB) to confer monetary awards for inventions related to military uses of atomic energy, which by law were not eligible for privately-owned patents. Fermi's patent on the production of radioactive isotopes, a foundational step in the process for producing plutonium, was awarded only $300,000 by the PCB. In addition, the PCB awarded only one million dollars for Robert Goddard's basic liquid rocket engine patents. As F.M. Scherer concluded, "Compared to the value of the inventions and the profits that might have been earned if exclusive patent rights could have been enforced, the Fermi and Goddard awards were miserly."[50]

Political Pressure and Rent-Seeking. Under a broad prize-based system, the areas selected for prizes and the amount of those prizes would come under tremendous pressure. While they might be determined by expert committees charged with awarding the prizes to the drugs with the highest assessed health benefits, assessments would be difficult to do in a completely objective and accurate way given they would be subject to the administrative burdens and information constraints discussed. They would be set with absent or limited market signals, and decisions would inevitably reflect the experiences and perspectives of committee members, which could be different than the preferences of the broader public. In Khan's historical analysis of prize systems that predominated in nineteenth-century Europe, she concludes that "Administered arrangements failed to induce inventions at appropriate prices, perpetuated errors because of a lack of monitoring

an Application to Prisons, 112 Q.J. Econ. 1127 (1997); Tomislav Vukina & Porametr Leegomonchai, *Oligopsony Power, Asset Specificity, and Hold-up: Evidence from the Broiler Industry*, 88 Am. J. Agric. Econ. 589 (2006); Hamish R. Gow & Johan F. Swinnen, *Up-and Downstream Restructuring, Foreign Direct Investment, and Hold-up Problems in Agricultural Transition*, 25 Eur. Rev. Agric. Econ. 331, 331–50 (1998); and M. Ariff, E. Cabanda & M. Sathye, *Privatization and performance: evidence from telecommunications sector*, 60 J. Oper. Res. Soc. 1315 (2009).

[50] F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 458 (2nd ed. 1980).

and feedback, and were associated with rent-seeking and significant deadweight losses. By contrast, market-oriented policies in the United States generated increasing returns associated with its larger and more diverse population of inventors and useful ideas, which encouraged self-sustaining endogenous growth and a global technological advantage that has persisted for well over a century."[51]

Prize award decisions for pharmaceutical innovations would be subject to lobbying from individuals and interested advocacy groups. As a result, political influence and rent-seeking activity could distort the selection of disease areas, or the amount of the prizes. The recent debate on whether Medicare should pay for weight reduction drugs, even in the case of medically obese patients illustrates the type of priority-setting issues such committees would face that could influence drug development decisions.

Underinvestment in Follow-on Innovation and Reduced Value for Serendipitous Innovation**.** Progress often occurs step-by-step as successive "best-in-class" and "advance-in-class" drugs are introduced in a therapeutic area. Approximately two-thirds of new drug introductions currently receive these designations by the FDA. Even for drugs that are considered "additions-to-class" (neither first-in-class, nor advance-in-class), there is clinical value in a variety of agents being available, given idiosyncratic, unpredictable patient responses. A study by Jena *et al.* found that when the first-in-class drug experienced initial generic entry, there was little impact on the demand for competing follow-on brand drugs in the same class, indicating that these follow-on drugs were viewed as therapeutically differentiated and clinically beneficial by patients and physicians.[52] In areas like oncology, there is extensive post-approval research, resulting in new indications and formulations with beneficial health effects.[53] Depending on how prizes were specified, another structural challenge could be reduced incentives for clinically valuable advances falling outside those rewarded by the prize system. These areas could include under-investment in follow-on innovation, and reduced incentives for unanticipated, serendipitous discoveries not encompassed by pre-specified prize awards.

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[51] KHAN, B. ZORINA, INVENTING IDEAS. PATENTS, PRIZES AND THE KNOWLEDGE ECONOMY (2020), Abstract.
[52] Anupam B. Jena *et al.*, *'Me-Too' Innovation in Pharmaceutical Markets*, 12 Forum for Health Econ. & Pol'y 1 (2009).
[53]See, for instance Henry Grabowski, Joseph A. DiMasi & Genia Long, *Postapproval Innovation For Oncology Drugs And The Inflation Reduction Act*, 43 Health Aff. 1400 (2024).

Global Free-Riding Incentives. If the United States were to unilaterally replace biopharmaceutical patents with a mandatory prize system, there could be global spillover issues with unintended adverse consequences. Countries with international reference price control schemes could free-ride by importing U.S. generic-level launch prices into their regulated price schemes, without any corresponding investment in R&D. Even if U.S. prizes were set at a level where manufacturers were "made whole" for the expected reduction in patent and exclusivity-driven U.S. prices, ex-U.S. prices referencing U.S. prices would drop, reducing manufacturers' innovation incentives and increasing free-riding on U.S. R&D. Recognizing such negative spillover problems, some previous proposals have embedded prizes schemes into a broader "Medical Research and Development Treaty (MRDT)" intended to maintain minimum innovation investment levels.[54] Under an MRDT, countries would be required to contribute a fixed GNP percentage to medical R&D. However, these proposals would face significant implementation problems. Getting all or most countries to agree to contribute a fixed portion of GNP year after year is unlikely, and a credible enforcement mechanism would be needed.[55]

C. Voluntary Prize Awards

In comparison to mandatory prize schemes, some proposals allow for voluntary firm choice between the patent-based regime and the new prize/"patent buyout" route. These voluntary approaches aim to mitigate the potential disincentives for innovation associated with compulsory approaches, while still capturing the benefits to purchasers of lower initial prices.

For instance, one proposal (Kremer, 1998) involves government offers "to purchase patents at their estimated private value, as determined in an auction, plus a markup to capture the inventions' full social value. Most patents purchased would be placed in the public domain, but to induce bidders to reveal their valuations, a few would be sold to the highest bidder."[56] Patent holders could choose between existing patent-based protections and the patent buy-out auction system.

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[54] *Medical Research and Development Treaty: Discussion Draft 4* (Consumer Project on Tech., 2005), http://www.cptech.org/workingdrafts/rndtreaty4.pdf. Also see, Jeffrey Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D*, 40 U.C. Davis L. Rev. 679 (2007)

[55] James A. DiMasi & Henry G. Grabowski, *Should the patent system for new medicines be abolished?*, 82 Clin. Pharmacol. Ther. 488, 488–90 (2007).

[56] Kremer, *supra* note 2.

Shavell and van Ypersele (2001) conclude that an optional choice between a patent and a prize is economically preferable to patent-only or prize-only regimes. They note that a voluntary choice regime would address an incentive to under-invest in research under a patent-only system (because private benefits from patents are less than social benefits), and when the reward is accepted in lieu of patent rights, it provides increased consumer surplus benefits to consumers as prices drop to marginal costs through free generic entry.[57]

More recently, Hylton (2024) reviews previous prize approaches and proposes, rather than constraining the options to a choice between patents and prizes, a "patent-plus-prize" system in which the patentee receives both the patent and a prize that approximates consumer surplus.[58] This proposal addresses the issue of underinvestment in innovation and maximizing associated societal benefits; it does not address the corresponding objectives relating to accelerating the achievement of lower pricing, The author also notes that this scheme would likely face substantial political opposition.

Voluntary prize schemes[59] have some major advantages over compulsory ones in terms of the incentives for innovation and avoidance of the inefficiencies discussed earlier. If a patentee always has the option to refuse the award and retain their IP rights to patents and legislative exclusivity, political hold-ups or government confiscation concerns are minimized. However, there may be cases where the patentee would come under strong political pressure to accept the prize and forgo enforcement of their IP rights, even when the prize is significantly undervalued (for example, a cure for Alzheimer's disease). These pressures to limit prices are especially strong when price-sensitive government purchasers represent a major share of sales. Prior examples include

[57] "We next consider the optional reward system, under which an innovator may choose between a patent and a reward. This system unambiguously dominates patent." Steven M. Shavell & Tanguy van Ypersele, *Rewards versus Intellectual Property Rights*, 44 J.L. & Econ. 525 (2001).
[58] Keith N. Hylton, *A Patent and a Prize*, 20 Rev. L. & Econ. 413 (2024). "Under an ideal prize system, the patentee would receive the entire consumer surplus generated by his innovation as a prize– and thus would innovate whenever the social benefit from innovation exceeds the cost. Under the patent system, by contrast, the patentee does not receive the entire consumer surplus from his innovation."
[59] Also called "inducement prizes" in a report of a National Academy special committee, to distinguish prizes that are "designed to stimulate innovative activity, whether it be the creation of a desired technology, orienting research efforts toward designing products that are capable of being used at scale by customers, or developing products with wide societal benefits" as opposed to "prizes that recognize past achievements." Nat'l Acads. of Scis., *supra* note 38.

pressure on launch pricing for hepatitis C drugs (where, notably, competition among agents was successful in quickly reducing acquisition prices).[60]

Information and administrative challenges still exist in voluntary schemes. For example, one analysis (Shavell and van Ypersele, 2001) notes voluntary prize valuations would be subject to information and administration challenges and also would be subject to political influence and rent-seeking.[61] In another (Kremer, 1998), patent buyouts and valuations would be based on third party auctions, moderating some of the possible political influences, but information and administrative issues still remain in such complex auction schemes, along with other distortions from an optimal prize approach.[62]

Despite these potential public choice issues, voluntary prize schemes could be a useful supplemental option in the "policy toolbox" in cases where social returns are high, but market failure due to uncertain or limited market returns and incentives under the existing patent and IP framework leads to systematic underinvestment. In these instances, one advocate of prize schemes acknowledges limitations to the prize approach: "the prize fund would not replace patents. It would be part of the portfolio of methods for encouraging and supporting research."[63]

D. U.S. Prize Programs and Other Targeted Supplements to Patent Incentives

Some limited U.S. prize programs already exist. For example, the America COMPETES Reauthorization Act of 2010 provided authorized federal agencies to award prizes to stimulate innovation with potential to advance their missions.[64] Between 2011 and 2024, the NIH reported it had run 130 prize competitions, with total prizes offered nearing $85 million.[65] Examples include: the Long COVID Computational Challenge and the Rare Diseases are Not Rare! 2020

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[60] "Competitive pressures pushed the average annual cost of treatment down from $55,500 in 2015 to $14,400 by 2019." Garrison *et al. supra* note 31. Other examples include pressure on HIV therapy pricing.
[61] Shavell and Ypersele *supra* note 57.
[62] Kremer, *supra* note *2*.
[63] Stiglitz suggests further, "A prize fund would work well in areas in which needs are well known – the case for many diseases afflicting the poor – allowing clear goals to be set in advance. For innovations that solve problems or meet needs that have not previously been widely recognized, the patent system would still play a role." Stiglitz *supra* note 3.
[64] *America COMPETES Reauthorization Act of 2010*, Pub. L. No. 111-358, 124 Stat. 3982 (2011).
[65] Challenge.gov, *Federal Innovation Through Prize Competitions: National Institutes of Health*, CHALLENGE.GOV (Nov. 12, 2024), https://www.challenge.gov/blog/2024-11-12-national-institutes-of-health-webinar/.

Challenge. [66] The NIH summarizes the specific role of these prize competitions (also called "challenge grants"): "Compared to other mechanisms, prize competitions offer a lower barrier to entry allowing for increased participation and unanticipated solutions to challenges. Historically, prize competitions have also stimulated private sector investment in critical need areas. NIH has used prize competitions and challenges to set ambitious goals to be solved in a relatively short timeframe without high levels of risk by only paying for results."[67]

Antibiotic drugs are an example where prizes have been proposed. There has been a dearth of new antibiotics even as the problem of antibiotic resistance has grown. This is because powerful new antibiotics are kept "on the shelf" to meet future emergencies, reducing incentives for R&D on new agents. As noted, Congress has extended the market exclusivity period for antibiotics, but this does not directly address the disincentive associated with limited and uncertain demand. There have been proposals for advanced market guarantees and supplemental prize awards to address this problem.

Another area that has received attention is the development of drugs and vaccines for neglected diseases like malaria, leishmaniasis and Chagus, tropical diseases with large disease burdens in relatively poor countries. In such examples, supplements to the patent system may be needed to encourage R&D.[68] For example, advanced market guarantees, where public and private donors commit to help finance drugs and vaccines by committing in advance to certain levels of market demand, is one response. In the past, the Group of Eight finance ministers provided a pilot project in which five donor countries (UK, Italy, Canada, Russia, Norway) along with the Gates Foundation pledged $1.5 billion in 2007 toward an Advanced Market Commitment (AMC) program to encourage the development and production of a pneumococcal vaccine for low-income

[66] "The Long COVID Computational Challenge was an Analytics challenge run in 2022 with the goal of identifying who might be suffering from long term Covid using predictive AI with a total cash prize of $500,000. Rare Diseases are Not Rare! 2020 Challenge was a Design challenge sponsored by the National Center for Advancing Translational Sciences. This challenge was centered around finding innovative ways to communicate about rare diseases through social media or art with a total awards [sic] of $5,000." *Ibid*.
[67] *Ibid*.
[68] Others have raised the related concern that if developing countries refuse to honor patents, it undercuts incentives for firms to invest in drugs for such diseases.

countries. Under this program, three vaccines were developed and more than 150 million children vaccinated. It has been estimated to have saved more than 700,000 lives.[69]

Other complementary policies for neglected disease include the previously-discussed U.S. Priority Review Voucher (PRV) incentive that is targeted to a set of 27 tropical diseases that would otherwise receive little development investment.[70] In this program, the prize for FDA approval of medicine for tropical diseases is a transferable voucher entitling the holder to an FDA Priority Review for a medicine that would otherwise be reviewed under the standard guidelines.[71]

IV. Conclusion

The current R&D ecosystem is a dynamic system in which both public and private actors play critical and complementary roles. Government funding of basic research and private sector pharmaceutical development of new medicines encouraged by IP rights and protections have been key elements, along with vigorous generic competition when IP rights expire. Numerous studies document the improvements in public health and societal gains from this system of collaborative interactions and market competition.

Nonetheless, proposals have suggested replacing the market-based system of intellectual property rights in biopharmaceuticals that motivate private sector investment with a mandatory and comprehensive administrative system of government-funded prizes or contracts. Such proposals would eliminate all forms of market exclusivity and the enforcement of private patent rights. The goal would be to realize lower average drug prices earlier, by allowing generic entry at the time of FDA approval (since prize awards would replace patent rights).

However, a mandatory system of prizes would be subject to significant information and administrative barriers and high transaction costs. Another major issue would be the incentive for government to undercut the expected value of a new medicine prize. This is the so-called "hold-

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[69] For an economic analysis of this AMC pilot program and its design and implementation issues, see: Michael Kremer, Jonathan D. Levin & Christopher M. Snyder, *Advance Market Commitments: Insights from Theory and Experience* (Nat'l Bureau of Econ. Research, Working Paper No. 26775, 2020).

[70] See, FDA. Tropical Disease Priority Review Voucher Program. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program. Last accessed 6/5/25.

[71] Rewards for research outputs (such as prizes and advanced market commitments) are "pull" strategies, and subsidies for research inputs are "push" strategies. In neglected diseases, push strategies include public-private partnerships such as Medicines for Malaria Ventures (MMV) and Drugs for Neglected Disease initiative (DNDi) that garner resources and facilitate collaborative research between pharmaceutical firms, universities and public health organizations to address unmet medical needs in less-affluent countries.

up" problem when a firm makes substantial sunk cost investments on the basis of *ex ante* expectations of the prize amount (or agreed-upon contract value), but its relative negotiating power is much-diminished by the time the prize is awarded. Administered prize systems relying on expert decisions rather than market forces also have less transparency and error correction mechanisms and can be subject to intensive political influences and rent-seeking by participants.

Pragmatic factors also are important considerations. Systems which substitute public for private capital imply major upfront public outlays to maintain the same level of innovation investment, in the hope that they will be offset by earlier generic-level average pricing. Given mounting pressure on public sources of funding for biopharmaceutical basic research that are critical elements of the current innovation ecosystem, wholesale replacement of private risk capital for public funding sources seem unlikely to garner broad legislative support.

In contrast to a full mandatory replacement approach, targeted prize schemes and voluntary prize options can be useful supplements to existing economic incentives in circumstances where social returns are high, but intellectual property rights provide weak incentives for R&D investment. Neglected diseases and antibiotics are prominent examples where prize programs can bolster market R&D incentives. It is important to continue exploring areas where supplemental policy strategies and prizes can provide positive welfare benefits in underinvested areas.