

Should Prizes Replace Patents?
A Critique of the Medical Innovation Prize Act of 2005

Marlynn Wei¹

B.U. J. SCI. & TECH. L. (2007) (working paper)

Abstract

The Medical Prize Innovation Act of 2005 proposes replacing the current patent regime with a prize system. This paper is the first in the legal literature to evaluate and critique the weaknesses of such the proposed prize system. The prize system described in the Act faces challenges including, decisions of prize spending and values of prize payments, duplication of resources, loss of commercial and marketing development, and significant administrative costs. This paper looks both to historical and modern precedents to argue for a more modest change: a pilot program that distributes prizes in particular market segments to supplement the current patent regime and bridge gaps in NIH funding. The paper also suggests that a program could borrow from the NIH institutional structure, priority setting and review process as a workable starting point and also for comparison. Thus, one can observe the untested empirics of a prize system to better evaluate the impact and desirability for a total replacement of the patent system.

¹ JD, Yale Law School, 2007; MD, Yale School of Medicine, 2007. I am grateful to Professor Yochai Benkler for his generous and insightful comments. I would also like to thank Chad Flanders for his comments and support.

Should Prizes Replace Patents?
A Critique of the Medical Innovation Prize Act of 2005
Marlynn Wei

I. FROM PATENTS TO PRIZES	3
A. MISGUIDED INNOVATION, “ME-TOO” DRUGS, AND DEADWEIGHT LOSSES.....	3
B. THE MEDICAL INNOVATION PRIZE FUND PROPOSAL	4
C. HISTORICAL PRECEDENTS	6
II. PROBLEMS WITH PRIZE SYSTEMS: THE DEVIL IN THE DETAILS	8
A. DETERMINING PRIZE SPENDING AND VALUES OF PRIZE PAYMENTS	9
1. <i>Information Asymmetry</i>	10
2. <i>Measurement of Value to Health and Setting Prize Payments</i>	10
B. DUPLICATION OF RESOURCES	16
C. LOSS OF COMMERCIAL AND MARKETING DEVELOPMENT	16
D. ADMINISTRATIVE COSTS	17
1. <i>Industrial Influence, Agency Capture, and Risk of Favoritism</i>	17
2. <i>Litigation Costs</i>	20
III. A MORE MODEST PROPOSAL	21

I. From Patents to Prizes

The Medical Prize Innovation Act of 2005 proposes replacing the patent system with a prize system.² The change would allow the government to set specific goals and direct research to certain areas. The benefits of a prize system are untested and will not likely dislodge the deeply entrenched patent system, which has been successfully defended for many decades. But the political infeasibility does not necessarily mean that one should totally discard the idea, particularly since the shortcomings of the patent system are becoming more obvious. This paper suggests a small-scale, optional prize system so that we can observe how companies will participate and invest R&D. The optional system will at least allow us work out the details and increase our confidence in a 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 research and development (R&D).³ However, this rationale is under intense scrutiny. 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,⁴ and the production of drugs that have little incremental therapeutic value.⁵ In a system that rewards patent owners only when they can market their patented products to patients who can pay significant rents that cover the cost of research, development, and marketing, and cannot reflect social benefits that cannot be monetized in this fashion, pharmaceutical companies have little incentive to invest in R&D for low-return neglected diseases or other such “non-profitable” diseases.⁶ Moreover, the high prices, which reflect those rents, make

² H.R. 417, 109th Cong. (2005).

³ Lee N. Davis, *Should We Consider Alternative Incentives for Basic Research? Patents vs. Prizes* 6 (Paper presented to the DRUID Summer Conference, Elsinore/ Copenhagen, 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).

⁴ Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERK. 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).

⁵ Many authors have criticized the growing numbers of “me-too” drugs on the market, products that duplicate the therapeutic value of already existing drugs. See Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 6, available at <http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>; Youngme Moon & Kerry Herman, *Marketing Antidepressants: Prozac and Paxil*, available at <http://harvardbusinessonline.hbsp.harvard.edu>. For an argument favorable toward “me-too” drugs for creating competition, see Thomas H. Lee, “Me-too” products: Friend or Foe?, 350 NEW ENGL. J. MED 211 (2004).

⁶ Trouiller et al., *supra* note 4. See also Kapczynski et al., *supra* note 4, at 1042-57 (discussing the

those drugs that are created with wealthy markets in mind result in substantial welfare losses. The World Health Organization estimates approximately ten million lives could have been saved with access to existing medicines and vaccines.⁷ The deadweight loss of monopoly pricing of drugs⁸ is anywhere between \$3 billion to \$30 billion annually for the U.S. drug market alone.⁹

B. The Medical Innovation Prize Fund Proposal

Many different kinds of proposals have been set forth to improve access to medicines or address R&D gaps.¹⁰ Different prize systems have been suggested,¹¹ include multiple variations on government buyout of patents:¹² opt-in systems where the government pays at least the monopoly profits that the patent holder would expect to receive¹³ or a system where patents are exchanged for compensation through an auction.¹⁴ Others have suggested a coupon system that subsidizes consumers who value the patented product more than the marginal cost but cannot afford them at monopoly price.¹⁵

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,¹⁶ and reward economically valuable inventions that are not necessarily patentable. Prize-givers are able to specify particular problems and create a set of criteria for awarding the prize money, thereby stimulating R&D

R&D gap and how only 10% of the world's expenditure on R&D is spent on targeting 90% of the disease burden).

⁷ Kapczynski et al., *supra* note 4, at 1046.

⁸ *Id.* at 8 (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).

⁹ Dean Baker & Noriko Chatani, *Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research*, 2002, available at http://www.cepr.net/Promoting_Good_Ideas_on_Drugs.pdf; Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK QUARTERLY 213 (1995).

¹⁰ Kapczynski et al., *supra* note 4, 1058-68 (discussing top-down changes and private sector voluntary concession strategies).

¹¹ For a discussion of four major prize systems, see Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 127-70 (2003).

¹² For one of the earliest proposals of a prize system, see Michael Polanyi, *Patent Reform*, 11 REV. ECON. STUD. 61 (1944).

¹³ Steven Shavell & Tanguy van Ypersele, *Rewards versus Intellectual Property Rights*, 44 J. OF LAW & ECON. 525 (2001).

¹⁴ Michael Kremer, *Patent Buyouts: Mechanisms for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1147-48 (1998).

¹⁵ Douglas Gary Lichtman, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 HARV. J. L. & TECH. 123 (1997).

¹⁶ For a discussion of projects public good projects, including a brief look at the health care R&D situation, see James Love & Tim Hubbard, *Paying for Public Goods*, in CODE: COLLABORATIVE OWNERSHIP AND THE DIGITAL ECONOMY 207-20 (Rishab Aiyer Ghosh ed., 2005).

and providing ex ante incentives to achieve a particular goal.¹⁷ The government can signal the importance of certain problems through prize systems. Prize systems are also able to encourage nontraditional parties to participate since contests can lower the barriers to entry.¹⁸

The Medical Innovation Prize Act of 2005 has the benefits as a prize system. It proposes replacing the patent system with 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.”¹⁹ Prize payments would be distributed from a Medical Innovation Prize Fund (MIPF). The payments would be out of 0.5% of GDP of the preceding fiscal year.²⁰ The MIPF has three underlying goals: 1) to provide incentives for R&D investment in new, significantly better medicines; 2) to enhance access to medicines;²¹ and 3) to focus more resources on non-profitable diseases such as global infectious diseases, “orphan diseases” and neglected diseases.²²

The MIPF can reduce incentives to produce “me-too” drugs compared to the patent system. Since the MIPF would reward the drugs based on incremental benefit, the largest prizes will most likely be awarded to drugs that are the first in their class, encouraging investment 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 the first,²⁴ firms with similar drugs that arrive later may still garner large profits because of successful marketing strategies. But the 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,

¹⁷ Lee N. Davis, *Should We Consider Alternative Incentives for Basic Research? Patents vs. Prizes*. Paper presented to the DRUID Summer Conference, Elsinore/ Copenhagen, June 6-8, 2002, at 10.

¹⁸ Douglas Holtz-Eakin, *Economic and Budgetary Issues with Cash Prizes to Achieve NASA’s Objectives*, July 15, 2004, available at www.house.gov/science/hearings/space04/jul15/holtz.pdf (noting that prizes are most useful when the government seeks to have firms that might not otherwise participate in research through traditional procurement processes).

¹⁹ H.R. 417, §9(a).

²⁰ H.R. 417, § 16.

²¹ H.R. 417, § 3.

²² H.R. 417, § 10(b).

²³ However, some argue that it is actually better to have a wide variety of drugs in the same class since the drugs are more perfected and patients have more options. Thomas H. Lee, “*Me-too*” products: *Friend or Foe?*, 350 NEW ENGL. J. MED. 211 (2004); John Gapper, *In Praise of Big Pharma’s Me-Too Drugs*, FIN. TIMES, December 2 2004. For arguments against “me-too” drugs, see MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 74-93 (2004); David A. Kessler et al., *Therapeutic-Class Wars -- Drug Promotion in a Competitive Marketplace*, 331 NEW ENGL. J. MED. 1350 (1994).

²⁴ Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 183-90 (2003) (discussing the inefficiency of patent races such as excessive innovative activity and inefficient industrial structures).

but also whether these known costs would ultimately outweigh the relative advantages over the existing system.

C. Historical Precedents

The controversy between a patent system and prize system reaches as far back as the nineteenth century.²⁵ Instead of patents, 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 internationally.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 depth in Section II.D.

In fact, nineteenth century critics at the time had reason to worry, given the experience of one of the most prestigious and well-established prize systems at the time, the Royal Academy of Science in Paris.²⁸ The prize system in France served as a model for scientific societies in other countries during the late eighteenth and through the nineteenth century.²⁹ The lack of a central authority or specific policy for prize distribution made the prize system contentious and, some claimed, corrupt.³⁰ Academy members were at odds when trying to determine which scientists should receive general prizes; such disputes were only partly resolved by commissions in which different disciplines were represented.³¹ At the same time, prizes were becoming increasingly a matter solely of money, not honor. Prizes as financial rewards soon overshadowed the traditional honorific prizes by the third quarter of the nineteenth century.³²

This shift to monetary rewards only exacerbated the existing tensions within the Academy. Members of different disciplines became jealous that other sections funded specific contests.³³ In fact, the establishment of the very large Montyon Fund devoted to medical innovations in 1825 heightened such

²⁵ Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIS. 1, 17-22 (1950).

²⁶ *Id.* at 19.

²⁷ *Id.* at 20.

²⁸ Maurice Crosland & Antonio Galvez, *The Emergence of Research Grants within the Prize System of the French Academy of Sciences, 1795-1914*, 19 SOCIAL STUDIES OF SCIENCE 71 (1989).

²⁹ *Id.* at 71-73.

³⁰ *Id.* at 76.

³¹ *Id.* at 89.

³² *Id.* at 76.

³³ *Id.* at 76 (describing the competition of sections in reaction to the chemistry section’s Jecker contest).

tensions.³⁴ Unlike other prizes, the Montyon Fund did not state the amount of 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.”³⁵ With the large sums available under the Montyon Fund, tensions between the medical and non-medical members in the Academy grew. Finally, the administrators of the fund reached a compromise to award candidates in non-medical areas through “encouragements,” or grants.³⁶ These encouragements were awarded largely in secret, leading some to speculate that the system was corrupt.³⁷ Also, scientists grew more independent and less responsive to prize questions. This led to the overall decline of setting prize questions as a way of directing research.³⁸

The history of the prize system in France during the nineteenth century and especially the prize-granting of the Montyon Fund suggest that prize systems are vulnerable to internal disputes. Scientists will also balk at being “forced” to direct their research towards the prize question. This is particularly true when they feel that their own area of research is being undervalued compared to others. It also illustrates the importance of a central authority and a specific policy on how to judge entries. The Paris Academy, in response to these problems, eventually shifted away from prizes toward a grant system for funding and directing scientific research.³⁹

Prize systems have since become less prominent,⁴⁰ and limited to specific goals like aviation or technological prizes, like the Orteig Prize in 1927 won by

³⁴ *Id.* at 79-84.

³⁵ *Id.* at 78.

³⁶ *Id.* at 83-84, 94.

³⁷ *Id.* at 94.

³⁸ Not all attempts to set prize questions were unsuccessful. The Academy during 1807 to 1827 was able to use prize questions effectively. 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. Also, the Breant prize in 1858 for the cure of cholera encouraged research into infectious diseases generally, but the prize was never awarded. Notably, several prize questions did not generate sufficient interest or were too difficult, and this strategy of directing research declined. *Id.* at 92-93.

³⁹ 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. See also, Robin Hanson, *Patterns of Patronage: Why Grants Won Over Prizes in Science* (1998), available at <http://hanson.gmu.edu/whygrant.pdf>.

⁴⁰ 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*, Paper presented at DRUID Summer Conference (2004), available at www.druid.dk/conferences/summer2004/papers/ds2004-114.pdf.

Charles Lindbergh, the Ansari X Prize in 1996,⁴¹ or the Defense Advanced Research Project Agency's (DARPA's) challenge contest.⁴² Prizes like the Nobel Prize or the Pulitzer Prize are current examples of honorific prizes that reward outstanding achievement retrospectively, but are not designed to create ex ante incentives for research. Some federal prizes still exist to recognize accomplishments, but are mostly also honorific rather than monetary.⁴³

Modern proposals for patent reform by prize systems appeared as early as 1944.⁴⁴ The literature on prizes has been small compared to patent literature. Still, prize systems have gained recent attention.⁴⁵ 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 is that we do not have enough information about how it will compare with the patent system. The value of a prize system depends so much on the details of its administration. This Part uses the MIPF proposal as an example and will illustrate the costs of prize systems relative to the patent system. But the ultimate question of whether the costs of prize systems would in practice outweigh the benefits of a prize system over a patent system remains open and one that can only be answered empirically. The question would be best answered by a pilot program that would experiment and perfect the administration of the system. The problem with the MIPF as it stands now is its ambitious reach relative to the lack of support in empirical evidence. Few studies have focused on the economic effects of prizes,⁴⁶ and there

⁴¹ 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. For more information on the X-Prize, see www.xprize.org.

⁴² Douglas Holtz-Eakin, Economic and Budgetary Issues with Cash Prizes to Achieve NASA's Objectives, July 15, 2004.

⁴³ *Id.* at 7. (discussing the Malcolm Bladrige National Quality Award and the Vannevar Bush award for public service in science and technology).

⁴⁴ Michael Polanyi, *Patent Reform*, 11 REV. ECON. STUD 61 (1944).

⁴⁵ Eric A.A. de Laat, *Patents or Prizes: Monopolistic R&D and Asymmetric Information*, 15 Int'l J. of Industrial Organization 369, 370 n.2 (1996). See also, Davis, *supra* note 17; A. Dixit, *A General Model of R&D Competition and Policy*, 19 RAND J. OF ECON. 317 (1988) (proposing a prize system to resolve the common pool problem in R&D races); Nancy Gallini & Suzanne Scotchmer, *Intellectual property: When Is It the Best Incentive System?* (Inst. Working paper No. E01-303, 2002), available at <http://levine.sscnet.ucla.edu/archive/scotchmer-when-is-ip-best.pdf>; Barry J. Nalebuff & Joseph E. Stiglitz, *Prizes and Incentives: Towards a General Theory of Compensation and Competition*, 14 BELL J. OF ECON. 21 (1983); Steven Shavell & Tanguy van Ypersele, *Rewards versus Intellectual Property Rights*, 44 J. OF LAW & ECON. 525 (2001); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AMER. ECON. R. 691 (1983).

⁴⁶ Davis, *supra* note 17.

is no consensus on how prize systems should be designed.⁴⁷ This may be a weak objection, however, in light of the fact that the patent system has been defended on the basis of providing appropriate incentives for research and development—a claim that is not supported by much empirical proof either. Nevertheless, I suggest that we should proceed cautiously and seek more data on prize systems before overhauling the current 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 the problem of favoritism will be exacerbated. Both costs which will be explained in following sections.

The Act has partly addressed the problem of overcompensation through 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 Although the Act allows Congress to avoid overpayment and systematic errors of valuating projects by these caps, the bill does not address the problem of undercompensation, since all unused funds revert to the Treasury.⁵⁰ Kremer offers another response to the problem of maneuvering between the Scylla and Charybdis of undercompensation and overcompensation.⁵¹ He suggests that one should start low at first, and then raise the prices gradually in order to stimulate the desired amount of R&D. This method of course assumes that one has at least an accurate ballpark range of the appropriate low offer, and also that one has in mind already the “desired” amount of R&D in any particular area of drug or medical development. It relies on the ability of the agency both to monitor accurately and interpret the timing of the response of investment to changes in prize value. The challenges of prize determination are tied up in underlying difficulties of information asymmetry

⁴⁷ Abramowicz, *supra* note 24, at 121.

⁴⁸ Abramowicz, *supra* note 24, at 121 (“Prize system advocates recognize that the devil is in the details and the devil for the prize system is the government’s ability to dispense rewards accurately.”).

⁴⁹ H.R. 417 §§ 9(d)(3), (d)(4), 16(b), on both spending and cap. 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. Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 125-26 (2003). For a discussion of how a fund might be set to provide sufficient incentives in terms of global R&D, see Hollis, *supra* note 5, at 15.

⁵⁰ H.R. 417. Abramowicz, *supra* note 49, at 125 (noting that Congress could mandate that the fund be spent in order to avoid undercompensation of projects).

⁵¹ Michael Kremer, *Creating Markets for New Vaccines. Part II: Design Issues* 4 (NBER Working Paper Nr. 7717, 2000), available at www.nber.org/papers/w7717.

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.⁵² On the one hand, Wright shows that if the government is less informed about the costs of innovations, then prizes and contracts are better than patents; prizes and contracts in this situation can generate the same reward structure as patents, but without the welfare loss of monopolistic prices.⁵³ 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.⁵⁴ In the case of pharmaceutical companies, the government may be better at estimating the private or social benefits of medical innovations compared to cost of innovation. If this is the case, then prize systems are preferable. This is possible since companies do not currently release information about the costs of innovation by product.⁵⁵

2. Measurement of Value to Health and Setting Prize Payments

But the government may not be any better at estimating the private or social value of an innovation. The private or social benefits of the innovation may be equally difficult to estimate. Commentators have argued that the ideal prize system should distribute rewards based on the social value of the innovation.⁵⁶ Others have argued for a more modest prize system, where companies can opt into cash prizes that are a fixed proportion of the estimated social value in exchange for placing their innovation into the public domain.⁵⁷ The MIPF links the size of the prize to its social value by awarding prizes based on a set of pre-

⁵² For a comparison of the effect of different types of asymmetric information on the welfare properties of patent and prize systems, see Eric A.A. de Laat, *Patents or Prizes: Monopolistic R&D and Asymmetric Information*, 15 Int'l J. of Industrial Organization 369 (1996). 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.*

⁵³ Wright, *supra* note 45.

⁵⁴ *Id.*

⁵⁵ F.M. Scherer, *The Link Between Gross Profitability And Pharmaceutical R&D Spending*, 20 Health Affairs 216 (2001) (most diversified pharmaceutical companies rarely report operating margin results in enough detail to associate R&D indices with measures of profitability). For a discussion of how pharmaceutical company R&D expenditures should be treated as investments into a portfolio of different drugs, rather than companies knowing costs and benefits of drugs ahead of time, see F.M. Scherer, *The Pharmaceutical Industry- Prices and Progress*, 351 New Eng. J. Med. 927 (2004).

⁵⁶ See Dimasi & H. Grabowki, *Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D*, available at <http://www.who.int/intellectualproperty/news/en/submission3.pdf>.

⁵⁷ William A. Masters, *Research Prizes: A Mechanism to Reward Agricultural Innovation in Low-Income Regions*, 6 AGBIOFORUM 71 (2003).

determined criteria. Unlike other inducement prizes, which have a fixed amount promised to pay a specific time, the MIPF does not specify how much would be given, 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, biological product, or a manufacturing process.”⁵⁸ The prize awards will be based on the following criteria: 1) the number of patients benefited, including non-U.S. patients, by the innovation; 2) the incremental therapeutic benefits of the innovation; 3) the degree to which the innovation addresses the health care needs, including global infectious diseases, orphan illnesses, and neglected diseases affecting the poor in developing countries; and 4) the improved efficiency of manufacturing processes for drugs.⁵⁹

The 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 since they will not know what to expect.⁶⁰ The factors that it 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.⁶¹ This lack of clarity, which is in part attributable to the difficult task of measuring the value to health in the first place, opens up the MIPF prize payments to major disputes and to political influence.⁶² But 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.⁶³

One proposal is to use quality-adjusted life years (QALYs)⁶⁴ or disability-adjusted life years (DALYs),⁶⁵ which may be the best system available. But both

⁵⁸ H.R. 417, § 9.

⁵⁹ H.R. 417, § 9(c).

⁶⁰ Even if there were an equation, companies will likely dispute what numbers should be entered for the variables.

⁶¹ H.R. 417, § 9(c).

⁶² Holtz-Eakin, *supra* note 42, at 4 (discussing how unclear rules are an “invitation to conflict” and describing the problems with the Federal Communications Commission’s auction of licenses and Pioneer’s Preference policy as examples). See *infra* Section II.E for a discussion of costs of litigation and adjudication of disputes.

⁶³ Abramowicz, *supra* note 49, at 206 (noting that it is unclear whether a more formalized process would be less costly than an open-ended approach).

⁶⁴ For a review of the debate on the use of QALYs, see David L. B. Schwappach, *Resource Allocation, Social Values and the QALY: A review of the debate and empirical evidence*, 5 HEALTH EXPECTATIONS 210 (2002).

⁶⁵ Nuria Homedes, *The Disability-Adjusted Life Year (DALY) Definition, Measurement and Potential Use*, available at http://www.worldbank.org/html/extdr/hnp/hddflash/workp/wp_00068.html. For a discussion of the problems with using DALY, see The Value of DALY Life: Problems with Ethics and Validity of Disability Adjusted Life Years, 319 BRITISH MED. J. 1423 (1999).

methods come with their own significant limitations.⁶⁶ Another proposal is to announce a fixed dollar amount per incremental value to health, perhaps as measured by QALYs.⁶⁷ Secondly, companies could submit results of “head-to-head” studies with drugs in the same class for the agency to evaluate. But even these comparative studies, which companies are already very reluctant to conduct,⁶⁸ may not remedy the situation: It comes as no surprise that the company that funds the study usually prove that their own drug comes out ahead, and rivaling company studies conflict each other.⁶⁹ Since patent examiners do not consider the social or incremental benefits of drugs, the patent system avoids having to make these complex and controversial judgments.

The government will encounter other problems regarding how to evaluate the benefit of a drug or other medical product. Certain more nuanced problems exist in trying to compare drugs. First, the Act remains silent on whether off-label drug use will be considered when calculating overall social benefit of the drug. Such off-label uses are common⁷⁰ but less well-studied by companies. These uses take much longer to realize, and, thus, would be overlooked and lead to undervaluation of such drugs. This undervaluation of the social benefit of a drug may be particularly worrisome given that the off-label uses are most common in the treatment of AIDS, cancer, and pediatric illnesses.⁷¹ Second, administrators of the MIPF must confront the difficulty of drawing a line between drugs for medically necessary and lifestyle purposes. The struggle of insurance companies with this issue suggests that the administrators of the MIPF would face similar problems. Certain drugs like Viagra or acne medication may seem easily categorized as merely drugs for lifestyle purposes, but cases like psychotherapeutic drugs or drugs that both benefit medical and lifestyle drugs present challenges in prize determination. Is a drug that decreases the likelihood of anxiety in someone with social anxiety disorder more or less socially valuable than a drug that incrementally improves the eyesight of the minority of elderly

⁶⁶ For a description of how a prize fund could use QALYs or DALYs, see Hollis, *supra* note 5.

⁶⁷ Hollis, *supra* note 5, at 28.

⁶⁸ Hollis, *supra* note 5, at 17 n.34.

⁶⁹ See e.g. Shankar Vedantam, *Comparison of Schizophrenia Drugs Often Favors Firm Funding Study*, WASHINGTON POST, April 12, 2006.

⁷⁰ Certain drugs are more commonly prescribed for off label uses, and particular patient populations, such as oncology patients, are more frequently prescribed drugs with off label uses. See General Accounting Office. 1991. U.S. General Accounting Office Report: Off Label Drugs, GAO/PEMD 91-14 (finding that 56% of cancer patients have been given non-FDA-approved prescriptions, and 33% of all prescriptions in cancer treatment were off-label); Susan G. Poole & Michael J. Dooley, *Off-label Prescribing in Oncology*, 12 Supportive Care in Cancer 302 (2004) (showing that 85% of oncology patients were prescribed a drug for off-label use).

⁷¹ Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescribing*, 5 INDEPENDENT REV. 25,26 (2000).

patients? Third, administrators rewarding drugs simply by 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, but more African American patients in particular? The Board would have to decide how to handle negative information about the drug that emerges after prize payment has already been awarded, such as in the recent Vioxx controversy.⁷² They would have to decide whether to treat negative information that was known but intentionally kept secret differently than side effects were discovered later in good faith. Moreover, if the Board is considering impact on health in various countries, they may be faced with a deeper issue of how to value health impact of drugs depending on the population treated. For example, how does one compare the health impact of drugs that saves patients in the Japanese population, who have a higher average lifespan, compared to saving African patients, who may then later die from other diseases? Would the Board have to compensate drugs aimed toward Japanese populations more because they are technically adding more life-years than drugs aimed toward African populations?⁷³

The government will also struggle with other problems. The Act does not specify any screening mechanism to make sure that the studies and the reported benefits of the drugs compared to existing drugs are accurate. Companies producing rival drugs will likely dispute their relative efficacy, so a screening mechanism to review submitted information about drug results and studies is necessary.⁷⁴ Also, the Board must 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 qualified. All of these difficult questions will make it difficult to form a specific prize policy, leaving the system vulnerable to political pressures and inefficiency. These questions will be controversial battlegrounds for stakeholders' interests.

The National Institutes of Health (NIH) can provide a useful comparison and starting point for an example of a smoothly run organization with significant experience distributing its large annual budget of \$28.4 billion as ex ante funding for different research projects.⁷⁵ The Board could use the NIH template of its

⁷² Alex Berenson, *Follow-up Study on Vioxx Safety is Disputed*, N.Y. TIMES, May 13, 2006, at C.

⁷³ Thomas Pogge has raised this issue. Thomas Pogge, "Intellectual Property and Access to Medicines," Yale Law School, Sept. 8, 2006.

⁷⁴ Abramowicz, *supra* note 49, at 181 (discussing the need for screening mechanism of claims reported to those determining prize amounts). *See also* Davis, *supra* note at 17 (noting that the difficulties that prizegiver's information about determining who should win the prize may not be accurate).

⁷⁵ National Institutes of Health, *Fiscal Year 2006 and 2007 Budget*, available at <http://www.nih.gov/about/director/budgetrequest>.

rigorous priority setting, peer-review system as guidance.⁷⁶ 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,⁷⁷ or external political and lobbyist pressures.⁷⁸ Despite these issues, the NIH has managed to allocate NIH funding in a way that is at least correlated to the burden of disease, depending on how this burden is measured—a measurement which is controversial and difficult itself.⁷⁹

Some proposals for prize systems try to get around an agency determination of the optimal prize by using market mechanisms, and a pilot

⁷⁶ Working Group on Priority Setting. Setting research priorities at the National Institutes of Health. Bethesda, Md.: National Institutes of Health, 1997; Committee on NIH Research Priority-Setting Process. Scientific opportunities and public needs: improving priority setting and public input at the National Institutes of Health. Washington, D.C.: National Academy Press, 1998.

⁷⁷ 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 (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). For an NIH-initiated study comparing NIH funding of clinical versus basic science research, see David G. Nathan, *Clinical Research: Perceptions, Reality, and Proposed Solutions*, 280 JAMA 1427 (1998). See also Theodore A. Kotchen, et al., *NIH Peer Review of Grant Applications for Clinical Research*, 291 JAMA 836 (2004) (finding that grant application outcomes for clinical research fared less well than basic science/ laboratory research applications).

⁷⁸ 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 the NIH spent more than \$1000 per affected person on HIV/AIDS research but only \$93 on heart disease and \$26 on Parkinson's. NIH officials responded that critics were making simplistic arguments. Eliot Marshall, *Lobbyists Seek to Reslice NIH's Pie*, 276 Science 344-46 (1997); 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 (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, 9 J. NIH Research 26-28 (1997); Christopher Anderson, NIH budget: A New Kind of Earmarking, 260 Science 483 (1993) (discussing executive branch earmarking of funds in the NIH budget toward specific diseases).

⁷⁹ Gross et al.'s study found 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 associated with funding. Incidence or prevalence of the disease, as based on global health study were *not* predictive of NIH funding. Number of hospital days, used as a proxy for financial burden, according to estimates in the United States, was not predictive of NIH funding, which suggests that disease-specific consumption of resources does not play a large role in NIH fund allocation. However, the appropriateness of funding for some diseases varied according to number of deaths, years of life lost, and number of disability-adjusted life-years). *Id.*

program could experiment with these different strategies. Kremer suggests auctions to determine how much should be paid in a government patent buyout.⁸⁰ Guell and Fischbaum propose a prize system for prescription drugs and suggest that the government use the power of eminent domain to take patents for public use and provide just compensation to the patent holders, determined through a market test.⁸¹ Others recommend an optional rather than a mandatory prize system to alleviate the risk in having the government estimate prize payments.⁸² However, commentators are split on whether a mandatory system or an optional one would work better.⁸³ In an optional system, the government would calculate the lowest possible social surplus (or slightly more in order to induce more innovators to accept the optional reward) and offer that amount, which companies could then turn down and opt for a patent instead. However, enough companies may turn down the more socially optimal prize, and take the patent. The result would be that the only companies that would participate would be those who expect that the government would be willing to pay too much.

A mandatory system avoids that problem by not giving companies the option at all. But an optional system can be adjusted in order to overcome this inefficiency without having to move radically to a mandatory system. Abramowicz suggests that an opt-in system could be irrevocable.⁸⁴ This system would require companies to decide beforehand whether they want to choose the prize over the patent, before prize amounts would be announced. They would not be able to withdraw their decision to participate in the prize system upon hearing the amount. This may work at the earlier phase of the prize system but seems unlikely to continue to work as soon as companies figure out how prizes are calculated and get better at estimating expected prize awards. The government might counter the problem by not releasing prize payments publicly even after they are awarded to companies. But, even if this prevented companies from being able to predict rewards well, this 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.

⁸⁰ Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1147 (1998).

⁸¹ Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK QUARTERLY 213 (1995). For criticism of their proposal, see Abramowicz, *supra* note 49, at 128-36.

⁸² William A. Masters, *Research Prizes: A Mechanism to Reward Agricultural Innovation in Low-Income Regions*, 6 AGBIOFORUM 71 (2003); Shavell & van Ypersele, *supra* note 45 (demonstrating that an optional reward program can be better than a patent system).

⁸³ Abramowicz, *supra* note 49, at 142 (discussing that it is unclear whether a mandatory or optional system would be better).

⁸⁴ Abramowicz, *supra* note 49, at 123-24.

B. Duplication of Resources

Pharmaceutical companies that vie for the prize may work in the overlapping areas. The prize system may thus lead to the inefficient result of duplication of resources.⁸⁵ But this is a problem that applies to the patent system as well.⁸⁶ The patentee may not necessarily be the best to carry out the innovation and companies compete in patent races that lead them to duplicate resources as well.

It is not clear that the risk of duplication would be greater in the case of prizes. One can only speculate whether the prize system will be more burdened by this problem than the patent system. The criteria of prize payments is broad enough to allow companies to work in many non-overlapping areas, but it also specifies minimum levels of funding certain diseases.⁸⁷ These areas may be subject to more duplication of resources. One might reduce duplication by forcing contestants to publish progress reports, but such a requirement might have adverse effects, such as discouraging companies from participating or investing R&D toward the prize.⁸⁸ The same argument for disclosure of research activities and preemptive publishing has been made for patents.⁸⁹ 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 can give rewards when companies release preliminary research or allow shared rewards, leading to more collaborate research efforts.⁹⁰ But it is unclear whether this added reward would be worth the added cost or any more or less costly than just asking companies to disclose research activities in the existing patent system. Once again, this disadvantage of the prize system should not entirely rule it out, but its relative advantage over the patent system and other suggested reforms of the patent system remains equally unclear.

C. Loss of Commercial and Marketing Development

Even assuming that the prize system can accurately value the new medical innovations, replacing the prize system may deprive one of the benefits of commercialization.⁹¹ When winning entries of the prize system are not patented but are released into the public domain or when participants lose the right to

⁸⁵ Lee Davis, *Intellectual Property Rights, Strategy and Policy*, 13 *Econ. Innov. New Tech.* 399, 411 (2004).

⁸⁶ Abramowicz, *supra* note 49, at 185-86 (noting resource duplication in patent races as well).

⁸⁷ H.R. 417, § 10

⁸⁸ *Id.* at 411.

⁸⁹ *Id.*

⁹⁰ Abramowicz, *supra* note 49, at 189 (“proposals for prize systems . . . cannot be faulted for causing redundant research relative to the existing patent systems. But . . . [t]he ideal prize system would allow for shared rewards in context in which shared rewards are more efficient. . .”).

⁹¹ F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 *MINN. L. REV.* 697, 705-17 (2001).

exclusive marketing, as in the MIPF,⁹² companies may lack sufficient incentives to develop the product commercially or its marketing. Some have pointed to the example of penicillin, an unpatented discovery, which companies did not refine or market until 15 years later.⁹³ The concern for the loss of commercialization and marketing, however, should be weighed against possibly excessive and socially wasteful marketing that the industry currently employs, especially for drugs have relatively little incremental therapeutic benefit.⁹⁴

In order to counter the lack of incentives to develop the drug commercially, the prize system can respond in a few different ways. Besides patenting the winning innovations, which the MIPF does not allow, the government can incorporate a marketing goal by deferring prize payment until there has been more commercialization or can use co-payment commitments.⁹⁵ Another important way to overcome the loss of commercialization of the innovation is to use an opt-in system, as Shavell and van Ypersele propose.⁹⁶

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 distortion in the allocation of resources to different projects under the MIPF. The story of industrial influence in shaping intellectual property rights is both familiar and disheartening.⁹⁷ The MIPF will be no exception to the political economy. The Act creates a Board of Trustees for the fund for medical innovation prizes as a permanent part of the executive branch. The thirteen-member Board of Trustees is responsible for awarding prize payments, and will consist of: 1) the Administrator of the Centers for Medicare & Medicaid Services; 2) the Commissioner of Food and Drugs; 3) the Director of the National Institutes of Health; 4) the Director of the Centers for Disease Control and Prevention; and 5) nine members appointed by the President and approved by the Senate.⁹⁸

These positions are potentially vulnerable to intense political and industrial pressures.⁹⁹ The problem lies not only in those who award prize

⁹² HR. 417, § 4(a).

⁹³ See Davis *supra* note 40, at 21. See also Lee Adler, *Time Lag in New Product Development*, 30 J. OF MARKETING 17, 21 (1966).

⁹⁴ Hollis, *supra* note 5, at 9.

⁹⁵ Michael Kremer, *Creating Markets for New Vaccines. Part II: Design Issues* (NBER Working Paper Nr. 7717, 2000), available at www.nber.org/papers/w7717 (suggesting co-payment agreements for development of new vaccines).

⁹⁶ Abramowicz, *supra* note 49, at 175.

⁹⁷ WILLIAM LANDES & RICHARD POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* (2004). For a discussion of the effect of the political economy in copyrights, see JESSICA LITMAN, *DIGITAL COPYRIGHT* (2001).

⁹⁸ H.R. 417, § 7.

⁹⁹ Lee N. Davis, *Should We Consider Alternative Incentives for Basic Research? Patents vs.*

payments but those who determine the specifics of the rules in the first place. Manipulation of the rules of the prize system can result in those with the best effort, or whatever is the valuation method of the system, will not win.¹⁰⁰ 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 activity may outweigh the prize system's relative advantage over the patent system. This Board is a more concentrated, has overlapping responsibilities with other organizations and companies, and thus more potentially susceptible to political influences compared to the more broadly diverse committees, scientist-concentrated, peer reviewed process that determines NIH allocation of funds, which itself already suffers from political pressures.¹⁰¹

The historical precedent discussed in Section I.C provided an important example of how prize systems can be plagued by rent-seeking and favoritism. The Board of Trustees will be an easy and concentrated target for interest group lobbying. One may point out, however, that the patent system is not without rent-seeking of its own kind, with private companies seeking to influence government regulation.¹⁰² One might argue that the Patent and Trademark Office (PTO) is equally subject to the problem of agency capture as any of the other organizations represented on the Board of Trustees. But given the number of organizations involved on the Board of Trustees, perhaps even more resources will be wasted in trying to influence the multiple organizations. Also, the PTO is relatively independent and lobbying for directly beneficial legislation has been uncommon.¹⁰³ A review of the different organizations on the proposed Board of Trustees suggests that the prize system may be more vulnerable than the existing patent system.

One might hope that the well-reputed agencies represented on the Board of Trustees would be immune to industrial pressures, but history suggests the otherwise. In 1962, the FDA began to use external scientific advice in reviewing all new and existing drugs for efficacy and safety.¹⁰⁴ Many of the members of the 18 standing FDA advisory committees on drug approvals have ties with the industry, including financial connections and receiving high consulting fees from

Prizes. (Paper presented to the DRUID Summer Conference, Elsinore/ Copenhagen, June 6-8, 2002), available at www.druid.dk/conferences/summer2002/Papers/DAVIS.pdf.

¹⁰⁰ Chen Cohen & Aner Sela, *Manipulations in Contests*, 86 ECON. LETTERS 135-39 (2005).

¹⁰¹ See discussion, *supra* note 78, accompanying text.

¹⁰² Abramowicz, *supra* note 49, at 209-11 (discussing the problem of rent-seeking through regulation in both patent systems, with studies showing that such political contributions have a significant impact on legislator's votes).

¹⁰³ *Id.* at 210-11.

¹⁰⁴ DIVISION OF HEALTH CARE POLICY, INSTITUTE OF MEDICINE, FOOD AND DRUG ADMINISTRATION ADVISORY COMMITTEES 37 (1992) [*hereinafter* IOM REPORT].

drug companies.¹⁰⁵ The FDA put into place conflict of interest policies and the requirement to disclose any financial interests but, even the disclosure of financial ties may not have been sufficient, given that influence can come in forms others than simply financial interests.¹⁰⁶ Despite the conflict of interest policies and a waiver process regulating the relationships between its members and the industry, the Food and Drug Administration has suffered much embarrassment and criticism over their “loose standards”¹⁰⁷ toward conflict of interest with the industry.¹⁰⁸ The FDA Commissioner is no exception to industry pressures.

One disheartening example of the power of this influence is the behind-the-scenes pressures during the nomination of the FDA commissioner in 2002. The nomination of Dr. Alastair Wood, who had previously been recommended by Senator Bill Frist (R-Tenn.) and Health and Human Services Secretary Tommy Thompson, was withdrawn at the last minute. This withdrawal was reportedly due to pressures on the Bush White House, its close connections with the pharmaceutical industries, and their opposition to Dr. Wood’s support for strong regulatory action by the FDA. Senator Frist explained that “[t]here was a great deal of concern that he [Wood] put too much emphasis on [drug] safety.”¹⁰⁹

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. In 2003, Dr. McClellan actually advocated for higher drug prices in developing countries as a solution to the disparity between drug prices in the United States and other advanced countries and developing countries. He also supported higher prices in order to cover R&D costs and supported direct-to-consumer advertising since it “benefits the public health.”¹¹⁰ Angell describes his positions consistent with “a speech that could have been written by PhRMA.”¹¹¹ Dr. McClellan was later appointed to an even more prominent position in early 2004, coincidentally a position also on the proposed Board of Trustees: the Administrator of the Centers

¹⁰⁵ ANGELL, *supra* note 23, at 212; Elizabeth R. Glode, *Advising Under the Influence?: Conflicts of Interest Among FDA Advisory Committee Members*, 57 Food & Drug L. J. 293, 300 (2002).

¹⁰⁶ As the Institute of Medicine taskforce noted in its report of its investigation into the trustworthiness and reliability of the FDA’s advisory committee process: “Conflict of interest exists . . . if the recommendations or views of the person in question are distorted or skewed by that interest. . . . there is no way of predicting when it will occur and under what circumstances.” As one author explained, “using financial interests as a measure of potential bias is only a rough proxy.” Glode, *supra* note 105, at 306.

¹⁰⁷ Glode, *supra* note 105, at 313.

¹⁰⁸ Glode, *supra* note 105 (discussing a series of advisory committee members and FDA officials under attack by a series of reports challenging the loose standards of conflict of interest).

¹⁰⁹ ANGELL, *supra* note 23, at 212.

¹¹⁰ ANGELL, *supra* note 23, at 213 (criticizing the FDA commissioner’s statements).

¹¹¹ ANGELL, *supra* note 23, at 213.

for Medicare & Medicaid Services.

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.¹¹² 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.¹¹³ However, the NIH director himself is not directly in charge of funding allocation in the NIH, in contrast to the proposed prize system here. So one way that the prize system can address the political pressures might be to borrow from the NIH structure and shift the responsibility of awarding prizes away from the Board itself and appoint a separate committee or group of unbiased scientists or experts for such key decision-making.

One may point out that at least the three representatives from consumer and patient interests may offset the industrial pressures on the other members of the Board. But even patient advocacy groups are not impenetrable to industry pressures. Angell claims that some patient groups are even “fronts for drug companies” in which some people “aren’t even aware that a drug company is behind their advocacy group.”¹¹⁴ Pharmaceutical companies have, in fact, sponsored coalitions that look like grassroots efforts in education.¹¹⁵ Regardless, six other representatives will be from either the business sector or the private R&D sector.¹¹⁶ One important method of checking favoritism is through complete transparency, which James Love and Tim Hubbard have emphasized as the key to ensure fair allocation of resources in other public goods projects.¹¹⁷ However, this will not stop companies from investing resources in trying to influence the Board or attempting to get on the Board.

2. *Litigation Costs*

In terms of other costs of administration, the prize system needs a way to resolve disputes over the prize payments or enforce prize distribution. As the patent system has illustrated, when an agency distributes benefits, no matter how formulaic the method of distribution, controversy over prize distribution

¹¹² Robert Steinbrook, *Financial Conflicts of Interest and the NIH*, 350 NEW ENGL. J. MED. 327 (2004).

¹¹³ Robert Steinbrook, *Standards of Ethics at the National Institutes of Health*, 352 NEW ENGL. J. MED. 1290 (2005).

¹¹⁴ ANGELL, *supra* note 23, at 151.

¹¹⁵ *Id.* (describing examples of hepatitis C coalitions and education efforts sponsored by pharmaceutical companies).

¹¹⁶ H.R. 417 §7.

¹¹⁷ James Love & Tim Hubbard, *Paying for Public Goods*, in CODE: COLLABORATIVE OWNERSHIP AND THE DIGITAL ECONOMY 207-20 (Rishab Aiyer Ghosh ed., 2005).

inevitably follows. Although Section 12 of Act addresses problems during the transitional period, where parties can “determine equitable division of any prize payments” through an arbitration procedure established by the Board,¹¹⁸ it remains silent on the issue of other adjudicatory processes for prize payments. It is unclear whether the prize system will generate more disputes and socially wasteful activities in the current patent system, like patent prosecution and patent litigation.¹¹⁹ 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.”¹²⁰ In defining the scope of allowable litigation, the Board would have to decide whether the benefits of litigation, including ensuring a more accurate distribution of prizes or allowing due process for applicants, would outweigh 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.

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.”¹²¹ However, despite the costs of the prize system, some form of a prize system may still be desirable over a patent system. I have shown how 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 optional¹²² and focuses on a particular gaps unaddressed by current private sector or NIH funding¹²³ and in areas like neglected diseases more generally.

Narrowing the prize system to a particular area of medicines first will allow the rules for a particular set of diseases or medicines to be worked out, and for researchers to estimate the expected costs of prize systems first 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 to supplement that patent system for the agricultural industry in developing

¹¹⁸ H.R. 417 § 12.

¹¹⁹ Abramowicz, *supra* note 49, at 210-11.

¹²⁰ *Id.* at 207.

¹²¹ Abramowicz, *supra* note 49, at 123.

¹²² The prize system would be voluntary, but would use an irrevocable prize system to avoid problems mentioned before in Section II.A.

¹²³ Schechter, *supra* note 77 (noting that preventative studies like research on the value of chemopreventative agents for cancer and other types of research fare poorly in NIH review and are difficult to find private sector funding for).

countries.¹²⁴ But even these narrow proposals will struggle from the similar design issues: 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.¹²⁵ If these programs are enacted however, they will serve as valuable opportunities to evaluate the effectiveness and efficiency of a prize system.

The prize system is among several different approaches to supplement patents, including procurement contracts, publicly funded university research grants, subsidies to firms that conduct R&D, tax deductions for certain R&D investments.¹²⁶ One can also use alternative methods to address the access to medicines problem and neglected diseases through neglected disease clauses and innovative partnerships.¹²⁷ As in basic science, the government can also direct research to certain areas of medicine through research grants, subsidies, or contracts.¹²⁸ However, one should note that each type of suggested reform comes with its own set of costs and benefits.

Government grant or contract systems suffer from the inability for the government to know what kind of research would lead to innovation that would 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 called this option as inefficient and a “recipe for disaster.”¹²⁹ The government also commonly solves public good problems through the tax system. But a tax deduction for companies that invest R&D in socially valuable medical innovations has many of the same limitations. The government lacks the knowledge of what should be invented and how much 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. Interest groups would then shift gears to lobby for exemptions.¹³⁰

¹²⁴ Masters, *supra* note 57.

¹²⁵ Kremer, *supra* note 51.

¹²⁶ Davis, *supra* note 85, at 409.

¹²⁷ Kapczynski et al., *supra* note 4.

¹²⁸ Abramowicz, *supra* note 49, at 130.

¹²⁹ Guell & Fischbaum, *supra* note 9, at 222 (arguing that government contracting would be a “recipe for disaster.”). *See also* Michael Hart, *The Chimera of Industrial Policy: Yesterday, Today, and Tomorrow*, 19 CAN.-U.S. L. J. 19, 36 (1993) (arguing that 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).

¹³⁰ ROGER D. BLAIR & THOMAS F. COTTER, *INTELLECTUAL PROPERTY: ECONOMIC AND LEGAL DIMENSIONS OF RIGHTS AND REMEDIES* (2005).

Thus, the prize system could be used to supplement and close the gaps of both the patents regime and current NIH funding, while borrowing from the current institutional structure and mechanisms that 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 the other proposed reforms is a question that is best answered empirically and by experimenting with the details of administering a prize system. In particular, one of the most significant risks of a prize system, and one that has been demonstrated historically, is the problem of agency capture and political favoritism—but the prize system may not be any more susceptible to these pressures than the NIH has been in allocation of funding for research. The lack of research on prize systems suggests that a pilot program in prize systems would be the most helpful in weighing these costs against the patent system.