

ARTICLE

SHOULD PRIZES REPLACE PATENTS? A CRITIQUE OF THE MEDICAL INNOVATION PRIZE ACT OF 2005

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I. FROM PATENTS TO PRIZES

The Medical Innovation Prize Act of 2005 (the proposed Act) proposes a prize system to augment the incentives of the current patent system.¹ The proposed Act would allow the government to set specific goals and direct research to certain areas. The benefits of a prize system are untested and are unlikely to dislodge the deeply entrenched patent system. But infeasibility does not necessarily mean that one should totally discard the idea of a prize system, particularly because shortcomings of the patent system are becoming more obvious. This paper suggests a small-scale, optional prize system that

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¹ See Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. (2005) (“The purpose of this Act is to provide incentives to invest research and development of new medicines by establishment of a Medical Innovation Prize Fund . . .”).

will provide insight into how companies will participate and invest in research and development (R&D). The optional system will at least allow the government to work out the details of, and increase industry confidence in, a larger prize system.

A. *Misguided Innovation, “Me-Too” Drugs, and Deadweight Losses*

The monopoly power associated with the patent system is defended on the grounds that granting patents stimulates R&D.² However, this rationale is under intense scrutiny in the area of medical innovations. Critics point out that the patent system and other exclusive rights contribute to high drug prices, global health inequities, limited access to potentially life-saving medicines and medical technologies,³ and the production of drugs that have little incremental therapeutic value, such as follow-on drugs that are substantially similar to established blockbuster drugs (so-called “me-too” drugs).⁴ The patent system rewards patent owners when they can market their patented products to patients who can pay significant rents that cover the cost of research, development, and marketing. Under the current patent system, pharmaceutical companies have little incentive to invest in R&D for low-return, and consequently neglected, diseases or other “non-profitable” diseases.⁵ Moreover, monopoly rents make drugs unaffordable in developing countries, resulting in substantial welfare losses. The World Health Organization estimates approximately ten million lives could have been saved with access to existing medicines and vaccines.⁶ The deadweight loss of monopoly pricing of

² Lee N. Davis, *Should We Consider Alternative Incentives for Basic Research? Patents vs. Prizes* 6 (Paper presented to the DRUID Summer Conference, Copenhagen/Elsinore, June 6-8, 2002, available at www.druid.dk/conferences/summer2002/Papers/DAVIS.pdf (noting that the empirical basis of the claim that patent system induces innovation is weak or uncertain at best).

³ See Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005); Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188 (2002).

⁴ See Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 6 (Jan. 17, 2005) (Working paper), available at <http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf> (noting that many commentators have criticized the growing numbers of products that duplicate the therapeutic value of already existing drugs – so-called “me-too” drugs). For an argument favorable toward “me-too” drugs for creating competition, see Thomas H. Lee, *“Me-too” products: Friend or Foe?*, 350 NEW ENG. J. MED. 211 (2004).

⁵ See Trouiller et al., *supra* note 3, at 2191; see also Kapczynski et al., *supra* note 3, at 1042-57 (explaining that 10% of the world’s expenditure on R&D is spent on targeting 90% of the disease burden).

⁶ Kapczynski et al., *supra* note 3, at 1046.

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drugs⁷ is anywhere between \$3 billion to \$30 billion annually for the U.S. drug market alone.⁸

B. The Medical Innovation Prize Fund Proposal

Many different proposals for improving access to medicines or addressing R&D gaps have been set forth.⁹ In particular, different prize systems have been suggested.¹⁰ Some suggestions include variations on government buyouts of patents:¹¹ opt-in systems where the government pays at least the monopoly profits that the patent holder would expect to receive¹² or a system where patents are exchanged for compensation through an auction.¹³ Other suggestions include offering a cash subsidy to consumers who value the patented product more than the marginal cost but cannot afford the patented product at a monopoly price.¹⁴

Advocates of prize systems point out that prizes allow government intervention where private markets have failed due to lack of investment in R&D for the public good.¹⁵ Advocates further argue that prize systems reward economically valuable innovations that are not patentable. Further, prize-givers are able to target particular problems and specify criteria for awarding the prize money, thereby stimulating R&D and providing *ex ante* incentives to achieve a particular goal.¹⁶ The government can thus use prize systems to

⁷ See *id.* at 1044. See also Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1059 (2005). (defining deadweight loss as including pure loss to society when consumers do not get a product that they value more than the cost of producing it).

⁸ Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK Q. 213, 226 (1995).

⁹ See Kapczynski et al., *supra* note 3, 1058-68 (discussing top-down changes and private sector voluntary concession strategies).

¹⁰ For a discussion of four major prize systems, see Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 127-70 (2003).

¹¹ For an early proposal of a prize system, see Michael Polanyi, *Patent Reform*, 11 REV. ECON. STUD. 61 (1944).

¹² Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, (2001).

¹³ See Michael Kremer, *Patent Buyouts: Mechanisms for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1147-48 (1998) (describing an auction mechanism for patent buyouts).

¹⁴ Douglas Gary Lichtman, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 HARV. J. L. & TECH. 123, 124 (1997).

¹⁵ For a discussion of public good projects, including a brief look at health care R&D, see James Love & Tim Hubbard, *Paying for Public Goods*, in CODE: COLLABORATIVE OWNERSHIP AND THE DIGITAL ECONOMY 207-29 (Rishab Aiyer Ghosh ed., 2005).

¹⁶ See Davis, *supra* note 2, at 10 (describing the use of prizes to stimulate R&D).

signal the importance of certain problems. By lowering barriers to entry, prize systems are also able to encourage nontraditional parties to participate.¹⁷

The Medical Innovation Prize Act of 2005 offers some of the benefits of a prize system. The proposed Act defines a prize system for all “medical innovation[s] relating to a drug, a biological product, or a new manufacturing process for a drug or biological product.”¹⁸ Prize payments would be distributed from a Medical Innovation Prize Fund (MIPF). The payments would total 0.5% of GDP of the preceding fiscal year.¹⁹ The MIPF would be distributed to meet three underlying goals: 1) to provide incentives for R&D investment in new and significantly better medicines; 2) to enhance access to medicines;²⁰ and 3) to focus more resources in non-profitable areas such as global infectious diseases, “orphan drugs” and neglected diseases.²¹

The MIPF can reduce incentives to produce “me-too” drugs compared to the patent system.²² Because the MIPF would reward innovations based on incremental benefit, the largest prizes would be awarded to first-in-class drugs. Accordingly, the proposed Act encourages parties to invest in major breakthrough drugs, rather than trying to improve drugs in existing classes.²³ In contrast, while the patent system creates similar incentives to be first,²⁴ the patent system allows later-arriving firms to garner profits through successful marketing. . Nevertheless, a prize system comes with many known costs as well. The question is not simply whether the prize system can resolve the problems of the current patent system, but also whether the known costs ultimately outweigh the relative advantages of a prize system over the existing patent system.

¹⁷ *NASA Contests and Prizes: How Can They Help Advance Space Exploration?: Hearing Before the Subcomm. on Space and Aeronautics H. Comm. on Science*, 108th Cong. 42-43 (2004) [hereinafter *NASA Contests*] (statement of Douglas Holtz-Eakin, Director, Congressional Budget Office).

¹⁸ Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(a) (2005).

¹⁹ *Id.* § 16.

²⁰ *Id.* § 3.

²¹ *Id.* § 10(b).

²² See MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 74-93 (2004) (arguing that the pharmaceutical industry currently chooses to profit at a low cost by aggressively marketing these “me-too” drugs).

²³ However, some argue that it is better to have a wide variety of drugs in the same class because the drugs are more perfected and patients have more options. See Lee, *supra* note 4; John Gapper, *In Praise of Big Pharma’s Me-Too Drugs*, *FIN. TIMES*, Dec. 2, 2004, at 19. But see David A. Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 *NEW ENG. J. MED.* 1350 (1994).

²⁴ See Abramowicz, *supra* note 10, at 183-90 (discussing patent races).

C. *Historical Examples*

The controversy between a patent and prize systems reaches as far back as the nineteenth century.²⁵ Instead of patents, early commentators proposed “bonuses” granted to inventors by the government, professional associations financed by private industries, intergovernmental agencies, or an international association funded by private industries.²⁶ However, these proposals did not garner much support. The primary objection was that the “administration would give rise to partiality, arbitrariness, or even corruption—the dangers of all institutions giving discretionary power to administrators.”²⁷ This powerful objection applies equally to the MIPF and is explored in Section II.D.

Nineteenth century critics of prize systems had reason to worry given the experience of one of the most prestigious and well-established prize systems of that time, the Royal Academy of Science in Paris, which served as a model for scientific societies in other countries during the eighteenth and nineteenth centuries.²⁸ The lack of a central authority or specific policy for prize distribution made nineteenth century prize systems contentious.²⁹ Academy members were at odds when trying to determine which fields should receive general prizes. Such disputes were only partly resolved by commissions represented by multiple disciplines.³⁰ At the same time, prizes were becoming increasingly a matter of money, not honor. Prizes as financial rewards overshadowed traditional honorific prizes by the third quarter of the nineteenth century.³¹

The shift to monetary rewards only exacerbated the existing tensions within the Academy. Members of different disciplines became jealous that other sections funded specific contests.³² In 1825, establishment of the well-endowed Montyon Fund devoted to medical innovations heightened such tensions.³³ Unlike other prizes, the Montyon Fund did not state the amount of

²⁵ See generally Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1(1950).

²⁶ *Id.* at 19.

²⁷ *Id.* at 20.

²⁸ See generally Maurice Crosland & Antonio Gálvez, *The Emergence of Research Grants within the Prize System of the French Academy of Sciences, 1795-1914*, 19 SOC. STUD. SCI. 71-73 (1989).

²⁹ *Id.* at 76.

³⁰ *Id.* at 89.

³¹ See *id.* at 76 (describing increased competition as a result of financial rewards of the system).

³² See *id.* at 76 (describing the competition of sections in reaction to the chemistry section’s Jecker contest).

³³ See *id.* at 79-84 (discussing the disagreement between medical and non-medical

the prize ahead of time, but stated that prize-winners “will receive recompense proportional to the service which they have rendered, either by preventing or considerably diminishing the unhealthy effects of certain trades or by contribution to the improvement of the medical sciences.”³⁴ With the large sums available under the Montyon Fund, tensions between the medical and non-medical members in the Academy grew. In the end, the administrators of the fund reached a compromise under which they would award funds to candidates in non-medical areas through “encouragements,” or grants.³⁵ These encouragements were awarded largely in secret, leading some to speculate that the system was corrupt.³⁶ This led to the overall decline of setting prize questions as a way of directing research.³⁷

The experiences of the French prize system of the nineteenth century, and particularly the Montyon Fund, suggest that prize systems are vulnerable to internal disputes. The French experience further suggests that scientists will balk at being “forced” to direct research toward a prize question. This is particularly true when scientists feel that their own area of research is being undervalued compared to other technical areas. These difficulties also illustrate the importance of a central authority and a specific policy on how to judge entries. In response to these problems, the Paris Academy eventually shifted away from prizes toward a grant system for funding and directing scientific research.³⁸

After the French experience, prize systems became less prominent³⁹ and

Academicians over the distribution of the Moynton Fund, particularly in the 1840s).

³⁴ *Id.* at 78.

³⁵ *See id.* at 83-84, 94 (describing use of the Moynton surplus for non-medical subjects).

³⁶ *Id.* at 94.

³⁷ From 1807 to 1827, the Academy was able to use prize questions effectively. *Id.* at 93. In the few years after the Montyon Fund was established in 1825, the Academy set a prize for developments in a bladder surgical procedure, which successfully stimulated research in the area. *Id.* at 92. Also, the Breant prize in 1858 for the cure of cholera encouraged research into infectious diseases generally, but the prize was never awarded. *Id.* at 92. Notably, several prize questions did not generate sufficient interest or were too difficult, and this strategy of directing research declined. *Id.* at 92.

³⁸ The shift toward grants was not easy at the time, however: “The traditional idea of prizes as rewards for past achievement was deeply ingrained in the Academy, and to make a more flexible system required several decades of negotiation both between the different interest groups within the Academy and between the Academy and potential donors.” *Id.* at 73.

³⁹ For a discussion of the use of prizes in the twentieth century, see Lee Davis & Jerome Davis, *How Effective Are Prizes as Incentives to Innovation? Evidence From Three 20th Century Contests (May 7, 2004)* (unpublished manuscript, presented at DRUID Summer Conference), available at <http://www.druid.dk/conferences/summer2004/papers/ds2004-114.pdf>.

limited to specific goals. Examples of such limited prize systems include aviation prizes like the Orteig Prize won by Charles Lindbergh in 1927, the Ansari X Prize established in 1996,⁴⁰ and the Defense Advanced Research Project Agency's (DARPA's) challenge contest.⁴¹ The Nobel Prize and the Pulitzer Prize are modern examples of honorific prizes that reward outstanding achievement retrospectively, but are not designed to create *ex ante* incentives for research. Today, some federal prizes exist to recognize scientific accomplishments, but these prizes are mostly honorific rather than monetary.⁴²

Modern proposals for patent reform via prize systems appeared as early as 1944.⁴³ The literature on prizes has been small compared to patent literature.⁴⁴ Still, prize systems have gained recent attention⁴⁵ The next Part will examine objections to the prize system more closely and consider whether a prize system would be better than the current patent system.

II. PROBLEMS WITH PRIZE SYSTEMS: THE DEVIL IN THE DETAILS

One of the fundamental problems with a prize system as a patent alternative is that the government does not have enough information about how a prize system compares with the patent system. The value of a prize system depends on the details of its administration. This Part uses the MIPF proposal as an example to illustrate the costs of prize systems relative to the patent system.

⁴⁰ The X Prize, established in 1996, promised a \$10 million prize for the first privately-funded team to build a 3-person spacecraft and was awarded in 2004. See X PRIZE Foundation: What Is an X PRIZE?, <http://www.xprize.org/xprizes> (last visited Jan. 10, 2007).

⁴¹ See *NASA Contests*, *supra* note 17, at 45 (describing DARPA's 2004 competition).

⁴² See *id.* (discussing the Malcolm Bladrige National Quality Award and the Vannevar Bush award for public service in science and technology).

⁴³ See generally Polanvyi, *supra* note 11.

⁴⁴ Eric A.A. de Laat, *Patents or Prizes: Monopolistic R&D and Asymmetric Information*, 15 INT'L J. INDUS. ORG. 369, 370 n.2 (1996). See generally Davis, *supra* note 2; Avinash Dixit, *A General Model of R&D Competition and Policy*, 19 RAND J. ECON. 317 (1988) (proposing a prize system to resolve the common pool problem in R&D races); Barry J. Nalebuff & Joseph E. Stiglitz, *Prizes and Incentives: Towards a General Theory of Compensation and Competition*, 14 BELL J. ECON. 21 (1983); Shavell & van Ypersele, *supra* note 12; Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AMER. ECON. REV. 691 (1983).

⁴⁵ For a list of literature on prizes for medical innovation, see Papers on Prizes and Other Proposals for More Accessible Medical Innovation, <http://www.cptech.org/ip/health/prizefund/other-articles.html#CPTech> (last visited Feb. 22, 2007). For literature on prize systems more generally, see Background on General Prizes for Innovation, <http://www.cptech.org/ip/health/prizefund/background.html#Economics> (last visited Feb. 22, 2007).

But the ultimate question of whether the costs outweigh the benefits of a prize system over a patent system remains open. This question can only be answered empirically. The question would be best answered by a pilot program that experiments with and perfects the administration of the system.

As it stands now, the proposed Act has an ambitious reach given the lack of empirical evidence supporting its relative benefits over a patent system. Few studies have focused on the economic effects of prizes,⁴⁶ and there is “no academic consensus on how a prize system should work.”⁴⁷ However, this may be a weak objection, given that the patent system is defended as providing appropriate incentives for R&D—a claim that is not supported by much empirical proof either. Nevertheless, this paper proposes a cautious approach to implementing a prize system, including seeking more data on prize systems before overhauling the patent system.

A. Determining Prize Spending and Values of Prize Payments

The Achilles’ heel of any prize system is its administration, including the ability for the government to distribute prizes.⁴⁸ One fundamental problem of prize systems is determining how much to spend on the prize system overall and how much to value and award individual innovations. If the prize is too low, then the system will inadequately stimulate R&D investment. If the prize is too high, then costs such as resource duplication and favoritism will be exacerbated. These problems will be discussed in following sections.

The proposed Act partly addresses the problem of overcompensation by capping both the overall amount that the MIPF receives annually and the amount that the Board of Trustees can award for any prize payment.⁴⁹ Because all unused funds revert to the Treasury, the proposed Act does not address the problem of undercompensation.⁵⁰

Kremer offers another response to the problem of maneuvering between the

⁴⁶ Davis, *supra* note 2, at 3.

⁴⁷ Abramowicz, *supra* note 10, at 121.

⁴⁸ *See id.* (“Prize system advocates recognize that the devil is in the details and the devil for a prize system is the government’s ability to dispense rewards accurately.”).

⁴⁹ *See* Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. §§ 9(d)(3), (d)(4), 16(b) (2005) (describing both spending and the cap on spending). Capping the overall amount that the agency can spend through congressional appropriation reduces the risk of agency capture and the risk of over or undercompensation of projects. Abramowicz, *supra* note 10, at 125-26.

⁵⁰ *See* Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 21 (2005) (“Any . . . funds that are unexpended . . . shall revert to the Treasury”); Abramowicz, *supra* note 10, at 125 (noting that Congress could mandate that the fund be spent in order to avoid undercompensation of projects).

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Scylla of undercompensation and Charybdis of overcompensation.⁵¹ He suggests starting with low payments at first, and then raising the payments to stimulate the desired amount of R&D.⁵² This method assumes that one has at least a ballpark range of what constitutes an appropriate low offer. This method also assumes knowledge of the “desired” amount of R&D in any particular area of drug or medical development. Kremer’s method further assumes that the government will be able to monitor and interpret the timing of investment responses to changes in prize amounts. The challenges of prize determination are tied up in underlying difficulties of information asymmetry between the government and the competing companies and the valuation of absolute and relative health benefits of drugs and other medical innovations.

1. Information Asymmetry

The impact of information asymmetry between the government and companies in patent and prize systems depends on the nature of the information.⁵³ On one hand, Wright shows that if the government is less informed about the costs of innovations, then prizes and contracts are better than patents. In this situation, prizes and contracts can generate the same reward structure as patents, without the welfare loss of monopolistic prices.⁵⁴ On the other hand, if the government does not know the private or social benefits of the innovation, then patents are better as a reward structure.⁵⁵ However, pharmaceutical companies do not currently release information about the costs of innovation by product.⁵⁶ Therefore, compared to pharmaceutical companies, the government may be better at estimating the private or social benefits of medical innovations but less adept at estimating

⁵¹ Michael Kremer, *Creating Markets for New Vaccines Part II: Design Issues 4* (Nat’l Bureau of Econ. Research, Working Paper No. 7717, 2000), available at <http://www.nber.org/papers/w7717>.

⁵² *Id.*

⁵³ For a comparison of the effect of different types of asymmetric information on the welfare properties of patent and prize systems, see de Laat, *supra* note 44, at 380-383. The study concludes that the relative efficiency of patents is less than prize systems where the government is less informed about the market for the innovation. *Id.* at 383.

⁵⁴ Wright, *supra* note 44.

⁵⁵ *Id.*

⁵⁶ See F.M. Scherer, *The Link Between Gross Profitability And Pharmaceutical R&D Spending*, 20 HEALTH AFF. 216 (2001) (noting that most diversified pharmaceutical companies rarely report operating margin results in enough detail to associate R&D indices with measures of profitability). For a view that R&D expenditures of pharmaceutical companies should be treated as investments into a portfolio of different drugs, rather than as *ex ante* costs and benefits of drugs, see F.M. Scherer, *The Pharmaceutical Industry- Prices and Progress*, 351 NEW ENG. J. MED. 927 (2004).

the cost of innovation. If this is the case, then prize systems are preferable.

2. Measurement of Value to Health and Setting Prize Payments

Some commentators argue that the ideal prize system should distribute rewards based on the social value of the innovation.⁵⁷ Others argue for a more modest prize system, where a company can opt into cash prizes that are a fixed proportion of the estimated social value in exchange for placing the company's innovation into the public domain.⁵⁸ The MIPF offers still another alternative, linking the size of the prize to its social value by awarding prizes based on a set of pre-determined criteria. The MIPF does not specify how much will be paid, but sets forth criteria by which the innovation will be judged. The government agency will distribute prize payments for any "medical innovation relating to a drug, a biological product, or a new manufacturing process for a drug or biological product."⁵⁹ The prize awards will be based on the following criteria: 1) the number of patients, including non-U.S. patients, benefited by the innovation; 2) the incremental therapeutic benefits of the innovation; 3) the degree to which the innovation addresses health care needs, including global infectious diseases, orphan illnesses, and neglected diseases affecting the poor in developing countries; and 4) the "[i]mproved efficiency of manufacturing processes for drugs or biological processes."⁶⁰

The proposed Act does not provide a formula for how the Board will determine the amount of each prize payment. Most companies will be forced to bear the risk of innovation because these companies will not know what to expect.⁶¹ The factors that the proposed Act does mention, like number of people treated by the medicine, are rough guidelines (at best) and oversimplistic standards (at worst) for judging the benefits of different drugs.⁶² This lack of clarity, which is partly attributable to the difficult task of

⁵⁷ See Joseph A. Dimasi & Henry G. Grabowski, *Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D* (Submission to Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), World Health Organization, June 25, 2004), <http://www.who.int/intellectualproperty/news/en/Submission3.pdf>.

⁵⁸ See William A. Masters, *Research Prizes: A Mechanism to Reward Agricultural Innovation in Low-Income Regions*, 6 *AGBIOFORUM* 71 (2003) (describing payments that would be used to "buy the innovation into the public domain.").

⁵⁹ Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9 (2005).

⁶⁰ *Id.* at § 9(c).

⁶¹ Even if there were an equation, companies will likely dispute what numbers should be entered for the variables.

⁶² See Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 9(c) (2005) (describing the criteria for selecting recipients and determining the size of the prize).

measuring the value to health in the first place, opens MIPF prize payments up to major disputes and to political influence.⁶³

Commentators are split on whether a predetermined, complex formula to measure the “social value” of a drug or product would be helpful or any less costly to administer than an open-ended approach.⁶⁴ Two options for measuring the social value of a drug or product are to use quality-adjusted life years (QALYs)⁶⁵ or disability-adjusted life years (DALYs)⁶⁶. Both options have significant limitations.⁶⁷ Another proposal for measuring the social value of a drug or product is to announce a fixed dollar amount per incremental value to health, perhaps as measured by QALYs.⁶⁸ Under yet another proposal for measuring the social value of a drug or product, companies could submit results of “head-to-head” studies with drugs in the same class for the agency to evaluate. Companies are reluctant to conduct comparative studies, however,⁶⁹ and when conducted, the company that funds the study usually proves that its own drug comes out ahead, while rival studies show conflicting results.⁷⁰

Under the proposed Act, the government will encounter certain nuanced problems involved with comparing drugs whenever it attempts to evaluate the benefits of a drug or medical product. First, the proposed Act remains silent on whether off-label drug use⁷¹ will be considered when calculating the overall

⁶³ See *NASA Contests*, *supra* note 17, at 43 (testimony of Douglas Holtz-Eakin, describing unclear rules as an “invitation to conflict” and further describing the problems with the Federal Communications Commission’s auction of licenses and Pioneer’s Preference policy as examples). See also *infra* Section II.E (discussing costs of litigation and adjudication of disputes).

⁶⁴ See Abramowicz, *supra* note 10, at 206 (noting that it is unclear whether a more formalized process would be less costly than an open-ended approach).

⁶⁵ See generally David L. B. Schwappach, *Resource Allocation, Social Values and the QALY: A review of the debate and empirical evidence*, 5 HEALTH EXPECTATIONS 210 (2002) (reviewing the debate on the role of QALYs in setting priorities in a health-care).

⁶⁶ See generally Nuria Homedes, *The Disability-Adjusted Life Year (DALY) Definition, Measurement and Potential Use*, (World Bank, Working Paper), available at http://www.worldbank.org/html/extdr/hnp/hddflash/workp/wp_00068.html (last visited Jan. 10, 2007); Trude Arnesen & Erik Nord, *The Value of DALY Life: Problems with Ethics and Validity of Disability Adjusted Life Years*, 319 BRITISH MED. J. 1423 (1999) (discussing the problems with using DALY as a way of expressing the burden of disease).

⁶⁷ See Hollis, *supra* note 4 (describing the use of QALYS and DALYS in a prize fund).

⁶⁸ See *id.* at 28 (proposing a reward based on a “pre-announced amount per QALY.”).

⁶⁹ See *id.* at 17 n.34 (“Companies rarely undertake comparative studies voluntarily, since it is ‘playing with fire.’”)

⁷⁰ See e.g. Shankar Vedantam, *Comparison of Schizophrenia Drugs Often Favors Firm Funding Study*, WASH. POST, Apr. 12, 2006, at A1 (noting that head-to-head trials of drugs usually favor the company sponsoring the trial).

⁷¹ The Food and Drug Administration (FDA) requires that the drug label information

social benefit of the drug. Such off-label uses are common⁷² but not well-studied by companies. These uses take much longer to realize and, thus, could be overlooked, leading to undervaluation of such drugs. This undervaluation of the social benefit of a drug may be particularly worrisome where off-label uses are most common, such as in the treatment of AIDS, cancer, and pediatric illnesses.⁷³

Second, administrators of the MIPF must confront the difficulty of drawing a line between medically necessary drugs and drugs that provide lifestyle benefits (e.g. acne medication or Viagra). Drugs that provide both medical benefits and lifestyle enhancements—certain psychotherapeutic drugs, for instance—present challenges in prize determination. The struggle of insurance companies with this classification issue suggests that the administrators of the MIPF would face similar problems.⁷⁴

Third, administrators rewarding drug discovery based simply on the total number of patients served or QALYs might unfairly disadvantage certain minorities. Is an ACE inhibitor that is much more effective for hypertension in more patients overall and for more white patients more valuable than a diuretic or calcium channel blocker that helps fewer patients overall, but more African American patients in particular?

Fourth, the Board would have to decide how to handle negative information about the drug that emerges after prize payment has already been awarded,

indicate certain approved doses and routes of administration for a particular condition. An “off-label” use is the use of a drug for a disease that is not listed on the label, or in a dose or by a route not listed on the label. Jacquelin van de Kamp, U.S. Dept. of Health and Human Services, Off-Label Use of Prescription Drugs, in *CURRENT BIBLIOGRAPHIES IN MEDICINE* 92-11, (1992), available at <http://www.nlm.nih.gov/archive/20040830/pubs/cbm/offlabel.html>.

⁷² Certain drugs are more commonly prescribed for off label uses, and particular patient populations (e.g., oncology patients) are more frequently prescribed drugs with off label uses. See U.S. GEN. ACCOUNTING OFFICE, OFF LABEL DRUGS: REIMBURSEMENT POLICIES CONSTRAIN PHYSICIANS IN THEIR CHOICE OF CANCER THERAPIES 4 (1991) (“GAO found that 56 percent of . . . cancer patients were given at least one drug off-label, and about a third of them received at least one drug for a treatment not cited in the compendia); Susan G. Poole & Michael J. Dooley, *Off-label Prescribing in Oncology*, 12 *SUPPORTIVE CARE CANCER* 302, 303 (2004) (showing that 85% of oncology patients were prescribed a drug for off-label use).

⁷³ Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescribing*, 5 *INDEP. REV.* 25, 26 (2000).

⁷⁴ Devora Mitrany, *Lifestyle Drugs: Determining Their Value and Who Should Pay*, 19 *PHARMACOECONOMICS* 441 (2001) (noting ambiguity and confusion surrounding the imprecise concepts of medical necessary and lifestyle drugs in the context of insurance coverage); Debi Reissman, *The Pros and Cons of Covering Lifestyle Drugs*, 6 *DISEASE MANAGEMENT & HEALTH OUTCOMES* 249 (1999).

such as in the recent Vioxx controversy.⁷⁵

In addition to valuation problems, the government may struggle with administrative problems. The proposed Act does not specify any screening mechanism to ensure that the studies and reported benefits of the drugs are accurate. A company producing a rival drug will likely dispute a competitor's relative efficacy studies. Therefore, a screening mechanism to review submitted information about drug results and studies will be necessary.⁷⁶ The Board must also deal with the difficult issue of awarding the prize at the right time. Without a specific stated goal, the MIPF risks prematurely awarding certain innovations that may not be the most deserving. Each of these issues could be a controversial battleground for stakeholders' interests, making it difficult to form a specific prize policy and leaving the system vulnerable to political pressures or inefficiency.

The National Institutes of Health (NIH) provides a useful comparison and starting point for defining a prize system. The NIH is an example of a smoothly run organization with significant experience distributing its large annual budget of \$28.4 billion as *ex ante* funding for research projects.⁷⁷ The Board could use the NIH's rigorous priority setting peer-review system as a template for its own system.⁷⁸ It is notable, however, that even a well-organized, long-standing system like the NIH is not completely immune to criticism, contention among different research groups,⁷⁹ or external political

⁷⁵ See Alex Berenson, *Follow-up Study on Vioxx Safety is Disputed*, N.Y. TIMES, May 13, 2006, at C3 (describing "a 64 percent higher risk of cardiac problems among [patients] who had taken Vioxx, compared with a placebo.").

⁷⁶ See Abramowicz, *supra* note 10, at 181 (discussing the need for screening mechanism of claims reported to those determining prize amounts); Davis, *supra* note 2, at 17 (noting that inaccurate information creates difficulties in determining who should win the prize).

⁷⁷ See *Fiscal 2007 Appropriations Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the Comm. on S. Appropriations*, 109th Cong. (2006) (statement of Dr. Elias A. Zerhouni, Director, National Institutes of Health), available at <http://www.nih.gov/about/director/budgetrequest/fy2007directorsbudgetrequest.htm> ("The request for NIH is \$28.4 billion in FY 2007, the same as the FY 2006 level for the Agency.").

⁷⁸ See generally COMM. ON THE NIH RESEARCH PRIORITY-SETTING PROCESS, INST. OF MEDIC., SCIENTIFIC OPPORTUNITIES AND PUBLIC NEEDS: IMPROVING PRIORITY SETTING AND PUBLIC INPUT AT THE NATIONAL INSTITUTES OF HEALTH (1998).

⁷⁹ One example has been the controversy surrounding funding of clinical research in comparison to basic science research. See Alan N. Schechter, *The Crisis in Clinical Research: Endangering the Half-Century National Institutes of Health Consensus*, 280 JAMA 1440, 1441 (1998) (arguing that patient-oriented research suffers from the NIH review process compared to basic science studies and, as a result, certain diseases and clinical research are underfunded); David G. Nathan, *Clinical Research: Perceptions*,

and lobbyist pressures.⁸⁰ Despite these issues, the NIH has managed to allocate funding in a way that is at least purportedly correlated to the burden of various diseases, depending on how this burden is measured—a matter which is itself controversial and difficult to resolve.⁸¹

Some proposals for prize systems try to get around an agency determination of the optimal prize by using market mechanisms. A pilot program could experiment with these strategies. Kremer suggests auctions to determine how much should be paid in a government patent buyout.⁸² Guell and Fischbaum, in their proposal for a prize system for prescription drugs, suggest that the government use the power of eminent domain to take patents for public use and provide just compensation to the patent holders as determined through a market test.⁸³

Other proposals recommend an optional rather than mandatory prize system to alleviate the risk inherent in having the government estimate prize

Reality, and Proposed Solutions, JAMA 1427, 1427-28 (1998) (comparing NIH funding of clinical versus basic science research); Theodore A. Kotchen, et al., *NIH Peer Review of Grant Applications for Clinical Research*, 291 JAMA 836, 836 (2004) (finding that grant application outcomes for clinical research fared less well than basic science/laboratory research applications).

⁸⁰ Despite the common goal of trying to increase the pot of money available for research funding in general, several lobbying organizations and legislators grew divisive and complained that certain diseases were not getting their fair share of NIH's budget growth. For example, the Parkinson's Action Network claimed that "in 1994, NIH spent more than \$1000 per affected person on HIV/AIDS research but only \$93 on heart disease and \$26 on Parkinson's . . .". Eliot Marshall, *Lobbyists Seek to Reslice NIH's Pie*, 276 SCIENCE 344-46 (1997). NIH officials responded that critics were making simplistic arguments. *Id.* at 346. See also Cary P. Gross et al., *The Relation Between Funding by the National Institutes of Health and the Burden of Disease*, 340 NEW ENG. J. MED. 1881, 1885 (1999) ("[E]xternal pressure can also influence funding priorities. It was partially in response to such pressure that the Institute of Medicine panel recommended that the NIH explicitly compare the burden of disease and the amount of research funding."); Ernest Istook, Jr., *Research Funding on Major Diseases is not Proportionate to Taxpayers' Needs*, J. NIH RES, Aug. 1997, at 26, 26-28; Christopher Anderson, *NIH budget: A New Kind of Earmarking*, 260 SCIENCE 483 (1993) (discussing executive branch earmarking of NIH funds toward specific diseases).

⁸¹ See Gross et al., *supra* note 80, at 1883-84 (finding that the number of deaths and years of life lost, based on estimates in the United States, were weakly correlated with amount of NIH funding to that disease, while the number of disability-adjusted life-years was strongly correlated with funding).

⁸² See Kremer, *supra* note 13, at 1147 (describing an auction mechanism for patent buyouts).

⁸³ See Guell & Fischbaum, *supra* note 8, at 220-25. *But see* Abramowicz, *supra* note 10, at 128-36 (criticizing the market test proposed by Guell & Fischbaum).

payments.⁸⁴ However, commentators are split on whether a mandatory system or an optional one is preferable.⁸⁵ In an optional system, the government calculates the lowest possible social surplus (or slightly more in order to induce more innovators to accept the optional reward) and offers that amount. Companies can turn down the optional prize and opt for a patent instead. Thus, the companies that would participate in this opt-in system would be those that estimate that the government is offering to pay more than is necessary.

Nevertheless, an optional system can be adjusted to overcome the potential problem of overpayment without having to move to a mandatory system. Abramowicz suggests that a patent holder's decision to opt-in to a prize system could be made irrevocable.⁸⁶ A company would not be able to withdraw its decision to participate in the prize system upon learning the amount. This may work initially but seems unlikely to continue to work as companies figure out how prizes are calculated and become better at estimating expected prize awards. The government might counter this problem by not releasing prize payments publicly even after payments are awarded to companies. But, this solution compromises the transparency of the prize system and leads to an alternative problem of less public accountability. Only a pilot program can truly determine the costs and benefits of each of these proposed mechanisms.

B. Duplication of Resources

Pharmaceutical companies vying for a prize may work in overlapping areas. The prize system may thus lead to the inefficient result of duplication of resources.⁸⁷ However, this is a problem that applies to the patent system as well.⁸⁸ One can only speculate whether the prize system will result in greater duplication of resources than the patent system. In the proposed Act, the criteria of prize payments are broad enough to allow companies to work in many non-overlapping areas, but these criteria also include minimum levels of funding for certain diseases.⁸⁹ These areas may be subject to more duplication

⁸⁴ See Masters, *supra* note 58, at 71 (describing a system that allows “innovators to choose between [patent] protection and a sale to the public sector.”); Shavell & van Ypersele, *supra* note 12, at 525-26 (demonstrating that an optional reward program can be better than a patent system).

⁸⁵ See Abramowicz, *supra* note 10, at 142 (discussing that it is unclear whether a mandatory or optional system would be better).

⁸⁶ *Id.* at 123-24.

⁸⁷ See Lee Davis, *Intellectual Property Rights, Strategy and Policy*, 13 *ECON. INNOVATION & NEW TECH.* 399, 411 (2004) (noting that a prize system may result in duplication of resources).

⁸⁸ See Abramowicz, *supra* note 10, at 185-86 (noting resource duplication in patent races as well).

⁸⁹ See Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 10 (2005)

of resources.

One might reduce duplication by forcing contestants to publish progress reports. The same argument for disclosure of research activities and preemptive publishing has been made for patents.⁹⁰ However, such a requirement might have adverse effects, such as discouraging companies from participating or investing R&D toward the prize.⁹¹

The prize system may have additional ways of addressing duplication of resources that are not available to patent systems. Abramowicz suggests that a prize system could reward companies which release preliminary research; or allow shared rewards, which could lead to more collaborative research efforts.⁹² It remains unclear, however, whether these suggestions would create a system any less costly than the patent system.

C. Loss of Commercial and Marketing Development

Even assuming that the prize system can accurately value new medical innovations, replacing the patent system may eliminate incentives for commercialization.⁹³ When winning entries of the prize system are released into the public domain or when participants lose the right to exclusive marketing, as under the MIPF,⁹⁴ companies may lack sufficient incentives to develop the product commercially. Some have pointed to the example of penicillin, an unpatented discovery, which companies did not refine or market until 15 years after its discovery.⁹⁵ The concern for the loss of commercialization and marketing, however, should be weighed against possibly wasteful marketing that the industry currently employs, especially for drugs have little therapeutic benefit.⁹⁶

To counter the lack of incentives to develop a drug commercially, a prize

(specifying the initial minimum levels of funding under the Act).

⁹⁰ See Abramowicz, *supra* note 10, at 187-88.

⁹¹ See Davis, *supra* note 87, at 411 (noting that requiring progress reports as part of a prize system might discourage potential entrants).

⁹² *Id.* at 189 (“[p]roposals for patent prize systems . . . cannot be faulted for causing redundant research relative to the existing patent systems. But . . . [a]n ideal prize system would allow for shared rewards in context in which shared rewards are more efficient . . .”).

⁹³ See F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 705-17 (2001).

⁹⁴ See H.R. 417 § 4(a) (eliminating the exclusive right to market drugs and biological products under the prize system).

⁹⁵ See Davis & Davis *supra* note 39, at 21 (discussing the discovery and further refinement of penicillin). See also Lee Adler, *Time Lag in New Product Development*, J. OF MARKETING, Jan. 1966 at 17, 21.

⁹⁶ See Hollis, *supra* note 4, at 9 (noting that some types of marketing increase market share of a particular firm, but do little to benefit society as a whole).

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system can be arranged in a few different ways. Besides allowing the winner to patent innovations, which the MIPF does not allow, the government can incorporate incentives to bring drugs to market by deferring prize payments until there has been some degree of commercialization.⁹⁷ Another important way to overcome the loss of commercialization of the innovation is to use an opt-in system.⁹⁸

D. Administrative Costs

1. Industrial Influence, Agency Capture, and Risk of Favoritism

Among the strongest, and oldest, objections to the prize system is the risk of the system resulting in a distorted allocation of resources. The story of industrial influence in shaping intellectual property rights is both familiar and disheartening.⁹⁹ The MIPF is unlikely to be an exception to the political economy. The proposed Act creates a Board of Trustees for the MIPF as a permanent part of the executive branch. The Board of Trustees is responsible for awarding prize payments, and will “be composed of 13 members as follows: (1) [t]he Administrator of the Centers for Medicare & Medicaid Services[;] (2) [t]he Commissioner of Food and Drugs[;] (3) [t]he Director of the National Institutes of Health[;] (4) [t]he Director of the Centers for Disease Control and Prevention[;] and (5) [n]ine members appointed by the President, with the advice and consent of the Senate.”¹⁰⁰

These Board positions are potentially vulnerable to political and industrial pressures.¹⁰¹ The problem lies not only in those who award prize payments, but also in those who determine the rules in the first place. Manipulation of the rules of the prize system can result in sub-optimal distribution of rewards.¹⁰² To the extent that companies will invest resources to influence the members of the Board of Trustees, their respective organizations, or other administrators who determine or implement the rules of the prize system, the costs of such wasteful activities may outweigh the prize system’s relative advantage over the patent system. The Board the proposed Act creates is

⁹⁷ Kremer, *supra* note 51, at 14-16 (suggesting co-payment agreements for development of new vaccines).

⁹⁸ See Abramowicz, *supra* note 10, at 175 (discussing the method for rewarding commercialization under the Shavell-van Ypersele approach).

⁹⁹ See WILLIAM LANDES & RICHARD POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* (2004).

¹⁰⁰ Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. §§ 6-7 (2005).

¹⁰¹ See Davis, *supra* note 2, at 17-18.

¹⁰² See Chen Cohen & Aner Sela, *Manipulations in Contests*, 86 *ECON. LETTERS* 135-39 (2005).

potentially more susceptible to political influences compared to the more broadly diverse committees and scientist-concentrated, peer reviewed process that determines NIH allocation of funds, which itself suffers from political pressures.¹⁰³

The historical examples discussed in Section I.C demonstrate that prize systems can become plagued by rent-seeking and favoritism. The patent system is not wholly without rent-seeking of its own, with private companies seeking to influence government regulation.¹⁰⁴ However, the PTO is relatively independent and lobbying for directly beneficial legislation is uncommon.¹⁰⁵ A review of the different organizations on the proposed Board of Trustees suggests that the prize system may be more vulnerable to problems of rent-seeking and favoritism than the existing patent system.

One might hope that the agencies represented on the Board of Trustees would be immune to industrial pressures, but history suggests otherwise. In 1962, the FDA began to use external scientific advice in reviewing all new and existing drugs for efficacy and safety.¹⁰⁶ Many of the members of the 18 standing FDA advisory committees on drug approvals have ties with the industry, including financial connections to drug companies.¹⁰⁷ The FDA put into place conflict of interest policies and the requirement to disclose any financial interests. However, the disclosure of financial ties was insufficient, given that influence can come in forms other than financial interests.¹⁰⁸ Despite conflicts of interest policies and a waiver process regulating the relationships between its members and the industry, the Food and Drug

¹⁰³ See *supra* note 80 and accompanying text.

¹⁰⁴ See Abramowicz, *supra* note 10, at 209-11 (discussing the problem of rent-seeking through regulation, with studies showing that political contributions have a significant impact on legislator's votes).

¹⁰⁵ *Id.* at 210-11.

¹⁰⁶ COMM. TO STUDY THE USE OF ADVISORY COMMS. BY THE FOOD AND DRUG ADMIN., INST. OF MED., FOOD AND DRUG ADMINISTRATION ADVISORY COMMITTEES 37 (Richard A. Rettig et al. eds., 1992) [*hereinafter* IOM REPORT].

¹⁰⁷ See ANGELL, *supra* note 22, at 210-11 (discussing the financial connections between interested companies and FDA committee members); Elizabeth R. Glode, *Advising Under the Influence?: Conflicts of Interest Among FDA Advisory Committee Members*, 57 FOOD & DRUG L.J. 293, 300 (2002) (“The issue of public disclosure of committee members’ financial conflicts and other advisory committee information is an on-going problem with which the agency must grapple.”).

¹⁰⁸ See *id.* at 306 (“[U]sing financial interests as a measure of potential bias is only a rough proxy—financial ties may or may not influence a committee member’s views, and there is no sure way to determine whether an expert’s investments or employment affect his/her [performance] as an advisor to the FDA.”).

Administration has suffered much criticism over their “loose standards”¹⁰⁹ toward conflicts of interest with the industry.¹¹⁰

One example of the power of this influence was the behind-the-scenes pressure during the nomination of the FDA commissioner in 2002. The nomination of Dr. Alastair Wood was withdrawn at the last minute. This withdrawal was reportedly due to pressures on the Bush White House by the pharmaceutical industry, which opposed Dr. Wood’s support for strong regulatory action by the FDA. Senator Bill Frist explained that “[t]here was a great deal of concern that [Wood] put too much emphasis on [drug] safety.”¹¹¹

Instead, Dr. Mark McClellan, brother of then-White House Press Secretary Scott McClellan and a physician with views much more aligned with the pharmaceutical industry, was appointed as the new FDA commissioner.¹¹² In 2003, Dr. McClellan advocated for higher drug prices in developing countries as a solution to the disparity between drug prices in the United States and other countries.¹¹³ He also supported higher prices to cover R&D costs and direct-to-consumer advertising as a benefit to public health.¹¹⁴ Angell describes Dr. McClellan’s positions as consistent with “a speech that could have been written by PhRMA [sic].”¹¹⁵ Dr. McClellan was later appointed to another prominent position in early 2004: the Administrator of the Centers for Medicare & Medicaid Services. Incidentally, this position is also on the Board of Trustees of MIPF.¹¹⁶

The Director of the National Institutes of Health (NIH) has not always represented a research institution isolated from industry pressures either. In fact, in 1995, the then-director of the NIH, Harold Varmus, actually lifted the strict restrictions on the amount that NIH senior scientists, including the director, could earn from outside work or the time that they could devote to it.¹¹⁷ It was not until 2005, as a result of pressure from Congress and public, that the NIH promulgated stricter regulations on ties between NIH and the industry.¹¹⁸ This suggests that a prize system can address political pressures by

¹⁰⁹ See *id.* at 313 (quoting a Committee on Government Reform report that characterized the FDA’s conflict procedures as “loose standards”).

¹¹⁰ See *id.* (summarizing the conflicts of interests of FDA advisory committee members, as detailed in a report by the Committee on Government Reform).

¹¹¹ ANGELL, *supra* note 22, at 212.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ See *id.* at 212-13 (criticizing Dr. Mark McClellan’s statements).

¹¹⁵ *Id.* at 213.

¹¹⁶ Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 7 (2005).

¹¹⁷ See Robert Steinbrook, *Financial Conflicts of Interest and the NIH*, 350 NEW ENG. J. MED. 327 (2004).

¹¹⁸ See *id.*

borrowing from the NIH structure and shifting the responsibility of awarding prizes away from the Board itself.

The three representatives on the Board representing consumer and patient interests may offset pressures from industry imposed on other Board members. But even patient advocacy groups are not immune to industry pressures. Angell claims that some patient groups are even “fronts for drug companies” in which “[s]ome people aren’t even aware that a drug company is behind their advocacy group.”¹¹⁹ Pharmaceutical companies have, in fact, sponsored coalitions that look like grassroots efforts in education.¹²⁰ One important method of checking favoritism is through complete transparency, which James Love and Tim Hubbard have emphasized as the key to ensuring fair allocation of resources in other public goods projects.¹²¹

2. Litigation Costs

In terms of other costs of administration, the prize system requires a mechanism for resolving disputes over prize payments and enforcing prize distribution. As the patent system demonstrates, when an agency distributes benefits, controversy over the distribution inevitably follows. Section 12 of the proposed Act addresses such problems during the transitional period, where parties can “determine equitable division of any prize payments” through an arbitration procedure established by the Board.¹²² However, the proposed Act remains silent on the issue of other adjudicatory processes for prize payments. It is unclear whether the prize system will generate more disputes and other socially wasteful activities than the current patent system.¹²³

Whether the prize calculation is a formulaic method or a more open decision-making process, the problem is that “[r]easonable people might disagree about how large a prize an applicant should receive.”¹²⁴ In defining the scope of allowable litigation, the Board will have to decide whether the benefits of litigation, including ensuring a more accurate distribution of prizes or allowing due process for applicants, outweighs the social costs to the executive and judicial branches. The relative costs of the prize system and the patent system in resolving disputes remains unknown.

¹¹⁹ ANGELL, *supra* note 22, at 151-52.

¹²⁰ *See id.* at 152 (describing examples of hepatitis C coalitions and education efforts sponsored by pharmaceutical companies).

¹²¹ *See* Love & Hubbard, *supra* note 15.

¹²² Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. § 12 (2005).

¹²³ *See* Abramowicz, *supra* note 10, at 210 (noting that the costs of rent-seeking activity associated with a prize system “might outweigh the benefits of a prize system relative to a patent system.”).

¹²⁴ *Id.* at 207.

III. A MORE MODEST PROPOSAL

The MIPF may be riddled with these specific costs of a prize system, but one should not lose sight of the much larger problem that the MIPF, as a mandatory system, is “both politically impossible to implement and quite risky given the unproven empirics of any prize proposal.”¹²⁵ However, despite the costs, some form of a prize system may still be more desirable than a patent system. As the previous discussion suggests, the MIPF has room for improvement and can borrow from other prize proposals. In light of the uncertainties and vulnerabilities, I suggest that a more modest prize system—one that is optional¹²⁶ and focuses on a particular gaps left unaddressed by current private sector or NIH funding.¹²⁷

Narrowing the prize system to a particular area of medicine will allow the rules for a particular set of diseases or medicines to be worked out. Such narrowing will further allow the government to estimate the expected costs of prize systems before enlarging the scope of the program. For example, the World Health Organization and the World Bank have suggested prizes for developing vaccines, with criteria that are tailored to vaccines. Masters also proposes an optional prize system for the agricultural industry to supplement patent systems in developing countries.¹²⁸ But even these narrow proposals will struggle from familiar design issues including: how to determine whether a vaccine deserves a prize; how to make sure a prize is not given prematurely in a way that would discourage other higher-quality vaccines; how to ensure that prizes are actually awarded; and how to handle disputes about awards.¹²⁹ Despite potential difficulties, a narrowly tailored program will serve as a valuable opportunity to evaluate the effectiveness and efficiency of a prize system.

The prize system is among several different approaches to supplementing patents, including “procurement contracts, publicly funded university research grants, subsidies to firms that conduct R&D, [and] tax deductions for certain R&D investments. . . .”¹³⁰ The government can also address access to medicines and the problem of neglected diseases through neglected disease

¹²⁵ Abramowicz, *supra* note 10, at 123.

¹²⁶ To avoid problems discussed in Section II.A, the prize system would be an irrevocable, opt-in prize system.

¹²⁷ See Schecter, *supra* note 79.

¹²⁸ See Masters, *supra* note 58 at 71 (proposing “a way to complement intellectual property rights (IPRs) and public investment with a [prize system], designed particularly to promote innovation [in agriculture] in the lowest-income regions such as Sub-Saharan Africa”).

¹²⁹ See Kremer, *supra* note 51.

¹³⁰ Davis, *supra* note 87, at 409.

clauses and innovative partnerships.¹³¹ As in basic science, the government can also direct research to certain areas of medicine through research grants, subsidies, or contracts.¹³² However, each of these suggested reform comes with its own set of costs and benefits.

Government grant or contract systems are unable to identify the kind of research that will lead to innovations which best improve health care. The government does not have a great track record for identifying the best company to perform this research—so much so that some authors have criticized this option as inefficient and a “recipe for disaster.”¹³³

The government also commonly solves public good problems through the tax system.¹³⁴ But a tax deduction for companies that invest R&D in socially valuable medical innovations has many of the same limitations as a contract system. The government lacks the knowledge of what should be invented.¹³⁵ Furthermore, the government does not know how much of a tax deduction is appropriate beforehand. Incorrect decisions about valuation will lead to the same problems of inadequate investment, investment in suboptimal products, or undercompensation and overcompensation.¹³⁶ Interest groups would then shift gears to lobby for exemptions.¹³⁷

Thus, the prize system could be used to supplement and close the gaps of both the patent regime and current NIH funding, while borrowing from the current institutional structure and mechanisms that the NIH employs to evaluate prize work and distribution more efficiently and effectively. Whether a prize system would be superior to the existing patent system, NIH funding, or other proposed reforms remains a question that is best answered empirically. The lack of empirical research on the effectiveness of prize systems suggests that a pilot program in prize systems would be the most helpful approach to weighing these costs against the patent system.

¹³¹ See Kapczynski et al., *supra* note 3, at 1109.

¹³² Abramowicz, *supra* note 10, at 130.

¹³³ Guell & Fischbaum, *supra* note 8. See also Michael Hart, *The Chimera of Industrial Policy: Yesterday, Today and Tomorrow*, 19 CAN.-U.S. L.J. 19, 36 (1993) (“Governments do not have a good track record for picking winners. . .”); Steve Charnovitz, *Designing American Industrial Policy: General Versus Sectoral Approaches*, 5 STAN. L. & POL’Y REV. 78, 85 (discussing the difficulty in selecting winners ahead of time).

¹³⁴ Randall G. Holcombe, *Tax Policy From a Public Choice Perspective*, 51 NAT’L TAX J. 359, 364 (1998).

¹³⁵ Guell & Fischbaum, *supra* note 8.

¹³⁶ See ROGER D. BLAIR & THOMAS F. COTTER, *INTELLECTUAL PROPERTY: ECONOMIC AND LEGAL DIMENSIONS OF RIGHTS AND REMEDIES* 15 n.21 (2005).

¹³⁷ *Id.*