

# Infection

## The Health Crisis in the Developing World and What We Should Do About It

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### Chapter 5: Prizes\*

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As we saw in Chapter 2, producing new pharmaceutical products – and then verifying their effectiveness and safety – is both expensive and risky. Substantial financial incentives are essential to induce firms to engage in this activity. The primary mechanism that we currently employ to provide those incentives is the patent system. Specifically, we empower the firms that develop novel and nonobvious pharmaceutical products to prevent others from making, using, selling, or importing those products. Armed with that authority, the firms are able to sell the products for prices much higher than the costs of manufacturing them. The resultant profits provide the carrots necessary to prompt the firms to engage in the inventive activity in the first instance. This chapter considers a radically different approach. Suppose that we replaced or supplemented the patent system with a system of government prizes.

The central principle of a prize system is that, instead of authorizing the developers of new drugs to recoup their costs (and make a profit) by excluding competitors, the government would pay the developers. Other firms, including generic drug manufacturers, would be free to make and sell the drugs in question. The resultant competition would keep drug prices close to the modest costs of manufacturing them. The money necessary to run such a system would come, not from consumers (or their insurers), but from taxpayers.

Would a prize system of this general sort be better than the patent system? More to the point, would it be more effective in alleviating the health crisis in the developing world? A substantial body of literature addresses those questions. In the following pages, we marshal and critically evaluate that literature – and add to it some new arguments of our own.

The discussion is organized as follows. In Section A, we explore the major potential strengths and weaknesses of prize systems. In Section B, we consider how a prize system focused on the production of drugs and vaccines aimed at communicable diseases might be designed so as to capitalize on its strengths and mitigate its weaknesses.

## A. A General Framework

### 1. Opportunities

A prize system of the sort sketched briefly above has three potential benefits. First, it would enable us to avoid the most serious of the drawbacks of the current patent system – namely, the social-welfare losses caused by the monopoly pricing of patented products. The patent system, as we have seen, enables the firms holding the patents to charge consumers much more for the drugs to which they pertain than the cost of producing those drugs. Indeed, that’s the point of the system. Unfortunately, pursuit of this strategy has the effect of placing the drugs out of the financial reach of some people. Economists commonly refer to the deaths or suffering of the people who are thus “priced out of the market” as forms of “deadweight loss.” In the developing world, this effect is especially grave, because so many people are both poor and uninsured and thus unable to afford the prices of patented products.

This drawback of a patent system can be mitigated in various ways. For example, as we saw in the preceding chapter, an appropriately disciplined system of price discrimination

can reduce the number of persons who are “priced out of the market.” However, such devices at best can reduce the problem, not solve it.

A prize system, by contrast, is capable of eliminating this problem altogether. As indicated above, competition among manufacturers of the drugs whose development is stimulated by the prizes would keep prices low for everyone. Access to the drugs would thus be radically increased.<sup>1</sup>

Second, a prize system can take advantage of the way in which knowledge concerning actual or potential pharmaceutical products is typically distributed.<sup>2</sup> Ordinarily, governments have (or can obtain) better information concerning the aggregate health benefits of drugs than private parties. Why? Because government agencies regularly collect and assess data concerning the incidence and impact of diseases and thus are well positioned to ascertain the welfare gains that could be reaped by developing and distributing vaccines or treatments for each ailment. By contrast, governments ordinarily have knowledge inferior to that of private firms concerning the relative merits of potential lines of innovation – which drugs aimed at particular diseases would work best, which of the possible ways of developing such drugs are most promising, and the cost of each of those routes.

The inferiority of the government’s information concerning the merits of potential lines of research gives both a prize system and a patent system a clear advantage over a system of government grants as a way of inducing innovation. In a grant system (sometimes called a “push” system), government officials must decide which projects are most likely to generate solutions to particular health problems. Too often, they make those decisions poorly.<sup>3</sup> By contrast, in both a patent system and a prize system, private firms compete to develop solutions to health problems. In doing so, they are able to rely upon their own information concerning the costs and probability of success of alternative routes – and to respond quickly to new information on those fronts.

The superiority of the government’s information concerning the social benefits of particular innovations gives a prize system an equally clear advantage over a patent system, under which research-and-development investments are directed toward lines of innovation that private firms consider most potentially lucrative, not those that are most socially beneficial. Specifically, a government, relying on its superior knowledge, can construct and

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<sup>1</sup> See Robert C. Guell and Marvin Fischbaum, "Toward Allocative Efficiency in the Prescription Drug Industry," *Milbank Quarterly* 73(1995); Steven Shavell and Tanguy van Ypersele, "Rewards Versus Intellectual Property Rights," *Journal of Law and Economics* 44(2001).; Thomas Pogge, "Human Rights and Global Health: A Research Program," *Metaphilosophy* 36, no. 1/2 (2005).

<sup>2</sup> See Michael R. Kremer, "Creating Markets for New Vaccines, Part I: Rationale," *NBER Working Paper #7716* (2000): 53; Brian D. Wright, "The Economics of Invention Incentives: Patents, Prizes, and Research Contracts," *American Economic Review* 73, no. 4 (1983).; Winters and Nelson.

<sup>3</sup> The most notorious example of poor decision-making in this regard is the failed effort of USAID to stimulate the development of a malaria vaccine. During the 1980s, the agency spent over \$60 million on a project that, in its judgment, would likely lead to an effective vaccine. In the end, the initiative produced nothing of value. See Robert S. Desowitz, *The Malaria Capers: Tales of Parasites and People*(New York: W.W. Norton, 1991). In truth, the probative value of this example is limited. The principal investigator, it turned out, was lining his own pockets, and the agency’s project director was receiving kickbacks. Thus, this particular episode may reveal more about the potential for a few corrupt actors to waste a great deal of money than it does about the merits of “push” programs in general.

administer a prize system in ways that correct for all three of the biases (examined in detail in Chapter 4) that distort (from a social welfare standpoint) the output of new pharmaceutical products under the current patent-based system: the bias toward drugs aimed at ailments that disproportionately afflict the rich; the bias toward “me-too drugs” (the term conventionally used to describe drugs that, when introduced into the market, offer little or no health benefits over extant drugs); and the bias away from vaccines. All of these distortions could be reduced or eliminated by a prize system – most simply, by ensuring that the sizes of the prizes are adjusted to match the incremental health benefits of each innovation.

Brian Wright has suggested that the advantages of prizes over patents in correcting these biases are not so certain. In theory, he points out, a government administrator could simply adjust the duration of – or the set of rights associated with – each individual patent to reflect the social value of the specific invention at issue. A patent system that incorporated such a mechanism would be just as good as a prize or grant system in capitalizing on the government’s superior knowledge concerning the social benefits of drugs.<sup>4</sup> In some contexts, this might be true. For instance, to address the second bias in favor of me-too drugs, the patents covering truly innovative or “pioneer” drugs might be amplified in breadth or duration, while those covering me-too drugs diminished. But conferring upon the government the capacity to make such adjustments would give rise to a patent system fundamentally different from the one we have inherited. So long as all patents (or at least all patents within a given technological field) last the same amount of time and carry with them the same set of rights, the precision that Wright proposes will be infeasible, and a prize system, which invites such fine tuning, will be superior to it.

A more fundamental response to Wright’s suggestion is as follows: in many contexts, the divergence between the social value of an innovation and its private value for a patentee cannot be overcome even if we were willing to fine tune the patent system. This is because of two significant restrictions on the way all patent regimes work. First, patent incentives are parasitic on the underlying market demand for innovations – in the sense that patent-enabled returns are simply augmentations, through price hikes, of the returns that would be available to the innovator through competitive market prices. In economic terminology, varying the breadth or duration of a patent means varying how much of the social surplus from an innovation that lies “under” the “effective demand” curve can be captured by the patentee (as opposed to the consumers of the innovation).<sup>5</sup> Those demand curves, however, fail to capture much of the social value of many of the innovations with which we are concerned. For instance, much of the social value of a vaccine consists of “positive externalities” reaped by persons other than the recipients of the vaccine – the diminution in the likelihood that they will contract the disease resulting from the immunization of the recipient. Another example: from a social-welfare standpoint, the demand curves for many drugs aimed at tropical diseases are “depressed,” in the sense that their potential beneficiaries are too poor to have their preferences “effectively” register on

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<sup>4</sup> Wright, "The Economics of Invention Incentives: Patents, Prizes, and Research Contracts," 703.

<sup>5</sup> With, roughly, increased duration enabling the capture of the same stream of surplus over a longer period, and increased breadth enabling the capture of a proportion of a larger surplus (larger due to the expanded area of technology space now protected) for the same period.

the market. In such cases, no amount of fiddling with patents can enable innovators to capture the social benefits of their creations.

Yet another, contingent feature of patent systems compounds the problem: a patent system is hamstrung, in a way a prize system is not, regarding the proportion of effective social surplus that it enables innovators to capture. If the patentee is able to charge only one, uniform (supra-competitive) price for the innovation, it must give up the surplus from some consumers (those who would have purchased the good at a lower price) in order to capture more surplus from others (those paying the higher price). Again, price discrimination can mitigate this problem but not eliminate it. A prize system faces no such inherent limitation; prizes can be adjusted to achieve whatever proportion of private incentive to social value is deemed best.<sup>6</sup> In sum: a prize system enables a government to capitalize more effectively on its superior knowledge concerning the social value of innovations than it could through adjustments of a patent system.

The third and final potential benefit of a prize system is that it could reduce socially wasteful expenditures by pharmaceutical firms. The largest potential source of savings consists of marketing costs. Estimates of the magnitude of those costs under the current regime vary. Some scholars contend that pharmaceutical firms devote roughly one third of their revenues to marketing their products.<sup>7</sup> Meredith Rosenthal and her colleagues suggest that the number is closer to 15%.<sup>8</sup> Dean Baker and Noriko Chatani point out that “[a]ccording to the industry’s own data, in 2000 it employed almost twice as many people in sales promotion as in research, 87,810 in sales compared to 48,527 in research.”<sup>9</sup> These differences aside, there is little question that the amount that the firms are currently spending on marketing is substantial. For reasons we explored in chapter 4, only a portion of those expenditures redound to the benefit of society at large. In brief: To the extent that advertising better informs either patients or doctors concerning the merits of drugs and thus enables them to improve their own or their patients’ health, it is plainly beneficial. However, to the extent that advertising functions to expand or stabilize the market share of one of several substitute products – or leads to increases in drug consumption unjustified by health benefits – it is wasteful or pernicious. A prize system, if it were structured properly, might reduce these outlays. Most intriguing is the possibility that the mechanism for determining the magnitude of the awards might be designed so as to reduce firms’ incentives to engage in pernicious forms of promotion, while preserving their incentives to engage in beneficial forms of promotion. Another potential source of savings involves litigation costs. The resources currently consumed by lawyers and the court system resolving disputes involving pharmaceutical patents are enormous.<sup>10</sup> A prize system would not be free of disputes, of

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<sup>6</sup> See Shavell & van Ypersele and Michael R. Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation," *Quarterly Journal of Economics* 113(1998).

<sup>7</sup> See Angell 2004; Love and Hubbard

<sup>8</sup> See Meredith B. Rosenthal et al., "Demand Effects of Recent Changes in Prescription Drug Promotion," *Frontiers in Health Policy Research* 6(2003).

<sup>9</sup> Dean Baker and Noriko Chatani, "Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research," *Center for Economic and Policy Research Briefing Paper* (2002): 9.

<sup>10</sup> See *ibid.*, 11. For an extensive discussion of the rapidly rising costs of resolving patent disputes of all sorts, see James Bessen and Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton, N.J.: Princeton University Press, 2008), 120-46.

course. But it might be designed to reduce the incidence of those controversies and the costs of resolving them.

## 2. Hazards

Unfortunately, the picture painted thus far is misleadingly rosy. Prize systems have major potential disadvantages as well. The first and perhaps most serious is that the increase in tax burdens necessary to finance a prize system can lead to an inefficient diminution in labor.<sup>11</sup> Knowing that they will earn less per hour, at least some of the residents of developed countries (upon whom the bulk of the taxes would be imposed) would likely work fewer hours. Predicting the magnitude of this effect is extremely difficult. One source of the difficulty is that some people are likely to react to an increase in their tax burdens in precisely the opposite way – by working harder or longer to offset their loss of income and thus maintain their standard of living. Most economists think that the diminution in labor of the former group will be larger than the increase in labor of the latter group, but economists disagree sharply concerning the magnitude of the net effect – and specifically concerning the magnitude of the welfare loss caused by this distortion. The majority think that it would be modest,<sup>12</sup> but not all agree.<sup>13</sup>

The issue is further complicated by two additional factors. The first is the uncertain normative footing of economists' depiction of this effect as a "distortion." A distortion of what? Presumably, the overall pattern of labor and investment that existed prior to the imposition of the extra taxes necessary to run the prize system. But why should we consider that pattern optimal, and regret deviations from it? The usual response is that we have no reason to doubt its optimality.<sup>14</sup> Perhaps, but that seems a weak foundation. Until it is shored up, we will have trouble assessing the magnitude of this problem.

Further, whatever the extent of the *efficiency* loss caused by the tax distortion, the loss in *welfare* associated with that inefficiency is likely to be considerably less than the welfare loss associated with the inefficiency that is caused by patent pricing (which prizes would

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<sup>11</sup> See Michael Abramowicz, "Perfecting Patent Prizes," *Vanderbilt Law Review* 56(2003).

<sup>12</sup> See Arthur Snow and Ronald S. Warren, Jr., "The Marginal Welfare Cost of Public Funds: Theory and Estimates," *Journal of Public Economics* 61(1996). (review article); Baker and Chatani, "Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research," 7 n.4. Louis Kaplow argues persuasively that, in one context, the diminution in labor would be zero – namely, when the distribution of tax burdens precisely matched the distribution of benefits from the innovation induced by those taxes. See Louis Kaplow, "The Optimal Supply of Public Goods and the Distortionary Cost of Taxation," *National Tax Journal* 49(1996); "A Note on the Optimal Supply of Public Goods and the Distortionary Cost of Taxation," *National Tax Journal* 51(1998); "On the (Ir)Relevance of Distribution and Labor Supply Distortion to Public Goods Provision and Regulation,"(2004). This insight would provide a powerful justification for a prize system for drugs that addressed the diseases common in the United States, insofar as the set of beneficiaries of such a system would closely resemble the set of taxpayers. Unfortunately, a prize system of the sort we are considering, which would most benefit the residents of developing countries while imposing most of its burdens on the residents of developed countries, would not benefit from the feedback effect identified by Kaplow.

<sup>13</sup> See Martin Feldstein, "How Big Should Government Be?," *National Tax Journal* 50(1997).

<sup>14</sup> See Douglas Gary Lichtman, "Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals," *Harvard Journal of Law and Technology* 11(1997); Barton H. Thompson, Jr., "The Endangered Species Act: A Case Study in Takings & Incentives," *Stanford Law Review* 49(1997).

remedy).<sup>15</sup> The patent inefficiency, recall, consists primarily of the “deadweight loss” from residents of the developing world who are priced out of the market despite being willing and able to pay the marginal cost of the drug. The tax inefficiency arises from the diminution in labor by residents of the developed world. In the former case, the inefficiency is caused by failing to satisfy the “effective preferences” of comparatively poor people. These preferences must, on any plausible account, be magnified when counted as utility inputs into the social welfare function, and thus the welfare loss, in terms of *utility-efficiency*, is higher than that indicated by the loss in wealth-efficiency.<sup>16</sup> The converse is true with the tax case, where the effective preferences that are frustrated are those of the suppliers and purchasers of high-income labor, who would likely be at least be at the average income/wealth level overall and likely above that.<sup>17</sup> Thus, their effective preferences would be given comparatively less weight in a social welfare function, resulting in a proportionately smaller welfare loss from the same magnitude of efficiency loss. Where does this leave us? With a plausible basis for thinking that, from a welfare point of view, we should give greater weight to reducing the patent inefficiency than we give to the inefficiency caused by the tax increase associated with a prize system.

The bottom line, then, for this first disadvantage is that the welfare benefits we would reap in the form of reduced deadweight losses by replacing the patent system with a prize system would likely be partially – but only partially – offset by an increase in the welfare losses caused by a reduction in the output of labor in developed countries.

A second potential disadvantage of a prize system is that it could foster inefficient “rent seeking.” Pharmaceutical firms already spend substantial sums on campaign contributions and lobbyists, seeking to persuade government officials to modify the patent system to their advantage.<sup>18</sup> From the standpoint of aggregate social welfare, such

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<sup>15</sup> To explain: “efficiency” is used here in its standard economic sense, to denote “wealth-efficiency” or social value measured in terms of consumer “bids,” meaning how much people are willing and able to pay for the relevant goods. Wealth, however, is widely recognized to be a highly imperfect measure of social welfare, in part because it is measured against the current distribution of income, wealth and legal entitlements, which distribution heavily shapes people’s bids and requires some independent normative evaluation. Thus, at a minimum, any satisfactory measure of social *welfare* will need also to take up the question of what is a normatively acceptable distribution of income/wealth and thus be comprised of at least two inputs: wealth-efficiency and wealth-distribution.

<sup>16</sup> The reasons (rooted in the assumptions of diminishing marginal utility and random distribution of utility curves across the population) for amplifying the effective preferences of the poor when measuring their utility magnitude are explained in detail in William W. Fisher, III and Talha Syed, “Global Justice in Health Care: Developing Drugs for the Developing World,” *U.C. Davis Law Review* 40(2007). Note that for social welfare functions more egalitarian than the utilitarian one, the distribution of utility per se may also matter, as opposed to the utilitarian view that cares only about maximizing total or average utility. Our argument here, however, requires only the purely utilitarian consideration of utility-efficiency.

<sup>17</sup> On a first approximation, the lost surplus from the foregone transactions for labor time is split in some proportion between the high-income labor suppliers and the close-to-marginal buyers of that labor (employers and the end-consumers of the relevant good or service, whose relative shares of the loss depend on the elasticities for the end-product good/service). The more progressive the tax system, the higher the income of the former group. And there seems little reason to believe that the latter groups are at a less-than-average-income level and some reason to believe the opposite.

<sup>18</sup> The following chart (current as of November 15, 2010), showing total U.S. campaign contributions by pharmaceutical firms during the past two decades, was created by the Center for Responsive Politics, relying on information from the Federal Election Commission:

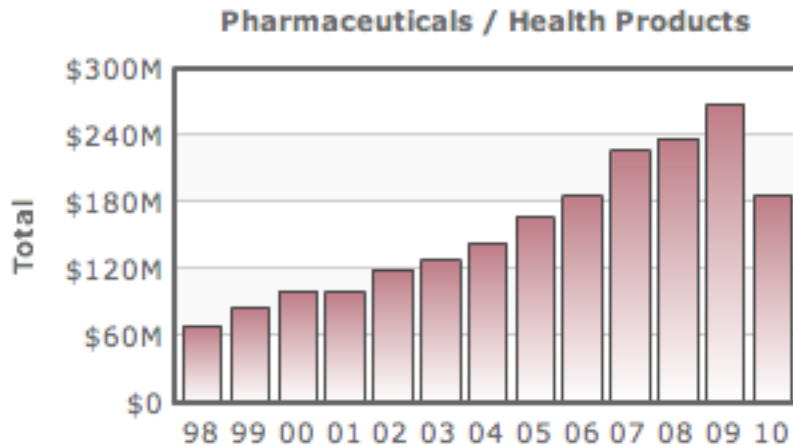
expenditures represent pure waste. Unfortunately, under a prize system, the amount spent on efforts to influence government – specifically, to affect the ways in which the prizes are calculated and allocated – could increase.

A third potential problem is that, in general, prize systems are clumsy in dealing with sequential innovation.<sup>19</sup> Suppose Firm A develops a breakthrough product. Firm B, building on A’s research, develops a slightly improved version of the product. What should be the magnitude of the prize awarded to each? The answer is far from clear, and on that answer depends the capacity of the system to provide optimal incentives for innovation.

Election Cycle	Rank†	Total Contributions	Contributions from Individuals	Contributions from PACs	Soft Money Contributions	Donations to Democrats	Donations to Republicans	% to Dems	% to Repubs
2010*	13	\$19,643,925	\$6,603,669	\$13,040,256	N/A	\$10,513,627	\$8,976,488	54%	46%
2008*	19	\$29,948,895	\$14,800,657	\$15,148,238	N/A	\$15,200,874	\$14,716,345	51%	49%
2006*	15	\$19,985,474	\$7,490,802	\$12,494,672	N/A	\$6,480,021	\$13,195,055	32%	66%
2004*	21	\$18,017,015	\$8,776,608	\$9,240,407	N/A	\$6,110,752	\$11,880,638	34%	66%
2002	10	\$29,703,021	\$3,468,110	\$6,957,382	\$19,277,529	\$7,703,482	\$21,974,532	26%	74%
2000	13	\$27,181,301	\$5,956,208	\$5,649,913	\$15,575,180	\$8,398,797	\$18,718,924	31%	69%
1998	16	\$13,241,024	\$2,745,175	\$4,107,068	\$6,388,781	\$4,763,279	\$8,432,900	36%	64%
1996	16	\$14,074,392	\$3,609,812	\$3,584,217	\$6,880,363	\$4,917,465	\$9,128,373	35%	65%
1994	20	\$7,972,033	\$2,081,080	\$3,477,146	\$2,413,807	\$3,536,938	\$4,431,918	44%	56%
1992	22	\$7,423,635	\$2,511,596	\$2,589,241	\$2,322,798	\$3,172,617	\$4,221,421	43%	57%
1990	29	\$3,280,293	\$816,722	\$2,463,571	N/A	\$1,521,029	\$1,757,049	46%	54%
<b>Total</b>	<b>16</b>	<b>\$190,471,008</b>	<b>\$58,860,439</b>	<b>\$78,752,111</b>	<b>\$52,858,458</b>	<b>\$72,318,881</b>	<b>\$117,433,643</b>	<b>38%</b>	<b>62%</b>

“Pharmaceuticals/Health Products: Long-Term Contribution Trends,” <http://www.opensecrets.org/industries/indus.php?ind=H04>.

Total spending by the industry on lobbyists, as reported by the Center for Responsive Politics, was substantially more:



“Annual Lobbying on Pharmaceuticals/Health Products,” <http://www.opensecrets.org/lobby/indusclient.php?lname=H04&year=2009>.

<sup>19</sup> For discussion of the difficulty of designing a system that will deal effectively with situations in which innovation is cumulative, see Nancy Gallini and Suzanne Scotchmer, "Intellectual Property: When Is It the Best Incentive System?," *UC Berkeley Working Papers, Department of Economics*, no. E01-303 (2001): 16-20; *ibid*.



A fourth potential disadvantage of a prize system is that distrust of government may increase its costs. In the past, governments have not always made good on their promises to award prizes to successful innovators. For example, the British government long delayed awarding a promised prize to the developer of a device or technique that would enable mariners to determine longitude.<sup>20</sup> Such breaches of faith may make pharmaceutical firms hesitate to commit huge sums of money to new research ventures in reliance on a government's commitment to reward them if they are successful. To overcome that hesitation, the government may need to increase the magnitude of the promised prize. Bonuses of that sort would plainly increase the cost of the program.<sup>21</sup>

The implications of the last of the differences between a prize system and the patent system are more ambiguous. The carrot of a patent commonly leads multiple firms to pursue a particular research goal simultaneously and to keep their work secret from one another. Whether such a "patent race" is socially beneficial is unclear. On one hand, it can increase the likelihood that the goal will be achieved or the speed with which it is achieved, which both benefits the consumers of the patented innovation and may accelerate socially beneficial follow-on innovation.<sup>22</sup> On the other hand, it may lead to truly duplicative and thus plainly wasteful research, and it may engage minds and money that could be better applied to other projects.<sup>23</sup> Some level of overlapping activity is probably socially advantageous, but how much is uncertain.<sup>24</sup>

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<sup>20</sup> See Dava Sobel, *Longitude* (New York: Walker & Company, 1995).

<sup>21</sup> See Stephen M. Maurer, "The Right Tool(S): Designing Cost-Effective Strategies for Neglected Disease Research," (2005).

<sup>22</sup> See Richard R. Nelson, "Uncertainty, Learning, and the Economics of Parallel Research and Development," *Review of Economics and Statistics* (1961).

<sup>23</sup> See Steve Calandrillo, "An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System," *Fordham Intellectual Property, Media & Entertainment Law Journal* 9(1998): 329.

<sup>24</sup> Efforts by economists to resolve these extraordinarily difficult issues include F.M. Scherer, "Parallel R&D Paths Revisited," *Kennedy School of Government, Faculty Research Working Paper Series* (2007). F.M. Scherer, "Research and Development Resource Allocation Under Rivalry," 81 *Quarterly Journal of Economics* 359, 364-66 (1967); Yoram Barzel, "Optimal Timing of Innovations," 50 *Review of Economics & Statistics* 348 (1968); Partha Dasgupta, "Patents, Priority and Imitation or, The Economics of Races and Waiting Games," 98 *Economics Journal* 66, 74-78 (1988); Partha Dasgupta and Joseph Stiglitz, "Uncertainty, Industrial Structure and the Speed of R&D," 11 *Bell Journal of Economics* 1, 12-13 (1980); Drew Fudenberg, Richard Gilbert, Joseph Stiglitz, and Jean Tirole, "Preemption, Leapfrogging, and Competition in Patent Races," 77 *European Economic Review* 176 (1983); Michael L. Katz & Carl Shapiro, "R & D Rivalry with Licensing or Imitation," 77 *American Economic Review* 402 (1987); Steven A. Lippman & Kevin F. McCardle, "Dropout Behavior in R&D Races with Learning," 18 *Rand Journal of Economics* 287 (1987); Glenn C. Loury, "Market Structure and Innovation," 93 *Quarterly Journal of Economics* 395 (1979); Pankaj Tandon, "Rivalry and the Excessive Allocation of Resources to Research," 14 *Bell Journal of Economics* 152 (1983); Brian D. Wright, "The Resource Allocation Problem in R & D," in *The Economics of R & D Policy* 41, 50 (George S. Tolley, James H. Hodge & James F. Oehmke eds., 1985). Efforts by legal scholars, building on the economics literature, include Peter Menell, "Intellectual Property: General Theories," *Encyclopedia of Law & Economics*, available at <http://encyclo.findlaw.com/1600book.pdf>; Louis Kaplow, "The Patent-Antitrust Intersection: A Reappraisal," 97 *Harvard Law Review* 1813 (1984); Edmund Kitch, "The Nature and Function of the Patent System," 20 *Journal of Law and Economics* 265 (1977); idem, "Patents, Prospects, and Economic Surplus: A Reply," 23 *Journal of Law and Economics* 205 (1980); Mark F. Grady & J.I. Alexander, "Patent Law and Rent Dissipation," 78 *Virginia Law Review* 305 (1992); Robert Merges & Richard Nelson, "On the Complex Economics of Patent Scope," 90 *Columbia Law Review* 839 (1990); and Mark Lemley, "The Economics of Improvement in Intellectual Property Law," 75 *Texas Law Review* 993 (1997).

Some scholars have tried to provide us better guidance on this question with respect to pharmaceutical products. A recent study by Joseph DiMasi and Cherie Paquette confirms the prediction that multiple pharmaceutical firms often work independently on the same problem – as evidenced by the frequency with which breakthrough drugs are succeeded by other drugs in the same therapeutic categories more quickly than would be possible if the later entrants were building on the work of the pioneer.<sup>25</sup> F.M. Scherer has argued that this practice may be socially beneficial. When all possible projects that have the potential to generate a particular therapeutic outcome are risky, Scherer argues, a given firm will maximize its profits by pursuing in parallel several such projects – or, more subtly, by undertaking a series of groups of parallel projects. The lower the probability that any one path will succeed (and the more lucrative the goal) the greater the number of paths the firm will rationally pursue simultaneously. The same principle, Scherer suggests, may justify, from the standpoint of aggregate social welfare, the pursuit of parallel research paths by many firms within the pharmaceutical industry as a whole.<sup>26</sup>

Scherer's analysis neglects, however, some differences between the profit-maximizing behavior of a single firm, and the pattern of behavior induced by the patent system in the industry as a whole. First, an individual firm is unlikely to ask two or more teams to pursue two identical paths at the same time. Rather, it will (rationally) explore simultaneously several different possible routes to the same end – for example, several different molecules, each of which has a chance of achieving the desired outcome. By contrast, patent races may result in two or more firms pursuing identical projects.<sup>27</sup> Moreover, an individual firm will likely encourage its various teams to share information in order to avoid reinventing wheels. Competitive firms, by contrast, do not share such information. The likelihood of waste at the industry level is thus significantly higher.

Another potentially important source of waste is obscured by Scherer's argument. Under the patent system, individual firms have an incentive to invest more resources into the development of me-too drugs than would be justified by the profits attributable solely to the therapeutic advantages (by definition, modest in amount) of those drugs. The reason: they can appropriate some of the market for the pioneer drug. As a result, each firm may be less discouraged from entering a crowded field than it would be under a truly winner-take-all

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<sup>25</sup> Joseph A. DiMasi and Cherie Paquette, "The Economics of Follow-on Drug Research and Innovation: Trends in Entry Rates and the Timing of Development," *Pharmacoeconomics* 22(2004).

<sup>26</sup> See F.M. Scherer, "Markets and Uncertainty in Pharmaceutical Development," *Kennedy School of Government, Faculty Research Working Paper Series* (2007): 10-16.

<sup>27</sup> Michael Kremer and Rachel Glennerster provide a hypothetical example that shows how this inefficient duplication might occur even if each firm is aware of what the others are working on. Suppose that "there are two promising ways to develop a vaccine." One has a 60% chance of success, the other a 25% chance of success. Each of two firms is considering working on the project. From a social welfare standpoint, we would want one firm to pursue the first route, the other firm to pursue the second. But both may instead choose to pursue the first route, figuring that they each have a 50% chance of winning the resultant race and thus a 30% chance of obtaining a patent on the vaccine – better odds than those associated with the second route. See Michael Kremer and Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton, N.J.: Princeton University Press, 2004), 66. A possible response: the two firms could and should strike a deal in which they pursue separate routes, and the firm taking the promising road compensates the other in some way. In any event, the likelihood that firms acting independently will engage in an inefficient pattern of research are much greater – and opportunities for such corrective deals are much scarcer – when they don't know what each other is doing.

regime by the fear of losing the patent race.<sup>28</sup> It is not certain that this effect would occur. The prospect of earning substantial profits from a me-too drug depends upon the ability of the pioneer and the follower(s) to engage in oligopolistic pricing, which might be difficult.<sup>29</sup> And the prospect that one would have to share one's gains with a follower plainly reduces the incentives of the pioneer, which may diminish the number of firms willing even to start races. However, from the other side, even when firms would prefer to steer clear of crowded lines of research, the secrecy with which other firms carry out their projects may disable them from doing so, and hence involve them in races they would sooner avoid. In short, many factors are at play here. And we may be able, through adjustment of other legal doctrines, such as antitrust law, to affect some of those factors. But the data offered by DiMasi and Paquette suggest that, under the present patent regime, the amount of research devoted to the development of what will become me-too drugs is higher than optimal. Especially telling is that fact that many losers of patent races initiate clinical trials – the most expensive phase of the research – even after it is clear that they have been beaten to the punch and that the incremental health benefits of their own products are slight.<sup>30</sup>

The complexity of the issue makes it very difficult to determine whether a prize system would be better or worse in this respect than the current patent system. The fact that the levels of duplication under the present regime appear to be too high creates at least the possibility that a well-designed prize system could achieve significant social gains. On the other hand, anecdotal evidence suggests that some prize systems are even worse than the patent regime in this regard.<sup>31</sup> An extreme example: Netflix recently offered a prize of \$1 million to the creator of a computer program that was better (by a specified amount) than Netflix' own "recommendation engine" (a piece of software that suggests movies that a person might enjoy based on the movies that she has already seen and enjoyed).<sup>32</sup> The contest attracted more than 27,000 competitors, organized into more than 2,500 teams.<sup>33</sup> It is hard to believe that that number is optimal. Less troubling are the fruits of a prize system aimed at problem more closely analogous to the kinds of pharmaceutical research with which we are concerned: The J. Craig Venter Science Foundation recently joined forces with the X Prize Foundation to offer a \$10 million prize to "the first Team that can build a device and use it to sequence 100 human genomes within 10 days or less, with an accuracy of no more than one error in every 100,000 bases sequenced, with sequences accurately covering at least 98% of the genome, and at a recurring cost of no more than \$10,000 per

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<sup>28</sup> This same factor may also lead to the more troubling phenomenon of purely ex-post invent-around duplicative activity. As discussed above at \_\_\_, reducing the wastes from that activity is more easily achieved by a well-fashioned prize system and doing so is one of its the key advantages.

<sup>29</sup> Although, as we review in chapter 4 of our book, the available evidence suggests that such oligopolistic pricing is indeed the norm: in the top ten or so therapeutic classes (a suitable measure of specific "markets" or product spaces in the pharmaceutical sector), two to three firms account for the bulk of total sales (roughly 70% or more), and, more generally, the average price of all brand-name pharmaceutical products is roughly three times the marginal cost, after all discounts and price discrimination are accounted for (and including those brand-name drugs that are now off-patent and face price competition from generics).

<sup>30</sup> See DiMasi and Paquette, "Follow-on Drugs," ---.

<sup>31</sup> For the argument that prize systems are worse on this score than the patent system, see Newell & Wilson.

<sup>32</sup> See Katie Hafner, "And If You Liked the Movie, a Netflix Contest May Reward You Handsomely," *New York Times*, October 2, 2006 2006.

<sup>33</sup> See Tim Harford, "Cash for Answers," *FT Magazine* (2008), available at <http://timharford.com/>.

genome.”<sup>34</sup> As of October 9, 2009, seven teams had registered to compete in the competition.<sup>35</sup> The potential for redundancy on that scale is much less worrisome.

In short, whether a prize system is more or less likely than the patent system to foster socially excessive levels of research redundancy seems to depend, in significant part, on how the prize system is designed. To such matters we now turn.

## B. Optimal Design

Plainly, in constructing and administering a prize system, one should strive to capitalize on the potential advantages and minimize the potential disadvantages just reviewed. This section relies on that guideline in considering what sort of prize system would be most effective in alleviating the health crisis in the developing world.

### 1. Defining the Contest

The first question we must consider is what the prizes would be awarded for. A wide variety of frameworks has been proposed or might be imagined. The most tightly focused approach would involve a government agency identifying a specific neglected disease and offering a prize to the first person or firm to develop a vaccine for it. Historically, most prize systems have taken this form. A government official, foundation, or private firm has identified a specific pressing problem and has offered a reward to anyone able to solve it. Examples include a prize offered by Napoleon for the best method of extracting sugar from beets, a series of prizes offered by the industrialist, Henry Kremer, for human-powered flying machines, and the prize offered recently by regional governments in Australia for the best method of trapping poisonous cane toads.<sup>36</sup>

The influential proposal for “advanced market commitments” (AMCs), which has been made by Michael Kremer and Jeffrey Sachs (separately and in tandem) employs the same general approach.<sup>37</sup> Kremer and Sachs urge coalitions of governments and private foundations to commit<sup>38</sup> to purchasing a particular number of doses (at a particular price) of a vaccine that effectively prevents contraction of a particular disease – say, malaria.<sup>39</sup> Their

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<sup>34</sup> See <http://genomics.xprize.org/genomics/archon-x-prize-for-genomics/prize-overview>.

<sup>35</sup> See <http://genomics.xprize.org/teams/registered-teams>.

<sup>36</sup> A comprehensive list of such prizes can be found in Knowledge Ecology International, “Selected Innovation Prizes and Reward Programs,” *KEI Research Note 2008:1* (2008). For a large catalogue of current prizes of this highly focused sort, visit the website of Innocentive: <http://www.innocentive.com/>.

<sup>37</sup> See Jeffrey Sachs, Michael Kremer & Amar Hamoudi, *The Case for a Vaccine Purchase Fund* (Center for International Development, Harvard); Jeffrey Sachs, *Helping the World’s Poorest*, 352 *THE ECONOMIST* 17 (1999); Rachel Glennerster, Michael Kremer, and Heidi Williams, “Creating Markets for Vaccines,” *Innovations* Winter 2006(2006); Kremer and Glennerster, *Strong Medicine*; Kremer, “Patent Buyouts.”; “Creating Markets, Part I.”; “Creating Markets for New Vaccines, Part II: Designing Issues,” *NBER Working Paper #7717* (2000).

<sup>38</sup> How could such commitments be made credible? Kremer advocates the use of legally enforceable contractual obligations, pointing to cases where courts have held that public commitments to reward winners or to purchase specified goods constitute legally binding contracts, holding governments to them in cases where changed circumstances motivated attempts at renegeing. See Kremer and Glennerster, *Strong Medicine*, , Chpt. 12; *ibid.*, Chpt. 12.

<sup>39</sup> The tax credit proposed by Lawrence Summers when he was Secretary of the Treasury in the United States would have taken the same general form. See Lawrence H. Summers, Testimony Before the Senate

proposal has several other important dimensions, some of which we will consider shortly, but its key feature, for present purposes, is that it would target specific diseases.<sup>40</sup>

The principal strength of this strategy is that it is likely to be politically attractive. The misery associated with a specific disease is easier to understand and to explain to skeptical officials (or constituents) than the general problem of neglected diseases. It is thus unsurprising the Kremer/Sachs proposal has gained significantly more traction to date than any other prize-system idea. In 2007, the governments of Britain, Italy, Canada, Norway, and Russia, along with the Gates Foundation, committed \$1.5 billion to purchase doses of a successful vaccine for pneumococcal disease, which currently kills roughly 700,000 children per year in developing countries.<sup>41</sup> Senator Kerry has urged the United States to join the effort.<sup>42</sup> If this initial, “pilot” version of the AMC system works, backers hope to extend it to other diseases.

This approach does, however, have two serious weaknesses. First, it risks drawing research funds away from fields where greater health benefits could be reaped per dollar invested. Recall that, although government officials have good information concerning the potential welfare gains associated with preventing or curing particular diseases, they have poor information concerning the costs and the probability of success of the various lines of research that might generate those gains. Would we get more bang for our research buck by focusing on diarrhea or malaria? Government officials have no way of knowing. Awarding prizes for addressing particular diseases thus risks inducing firms to put their time and money into suboptimal zones.

The second problem is that the specific-disease approach exacerbates the hazard of research redundancy. Even if malaria research would provide us the greatest bang per research buck, we may not want to encourage all pharmaceutical firms to focus on it. It would be better if some concentrated their energies on other diseases. (The pneumococcal AMC is not particularly vulnerable to criticism on this ground, because two firms – GlaxoSmithKline and Wyeth – have already progressed far down the line toward developing

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Appropriations Committee Subcommittee on Foreign Appropriations (6 April 2000). The credit would have applied to sales of vaccines for malaria, TB, HIV/AIDS “or any infectious disease that causes over one million deaths annually worldwide.” It would have allowed the seller of a qualified vaccine to claim a credit equal to 100 percent of the amount paid by any nonprofit organization, such as UNICEF, selected for the program by US AID. The effect of the credit would have been to double the purchasing power of such organizations, with US AID setting the total amount eligible for the program (the figure of \$1 billion for all vaccines from 2002 to 2010 was suggested). The aim was to “provide a specific and credible commitment to purchase vaccines”, one that would be further bolstered if other governments made similar commitments, in an effort to “ensure a future market” for innovators’ products. The proposal also contained two other prongs: an increase in direct funding of NIH research on AIDS vaccines and a 30% tax credit, akin to the orphan drug tax credit, for qualified clinical testing expenses for certain vaccines.

<sup>40</sup> See also Davis 2002.

<sup>41</sup> See GAVI Alliance, “Five nations and the Bill & Melinda Gates Foundation launch Advance Market Commitment for vaccines to combat deadly disease in poor nations,” (February 7, 2007), [http://www.vaccineamc.org/news\\_launch\\_event\\_01.html](http://www.vaccineamc.org/news_launch_event_01.html); Nick Timiraos, “Push to Develop Vaccines for Poor,” *The Globe and Mail* December 31, 2007

<sup>42</sup> See Anon., “Kerry Provisions on Vaccines, Anti-Discrimination Included in Pefpar,” *Congressional Documents and Publications*, March 13, 2008.

an effective vaccine, and other firms are unlikely to enter the field.<sup>43</sup> But, for the same reason, the pneumococcal pilot project is not a good test of the AMC strategy; in effect, it more closely resembles a procurement contract than a prize.)

Both of these problems could be avoided if we framed the contest more broadly. For example, we could follow Joseph Stiglitz' lead in offering prizes to the developers of pharmaceutical products that address any neglected disease.<sup>44</sup> For the reasons just sketched, this would be better than the AMC approach. Nevertheless, even this may not go far enough. Medical innovations pertaining to neglected diseases that do not involve new products – for example, better delivery systems for existing drugs, better diagnostic procedures, and new non-pharmaceutical infection-prevention systems<sup>45</sup> – might reap larger health gains per research dollar than some new drugs. Arguably, a sensible prize system should encompass them as well.<sup>46</sup>

But why stop with neglected diseases? The same considerations presumably should prompt us to extend the competition to all new pharmaceutical projects, or all medical innovations. For that matter, why not include all kinds of potentially patentable innovation – or even innovations of sorts traditionally managed by the copyright system, such as musical compositions or sound recordings, as one of us has elsewhere proposed?<sup>47</sup> Although a prize system that broad might indeed be socially optimal, two considerations argue against its adoption.

First, there are some significant advantages of administrability in restricting the scope of the system to pharmaceuticals. Any prize system faces two major evaluative tasks: determining the extent of the technical advance held out by a candidate innovation and placing a social value on that technical advance (with each of these involving a number of sub-components). A number of factors combine to make these tasks significantly more tractable for innovations that take the form of pharmaceutical products than for other sorts of innovation: (1) The requirement of FDA-mandated testing of pharmaceutical products provides an appropriate filter for identifying prize candidates. Eligibility could be limited to drugs sufficiently different from existing treatments as to require clinical testing before general public use. This relieves the prize system from having to undertake a detailed examination of whether a candidate represents a genuine technical advance.<sup>48</sup> (2) The ready

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<sup>43</sup> See Timiraos, "Push to Develop Vaccines for Poor."

<sup>44</sup> See Stiglitz 2007.

<sup>45</sup> For a thorough review of the relative efficacy of such nonpharmaceutical strategies – some of them novel, others quite old – in reducing the incidence of diarrhea, see Alix Peterson Zwane and Michael R. Kremer, "What Works in Fighting Diarrheal Diseases in Developing Countries? A Critical Review," *World Bank Research Observer* (2007).

<sup>46</sup> See Bryan P. Schwartz and Marhi Kim, "Economic Prizes: Filling the Gaps in Pharmaceutical Innovation," (2005), 48.

<sup>47</sup> See William W. Fisher, III, *Promises to Keep: Technology, Law, and the Future of Entertainment* (Stanford University Press, 2004), chapter 6. See also Calandrillo, "An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System."

<sup>48</sup> Couldn't a prize system for non-pharmaceuticals similarly rely on the patent system's determinations of what constitutes a technical advance? Yes, but relying on the regulatory process as a proxy for innovations has a distinct additional benefit: it allows a prize system to reward potentially valuable activities – such as the

availability of expert assessments of the safety and efficacy of new products, by FDA-type agencies and other bodies,<sup>49</sup> provides a strong foundation for the prize system's more long-term and nuanced assessments. (3) To translate technical advances into health benefits, the prize system can rely on well-developed health utility metrics such as DALYs (disability-adjusted life years).<sup>50</sup> (4) Measuring the overall health impact of pharmaceuticals though far from simple, is manageable. At least a rough approximation can be obtained by estimating (a) the number of doses that are effectively administered to patients and (b) the therapeutic benefits of those doses (with suitable modifications to encompass network effects from vaccines).<sup>51</sup> By contrast, health benefits of many other types of innovation – such as improvements to drug delivery systems, infrastructural prevention technologies, or public-health initiatives – are much harder to measure. (5) Although placing a non-market based social value on innovative advances will always be controversial, it is less so in the case of pharmaceuticals, since putting a non-subjective dollar value on health benefits is, for a number of reasons, increasingly widely accepted as necessary.<sup>52</sup>

Unfortunately, as we expand the prize system beyond pharmaceuticals, even just to encompass all medical or health-related innovations, we lose many (although not all) of the foregoing advantages.<sup>53</sup> A further expansion to cover all patentable innovations loses even more. With each extension, then, we increase considerably the informational costs and

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refinement and clinical testing of already known chemicals for new medicinal applications – that, due to the vagaries of patent protection, remain vulnerable to corrosive “free-riding” absent some other form of government intervention. The availability of the FDA system also provides a further advantage, discussed next.

<sup>49</sup> See Michael Dickson, Jeremy Hurst, and Stéphanie Jacobzone, "Survey of Pharmacoeconomic Assessment Activity in Eleven Countries," *OECD HEALTH WORKING PAPERS NO. 4* (2003).

<sup>50</sup> The DALY metric was developed under the auspices of the World Health Organization and the World Bank. It measures the losses caused by a particular disease in terms of both premature deaths and time spent in suffering or disability (as opposed simply to lost lives or even lost years of life). One DALY can be thought of as “one lost year of ‘healthy’ life,” and the DALY burden of disease “as a measurement of the gap between the current health of a population and an ideal situation in which everyone in the population lives into old age in full health.” WHO 2004, *supra* at 137. DALYs are a close cousin of another health utility index commonly used to assess the cost-effectiveness of health interventions, QALYs or quality-adjusted life years. The two are inversely related, the former being a negative measure of disease burden and the latter a positive measure of good health. For a more detailed discussion, with additional references, see Fisher and Syed, "Global Justice in Health Care."

<sup>51</sup> Various ways of refining this initial rough approximation are considered in the text accompanying notes \_\_\_\_, *infra*.

<sup>52</sup> Among the principal reasons: the seemingly more “objective” aspects of health as a source of welfare; information deficits and asymmetries facing patients as “consumers” of health care; the role of health insurance in reducing consumers’ sensitivity to costs, giving rise to the need for cost-effectiveness metrics; and the economic factors (primarily, the need to curb adverse selection in risk pools) and political-moral considerations (the widespread moral sentiment that access to health care should not be left to purchasing power alone) that lead to substantial government involvement in health insurance and spending decisions.

<sup>53</sup> Specifically, the advantages from DALYs and social pricing of health are retained, while the others are significantly foregone (with a partial exception for other innovations that are also subject to FDA approval but do not receive as extensive safety and efficacy assessments). The resulting increase in administrative complexity is highest for innovation areas that are an uneasy fit with the requirements of patentability (as may be the case for some non-technologically-based prevention methods). In such cases, a further exacerbating factor would be if innovation in the sector was especially cumulative, since the options proposed below, *supra* \_\_\_\_, for handling sequential innovation would no longer be available.

hazards associated with making the necessary assessments. Thus, for present purposes we will restrict our discussion to a prize system limited to pharmaceutical innovations (and, at least initially, to those addressing neglected diseases). But bear in mind that the option remains to extend this scope; consequently, our exploration of such a system's contours and details may serve as an examination of a core "pilot" case, with expansions raising correspondingly more complex issues of manageability and cost.

A second, more important consideration against a general prize system has already been mentioned: political palatability. It's hard enough to imagine Congress (or any other national legislature) adopting in the foreseeable future a prize system that would encompass all pharmaceutical or medical innovations pertaining to the diseases that currently ravage developing countries. The unpopularity of tax increases, coupled with the widespread sentiment that the patent system, outside the sphere of neglected and global diseases, is not yet "broken," make it extremely unlikely that Congress would be willing to reach even further.

## 2. The Nature and Size of the Prize

What should be the form and magnitude of the prize awarded to the developers of effective vaccines or cures? This is the issue that, thus far, has attracted the most attention in the literature on prize systems. Myriad plans have been proposed, but they can be grouped into five clusters. In proposals of the first type, the prize would consist of enhanced patent protection for some other drug, presumably a lucrative drug that addresses a disease common in developed countries.<sup>54</sup> The enhancement might be achieved in various ways. The simplest, proposed by GlaxoSmithKline and by the late Jonathan Mann, would extend the life of the patent on the lucrative drug. Another variant would allow the applicant for a patent on a potentially lucrative drug to obtain "priority review" by the FDA, rather than "standard review."<sup>55</sup> The former procedure is ordinarily only available for drugs that offer "significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease," while latter is employed in situations in which "[t]he drug appears to have therapeutic qualities similar to those of one or more already marketed drugs."<sup>56</sup> Thus, the prize essentially would consist of the right to obtain expedited review of a "me-too" drug.

In most proposals within this family, the enhanced rights would be transferable. Thus, if firm A succeeded in developing a malaria vaccine, it could sell to firm B the right to obtain priority review of a new drug for erectile dysfunction or high cholesterol.

Congress recently adopted a system of this sort. As part of the FDA Amendments Act of 2007, it authorized a firm that obtains FDA approval for a novel drug that addresses one of a set of specified tropical diseases to obtain a transferable "priority review voucher"

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<sup>54</sup> See Hannah E. Kettler, "Narrowing the Gap between Provision and Need for Medicines in Developing Countries," *Office of Health Economics* (2000): 49-50. (referring to this approach as "roaming market exclusivity")

<sup>55</sup> See Ridley 2004; David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe, "Developing Drugs for Developing Countries," *Health Affairs* 25, no. 2 (2006).. Cf. Moran 2005.

<sup>56</sup> See U.S. Food and Drug Administration, "Cder Ndas Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type," (2008). *ibid.* available at <http://www.fda.gov/cder/rdmt/pstable.htm>.



that can be employed to obtain accelerated review by the FDA of any other drug.<sup>57</sup> In a recent paper, Henry Grabowski, David Ridley, and Jeffrey Moe argue persuasively that such vouchers could be highly valuable.<sup>58</sup> They point out that, in the past few years, priority review by the FDA has been roughly seven months faster than standard review. Even if the overall life of the patent on the drug for which the priority review was obtained remained the same, the ability to start collecting money seven months earlier could be worth a great deal. First-mover advantages – the ability to establish a reputation and a market before competitive drugs enter the field – would add to that benefit. Last but not least, Grabowski and his colleagues show that the interaction of the new system with the complex provisions of the Hatch-Waxman Act governing permissible extensions of the terms of pharmaceutical-product patents will, under some circumstances, have the effect of accelerating the date on which the patentee may begin to collect money, without accelerating the termination date of the patent – thus effectively extending the patent life. The bottom line: in the right hands (and getting it into the right hands is, of course, made possible by its transferability), such a voucher is likely to be worth \$100 million and possibly much more.

A system of this sort has the obvious merit of channeling substantial resources into the development of new drugs that address neglected diseases. For that reason, Congress' action should surely be applauded. But such a system has four drawbacks, which, in combination, make it the least attractive of the design options. First, the new statute contains no requirement that the novel drug addressing tropical diseases be made available inexpensively in the countries in which those diseases are rampant. In other words, the new system is cumulative; it in no way alters the background rules of patent law. The upshot is that a firm might develop a new treatment for Buruli ulcer, rely upon that accomplishment to obtain priority review for its next anti-depression drug, and then sell both drugs at profit-maximizing prices, in developing countries as well as developed countries. The availability of this option means that the new system promises to address the “incentive” problem – the fact that too few financial carrots currently exist for the creation of drugs focused on neglected diseases – but will do nothing to solve the “access” problem – the fact that the drugs that do exist are often priced out of the reach of most developing-country victims.

This first drawback, though very serious, could be redressed easily. The statute could be modified to require the patentee on the tropical-disease drug to grant royalty-free licenses to generic firms, permitting them to manufacture the drug and to distribute it on whatever terms they wish in developing countries. The result, of course, would be to drive the cost of the drug in those regions down close to the cost of production.

The other drawbacks of this approach, unfortunately, could not be remedied so easily. The most serious of the problems involves the pattern of incentives it creates. Suppose that a firm wishing to obtain a priority review voucher for an upcoming cholesterol

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<sup>57</sup> 21 U.S.C. 360n. The diseases, specified in the statute, that, when addressed, will give rise to such a voucher are: Tuberculosis; Malaria; Blinding trachoma; Buruli Ulcer; Cholera; Dengue/dengue haemorrhagic fever; Dracunculiasis (guinea-worm disease); Fascioliasis; Human African trypanosomiasis; Leishmaniasis; Leprosy; Lymphatic filariasis; Onchocerciasis; Schistosomiasis; Soil transmitted helminthiasis; Yaws; and “any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.”

<sup>58</sup> See Henry Grabowski, David Ridley, and Jeffrey Moe, "Priority Review Vouchers to Encourage Innovation for Neglected Diseases,"(2008).

drug might earn that right by successfully completing one of three projects currently on its drawing boards: the development of a palliative treatment for yaws, a serious but nonfatal disease currently afflicting roughly 500,000 people;<sup>59</sup> the development of a vaccine for dengue fever, which causes roughly 19,000 deaths per year and a loss of 528,000 DALYs; and the development of a vaccine for leishmaniasis, which causes roughly 51,000 deaths per year and a loss of 1,757,000 DALYs.<sup>60</sup> Assume, for simplicity, that the three projects would cost the same amount and (as is likely) would generate little or no profit for the firm because most of the beneficiaries are too poor to pay for them. Plainly the firm will choose the project with the greatest chance of success – i.e., the greatest chance of earning the firm a valuable voucher – and will ignore the radical differences in their potential health benefits. (Conversely, if the projects have the same chance of success, the firm will choose the cheapest, even if its health benefits are modest.) The bottom line: the system fails to direct research and development toward areas that will most efficiently improve public health.

The third drawback is that the new statute will increase the already excessive degree to which pharmaceutical firms are induced to concentrate R&D resources on “me-too” drugs. All of the drugs upon which the vouchers will be used are “me-toos”; otherwise they would already be entitled to priority review. By permitting firms to introduce those drugs into the market sooner, and then to protect them against competition longer, the statute will prompt firms to shift even more resources toward them – precisely the behavior we don’t want to induce.

Finally, the new statute may increase the safety risks of those drugs that receive expedited FDA review.<sup>61</sup> This is a controverted issue; in their review of the somewhat conflicting evidence, Grabowski and his colleagues conclude that priority review is not correlated with any increase in the frequency of adverse events. We are not in a position to assess that claim here. We merely observe that, if they were correct, then the appropriate response would be to institute priority review for all drugs, not merely for those for which firms can obtain a voucher.<sup>62</sup> In other words, the pace at which the FDA evaluates all applications should be increased, thereby enabling all people to gain access to all beneficial

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<sup>59</sup> See Associated Press, "Who: Flesh-Eating Disease Making Comeback," *FoxNews.com*, January 25, 2007.

<sup>60</sup> See Pierre Cattand et al., "Tropical Diseases Lacking Adequate Control Measures: Dengue, Leishmaniasis, and African Trypanosomiasis," in *Disease Control Priorities in Developing Countries*, ed. Dean Jamison, et al. (New York: Oxford University Press, 2006), 454-55.

<sup>61</sup> The increased risks might result, straightforwardly, from a relaxation of safety scrutiny in the expedited review process. Or there might be a more indirect route: All drugs face the risk of post-approval “adverse events” from harmful effects that go undetected by FDA review, only showing up after use over longer periods or in larger patient populations than those involved in pre-approval clinical testing. However, as Grabowski et. al point out, there is some evidence that a subset of drugs face a lower such risk in the U.S.: those that were first approved outside the U.S., in which cases FDA decisions might have benefited from a longer/larger data set made available by post-clinical-trial use in the country granting prior approval. To the extent that increasing the availability of priority review in the U.S. would reduce the frequency or duration of pre-U.S. approvals, it might increase the frequency of post-approval adverse events in the U.S. (while, it should be noted, either keeping constant or reducing the frequency of post-approval adverse events in the other countries). See Grabowski et. al at 9-10.

<sup>62</sup> An objection: the FDA has limited resources and cannot afford to provide accelerated review for all drugs. Of the possible responses, the most plausible would be simply to generalize the approach recommended by Grabowski et al. and embodied in the new statute: a firm not otherwise entitled to priority review would simply pay the agency the extra costs – currently, roughly \$1.1 million.

drugs more quickly, and we should look for other ways to provide incentives for the development of drugs focusing on neglected diseases.

The second family of proposals would tie the size of the prize to the value of the patent that the drug developer could obtain. This might be achieved in various ways. The simplest would be to require the drug developer to obtain a patent in the ordinary course, after which the government would acquire the patent, either by purchasing it for a mutually acceptable price, or by exercising its power of eminent domain. The government would then release the invention governed by the patent into the public domain, enabling generic manufacturers to make and sell the drug in question at close to the marginal cost of producing it.

The practical problem that besets all proposals of this type is how much money the government should pay. If it uses its power of eminent domain to compel the patentee to surrender the patent, then the government is obliged, both by the Constitution and by the arguably pertinent federal statute,<sup>63</sup> to pay the patentee the fair-market value of the patent – i.e., the net present value of the profit that the firm could have earned through sales of the patented drugs during the duration of the patent.<sup>64</sup> To induce the patentee to sell the patent voluntarily, the government would have to offer at least that much. But how is that amount to be determined? Scholars have suggested various solutions. Robert Guell and Marvin Fischbaum propose that the drug be test marketed in a small geographic area, enabling the government to extrapolate the profits that the firm might earn globally. Michael Kremer has suggested a more complex and ingenious scheme, the heart of which is an auction. In brief: Firm A develops a drug and patents it. The government invites Firm A to submit the patent for valuation. If Firm A accepts, the government solicits bids from other firms (most of which are likely to be other pharmaceutical firms). In 10% (selected at random) of the cases of this sort, the government offers to buy the patent for the price named by the highest bidder and then, if the patentee agrees to sell, resells the patent to the highest bidder for the same amount. In the other 90% of the cases, the government offers to buy the patent for the price named by the highest bidder and then, if the patentee accepts, releases the technology into the public domain. The 10% chance of actually obtaining the patent is what induces the other firms to participate in the auction.<sup>65</sup>

Each of these approaches has difficulties, most of which are thoroughly discussed in a recent paper by Michael Abramowicz.<sup>66</sup> For example, the technique suggested by Guell

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<sup>63</sup> 28 USC 1498(a) provides that "[w]henver an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." It is not clear that this provision could be construed to permit the government to authorize third parties (i.e., generic firms) to make and distribute the drugs at issue. If not, then implementation of this approach could be achieved only by an amendment of section 1498 or by the exercise of the government's authority to engage in so-called "straight condemnation." See *Kirby Forest Industries v. United States*, \_\_\_ U.S. \_\_\_ (1984).

<sup>64</sup> In proceedings brought under section 1498(a), the patentee is typically awarded a "reasonable royalty." For a persuasive argument that the award should also include lost profits, see Cahoy 2002.

<sup>65</sup> See Kremer, "Patent Buyouts."

<sup>66</sup> See Abramowicz, "Perfecting Prizes," 128-36, 48-58.

and Fischbaum would result in a significant delay, while the test marketing occurred, and would require the drug developer to spend substantial sums on marketing, in order to stimulate demand for the drug and simulate a real market. Kremer's system would encounter other problems. To induce firms to invest the substantial resources necessary to prepare bids, the frequency with which the government resold the patent to the highest bidder would probably have to be well above 10%, which would of course reduce the coverage (and thus the efficacy) of the system. In addition, Firm A would have an incentive to collude (explicitly or implicitly, through repeat behavior) with one or more of the bidders, which would then result in misleadingly high auction prices. The system would result in an excessively low price if both of two substitute drugs were submitted (because of the high probability that one of them would end up in the public domain), and an excessively high price if both of two complementary drugs were submitted (again, because of the high probability that one would end up in the public domain, which in this context would enable the holder of the patent on the other to reap all of the monopoly profits on the cocktail). Last but not least, because the system requires many firms to expend substantial resources preparing bids (most of which have no chance of winning), the system would be socially wasteful. There are techniques – some proposed by Kremer, others by Abramowicz – for mitigating these problems, but none would be perfect.

The principal drawback of all members of this family of approaches is not, however, the difficulty associated with valuation; it's rather that tying the size of the prize to the value of the patent that it would displace fails to generate a socially optimal pattern of incentives. It would do a decent (not perfect) job of getting the drugs that would be developed anyway into the bodies of people who desperately need them. But it would do nothing to redirect the research activities of the pharmaceutical firms toward neglected diseases.<sup>67</sup>

The third approach is very different in form, but in the end founders on the same rock. Douglas Lichtman has proposed that, instead of purchasing (or expropriating) a pharmaceutical patent by paying the developer its market value, the government should leave the patent in the hands of the developer, and pay poor potential consumers enough to enable them to buy the drug. If the government had very good information concerning the demand for the drug, this strategy would have much to recommend it. Each eligible consumer could be given a coupon, redeemable by the government, equal in value to the difference between that consumer's willingness and ability to pay for the drug and the price of the drug as set by the patentee.<sup>68</sup> As a result, the recipients of the coupons would no longer be priced out of the market. Indeed – and this is the most striking aspect of Lichtman's proposal – the ability of the drug company to reach this new group of subsidized consumers should make the developer willing to reduce the price of the drug for all consumers. The government could prompt the company to reduce the price by capping the value of each coupon. The establishment of such a ceiling would have two beneficial effects: enhancement of the consumer surplus reaped by the unsubsidized consumers (who would

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<sup>67</sup> See Aidan Hollis, "An Optimal Reward System for Neglected Disease Drugs," (2005).

<sup>68</sup> To be eligible for the coupon, consumers must be willing and able to pay at least the marginal cost of producing and distributing the drug. To subsidize any other consumers would be "inefficient" from a standard economic point of view, and is not something proposed by Lichtman. However, as we discuss below at text accompanying note 75, for reasons of both principle and practicality, a reward system may well wish to subsidize some such consumers.

have bought the drug at the original, higher price), and a reduction in the amount of money that the government would have to spend to redeem the coupons. Clever.

Two circumstances unfortunately deprive this proposal of most of its potential for alleviating the health crisis in the developing world. First, the demand curves for pharmaceutical products in developing countries are typically, to use the economists' jargon, "convex to the origin."<sup>69</sup> In other words, there exist a small number of consumers able and willing to pay quite high prices for access to the drug in question, a very large number able to pay very little, and not very many in between. The cost (to the government) of the coupons necessary to achieve the leveraging effect identified by Lichtman would be higher when demand curves are shaped in this fashion than when the curves are linear (as, for simplicity, he assumed). Second and more seriously, the governments of developing countries typically have even poorer information concerning each potential consumer's ability and willingness to pay for a given drug than do the governments of developed countries.<sup>70</sup> If a government had that information, it should supply it to the patentee and encourage it to engage in precise, "first-degree" price discrimination – the economic efficiency effects of which would be even better than Lichtman's proposal. Lacking it, the government would be forced either to issue coupons to some people who don't need them or deny coupons to some people who do, or both. As Abramowicz observes, errors of the first sort would cause the patentee to raise the market price (or at least be less willing to reduce the price to reach poor consumers, thus increasing the cost of the program to the government), whereas errors of the latter sort will reduce the efficacy of the program.<sup>71</sup>

The bottom line: In the context of developing countries, Lichtman's approach is likely to be worse, not better, than a straightforward patent-purchase program of the sort we just considered. But even if this were not true, his proposal would share with patent-purchase programs a fundamental flaw: it fails to shift research incentives in beneficial directions.

The fourth and fifth families of proposals both seek to remedy this problem by tying the amounts of the prizes issued to drug developers to the social value of their products, measured by the DALYs they would save. The two families differ in one main respect: proposals of the fourth type would have the government allocate a fixed sum of money to be distributed in a given year to drug developers; that pot would then be divided among the participating firms in proportion to the relative social value of their inventions. Proposals of the fifth type, by contrast, would have the government pay each participating firm a specified amount of money for each DALY saved through the distribution of its products. Both approaches have important strengths; the choice between them is not easy. We will suggest that, on balance, the fifth approach is superior, but adoption of the fourth approach would not be irresponsible.

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<sup>69</sup> For clarification of the sometime confusing terminology, see Adolf Kozlik, "Note on Terminology Convex and Concave," *American Economic Review* 31, no. 1 (1941).

<sup>70</sup> The kinds of things that, Lichtman argues, would enable a government to estimate individual consumers ability and willingness to pay for drugs – such as income-tax returns or health-insurance applications – are unlikely to be available to the governments of developing countries.

<sup>71</sup> See Abramowicz, "Perfecting Prizes."

Assessment of their relative merits is complicated by the fact that, within each family, there are several variants, each of which has pros and cons. The simplest version of the fixed-pot approach would give each participating firm a share of the pot proportional to the number of DALYs saved as a result of the creation and administration of its drugs.<sup>72</sup> How would we ascertain those numbers? At first glance, the task seems relatively straightforward. The World Health Organization already gathers and publishes data concerning the disease burdens (measured in DALYs) associated with particular diseases. As previously noted, many governments, including the United States, already employ reasonably sophisticated pharmacoeconomic assessment systems to determine the efficacy of particular drugs in curing or preventing those diseases.<sup>73</sup> To determine the health benefits of a particular drug during a particular time period, we would thus need only the number of doses of that drug administered during that interval to patients suffering from particular diseases.

Unfortunately, several complications may necessitate refinement of that methodology. The first relates to gathering the sales data. We would need to ascertain, not just how many doses were manufactured and distributed by the inventor, but also how many were manufactured and distributed by generic firms. Impediments to getting the necessary numbers would include the notorious reluctance of pharmaceutical firms to release information concerning their operations and the fact that many of the generic manufacturers would not operate in the United States and thus would not be subject to American licensing requirements. Note, however, that the numbers we would need do not include prices, costs, or profits. All we would need are retail sales data (which the generic firms would have no incentive to exaggerate). In the end, that could probably be obtained – if necessary, by paying the firms in question a fee.<sup>74</sup>

Second, as Aidan Hollis has pointed out, if we wished to award prizes solely for the intangible, innovative R&D activity underlying each drug product, we would have to subtract from the foregoing sales figures the per-unit costs of manufacturing and distributing the drug at issue.<sup>75</sup> Accommodation of this principle would, however, be difficult for two reasons: First it would require converting DALYs to dollars – a task we will take up shortly, but which is obviously fraught with controversy. Second, it would require obtaining data concerning manufacturing costs from the generic firms, which would likely be a good deal harder than obtaining sales data. Thus, ignoring Hollis' point is probably necessary as a practical matter. Because of the low costs of producing most drugs, it is probably tolerable as well.

Further, even (or especially) when the costs of producing and distributing the drugs are more substantial (as may be the case with “biologics” or vaccines), there is a reason why we might reject Hollis' proposal: In some circumstances, we might want the prize system to go beyond rewarding the underlying R&D, so as also to subsidize some, perhaps a significant, proportion of the manufacturing and distribution costs. This is where those afflicted with the disease are so poor that, while they would be willing to pay the marginal costs of producing and distributing the drug against a just background distribution of

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<sup>72</sup> See, for example, Hollis, "Optimal Reward System."; *ibid.*

<sup>73</sup> See DICKSON, et al., *supra*.

<sup>74</sup> Cf. Hollis, "Optimal Reward System." (suggesting that licensees could be required to submit sales data).

<sup>75</sup> *Id.*

income/wealth, they cannot in current circumstances afford even that. In such circumstances, the case for subsidizing their purchase would be essentially the same as that motivating the substitution of DALYs for market prices as a measure of the social value of the drugs. Consequently, to subtract the entire marginal costs from the prize risks under-incentivizing either the invention itself (when, roughly, the ratio of average-cost to DALY-price is high) or effective post-invention distribution (when the ratio of marginal-cost to DALY-price is high).

The third, and most significant, set of complications results from drawbacks to relying, for the measure of the aggregate therapeutic impact of a drug, solely on sales volume multiplied by an FDA-type measure of safety and efficacy. As Aidan Hollis and Thomas Pogge have persuasively argued, the data concerning safety and efficacy derived from regulatory testing represent only a partial approximation of the real-world therapeutic effects of a drug. The principal reasons for their limitations are: the patients chosen to participate in clinical trials may be better suited for showcasing a drug's advantages than the general population of diagnosed patients, especially in countries with poor diagnostic systems; the use of a drug over longer time periods and in a larger patient population may reveal greater variations in efficacy, dangers, or side effects than are observed during testing; and the administration of drugs in real-world settings, especially in countries with poor drug delivery infrastructure, may be significantly less optimal than in trials with closely-monitored patients.<sup>76</sup> Moreover, relying only on sales data leaves the system vulnerable to gaming by prize recipients who have an incentive to exaggerate the numbers, either through outright distortion or through product "dumping."<sup>77</sup> Although, as mentioned above, generic firms would not by themselves have the same incentive, the possibility of collusion remains.

To address these various deficits of "naïve aggregation of unit sales times estimated superiority as demonstrated in clinical trials," Hollis and Pogge persuasively advocate a more sophisticated approach to measuring the health impact of drugs. Its key elements include: supplementing regulatory clinical-trial data with "evidence from observational studies and pragmatic or practical trials which use data from normal clinical practice," evidence that will take some time to accumulate and hence lead to revised estimates over the life of the reward; audits to ascertain how many of the doses sold are ultimately dispensed; and, in some cases of widely sold products, population-level studies that measure overall disease burdens "before" and "after" the introduction of the innovation.<sup>78</sup> Although there is a significant increase in discretion and hence uncertainty and potential disputes – not to mention administrative costs – associated with this more complex approach, it seems to us to be, on balance, worth it.<sup>79</sup>

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<sup>76</sup> Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* 29-30 (2008).

<sup>77</sup> *Id.* at 30.

<sup>78</sup> *Id.* at 30-31.

<sup>79</sup> The authors provide an estimate of \$600 million annually devoted to this task, or 10% of the projected \$6 billion pot for their Health Impact Fund. This comes to \$30 million per registered pharmaceutical (they anticipate 20 prize recipients per year). Hollis and Pogge, *supra* at 31. To reduce the risk of costly disputes, the authors wisely insist that it is imperative that the system establish and announce as "clear and fair" a methodology as possible "*before* it begins actual assessment of health impact," so "that innovators can know what to expect if they register their products" with the system. *Id.* at 33.

The fourth and final complication relates to an important category of benefits from innovations in pharmaceuticals that are, strictly speaking, not the result of any added therapeutic value held out by a new drug product over existing treatments. Rather, these benefits stem from improvements in the suitability of pharmaceuticals to the drug delivery conditions of developing countries. Existing drugs, even if effective, are often hard to administer in poor tropical countries. For instance, Medecins Sans Frontieres (MSF) observes that the standard recommended therapy for tuberculosis – the “Directly Observed Therapy, short course (DOTS)” strategy – is “lengthy and difficult to apply,” as it “lasts 6-8 months and requires each patient to swallow the drugs in front of a health care worker every day for at least the first two months. It requires an effective health service, well-trained staff, and a regular supply of quality drugs.”<sup>80</sup> The existing treatments for malaria and leishmaniasis suffer from similar limitations.<sup>81</sup> In such cases, a new pharmaceutical innovation might provide significant value in terms of added health impact without at all improving upon the strict therapeutic properties of the treatments already available. For instance, a more streamlined TB treatment might offer no improved safety or efficacy against DOTS, but provide massive health benefits by enabling greater penetration of and more effective administration to the patient population. Unfortunately, even the expansive Hollis and Pogge approach to measuring the overall health impact from innovations neglects these benefits of this kind.<sup>82</sup> To capture them, we offer the following friendly amendment to the Hollis-Pogge methodology: at the behest of the reward applicant, the prize authority may investigate and make estimates (subject to ongoing revision, like the other estimates) of the added value, in DALYs, of innovations of a non-strictly-therapeutic sort, which improve a drug or vaccine’s suitability for administration in developing-country conditions.

Now let’s return to the problem at hand: organizing a “fixed pot” approach to determining the form and size of the prizes awarded to innovators. Suppose that, using the foregoing method (refined in the ways we have suggested), we generated estimates of the aggregate health benefits of each participating firm’s innovation. Then, under the simplest variant of the fixed-pot approach, we would give each innovator a share of the prize pot proportionate to the relative health benefits of his or her innovation. The obvious advantage of this procedure is that it would draw R&D resources into fields where they would provide the greatest health-care benefits. However, Jamie Love and Tim Hubbard argue, plausibly, this variant has two related drawbacks: it ignores the fact that drug development costs are often unrelated to the number of people served by the drug at issue, and it fails to provide adequate incentives for the development of orphan drugs. In other

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<sup>80</sup> See Medecins Sans Frontieres, Campaign for Access to Essential Medicines – Target Diseases: Tuberculosis, available at <http://www.accessmed-msf.org/campaign/tb01.shtm>.

<sup>81</sup> Regarding malaria, MSF observes that artemisinin-based therapy, while more effective against new strains than chloroquine, “must be administered over a longer period and used in combination with another drug in order to avoid resistance.” <http://www.accessmed-msf.org/campaign/mlr01.shtm> With respect to leishmaniasis, what is “[p]ossibly the most effective drug available”, AmBisome, requires, in addition to its high purchase price, intravenous administration, “making treatment in field conditions more difficult.” [http://www.msfacecess.org/fileadmin/user\\_upload/diseases/other\\_diseases/kalaazarfactsheet.pdf](http://www.msfacecess.org/fileadmin/user_upload/diseases/other_diseases/kalaazarfactsheet.pdf)

<sup>82</sup> Their approach aims to capture more fully the added therapeutic benefits, in terms of the QALY/DALY value of improved safety, efficacy or side effects, held out by a new pharmaceutical. But the benefits from streamlining TB treatment will not show up in any measure of overall health impact that ultimately works only by amplifying an underlying measure of improved safety, efficacy or side effects of a new drug or vaccine compared to existing baseline treatments.



words, this procedure will direct too much money to the developers of drugs that address common diseases and too little to the developers of drugs that address rare diseases.

To correct these biases, Love and Hubbard propose that the pot be divided on the basis of multiple factors. The Medical Innovation Prize Fund Act, a bill recently introduced by Senator Sanders, who in turn relied heavily on advice from Love and Hubbard, provides a good illustration of the method they prefer. It would create an annual fund equal in amount to 0.6% of the gross domestic product of the United States during the preceding year. (In fiscal year 2008, that would come to roughly \$83 billion.) The money would be divided among the firms that developed new “drugs, biological processes, and manufacturing processes for drugs or biological processes” during the year in question or during any of the preceding ten years. The criteria for making the division would be set by a Board of Trustees, composed partly of government officials and partly of persons drawn from specified subsets of the private sector. In setting the criteria, the Board would be obliged to take into account (and weight) the following factors: the number of people who would benefit from each drug or process; the incremental therapeutic benefit of each drug or process; the degree to which each drug or process addressed priority health-care needs, including global infectious diseases, rare severe illnesses, and neglected diseases that primarily afflict the poor in developing countries; and finally the improved efficiency of each manufacturing process. In designing and administering the distribution system, the Board would be required to ensure that minimum amounts were applied to three areas of special need: 4% for innovations addressing neglected diseases; 4% for global infectious diseases and other public-health priorities; and 10% for orphan drugs. Finally, in a given year no one drug or process could earn its creator more than 5% of the pot.<sup>83</sup>

Adoption of this bill would indeed address the two problems identified by Hubbard and Love. It would, however, have a major disadvantage: As Marlynn Wei observes (when commenting on a predecessor proposal), the ambiguity of the factors used to determine each firm’s share, plus the discretion enjoyed by the administrative tribunal in balancing them, plus the large stakes of the game, would give rise to many disagreements among the potential claimants, the resolution of which would consume considerable resources.<sup>84</sup> In other words, this approach would likely give rise to especially severe forms of the rent-seeking and dispute-resolution problems that Section A suggested potentially afflict prize systems. To avoid this outcome, some way of making the distribution of the funds more mechanical and predictable seems imperative.<sup>85</sup>

How might this be achieved without undercompensating the developers of orphan drugs?<sup>86</sup> One technique, also suggested by Hubbard and Love, would be to divide the pot

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<sup>83</sup> "S.2210, Medical Innovation Prize Act," (2007).

<sup>84</sup> See Marlynn Wei, "Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005," *Boston University Journal of Science and Technology Law* 13(2007).

<sup>85</sup> How does this tally with our endorsement of the more open-ended approach advocated by Hollis and Pogge to measuring the health impact of innovations? Simply put, in that context we think that there is no alternative to some increased ambiguity, in attempting to overcome serious deficits of a more mechanical approach. Here, it seems to us that a suitable alternative that remains sufficiently simple is available.

<sup>86</sup> We focus on the orphan drugs issue because it seems to be the only one that a more streamlined DALYs-based approach might jeopardize. The two other suggested minimum quotas, pertaining to neglected diseases and global infectious diseases and other public-health priorities, seem to us unnecessary. Although both areas

into two parts. The money in the first sector would be allocated to drug developers on the basis of the DALY benefits of their creations; the money in the second would be allocated to all “successful new drugs.”<sup>87</sup> Unfortunately, this strategy fails to differentiate optimally among the developers of orphan drugs.

A better approach, we suggest, would be to maintain a focus on the DALYs saved through the distribution of each eligible drug, but to use a nonlinear formula for taking them into account. For example, before multiplying the number of DALYs saved by a drug by the number of persons affected (to determine the most important component of the health benefits of the drug), we might square or cube or apply some other exponential function to the number of DALYs saved per person.<sup>88</sup> This adjustment would embody a judgment that, when making trade offs across persons, serious afflictions suffered by a minority should be given due weight, and not swamped by the aggregate benefits of addressing a comparatively trivial affliction suffered by a large number of persons.<sup>89</sup> More elaborate nonlinear formulae can of course be imagined.<sup>90</sup> Adoption of this proposal would have the effects of reducing the share of the pot awarded to the developers of “blockbuster” drugs that treat comparatively mild conditions, enhancing the share awarded to the developers of orphan drugs that address comparatively more serious conditions, while still giving firms of all sorts incentives to direct their resources toward areas with greater potential aggregate health benefits. To be sure, the returns available to a firm considering pursuing a drug aimed at a disease that afflicted a truly tiny group of people might still be insufficient to justify the cost,<sup>91</sup> but to us that seems morally acceptable.<sup>92</sup>

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are indeed under-incentivized by current patent/market arrangements, they are so for precisely the sorts of reasons outlined above at \_\_\_ (the poverty of those afflicted in the former case and externalities in the latter case), and for which a DALYs-based approach is the appropriate remedy.

<sup>87</sup> See James Love and Tim Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines," *Chicago-Kent Law Review* 82(2007): 17-19. A more elaborate version of the two-part approach can be found in James Packard Love, "Modeling Prize Fund Rewards," *Drug Development* (2006). ("One can imagine, for example, that the rewards for QALYs should follow a simple decay function, such as:  $\text{Reward} = a + b * (\text{QALYs}^k)$ , where  $k$  (less than 1) is the decay parameter, and  $a$  and  $b$  are parameters that reflect the fixed and variable value of new products, both determined within the context of a budget constraint.").

<sup>88</sup> We thank Roni Mann for helpful discussion of this issue.

<sup>89</sup> Our judgment on this issue is rooted in the views that: (i) each person has a legitimate claim – a right, if you will – to a portion of society’s resources necessary to protect that person from a serious illness, even if it is rare; (ii) such a claim should prevail over the interest of many people to a share of society’s resources necessary to relieve them from a minor ailment (e.g., the common cold), even if the total suffering caused by the ailment afflicting the many exceeds the total suffering caused by the serious illness affecting the few; but (iii) there is a limit to such a claim – in other words, at some point a disease becomes so rare or the costs of preventing or curing it become so high, that the interests of its victims may, indeed must, be ignored. Explaining and defending this composite argument will take many pages in Chapter 7 of our book.

<sup>90</sup> Our own sense is that to arrive at the actual function to apply to DALYs – be it squaring, cubing or some other exponential function – we would need to engage in something like the following trial-and-error process: We determine the actual DALYs associated with different rare diseases, try out different functions and then assess the trade-offs that would result against blockbusters addressing comparatively minor conditions. We keep going back and forth, between our intuitive responses to different outcomes and the underlying normative arguments supporting this safeguard, until we arrive at a function that satisfies us in reflective equilibrium.

<sup>91</sup> To illustrate, consider the following hypothetical example, an extension of an example offered by Love and Hubbard to explain their own approach. Suppose that “the risk-adjusted cost of drug development is fixed at \$200 million, the size of the prize fund is \$2 billion, and there are 5 potential candidates for R&D, expecting to yield 1,000; 2,000; 3,000; 7,000 and 25,000 QALYs.” Love and Hubbard, "The Big Idea: Prizes to Stimulate

To summarize, the variant of the fixed-pot approach that seems most attractive is one in which the pot were divided in proportion to some nonlinear function of the number of DALYs saved by each eligible. Now let's step back from these details and consider the strengths and weaknesses of this family as a whole. As Love and Hubbard point out, its great advantage is that it enables government officials to know, in advance, how much the program will cost. 83 billion dollars is a lot of money, but at least it's a known quantity. Legislators considering adopting such a plan would know its cost, and the tax laws could be adjusted to raise the necessary revenue.

Love and Hubbard argue that the fixed pot approach has another benefit as well: "[B]y fixing the size of the prize fund, the developers of products will have an incentive to lobby for fair and efficient methods of valuing inventions. If too much money is given to one inventor, prizes available for everyone else are smaller."<sup>93</sup> This strikes us as overly optimistic. To be sure, each participating firm would have an incentive to challenge the data concerning the public-health benefits of its competitors' drugs. But this is more likely to lead to assaults on the competitors' data than an effort to establish "fair and efficient" valuation techniques. Thus, what Love and Hubbard see as a strength we see as a weakness: even variants of this approach that use mechanical distribution formulae will be beset by the kind of rent-seeking and waste of resources highlighted by Wei.

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R&D for New Medicines." Love and Hubbard point out that, "[i]f the prizes were allocated with a strictly proportional payout per share of QALYs, ... only two the projects would be brought to market. If the prize fund were allocated half on the basis of QALYs and half for bringing a new product for market, all five projects would be brought to market." To see how our own proposal compares to the two options discussed by Love and Hubbard, suppose that the total number of QALYs saved through administration of the five candidates are generated as follows: Drug A would save 0.2 QALYs per person treated and would be administered to 125,000 people; Drug B would save 0.5 QALYs per person treated and would be administered to 14,000 people; Drug C would save 0.5 QALYs per person treated and would be administered to 6,000 people; Drug D would save 0.8 QALYs per person treated and would be administered to 2,500 people; Drug E would save 0.8 QALYs per person treated and would be administered to 1,250 people. On these assumptions, if we allocate the fund on the basis we propose, taking the square of the QALYs benefit per person before multiplying it by numbers of person benefited, four of the five projects would be brought to market and one would not. The calculations that lead to these outcomes are summarized in the following chart:

Drugs	Number of individuals treated	QALYs per person	Total QALYs	Approach #1: Rewards proportional to QALYs (\$millions)	Approach #2: Half allocated proportional to QALYs; half to successful projects (\$millions)	Approach #3: Rewards proportional to square of QALYs per person (\$millions)
A	125000	0.2	25000	1,316	858	806
B	14000	0.5	7000	368	384	564
C	6000	0.5	3000	158	279	241
D	2500	0.8	2000	105	253	248
E	1250	0.8	1000	53	226	129

Note that, under the Approach #1, the prizes available to the developers of drugs C, D, and E are less than the costs of producing them (\$200M). Under Approach #2, all of the projects are cost-justified. Under Approach #3 (our own proposal), the prize available to the developer of drug E is less than its cost.

<sup>92</sup> See note 89, *supra*.

<sup>93</sup> See Love and Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines."

An even more serious drawback of the fixed-pot approach is that it renders highly unpredictable the amount of money that a firm could earn by developing a drug aimed at a particular disease. The problem is especially severe with discretionary, multi-factored variants, like the proposed Medical Innovation Prize Fund Act. But it would be serious even if the distribution formula were mechanical and stable. The reason is that the amount of money that a firm could earn for a given drug depends upon what other drugs qualify for participation in the fund and the health benefits of each. Suppose, for example, a firm is considering investing in the development of a malaria vaccine. The amount that it stands to earn, if successful, would depend heavily upon whether, during the ten-year window in which the vaccine were eligible for prizes, another firm developed an effective HIV vaccine. Why? Because the health benefits of a malaria vaccine, large as they are, would pale in comparison to the health benefits of an HIV vaccine, and thus the latter would get the lion's share of the prize fund. This problem could be mitigated if, as in the Medical Innovation Prize Fund Act, the amount that any one drug could earn its maker were capped, but the imposition of such a cap would undermine the ability of the system as a whole to draw R&D resources into areas of greatest social need – such as HIV/AIDS. And, at most, caps could reduce, but not eliminate the problem.<sup>94</sup>

Approaches within the fifth family would avoid these problems – although, as we will see, they would have some difficulties of their own. The feature common to the members of this family is that the government would commit to paying the inventors of new drugs a certain amount of money for each DALY saved as a result of their inventions. Somewhat more specifically, under these systems the inventor would be paid a certain amount of money per DALY for the incremental health benefits of the new drug as compared to drugs already on the market at the time the new drug is introduced – estimated using the refined methodology outlined in the previous subsection.

As already suggested, it would make most sense, not to try to predict the DALY benefits of a drug at the time it is first introduced, but rather to measure them over time. Each year, the government would collect sales, consumption, and pharmacological efficacy data in the manner described above<sup>95</sup> pertaining to each registered drug and derive from that data a total number of DALYs saved through administration of the drug. It would then multiply that number by the promised fee, and issue a prize to the inventor of the drug. To keep making such payments forever would be unwieldy and unnecessary; a limited term would suffice. Following Love and Hubbard, we might select, for simplicity, a term of 10 years from the date the new drug is first introduced to the market.

Notice that in setting the duration of the payout period, we face a trade-off: On one hand, we need an amount of time sufficient to evaluate accurately the health impact of the drug. Also, to ensure that we do not prematurely pay too much, we might wish to leave some time for an independently developed substitute innovation to come along and replace the drug (an issue discussed in more detail below). On the other hand, if we expedite payments we can capitalize on the differential time preferences (and corresponding discount rates) that it is standard to attribute to public versus private agents. That is, the sooner we

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<sup>94</sup> A less serious, but not trivial, related drawback: In a lean year for innovation, the government could end up paying a great deal for modest technological advances.

<sup>95</sup> See supra page \_\_\_\_.

make the payments, the lower their overall cost to the public purse, net of future discounting, because future money costs, comparatively, more to public funders (due to a lower discount rate) than it is worth to private firms (which have a higher discount rate). Put another way, present money is more valuable to private than public actors, and thus paying out more upfront reduces the net cost. The bottom line is that in setting the time span for payouts, we should be cognizant of the need to adopt the shortest duration compatible with a reasonably accurate estimate of each drug's net added value, something that seems not to have been recognized (at least explicitly) in existing proposals.

The issue that most plagues and divides the proponents of this fifth approach is how much the government should pay per DALY. Plainly, the higher the amount, the more innovation we will stimulate and the more quickly we will alleviate the health crisis in the developing world. On the other hand, the higher the amount, the more expensive the program and the greater the difficulty of securing its adoption.

The range of options is considerable. At one extreme, we might strive, as Professors Shavell and van Ypersele suggest, to select a number that will generate prizes equal in amount to the total social-welfare benefits of each invention. That might, as they argue, generate optimal incentives for innovative activity – although the fact that we don't pay innovators in any other sector of the economy the full social value of their innovations casts doubt on that judgment.<sup>96</sup> But, in any event, it would be prohibitively costly. To illustrate, in the United States, when assessing safety or pollution-control proposals, we commonly implicitly use cost-effectiveness thresholds of between \$50,000 and \$100,000 per DALY.<sup>97</sup> If we relied upon that number when selecting a prize for an effective, widely-used vaccine for malaria, which currently has a global annual disease burden of 44,716,000 DALYs, we would have to pay the developer between two and four trillion dollars per year. Clearly, this is out of the question. Even if we could afford such a sum, the rent dissipation it would generate would likely be prohibitive.

Another possible approach: We might try to pick a number that, in practice, would provide the developer of a drug focused on a neglected disease a stream of revenues comparable to the stream that it could earn from a drug aimed at a non-neglected disease – adjusted upward or downward depending upon whether we thought that the technical challenges associated with solving neglected diseases were either greater or lesser than the challenges associated with the typical commercial drug.

A variant of this approach is employed by Kremer and his colleagues in calculating the magnitude of the AMCs that would be necessary to induce the development of vaccines for malaria and similar diseases. Their conclusion: “a commitment to pay \$13-\$15 per person immunized for the first 200 million people” would be necessary and sufficient.<sup>98</sup> If

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<sup>96</sup> See Fisher, *Promises to Keep*, chapter 6.

<sup>97</sup> See Ernst R. Berndt et al., "Advance Market Commitments for Vaccines against Neglected Diseases: Estimating Costs and Effectiveness," *Health Economics* 16, no. 5 (2007).; P.J. Neumann, "Are Pharmaceuticals Cost-Effective? A Review of the Evidence," *Health Affairs* 19, no. 2 (2000). [\*Insert additional data from Viscusi.]

<sup>98</sup> The complex set of calculations that underlie this conclusion are set forth in Berndt et al., "Advance Market Commitments for Vaccines against Neglected Diseases: Estimating Costs and Effectiveness," 492. See also Kremer and Glennerster, *Strong Medicine*, 86-90 (similar methodology and result).

they are right, and if such a commitment led to the development of an effective malaria vaccine, the cost per year of life saved would be (coincidentally) roughly \$15. If similar commitments led to development of an HIV/AIDS vaccine and a tuberculosis vaccine, the cost per year of life saved would be \$17 and \$31, respectively.<sup>99</sup> If, for the reasons discussed above, we were skeptical of AMCs for specific diseases, and wished simply to offer drug developers prizes consisting of a certain amount of money per DALY saved as a result of the administration of their drugs, we could employ an average of the last set of numbers produced by Kremer and his colleagues: \$21 per DALY.

There are reasons to be uneasy about this strategy, however. Most importantly, it takes as given the current costs of commercial drug development and seeks to offer the pharmaceutical firms similar returns for working on neglected diseases. To their credit, Kremer and his colleagues do not simply accept the profits levels that the firms themselves claim they achieve (or need), or the oft-criticized estimates of the costs of drug development generated by Joseph DiMasi and colleagues,<sup>100</sup> but seek to derive more realistic numbers. They also make an effort to adjust the figures downward to take into account the savings in firms' marketing costs that implementation of their system would enable. But they still aspire to match "the net present value of the revenues earned by a sample of recently launched commercial pharmaceutical products."<sup>101</sup> Unless one believes that the R&D systems that have arisen under the extant patent-based regime are ideal,<sup>102</sup> that number is excessive.

A radically different approach would ask, not how much is necessary to stimulate innovation, but how much are "we" (the residents of developed countries who would have to approve of and pay for such a program) willing to pay to save a year of the life of a resident of a developing country. An answer might be obtained from a loosely democratic political procedure: We could set the figure at a low level in the first year of the program – say, \$10 per DALY – and then gradually increase it in subsequent years. The overall cost of the program would of course rise over time, not just because we would be paying more per DALY, but because more firms would be opting for prizes rather than patents, and because more and more projects aimed at neglected diseases would come to fruition. At the same time, the health benefits of the program – the lives and pain saved in developing countries – would become increasingly concrete and visible. At some point, median public sentiment (reflected in the miscellaneous collection of polls, grass-roots campaigns, lobbying initiatives, etc., that – for better or worse – we rely upon for gauges of public attitudes) would deem us to have gone far enough to satisfy our moral obligations. Thereafter, we would hold the number steady – until such time as our collective altruism increased a notch.

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<sup>99</sup> Berndt et al., "Advance Market Commitments for Vaccines against Neglected Diseases: Estimating Costs and Effectiveness," 502.

<sup>100</sup> Joseph DiMasi, Ronald W. Hansen, Henry G. Grabowski & Louis Lasagna, *The Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107 (1991); and Joseph DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH. ECON. 151 (2003).

<sup>101</sup> Berndt et al., "Advance Market Commitments for Vaccines against Neglected Diseases: Estimating Costs and Effectiveness," 495.

<sup>102</sup> Reasons to doubt this assumption are explored in Chapter 4 of our forthcoming book.

One advantage of this approach is that it would catalyze public discussion of the underlying public-health problem and our responsibilities to address it. The global health crisis currently does not figure prominently in political conversations in developed countries. For example it did not surface in the recent Presidential campaign in the United States. (During the debate on October 7, 2008 both candidates insisted that the United States would never again sit by while a holocaust occurred – without acknowledging that we are in effect doing so now.) In the current debate over how the American health-care system should be reformed, the plight of the residents of developing countries is almost never mentioned. One of the many reasons for our collective inattention is that the magnitude of the problem and the scale of our contributions to efforts to solve it are difficult to grasp. The procedure sketched above, by reducing the issue to a single question – how much are we willing to pay to save a year of the life of a person in a developing country? – should facilitate debate and foster more serious reflection on our duties.

A complication: But wouldn't such a procedure encourage firms to "game" the system? Knowing that the reward per DALY will increase over time, wouldn't they hold off either beginning research projects or submitting successful drugs for prizes, hoping in later years to get a better "price"? Probably not, because such strategic delays would increase sharply the risk that they would be beaten out by competitors and thus would get nothing. If this proved to be a serious problem, it could be mitigated (although not eliminated) by applying each increased fee not merely to drugs first submitted during the year in which the increase occurred, but also to drugs that were first submitted during previous years but are still within the ten-year prize-distribution window.

A final complication: The variant of a dollars-for-DALYs approach outlined above is vulnerable to the same objection raised by Love and Hubbard in the context of a fixed-pot system that relied solely upon DALYs to determine the relative social value of innovations – namely, that it would overpay the developers of drugs that addressed mild common illnesses and would underpay the developers of orphan drugs aimed at serious illnesses. To meet this objection, one could make an adjustment closely analogous to the adjustment discussed above: instead of paying a flat fee for each DALY saved by each drug, one could select a rate that would give greater weight to DALYs earned through alleviation of severe illnesses. The cleanest way to achieve this would be to take the square root (or apply some other negative exponent to) the number of DALYs saved per person by the drug in question, multiply the resultant figure by the number of persons benefited, and then multiply the product by a flat rate.

Admittedly, this adjustment would reduce the simplicity and clarity of the system, which, in turn, would undermine somewhat the system's capacity to facilitate public conversation concerning "our" moral obligations. But the adverse effect on public debate might not be as severe as it first appears. As we suggested earlier, ideally the exponential function used to make the key adjustment would be set through an iterative process of reflection and deliberation.<sup>103</sup> Central to such a debate would be the shape and extent of the ethical claims of persons suffering from serious illnesses to receive larger shares of society's total health-care resources than would be indicated by a purely utilitarian calculus. To be sure, raising that question runs the risk of distracting attention from the more fundamental

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<sup>103</sup> See note 90, *supra*.

moral issue of “our” collective obligations to help those truly badly off. On the other hand, it might foster among the citizenry a heightened awareness of and interest in the significant normative issues that lurk behind otherwise opaque, seemingly “hard” cost-benefit metrics such as wealth- or QALYS-maximization. Opening up such metrics to deliberative scrutiny may increase people’s sensitivity to the need for social policy choices that make explicit distributive and other moral judgments, thereby perhaps even reinforcing the case for neglected-disease research, based as it is on a rejection of the equation of the social value of drugs with their market value. The outcry triggered by the proposed use in Oregon’s state health plan of a QALYS-type cost-effectiveness metric in a reductive way – so as to provide, for instance, higher priority to dental caps than to potentially life-saving appendectomies<sup>104</sup> – is one indication of the potentially wide resonance of such concerns, and hence the potential that formally instantiating them in policy holds for catalyzing further conversations.

In sum, a dollars-for-DALYs approach of the sort we have outlined would not be perfect. But, on balance, it seems the best of the five approaches.

### 3. The Relationship between the Prize System and the Patent System

Currently, we rely almost entirely on the patent system to stimulate and channel drug research.<sup>105</sup> What adjustments should we make in the patent system if a prize system were introduced?

There are three possible answers to this question. This first is: none. Neither the content nor the coverage of the patent system should be altered at all. The prize system would thus be cumulative, offering drug developers rewards in addition to those they could receive by patenting their creations.

Several of the proposals we have already encountered take this general form. For example, the Advance Market Commitments advocated by Michael Kremer and others – and recently adopted by the G-8 countries – presume that the developer of a qualifying vaccine would patent it and then earn both the revenues guaranteed by the AMC and revenues from traditional sales of the patented product. Similarly, the new federal statute that will give “priority review vouchers” to the developers of drugs aimed at tropical diseases presume that those drugs would be patented in the usual way. Finally, Doug Lichtman’s ingenious proposal seeks to supplement, not supplant, the patent system.

The major benefit of this approach is political feasibility. Pharmaceutical firms can be expected to endorse proposals of this kind, for the obvious reason that all such proposals

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<sup>104</sup> See Peter J. Neumann, *Lessons from Oregon*, chapter 6 in Peter J. Neumann, *Using Cost-Effective Analysis to Improve Health Care: Challenges and Opportunities* 58, 60 (2004).

<sup>105</sup> More precisely, we rely most heavily on patents for the “downstream” or “developmental” stages of drug R&D: preclinical and clinical testing. For the more “upstream” or “research” stages, devoted to foundational knowledge of degenerative and regenerative aspects of human physiology and biological and chemical materials, we rely most heavily on university-centered “public-sector” research, based primarily on a system of government grants and other sources of non-profit funding. Finally, a mix of the two obtains for sustaining the “midstream” or “applied research” stages, of translating fundamental knowledge into the drug discovery phases of searching out molecular targets, synthesizing pharmacologically efficacious materials and screening the latter against the former. The details are provided in chapters two and three of our forthcoming book.



provide the firms new sources of revenue without affecting their old sources of revenue. The pharmaceutical firms have enormous political power. It is thus unsurprising that the only prize systems that thus far have made much headway have been cumulative systems of this general sort.

The major disadvantage of this strategy is equally obvious: it is very expensive. All of the costs of the present patent system are retained. To them are added the new costs associated with the prize system. Thus, if possible, we should strive to avoid this approach.

The second answer is that a prize system should replace the patent system with respect to all innovations eligible for the new prizes. The premier example of this approach is the Medical Innovation Prize Fund Act, which grows out of the work of Love and Hubbard. As we have seen, that Act would create a new prize system available to the developers of all new “drugs, biological processes, and manufacturing processes for drugs or biological processes.” It would also withdraw patent protection from eligible drugs or processes.<sup>106</sup> Pharmaceutical firms (and the inventors of eligible nonpharmaceutical innovations) would thus have no practical choice but to apply for one of the new prizes; patent protection would no longer be available. Guell and Fischbaum’s proposal, under which the government would expropriate some drug patents, would lead to the same outcome on a smaller scale. Proposals of this type are commonly referred to as “mandatory.”

The third approach would leave the patent system in place, but would force a drug developer to choose between retaining a patent or obtaining a prize. The simplest variant of this so-called “optional” approach would require the developer of a particular drug to decide, prior to introducing it to the market (but after receiving FDA approval and, typically, well after a patent application has been filed), whether to retain full patent rights or to give up some or all of them in return for a prize. The developer would not be permitted to change his mind later. The prize and patent systems would thus be two mutually exclusive

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<sup>106</sup> The pertinent section of the bill provides: “Notwithstanding title 35, United States Code, relevant provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including amendments made by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; referred to as the “Hatch-Waxman Act”), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), and any other provision of law providing any patent right or exclusive marketing period for any drug, biological product, or manufacturing process for a drug or biological product (such as pediatric extensions under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or orphan drug marketing exclusivity under subchapter B of chapter V of such Act (21 U.S.C. 360aa et seq.)), no person shall have the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, including the exclusive right to rely on health registration data or the 30-month stay-of-effectiveness period for Orange Book patents under section 505(j) of such Act (21 U.S.C. 355(j)). Section 5(a).” Note that this way of disarming patent barriers may not be optimal. As discussed above, a prize system may wish to incorporate aspects of the patent system in order to ease its administrative burden with respect to the technical determinations involved in establishing whether or not a later innovator built upon an earlier’s work. This consideration would seem to be as applicable to a mandatory prize system as an optional one. Thus, the drafters of any future iterations of this Bill might wish to alter this clause along the following lines: the recipient of any prize is constructively held to have waived his patent rights over his innovation subject to explicit permission by the prize system’s administrative authority to file infringement lawsuits for the purpose of determining follow-on activity. And the outcome from a successful lawsuit would be not judicially-determined damages but a share of the follow-on innovator’s reward as negotiated by the parties or determined by the prize system’s formula or Board.

paths (although, as we discuss below, the prize system might make selective use of aspects of the patent system to ease its administrative burden).

As a practical matter, a fixed-pot distribution system, of the sort considered in the preceding section, would have to be mandatory. If it were optional, there would be too many opportunities for firms to collude or otherwise to game the system. Suppose, for example, that in a particular year, Firm A and Firm B had each developed a blockbuster drug. If both opted for prizes, they would have to split the pot. It is plainly to their advantage to come to an agreement under which only one of them seeks a prize and the other seeks a patent. Explicit or tacit agreements of this general type would seriously distort the operation of the system. It is thus no accident that Love and Hubbard, the principal advocates of the fixed-pot approach, also support a mandatory system.

So which approach is better? The main advantage of a mandatory regime is that it could be much less expensive to fund, because it would not have to compete with the patent system. Unfortunately, a mandatory system would have three drawbacks. First, as Shavell and Ypersele point out, it would contain no safeguard against valuation mistakes by government officials. Under an optional system, if the prize formula were set too low, firms could opt out and instead obtain patent protection. In a mandatory system, this would not be possible. As Shavell and Ypersele suggest, the result is that a mandatory system could be worse, from a social welfare standpoint, from the current patent regime, with all of its faults.

Second, pharmaceutical firms would fiercely oppose a mandatory system, for the obvious reason that it could leave them worse off. The only reason why they have not mounted an attack on the Medical Innovation Prize Fund Act is that they don't think it has any chance of passage.

Finally, a mandatory system would likely violate the TRIPS Agreement, which binds the United States as well as the other 152 member countries of the World Trade Organization. Specifically, it would appear to violate Article 27, which provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" and in particular that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."<sup>107</sup>

This conclusion is not free from doubt; various arguments have been made that a mandatory prize system for pharmaceutical products patents is compatible with TRIPS. The most plausible of those arguments runs as follows:<sup>108</sup> The mandate of Article 27 is not

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<sup>107</sup> Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), Article 27(1), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

<sup>108</sup> A less plausible argument than the one summarized in the text would rely on Article 27(2), which permits member countries to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health." The weakness of this argument is readily evident: To invoke 27(2), one would be obliged, not merely to withdraw patent protection from pharmaceutical products, but also to prohibit their "commercial exploitation." That a prize system would not do. See Robert Weissman, "A Long, Strange Trips:

absolute; it is qualified by Article 30, which permits member countries to make “limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” Because a prize system would provide drug developers an alternative source of revenue, its interference with their ability to exploit their patents should not be deemed “unreasonable.”<sup>109</sup> Moreover, it bears emphasis that a prize system – at least one structured in the fashion proposed by Love and Hubbard – would not prevent the acquisition of patents on drugs; it would merely curtail patentees’ ability to enforce the patents after the drugs to which they pertain have been offered for sale.<sup>110</sup> In that sense, it is analogous to a compulsory licensing system, which Article 31 of the Agreement permits, provided that certain conditions are satisfied. The most important of those conditions is that “the right holder ... be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”; the prizes awarded to drug developers would constitute such substitute remuneration. Finally, the Doha Declaration, which construed (or, in the judgment of some observers, modified) the TRIPS Agreement, allows member countries considerable latitude both in defining and in responding to “national emergencies” within the meaning of subsection 31(b).<sup>111</sup> Among the germane provisions of the Declaration are paragraph 7, which “reaffirm[s] the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members,” and paragraph 4, which provides that “the Agreement can and should be interpreted ... in a manner supportive of WTO Members' right to ... promote access to medicines for all.”<sup>112</sup> A prize system designed to increase the development and distribution of drugs that address communicable diseases in developing countries is surely compatible with those aspirations.

Although both colorable and appealing, this argument would likely in the end fail, for the following reasons. First, it would be difficult to characterize a mandatory prize system for pharmaceutical products as a “limited” exception “to the exclusive rights conferred by a patent,” within the meaning of Article 30.<sup>113</sup> The legislative history of that provision suggests that it was designed “to exempt from infringement the use of patented inventions for (1) private, noncommercial purposes, (2) academic research, (3) experimentation for testing or improvement, and (4) educational purposes” – not to permit

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The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining Wto Alternatives Available to Third World Countries,” *University of Pennsylvania Journal of International Economic Law* 17(1996): 1100.

<sup>109</sup> This is the lead argument made by James Love in defense of his proposal. See James Love, “Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D,” *U.C. Davis Law Review* 40(2007): 704.

<sup>110</sup> In this respect, it is similar to the compulsory licensing system of section 115 of the copyright statute.

<sup>111</sup> Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WTO Doc. T/MIN(01)/DEC/2, ¶ 5(c).

<sup>112</sup> *Id.* at ¶ ¶ 7, 4.

<sup>113</sup> See Andrew W. Torrance, “Patents to the Rescue: Disasters and Health Care Law,” *DePaul Journal of Health Care Law* 10(2007): 332. (arguing that “Article 30 does not authorize either compulsory licensing or patent breaking, but rather, it allows member nations to stipulate that some specified uses of patented inventions do not constitute infringement.”); Alix Weisfeld, “How Much Intellectual Property Protection Do the Newest (and Coolest) Biotechnologies Get Internationally?,” *Chicago Journal of International Law* 6(2006): 844.

member countries to refuse to enforce patents on an entire category of products.<sup>114</sup> The most pertinent of the Dispute Resolution Panel reports interpreting Article 30 confirms the foregoing interpretation, holding that that “[t]he term ‘limited exception’ must . . . be read to connote a narrow exception - one which makes only a small diminution of the rights in question.”<sup>115</sup> It is especially unlikely that a future dispute-resolution panel would adopt a more expansive reading of the critical phrase in the context of pharmaceutical-product patents – the field of technology that Article 27 was primarily designed to reach.<sup>116</sup>

Efforts to rely on Article 31 are also problematic. To begin with, the characterization of a mandatory prize system as a compulsory license is something of a stretch. Assuming that characterization passed muster, one would still have to argue that a prize system covering *all* pharmaceutical products (not merely products necessary to address “HIV/AIDS, tuberculosis, malaria and other epidemics”) was necessary to address “national emergencies.”<sup>117</sup> Not only does that argument seem implausible on its face,<sup>118</sup> but an interpretation of subsection 31(b) that would have reached that far was considered and rejected during the deliberations that issued in the Doha Declaration.<sup>119</sup> Finally, Article 31 contains various requirements in addition to “adequate remuneration,” which a prize system could not satisfy.<sup>120</sup> For example, subsections (i) and (j) permit “use of the subject matter of a patent without the authorization of the right holder” only if “the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member” and “any decision relating

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<sup>114</sup> Thomas A. Haag, "Trips since Doha: How Far Will the Wto Go toward Modifying the Terms for Compulsory Licensing?," *Journal of the Patent & Trademark Office Society* 84(2002): 960-61. See also Daniel R. Cahoy, "Confronting Myths and Myopia on the Road from Doha," *Georgia Law Review* 42(2007): 150 n.78.

<sup>115</sup> Report of WTO Dispute Settlement Panel, Canada-Patent Protection of Pharmaceutical Products, ¶ 7.28, WT/DS114/R (March 17, 2000) [hereinafter Canada-Pharmaceuticals Panel Report]. It is worth emphasizing that this gloss was offered by the Panel in the course of upholding the so-called “Bolar” provision, which permits generic drug manufacturers to “make” and “use” (and any intermediate supplier to “sell”) patented pharmaceutical products for the purpose of obtaining regulatory approval to begin distributing the drug once the patents in question expire. This is noteworthy because the Bolar exception is offered by Love as a precedent example of a limitation on patent rights that may be upheld on the basis of Article 30. See Love, *supra* note \_\_\_ at 704. However, that that case is unlikely to provide much support for a mandatory-prize exception seems clear enough from the Panel Report’s painstaking emphasis on how the Bolar exemption is precisely the sort of “limited” exception that is allowed under its restrictive interpretation (in contrast, for instance, to an exception permitting generic “stockpiling” of a patented drug so as to be ready for full market penetration immediately upon patent expiration, which was held not to be covered by Article 30).

<sup>116</sup> Canada-Pharmaceuticals Panel Report, *supra* note \_\_\_, at ¶ 7.90.

<sup>117</sup> For an interpretation of 31(b) that would sweep this broadly, see Debjani Roy, "In Search of the Golden Years: How Compulsory Licensing Can Lower the Price of Prescription Drugs for Millions of Senior Citizens in the United States," *Cleveland State Law Review* 52(2004).

<sup>118</sup> See Bryan C. Mercurio, "Trips, Patents, and Access to Life-Saving Drugs in the Developing World," *Marquette Intellectual Property Law Review* 8(2004): 239.

<sup>119</sup> See Kevin J. Nowak, "Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27," *Michigan Journal of International Law* 26(2005): 915.

<sup>120</sup> See Markus Nolff, "Compulsory Patent Licensing in View of the Ministerial Conference Declaration on the Trips Agreement and Public Health," *Journal of the Patent & Trademark Office Society* 84(2002): 140.

to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority.”<sup>121</sup>

In sum, it is likely that, if push came to shove, a mandatory prize system would be deemed to violate the TRIPS Agreement. Thus, before adopting such a system, the United States would have to seek and then secure an amendment to TRIPS. Insofar as Article 27 was the most hotly contested provision in the agreement, and the provision that the United States regarded as its most important accomplishment, the chances of such a reform seem remote.

In our judgment, these three drawbacks of a mandatory system, in combination, are decisive. That same judgment reinforces our preference for a dollars-for-DALYs approach, as opposed to a fixed-pot prize system, insofar as the latter would likely have to be mandatory.

To be sure, an optional system would itself have some drawbacks. The most important is that it would require the government to offer innovators rewards that exceed the profits they could make under the patent system. That constraint would not significantly hamper the flexibility of the government with respect to neglected diseases, because the patent-based revenues that the firms could earn by developing drugs that addressed them are so low. But it would substantially affect the government’s flexibility with respect to global diseases, and non-neglected developing-region diseases such as HIV/AIDS, that afflict both large populations of poor residents in developing countries and significant populations of more prosperous residents of developed countries. To persuade the developers of drugs focused on the latter to opt for prizes rather than patents, the government would have to offer more substantial sums.

In the previous section, we sketched a possible way of rolling out a dollars-for-DALYs approach: begin with a low figure and gradually increase it over time. If, as we now suggest, such a system were optional, in the sense that drug developers could eschew it in favor of patents, then the likely result would be that, in early years, prizes would be sought only by the developers of drugs focused on neglected diseases. Gradually, as the potential prizes increased, one would see more prize applications from the developers of drugs focused on global diseases. If, as we have argued, the prize system would, on balance, be superior to the patent system, then the resultant delay in extending its reach to global diseases would of course be regrettable. But we are not unduly troubled by the fact that the system would initially redound only to the benefit of the victims of neglected diseases, which to date have attracted the least research.

#### 4. Managing Redundancy

As we suggested at the outset of this paper, both patent systems and prize systems lead to many researchers working in the same zone of potential innovation(s). Some of that overlapping activity is socially beneficial, increasing either the speed or the likelihood of

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<sup>121</sup> A narrower additional problem: at least under the Love-Hubbard plan, prizes would sometimes be awarded, not to the holder on the patent for a drug, but to the first firm “to receive market clearance.” MIPA § 9(b)(1). Plainly, under such circumstances the patentee would not receive “adequate remuneration.”

generating innovations; some of it is wasteful, leading either to redundant research or to diminishing returns for R&D investments. Plainly, we should strive, when tuning a prize system, to reduce bad overlap, while preserving good overlap.

Unfortunately, as suggested above, we currently have very little information concerning how much overlap is optimal. Until we do, conclusions concerning how, exactly, a prize system should be crafted to achieve optimality are out of our reach. We can, however, identify some tools that either are or could be incorporated in a prize system that would enable us either to increase or to decrease the amounts of parallel research in particular contexts, once we know which we wish to accomplish.

The first – and probably most obvious – point is that the size of the prize will affect the number of firms that enter each race. A simple example: Suppose that we offer innovators a prize of \$10 per DALY per year. Suppose further that within our technological capacity is a new drug that would save 10 million DALYs per year, yielding an annual payout to its creator of \$100 million for each of ten years. Now contemplate two alternative timelines for its generation: In Situation A, the drug is developed 11 years from now, while in B it is developed in one year. Assume further that in either case the drug will be eclipsed by a better, independently developed, alternative that is introduced 31 years from today. Thus in Situation A, the total stream of social benefits from the innovation (unadjusted for any social time preference) comes to 200 million DALYs saved,<sup>122</sup> while in B the total is 300 million DALYs saved.<sup>123</sup> Finally, suppose that to generate the innovation in one year would require six firms working away, each incurring a private cost of \$200 million, while to generate the innovation in 11 years would require only two firms, with the same costs of \$200 million each. On these radically simplified (and non-discounted) figures, in Situation B we would realize a greater net social benefit (300 million DALYs saved for \$1.2 billion) than in A (200 million DALYs saved for \$400 million).<sup>124</sup> However, the total private returns from the innovation (i.e., the total amount of the prize money awarded to the drug developer(s)) remain \$1 billion in both cases. If that amount is only paid out to the first firm to develop the drug, then fully-informed private firms would not enter the race in B, since their expected returns ( $1/6 * \$1$  billion) would be less than their expected costs (\$200 million). Thus, if we seek a more optimal social outcome, we must offer a higher price per DALY. The general point: We should not, when setting prize amounts, limit our attention to the costs that would likely be incurred by a single firm pursuing the project at issue.

Now a more subtle point: There is more than one technique we might employ in order to attract (the right number of) multiple innovators. The simplest, suggested above, would be to increase the size of the prize. An alternative approach would be to retain smaller prize amounts but pay them out in the same or closely equivalent amounts to the 2<sup>nd</sup>, 3<sup>rd</sup>, etc. finishers in the race. (Of course, under this option, we might have to stagger the amounts, giving earlier finishers more, so as to retain competitive fire during the race.) The former would be easier to implement. The latter, however, would reduce the uncertainty

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<sup>122</sup> 10 million DALYs per year multiplied by 20 years (the length of time between introduction of the drug and introduction of its replacement).

<sup>123</sup> 10 million DALYs per year multiplied by 30 years.

<sup>124</sup> We know that the additional 100 million DALYs saved in B are worth at least \$10 each and hence more than the added \$800 million cost.

faced by each prospective entrant and thus decrease the private costs of risk-reduction and thus the social costs of providing private incentives (on standard assumptions of risk-aversion).

One specific version of the latter option has been proposed by Hollis and Pogge. They recommend simply moving back by two years the baseline of treatments against which a new innovation's added value is measured. This, in effect, gives roughly similar rewards to all entrants who finish within two years of the winner. Although attractive in its simplicity, it has a serious drawback: it provides no way to distinguish between race-to-invent and invent-around activity. By also letting me-too drugs of the latter type benefit from being measured against an earlier baseline, this proposal increases the incentives for purely wasteful duplication.<sup>125</sup>

Another variant of the latter option, more complex but also more finely-tuned, is as follows. In deciding the prize amounts to be granted for drugs following a pioneer in the same therapeutic class, we should look to two factors, not one: (a) their incremental benefit (as compared to the pioneer drug); and (b) the amount of time by which their entry follows that of the pioneer drug. If the 2<sup>nd</sup>, 3<sup>rd</sup>, etc. finishers get FDA approval within some cut-off, say one year, we infer that they have been engaged in socially desirable race-to-invent activity rather than socially wasteful invent-around activity. As such, they should receive a prize amount reflecting more than their added therapeutic benefit over the first entrant, something equaling a significant share of the total pot to be held out for the innovation at issue.<sup>126</sup> After that period has lapsed, all subsequent entrants into the class are to be given rewards based only on the added value of their innovation when measured against the best or average of the pioneering entrants.

Whether all this is worth the candle is not yet certain. It may be that the costs of running a system of this sort would exceed the costs associated with the private-sector systems of risk spreading (diversified portfolios by venture capital firms, purchases of innovative biotech firms by major pharmaceutical firms, etc.) that would accompany the first (winner-take-all) option. More empirical research would have to be done before this crucial question can be answered.

So far, we have been primarily concerned with the danger that a prize system would attract too few contestants – and thus have sought to identify mechanisms that would enable us, efficiently, to attract more. What if we encountered the opposite problem? How could we mitigate it?

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<sup>125</sup> An additional drawback, somewhat less worrisome, is discussed in note \_\_\_\_, *infra*.

<sup>126</sup> The simplest option would be for all entrants who finish within 2 years to have their innovation's added value measured against the baseline existing prior to the first entrant, as Hollis and Pogge suggest. A drawback to that is that it provides no incentive to finish ahead of any others within the 2-year timeline. That is, finishing first provides the same reward as finishing fourth, as long as the fourth finisher enters/finishes within 2 years of the first. This diminishes some of the competitive fire during the race (although of course a substantial flame remains simply from the facts that to get that reward one must successfully bring a product to market and do so within 2 years of the first entrant). Thus, we might prefer to subtract something from the prize offered to all 2<sup>nd</sup>, 3<sup>rd</sup>, etc. finishers within 2 years, with the simplest option being that the duration of their payout is to be reduced in some proportion to the delay between their entry and that of the first finisher.

One possibility would be to incorporate into the system a registration requirement. Various versions could be imagined. Here's one: Suppose that a firm that anticipated applying for a prize were obliged to register at two stages. When it first commenced research directed toward a particular disease, it would have to so notify the FDA, which in turn would add its name to a publicly available list of firms pursuing the disease in question. Next, when the firm commenced clinical trials on a particular drug, it would have to notify both the FDA and the public at large.<sup>127</sup> The penalty for failure to register in a timely fashion would be disqualification for the prize system. The resultant increase in awareness of just how crowded is the field pursuing a particular goal would help each potential new entrant make more informed decisions concerning whether it made economic sense to join the competition, in light of the ultimate value of the prize.<sup>128</sup>

But what if the combined effect of many such privately rational decisions were still to attract more than a socially optimal number of firms into a given field? In that case, we could cap the number of firms permitted to register projects aimed at a particular disease. If necessary, we could reduce the number to one. New entrants would be permitted only when an initial registrant acknowledged failure and pulled out.

But wouldn't such a system produce an Oklahoma land rush? Pharmaceutical firms would quickly register for every conceivable disease, not just to preserve their options, but also to exclude competitors. Such abuse could be checked with a reporting requirement. Periodically, each registrant would be obliged to describe what it had done or is doing on a particular research venture. Failure to continue would result in delisting. Failure even to undertake a project would result in denial of the right to register for future projects.

Using these tools, the government could bring the total number of participants down to optimal levels. The levels would likely vary by field. As F.M. Scherer has shown, the optimal number increases as the probability of success decreases. Thus, for diseases with respect to which the science was still primitive and the likelihood that any given project would succeed were low, the government could not impose any ceiling. For diseases, such as pneumococcal disease, where the science was well advanced and the probability of success were higher, the government could set lower caps.

To repeat, crucial to all of these strategies would be good information concerning the optimal levels of multiple entrants. Such information is currently lacking – and we are not in a position to offer it. But, if and when we obtain it, the prize system could be adjusted to take advantage of it.

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<sup>127</sup> Explore extent to which this tracks extant requirements.

<sup>128</sup> To explain: a firm deciding whether to enter a specific area of potential innovation will look to the following main variables: (1) its chances of finishing first versus second, etc., versus not at all in developing a drug through to FDA approval; (2) the costs associated with each of the foregoing outcomes; and (3) the reward associated with each. As discussed above, the prize system will clarify what the reward amounts will be for 1<sup>st</sup>, 2<sup>nd</sup>, etc. finishers and the firm is in the best position to know its likely costs for various outcomes. Thus, all that is left is (1), which is a function of the firm's assessment of not only its chances of successfully running the technical-regulatory gauntlet to completion, but also its chances of doing so before others beat it to the punch. And for that, the information generated from the proposal in the text is invaluable. Without it, we risk that even an optimally calibrated prize system may incent too many or too few innovator entrants.



## 5. Sequential Innovation

How a might prize system deal with cases of so-called “sequential innovation,” in which Firm Y generates a “follow-on” innovation that builds upon the earlier work of Firm X, for which X has received a prize? This involves settling at least three intertwined questions: First, to what extent should X continue to enjoy patent rights against Y? For example, should X’s patent rights remain in force against rival innovators’ pre-commercial efforts to build upon X’s innovation? More broadly, should X be able to prevent the manufacture and distribution of commercial versions of Y’s product? Second, to what extent, if any, should the magnitude of X’s prize reflect the health benefits of Y’s innovation? Third, to what extent, if any, should the magnitude of the prize available to Y reflect the fact that it is derivative of the work of X?

The right answer to the first question hinges in part on which of two camps in a long-standing debate among patent-law theorists has the better of their argument. On one side are those who favor expansive patent rights for pioneer inventors, both to provide them strong incentives and to curb duplication wastes by centralizing control over follow-on innovation in the pioneers’ hands, empowering them efficiently to coordinate the activities of the followers.<sup>129</sup> On the other side are those who argue that centralized control risks inadequate follow-on development, due both to the impoverished information possessed by any single firm (regarding different technological possibilities) and to the suboptimal dynamic incentives of a monopolist pioneer, either from misaligned maximizing motives or from sluggish “satisficing” ones. The second group also argues that heightening pioneering incentives simply pushes duplication wastes further back in time, by intensifying races for pioneering innovations.<sup>130</sup> In our view, the second of these groups of scholars have the better of the argument. Their account of what happens when pioneers are given expansive rights is both more plausible as a matter of theory and more consistent with the historical record.

If that is correct, then we surely want to deny the recipients of prizes on pioneering drugs the ability to prevent other firms from using those drugs in experiments and tests intended to generate new drugs. Adoption of this guideline would require only a modest adjustment of patent law in the United States. Since the 2005 decision of the Supreme Court in *Merck v. Integra*, a rival innovator drug developer has enjoyed a substantial, albeit unclear, zone of privileges regarding pre-commercial use of patented materials.<sup>131</sup> That case expanded the existing statutory “regulatory-review” exemption to patent rights – which permits generic firms to use patented drugs for the sake of obtaining FDA approval, in order

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<sup>129</sup> See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 *J. L. & Econ.* 265 (1977); Suzanne Scotchmer, *Protecting Early Innovators: Should Second-Generation Products Be Patentable?*, 27 *Rand J. Econ.* 322 (1996); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 *Minn. L. Rev.* 697 (2001);

<sup>130</sup> See Donald G. McFetridge & Douglas A. Smith, *Patents, Prospects and Economic Surplus: A Comment*, 23 *J. L. & Econ.* 197 (1980); Robert Merges & Richard Nelson, *On the Complex Economics of Patent Scope*, 90 *Colum. L. Rev.* 839 (1990); and Mark Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 *Texas L. Rev.* 989 (1997). See also Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in Richard R. Nelson, ed. *The Rate and Direction of Inventive Activity* (1962).

<sup>131</sup> *Merck KGaA v. Integra Lifesciences*, 545 U.S. 193 (2005).

to have marketing approval in hand at the date of patent expiry<sup>132</sup> – into a *de facto* expanded experimental-use exemption for rival innovators, one specific to the pharmaceutical sector.<sup>133</sup> Under this exemption, a drug patentee cannot exclude rival developers from using compounds or other patented technologies (a) in clinical trials and (b) for most, if not all, pre-clinical testing and (c) likely even during some phases of the applied research stage of drug discovery.<sup>134</sup> Our proposal would clarify this situation by removing any ambiguity surrounding (b) and (c), so as to enable full pre-commercial rival innovator uses.<sup>135</sup> The simplest way to achieve this outcome is to require prize recipients to waive their rights to prevent others from making, using, selling, or importing the patented/rewarded invention for any purposes other than the actual sale of a post-FDA-approval drug product.<sup>136</sup>

Should we go further? Should the prize recipient be required to waive its patent rights to prevent unlicensed post-FDA-approval manufacture and sales of follow-on drugs – or to demand fees from firms that want to engage in such activities? Love and Hubbard seem to answer yes. Their view appears to be that upon payment of a reward, an innovation should in effect be placed in the public domain with no patent protection of any sort, so that follow-on innovators can build upon it for free. To suggest the drawbacks of that approach – and to lay the foundation for a discussion of alternatives – consider the following stylized scenarios:

Suppose, for simplicity, that the prizes awarded for pharmaceutical products are set at 50% of the total social benefits (measured in DALYs) of those products. (Ignore, for a moment, the advantages of paying prizes over time; assume that they are paid all at once.) Suppose further that R&D resources are scarce. Firm X is deciding which of the following three research tracks to pursue:

Track A will generate a new molecular entity (NME) A1, which (like the use of ether for anesthesia<sup>137</sup>) does not lead to any follow-on innovation. The social benefit of A1 will be 20. The prize X will earn is thus 10. The cost of the research necessary to generate A1 is 5. The ratio of social benefits to social costs associated with this track is thus 4.

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<sup>132</sup> 35 U.S.C. §271(e)(1) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention [...] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”)

<sup>133</sup> Or, more precisely, specific perhaps to any economic sector the products of which must undergo FDA regulatory testing and approval.

<sup>134</sup> Merck KGaA v. Integra Lifesciences, *supra* at 205-208.

<sup>135</sup> A number of cases since have applied *Merck’s* holding to find exempt various instances of FDA-related uses of patented materials in non-generic/ANDA contexts. See *Classen Immunotherapies, Inc. v. Biogen Idec*, 381 F. Supp. 2d 452 (D. Md. 2005); *Classen Immunotherapies, Inc. v. King Pharms., Inc.*, 466 F. Supp. 2d 621 (D. Md. 2006); *Genentech, Inc. v. Insmid Inc.*, 436 F. Supp. 2d 1080 (N.D. Cal. 2006); and *Amgen v Roche*, 519 F.3d 1343 (Fed. Cir. 2008). None, however, has directly addressed the issue of how far upstream such rival innovator uses may be before failing to be “reasonably related” to the generation and submission of data to the FDA.

<sup>136</sup> The “selling” and “importing” are necessary to enable innovators to obtain active ingredients from intermediate suppliers, which seems a common practice (at least for generic firms).

<sup>137</sup> See \_\_\_\_.

Track B will generate NME B1, which can be expected to generate a follow-on innovation B2. For example, B2 might be an “incrementally modified drug product” (IMP), such as a heat-stabilized version of B1. (We will discuss other issues raised by IMPs in the following section.) This new formulation would clearly be governed by the patent on B1. Commercial distribution of B2 would completely displace B1. The social benefit of B1 is 18. The prize that X will earn on B1 is thus 9. The cost of the research necessary to generate B1 is 5. The social benefit of B2 (i.e., its advantages over B1) is 5. The cost of the research necessary to generate B2 is 0.5. The ratio of social benefits to social costs associated with this track is thus  $23/5.5 = 4.18$ .

Track C will generate NME C1, which can be expected to generate a follow-on innovation C2. For example, C2 might be a new entrant to the same therapeutic class, significantly better than C1. C2 uses the same principle as C1 – and would not be developed but for C1 – but employs a compound outside of the scope of the patent on C1. Firm X anticipates that, if it develops and markets C1, a competitor (Firm Y) will develop and market C2. The social benefit of C1 is 17. The prize that X will earn on C1 is thus 8.5. The cost of the research necessary to generate C1 is 5. The social benefit of C2 (i.e., its advantages over C1) is 10. The cost of the research necessary to generate C2 is 1. The ratio of social benefits to social costs associated with this track is thus  $27/6 = 4.5$ .

Plainly social welfare will be maximized if X chooses track C. The next best option is track B. The Love/Hubbard proposal, which deprives X of the ability to control or to derive any revenue from follow-on innovation by other firms, would cause X to choose track A, the worst outcome. If possible, we should structure the prize system to avoid this result.

Permitting X to assert its patent rights against Y for post-FDA-approval sales would improve things somewhat. Now X will choose Track B over A, because the developer of B2 will be obliged to pay X a license fee (and X will certainly demand a fee large enough to make track B more lucrative than track A). The preservation of X’s patent rights will not, however, prompt X to choose track C, because C2 does not infringe the patent on C1.

At least in theory, it would seem that the best option would be to adjust upward the amount of the prize that X receives for its pioneering inventions to recognize the social benefits (if any) of the follow-on innovations that the pioneers enable. Optimal incentives would be achieved by requiring follow-on innovators to submit to the prize system – and to accept prizes in amounts reduced by the premiums paid to X. To illustrate: If X pursues Track C, it should be awarded both a prize of 8.5 (for C1) and a share of the prize of 5 that Firm Y could collect for C2 sufficient to bring the prize-to-cost ratio that X can expect by pursuing track C up to the total prize-to-cost ratio associated with track C as a whole – namely 2.25. The cost of C1 is 5, so the total prize awarded to X must be  $5(2.25)=11.25$ . Subtracting the 8.5 that X earns from C1 alone, that yields 2.75. Y’s prize for C2 should be reduced by the same amount, leaving Y with 2.25. That also yields (not surprisingly) a prize-to-cost ratio for Y of  $2.25/1=2.25$ .

For this system to work properly, the formula used to determine the total amount of prizes available from follow-on innovations would have to be the same as the formula used to award prizes for pioneer innovations – not, as Hollis and Pogge suggest, a less generous

formula to take into account the fact that the R&D costs associated with follow-on innovations typically are cheaper than those associated with pioneers.<sup>138</sup>

In sum, from a social-welfare standpoint, there is a strong prima-facie case for tuning the prize system to ensure that, in situations involving sequential innovation, both the pioneers and the follow-on innovators earn the right level of rewards. Unfortunately, that prima-facie case is vulnerable to several objections.

The first and most sweeping begins by observing that the adjustments illustrated in the preceding examples all involve increasing the rewards that would otherwise be earned by pioneers to ensure that those rewards take into account the potential of each line of research for sequential innovation. Increasing the amounts of the prizes generated by the system would have various drawbacks (most of which we have already discussed): an increase in the amount of the taxes necessary to fund the system, which in turn would exacerbate the distortionary effect of the regime as a whole (pp. 12-14, *supra*); greater incentives for wasteful rent-seeking (pp. 14-15, *supra*); an increase in the amount of wastefully duplicative research (pp. 18-21, 66-72, *supra*); an increase in the regressive distributional impact of the prize system as a whole; and so forth.

This objection proves less formidable than it first appears, because most of the increases in the prizes paid to pioneers would be offset by reductions in the prizes paid to follow-on innovators. But this is not a complete answer, because some of the adjustments – for example, the decision to reward IMPs at the same rate as NMEs, rather than at the reduced rate proposed by Hollis and Pogge – would indeed lead to increases in the total amount of the prizes paid to all recipients. To avoid the various negative side effects itemized in the previous paragraph, we could and should reduce the overall payout rate. For example, using the stylized figures employed in our example, we might reduce the formula used to calculate prizes of all sorts from 50% of social benefits to 47% of social benefits – whatever is necessary to keep total payouts the same.

A residual problem: But won't the increase in the prizes paid to pioneers exacerbate research redundancy at the pioneering stage of the innovation process, even if it reduces redundancy down the road? It surely could, but if so, that effect could be mitigated through use of the techniques discussed in the previous section for curbing redundancy.

A much more serious objection to the system outlined above is that it would work well only if all follow-on innovators opted for the prize system, rather than relied upon patent protection. In situations exemplified by Track B, that could be achieved by conditioning the enhanced prize to X on a commitment by X to require all licensees to submit to the prize regime. But in situations exemplified by Track C – in which the follow-on innovation does not infringe the patent on the pioneer innovation – that maneuver would not be available. Especially because the prize available to the follow-on innovator would be reduced by the magnitude of the premium paid to the pioneer, we could expect many

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<sup>138</sup> Specifically, Hollis & Pogge recommend that the developers of “new uses,” the introduction of which requires new clinical trials but typically little by way of additional research or pre-clinical testing, should be entitled to prizes only for five years – as opposed to ten years for the developers of NMEs. Hollis and Pogge, *supra* at 14, 17, 20.

follow-on innovators to eschew the prize regime, looking to patent protection instead. That unfortunate outcome could be prevented only by making the prize regime mandatory – which, for the reasons discussed above, would be both politically infeasible and substantively undesirable. The bottom line: We could expect pioneers to opt for prizes (including sequential-innovation premiums) and followers to opt for patents. Such a regime would, in the aggregate, be significantly more expensive than a prize system without sequential-innovation premiums, which would then give rise to all of the disadvantages discussed above.

An additional, loosely related objection: Who is going to make the determination that one innovation “follows from” or “is based upon” another? The patent regime contains a mechanism for determining when one innovation is sufficiently close to another to constitute infringement. Such judgments approximate only roughly what we really care about – namely, whether one innovation led to or enabled another – but at least we already have a reasonably reliable system for making them.<sup>139</sup> Situations exemplified by Track C, however, cannot be managed with the patent regime, because the follow-on innovation (C2) lies outside the scope of the pioneer’s patent. Who, then, is going to determine whether C2 is really a “follow-on” innovation? The only candidate would seem to be the agency charged with administering the prizes. Providing the agency with the guidelines necessary to make such determinations accurately, and the personnel capable of applying those guidelines, would be both difficult and expensive. In addition, we would most likely have to specify a process for testing the agency’s determinations on appeal, adding to the complexity and expense.

In combination, the last two objections just reviewed seem to us decisive. Fine tuning the prize system so as to give pioneers credit for all follow-on innovations, we reluctantly conclude, is impracticable. This does not mean we must abandon all efforts to adjust the system to deal with sequential innovation. But, at least for the time being, we think that such efforts must be limited to circumstances in which the follow-on innovations are determined to infringe the patents on the pioneers – despite the serious imperfections, from our standpoint, of both the rules used to make such determinations and the procedures for applying them.

To review, for the reasons set forth at the beginning of this subsection, we would require the recipients of prizes on pioneering innovations to renounce their rights, under the patent system, to block (i.e., to secure injunctions against) infringing follow-on innovations, but we would preserve their rights to collect revenue from the infringing followers. How might this be achieved? The simplest approach would be to rely upon the courts. So long as we are going to continue to rely on judicial interpretations of patent law to determine *when* a prize recipient is entitled to collect revenue from a follower, we might as well also rely on the courts to set the *amount* of the compensation. Since the decision of the Supreme Court in the *eBay* case,<sup>140</sup> judges have been required to make such determinations with much greater

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<sup>139</sup> But cf. David L. Schwartz, "Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases," *Michigan Law Review* 107(2008).

<sup>140</sup> *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

frequency.<sup>141</sup> We might capitalize on their growing experience to ask them to determine the magnitude of the compulsory licenses that our system would entail.

That approach has the virtue of simplicity, but suffers from the fact that the (evolving) standards the courts apply in awarding permanent damages bear little relationship to what we really care about: namely, providing both pioneers and followers optimal incentives.<sup>142</sup> It would be better, therefore, to delegate this task to the agency that administers the prize system. Specifically, the agency would be authorized to increase the prize otherwise awarded to a pioneering invention, and to decrease correspondingly the prize awarded to an infringing follow-on innovation, to ensure that the ratio of the pioneer's prize to the R&D costs borne by the pioneer approximated the ratio of the follower's prize to the R&D costs borne by the follower. Implementation of that guideline would not be simple, but, unlike determinations of which innovations infringe others, would fall well within the agency's competence.

## 6. Incrementally Modified Drug Products

For most of this paper, we have focused on the incentives necessary to induce the production and distribution of new molecular entities (NMEs). But there also exist four types of more modest innovations in pharmaceutical products: new chemical derivatives,<sup>143</sup> new pharmaceutical formulations,<sup>144</sup> new uses (or "indications"),<sup>145</sup> and new combinations<sup>146</sup> of known (typically already FDA-approved) molecular entities. Together, these are commonly known as "incrementally modified drug products," or IMPs. On the face of it, these should present no special complications for a prize system. For the reasons set forth in the preceding section, innovations of these sorts should presumably be treated the same as NMEs, with prizes awarded for the added health benefit provided by each advance measured against the baseline of existing treatments, according to whatever is the announced dollars-for-DALY formula – subject to an adjustment downward if they infringe on the patents on pioneering innovations. However, a few features specific to these products merit special attention.

First, as Hollis and Pogge point out, the development and introduction of IMPs by the holder of a patent on the parent drug is, under the current system, often the occasion for two sets of suboptimal dynamics: "evergreening" and delaying. The first refers to the fact

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<sup>141</sup> See S. Woloson, ed., Post-Ebay Permanent Injunction Rulings by District Courts, [http://www.patstats.org/Injunction\\_rulings\\_post-ebay\\_to\\_1-7-09.xls](http://www.patstats.org/Injunction_rulings_post-ebay_to_1-7-09.xls) (last visited October 11, 2009).

<sup>142</sup> For an analysis of the (slowly) emerging standards used by courts to award permanent damages in post-Ebay cases, see Stephen Ullmer, "Paice Yourselves: A Basic Framework for Ongoing Royalty Determinations in Patent Law," 24 Berkeley Technology Law Journal 75, 79-82 (2009).

<sup>143</sup> I.e., specific crystal forms, isomer variants, salts, etc. that may increase efficacy, reduce side-effects, or improve absorption rates, storability, etc., compared to alternative forms of the underlying molecular entity.

<sup>144</sup> I.e., alternative dosage forms and routes of administration (e.g., tablets, capsules, liquids, arm patches, inhalers, suppositories, injections) and variations in the strength and speed and duration of pharmacological effect (e.g., "extra-strength," "fast-acting," extended release).

<sup>145</sup> I.e., a new application of a known active ingredient, or some modification thereof, to provide a safe and effective treatment for a different condition, for which FDA approval has heretofore not been given.

<sup>146</sup> I.e., combinations of two or more known active ingredients that may increase efficacy or safety, or improve on side-effects, contra-indications, etc. compared to either of the single ingredients by themselves.

that a large proportion of IMPs (such as new dosage forms or strengths or chemical derivatives) are relatively standard or “me-too” products holding out little added health benefit; they are introduced by the holders of the patents over the parent molecular entities in an effort to sustain rents past the expiration of the patents on the parents.<sup>147</sup> Despite differences in the underlying causal dynamics, the upshot is similar to that of invent-around activity: a misalignment of private incentives and social value. And the solution, we believe, should be the same: setting prizes to be in strict proportion to the additional benefits provided over existing treatments. The second dynamic pertains to the incentive, mentioned above, even of profit-maximizing monopolists (as opposed to sluggish or satisficing ones) to delay suboptimally the generation or introduction of improvements on their patented products.<sup>148</sup> Our solution to the wider set of patent-based obstacles to effective pursuit of follow-on innovations is equally applicable to the specific version of the problem here: open up follow-on activity to rival innovators.

Hollis and Pogge would address these phenomena somewhat differently. To mitigate a firm’s incentive to delay introduction of improvements, they propose that a firm’s own (parent) products should be removed from the baseline pool when measuring the added value of modifications it is introducing.<sup>149</sup> As they recognize, however, this solution reintroduces the problem of evergreening, since a firm’s incremental innovations will no longer be rewarded in strict proportion to their added value. To address that concern, they propose endowing the prize administrator with discretionary authority to disallow the registration of some products for prizes.<sup>150</sup> However, it seems to us that, for two reasons, it is better to handle the problems of delays in the separate manner we propose, of opening up the zone of improvement innovations to rival drug developers. First, it is preferable to their solution on its own terms, since it disarms a broader set of delay incentives, those associated with “satisficing” behavior on top of those of maximizers. Second, our proposal has the added benefit of enabling the retention of a single approach to all modifications, measuring their added value against all existing innovations, which is a simpler and likely more effective way to curb evergreening, one less open to abuse and disputes.

Note that it is not clear from their discussion whether Hollis and Pogge’s focus here is, indeed, on addressing incentives to delay suboptimally, or whether instead they are attempting to solve a simpler problem associated with a prize system: When a firm introduces an improvement to its existing products, the improvement frequently replaces most or all of the sales of the parent product. Under such circumstances, the firm is rewarded for the added value of the improvement, but stands to forfeit the larger rewards it would be earning from the parent.<sup>151</sup> This of course would discourage the introduction of

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<sup>147</sup> The dynamics sustaining this phenomenon – which are complicated and tied up with specific features of the regulatory and market structure for pharmaceuticals – are explored in Chapter 4 of our book.

<sup>148</sup> See Arrow 1962.

<sup>149</sup> Hollis and Pogge, *supra* at 15.

<sup>150</sup> *Id.* at 17-18.

<sup>151</sup> The relevant passage of their text states as follows: “All innovations developed by the registrant and currently eligible for payments from the HIF will be excluded from the baseline for that registrant. Thus, a firm would find it profitable to introduce incremental improvements on its own products registered with the HIF without the risk of cannibalizing payments.” *Id.* at 15.

improvements during the life of the parent's prize payout.<sup>152</sup> However, this difficulty is better addressed as follows: whenever an IMP product is introduced, if the parent NME (as determined by the FDA classification system) is registered by the same rewarder, then the rewarder should receive, for the duration of the parent's payout, a prize whose amount reflects both the social value of the parent and the social value of the improvement. Between the expiration of the 10-year payout period for the parent, and the expiration of the 10-year payout period for the IMP, the rewarder's prize should only reflect the incremental social value of the IMP.

But what if the IMP were introduced by someone other than the registrant of the parent NME? If the ordinary rules of patent law were still in place, the registrant of the parent, which would almost surely own the patent on the parent, could prevent this from happening. But if the recommendation of the preceding section were adopted, the registrant of the parent would lack this veto power. In that case, we need not be worried that the registrant of the parent would delay the introduction of the IMP. But we should be worried that firms considering investing in the development of an NME would be deterred by the prospect of forfeiting all or most of the prize on the NME if its market share were reduced by the arrival of a rival's IMP. To avoid that deterrent effect, we would need to preserve the pioneer's prize.

This is essentially the situation presented by Track B, discussed in the preceding section. In that scenario, you will recall, firm X was considering pursuing a research track that could be predicted to generate first an NME B1 and then an IMP B2. X expects that commercial distribution of B2 would completely displace B1. The social benefit of B1 is 18. The prize that X could earn on B1 is thus 9. The cost of the research necessary to generate B1 is 5. The social benefit of B2 (i.e., its advantages over B1) is 5. The cost of the research necessary to generate B2 is 0.5. The ratio of social benefits to social costs associated with this track is thus  $23/5.5 = 4.18$ . The previous section argued that X should not be able to prevent Y from developing and marketing B2, but that X should be awarded a share of the prize on B2 sufficient to make its return on investment equal to the prize-to-cost ratio associated with the track as a whole. That would be achieved by giving X 1.45 of the total prize of 2.5 for which B2 is eligible, leaving Y with 1.05. The analysis of this section suggests that that solution must be clarified in one respect: X would receive a prize of 9 for B1 (which could be achieved by continuing to make payments to X for the entire 10-year payout period) even if, by hypothesis, B2 completely displaced B1.

## 7. Geographic Scope

Thus far, we have been assuming, vaguely, that the prize system would be global in coverage. In other words, the magnitude of the reward made to the developer would reflect the number of DALYs it saved (per year) throughout the world, and the drugs to which the system applied would not be subject to patent protection anywhere in the world. But

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<sup>152</sup> By contrast, under the current patent system, the patentee would enjoy, for the remainder of the life of the patent on the parent, returns from the combined value of the parent plus improvement rather than just the improvement and then, post-parent-expiry, whatever extra returns are brought in by the added value of the improvement when competing against generic versions of the parent. Although this might itself result in suboptimal incentives, as shown by Arrow 1962, nevertheless it would be rather less suboptimal than the scenario envisioned in the text.



implementation of a system on that scale would be far from simple. Formally at least, innovation policies are set at the national level;<sup>153</sup> within the limits set by the TRIPS Agreement and the Paris Convention, each country decides for itself how to stimulate research and development. The creation of a global reward system would thus require coordinating reform efforts in over 150 separate countries.

The obvious difficulty of persuading so many countries to move in parallel would be exacerbated by a collective-action problem. Each country would have an incentive to rely upon other countries' willingness to institute a prize system, funded by taxes on their own residents.

Suppose that, despairing of achieving global consensus, the United States were to implement a prize system unilaterally. More specifically, suppose that it adopted an optional reward system of the sort sketched above and then (building on a proposal by Jean Lanjouw)<sup>154</sup> required prize applicants to forego patent protection for their products, not just in the United States, but in all developing countries.

Although feasible, this option is not terribly realistic. It would have the practical effect of imposing on residents of the United States the entire burden of financing the development of drugs that meet the health needs of the developing world. In recent years, the United States has long been unwilling to shoulder even its fair share (on a per capita basis) of the costs of foreign aid or other humanitarian efforts.<sup>155</sup> The likelihood that the federal government would be willing to move to the opposite extreme seems slim.

A route somewhere in between these poles seems the most promising. Instead of either seeking to secure a global consensus, or of going it alone, the United States could collaborate with a small number of other developed countries to institute an optional reward system. The G-8, under whose auspices the pilot AMC program is being deployed,<sup>156</sup> might be a congenial institutional home. Each participating country would agree to bear a share of the total financial burden of the program (the cost of the prizes themselves plus the administrative costs) proportional to its population – or, perhaps, to its GDP. Prize recipients would be required to forego (the specified components of) patent protection for the discoveries at issue throughout the world.

Implementation of the prize system at the level of the G-8 or a similar organization unfortunately would complicate the process, proposed above, for setting the dollars-to-DALYs formula. The rate would have to be set – and then periodically adjusted – by a tribunal of some kind, created as part of the agreement among the participating countries. The governments of the participating countries, each responsive to their own residents, would vary in their tolerance for rate increases. The tribunal would have to balance their competing demands, turning the dial fast enough to satisfy the more altruistic, without causing defections by the less altruistic. Tricky, but possible.

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<sup>153</sup> But cf. Mossinghoff and Kuo (predicting that, in foreseeable future, we will shift to a global patent system).

<sup>154</sup> That proposal is discussed at length in the following chapter.

<sup>155</sup> See Carol Lancaster, *Foreign Aid: Diplomacy, Development, Domestic Politics* (University of Chicago Press 2007).

<sup>156</sup> See the text accompanying notes \_\_\_\_, *supra*.

## Conclusion

To summarize, the prize system that holds the greatest promise for alleviating the health crisis in the developing world would have the following features:

- 1) Prizes would be available for all pharmaceutical products (i.e., drugs and vaccines) that addressed neglected diseases, and then gradually expanded to pharmaceutical products addressing all other – global and non-neglected developing-region – diseases.
- 2) Prize amounts would be calibrated so as to reward only the additional health benefits, measured in DALYs, offered by innovations over existing treatments.
- 3) Prize recipients would be awarded, once a year for 10 years, a sum of money for each DALY saved anywhere in the world during the preceding year as a result of their innovations. The rate would initially be set at a low level, then gradually increased.
- 4) The system would be optional, not mandatory or cumulative.
- 5) The prize administrators would employ various tools to attract the right number of firms to therapeutic problems: varying the amount of the prize offered; offering prizes, not just to the winners of innovation races, but also to other contestants, provided that they finish within a prescribed period of time after the winners; requiring firms considering applying for a prize to register both before they initiated a research project and before they commenced clinical trials; and, if necessary, capping the number of firms permitted to work simultaneously on a particular disease.
- 6) Prize recipients would be required to waive their rights to enjoin follow-on innovation.
- 7) The question of whether an improved drug built upon a pioneering drug, for which the pioneer has received a prize, would be resolved (imperfectly) by the courts, construing the pioneer's patent. Upon a finding of infringement, the pioneer would require the follower to opt into the prize system. The pioneer would then be awarded a portion of the prize to which the follower would be entitled.
- 8) The system would be created and implemented by a small consortium of developed countries.

A system thus constituted would be superior to the current patent-based regime in several respects.

How does a prize system of the sort we have outlined here compare to other possible reforms of the current regime – such as a much-expanded system of compulsory licenses, enhanced facilitation of differential pricing, or a system of regulations designed to channel the research efforts of pharmaceutical firms in more socially beneficial directions? Hard questions. We'll take them up after we have a few more options on the table.

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