

# DELINKAGE PROPOSALS AND THE MEASUREMENT OF HEALTH BENEFITS

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## I. INTRODUCTION

Proposals to “de-link” the price of new drugs from the profits of innovators offer a new and important way of thinking about how to support innovation in pharmaceuticals. Currently, the revenue of pharmaceutical firms is a product of price and the volume of product shipped. In an effort to maximize profits, pharmaceutical companies routinely set high prices that result in greater revenue, even if it means decreasing the sales volume to some extent.

There are many undesirable effects of the current incentives model. First, it is almost always profitable to raise prices such that some patients lack effective access to the drugs. For many drugs, prices are raised so high as to exclude a large fraction of the total potential patients in the world. Notably, not even systems of universal insurance can solve this problem: firms will increase prices until some, not too many, insurers drop coverage of the drug. In principle, price discrimination, sometimes called “tiered pricing,” can help to solve this problem, although in practice income-based pricing strategies are an incomplete solution to problems of international drug pricing.<sup>1</sup>

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1. See Patricia M. Danzon, Andrew W. Mulcahy & Adrian K. Towse, *Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition and Procurement* 2-3, HEALTH ECON., (The Authors 2013) <http://onlinelibrary.wiley.com/store/10.1002/hec.3013/asset/hec3013.pdf?v=1&t=hvfauujz&s=f6a643e08de807656576b0f7f39d447befc15294>.

Secondly, the current incentives model makes it more profitable to invest in drugs that treat diseases that impact the rich, even if there are already many available treatments and the incremental health gains are small.

The disconnect between high price and therapeutic value leads to weakened incentives for the development of drugs that might have the most health benefit. Lastly, once a drug is on the market, firms are given incentives to maximize sales, regardless of the potential benefits to patients. This has led to enormous investments in detailing and drug promotion<sup>2</sup> as well as many scandals associated with misuse of new drugs.

Enormous benefits could be achieved from creating a supplementary or alternative system to better align social goals of improved health with incentives for firms to invest in new drugs. If firms were rewarded based on the extent that new drugs improve the health of patients, instead of the ability and/or willingness of patients to pay, investment in research and development would be better directed. At the same time, it is of critical global importance that pricing of new drugs should facilitate access to those drugs. Several proposals have been made to change the current incentive structure for pharmaceutical innovation, including, for example, the Sanders Bills, the Health Impact Fund, and the Bangladesh/Bolivia proposal. All of these proposals require that the rewards to drug developers be based on something other than willingness to pay. The obvious basis is, of course, the benefit to human health. Indeed, it is clear that rewards should incentivize innovation that generates the largest possible gains. This is exactly what these proposals recommend.

In 2011, United States Senator Bernie Sanders introduced two new bills that aimed to delink the cost of research and development from the cost of the products.<sup>3</sup> The Medical Innovation Prize Fund Act and the Prize Fund for HIV/AIDS Act, collectively referred to as the Sanders Bills, propose a mechanism to separate the market for innovation from the price of the drugs.<sup>4</sup> The first version of the Sanders

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2. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 1, 29, 32 (2008).

3. See Medical Innovation Prize Fund Act, S. 1137, 112th Cong. § 2 (2011); Prize Fund for HIV/AIDS Act, S. 1138, 112th Cong. § 2 (2011).

4. Medical Innovation Prize Fund Act, *supra* note 3, at 2.

bill was the Medical Innovation Prize Act.<sup>5</sup> Rewards would be based, *inter alia*, on the number of patients who benefit and the “incremental therapeutic benefit” of the new drug or vaccine, relative to the pre-existing standard of treatment.<sup>6</sup> Furthermore, the bills would eliminate any legal barriers to the production and sale of generic drugs and vaccines.<sup>7</sup> This would further enhance access by facilitating lower prices. It would also realign incentives for drug developers to focus on innovative drugs that would have the greatest impact. Contributions to the fund would be made by both the government and private insurance companies, amply financed by the substantial savings that would arise from lower prices. As first proposed in 2005, the evaluation of the value of the products would be made annually, over a period of ten years.<sup>8</sup>

The governments of Bangladesh and Suriname joined Barbados and Bolivia to propose a Chagas Disease Prize Fund to the World Health Assembly (WHA).<sup>9</sup> The idea stemmed from earlier proposals by Barbados and Bolivia to the WHA in 2008 and was used to show how a prize fund can be used to increase access by focusing on a currently neglected disease.<sup>10</sup> The Chagas Disease Prize Fund would be used to reward developers of new treatments, vaccines, or diagnostic devices that improve health outcomes.<sup>11</sup> The fund would be endowed with \$250 million from which prizes could be awarded to various products.<sup>12</sup> New vaccines and medicines could claim final product prizes, whereas innovative mechanisms for technical challenges would qualify for the best contributions funding. A portion of the best contributions funding would be allocated specifically for researchers in developing countries. All winners of the prize would have to license their intellectual property to a patent pool, enabling generic production and sales.

The Health Impact Fund (HIF) is a pay-for-performance proposal

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5. Medical Innovation Prize Act, H. R. 417, 109th Cong. (2005).

6. Medical Innovation Prize Fund Act, *supra* note 3, at 13.

7. *Id.* at 2; Prize Fund for HIV/AIDS Act, *supra* note 3, at 4.

8. H. R. 417 109th Cong. § 11(b) (2005).

9. *See generally* Chagas Disease Prize Fund for the Development of New Treatments, Diagnostics and Vaccines, Bangl.-Barb.-Bol.-Surin., WHO (proposed April 15, 2009).

10. *Id.* at 1.

11. *Id.* at 2.

12. *Id.* at 2, 6.

designed to use health impact assessment to incentivize the development and delivery of new medicines.<sup>13</sup> Pharmaceutical firms would have the option to register new medicines with the fund. By registering, a firm would agree to provide the drug at cost price globally. In return, the firm would be rewarded based on an assessment of the actual global health impact of the drug. Because registration with HIF would be voluntary, the mechanism would act as a supplementary option to the existing patent system. Firms could choose whether or not to register a drug with the HIF, based on which option they felt would be most profitable. In this way, the HIF would use market incentives to realign the interest of pharmaceutical companies with actual health impact, thereby facilitating lower prices, improved access to essential drugs, and increased innovation of drugs for currently neglected diseases. Once a drug is registered with the HIF, the firm would receive a share of a fixed fund for ten years, in proportion to the share of the health impact of the registered drugs. In exchange, the firm would agree to sell its product worldwide at a low price, roughly equal to the average cost of manufacture. Following the ten-year reward period, the firm would be required to offer a royalty-free open license for generic versions of the product. The HIF would be most attractive for products that are expected to have a large global health impact but relatively low profitability under monopoly pricing.

The proposals summarized above all have a reward mechanism based in whole or in part on incremental therapeutic benefit. If rewards are to be based on the incremental therapeutic benefit, it is necessary that there be some way of measuring this benefit and estimating the difference between it and the pre-existing standard of care. The questions we address in this brief paper are how accurate such measurement must be to improve outcomes and what issues could arise when implementing pay-for-performance mechanisms based on health benefits for pharmaceuticals.

Our analysis contains two broad components. First, we explore the question of how precise assessments of health outcomes need to be in order to limit reward risk. Second, we consider the problem of how precise measurements need to be to limit moral hazard on the part of firms that obtain rewards.<sup>14</sup> As we will show, neither risk nor moral

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13. AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL*, 3-4 (Incentives for Global Health 2008).

14. Moral hazard, as we discuss below, is a standard problem in agency, in which

hazard creates a requirement for extraordinary precision in measurement. This is an important observation for establishing the feasibility of the delinkage mechanisms.

As a preliminary, it is useful to describe the system that forms the basis of a comparison: the price system. In the price system, firms obtain their reward through the difference between the price and the cost of producing a dose of the medicine. The price is constrained by demand, as for other products, but demand is often driven by government policies concerning insurance. In most developed countries, state-financed insurance schemes use a cost-effectiveness analysis to decide how much to pay; and in developing countries, where insurance tends to be spotty, the set of drugs that is insured often excludes high-priced branded drugs. Thus, the price system is not a “free” market in the usual sense and it generally is heavily influenced already by government policy.

## II. UNCERTAINTY

One of the common criticisms of prize systems is that they may increase risk to the firms that participate, compared to other systems of rewarding intellectual property.<sup>15</sup> One of the concerns is that poor measurement of health outcomes could result in incorrect reward amounts.

To frame the issue more precisely, the question is whether a system in which an administrator assesses the value of a drug based on observed outcomes and clinical trial results increases risk to the firm, relative to a system in which insurers assess product quality based on pre-approval clinical trials and then negotiate price based on the trial results (i.e., the price system described above). That is, is a system with rewards more or less risky than a price system without on-going clinical evidence? Notably, we are not trying to assess risks against some alternative system in which pricing is not related to the assessed therapeutic benefit of the product.

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an “agent” (in this case the firm being rewarded) has incentives to behave inappropriately from the perspective of the “principal” (in this case the rewarding organization), given hidden information about the agent’s actions. Bengt Holmstrom, *Moral Hazard and Observability*, 10 BELL J. ECON. 74, 74-75 (1979).

15. Marlynn Wei, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, B.U. J. SCI. & TECH. L. 25, 32, 34, 44 (2007); Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 123 (2003).

To simplify the problem, it is useful to divide the risks into two types. The first relates to the overall level of reimbursement per QALY, or whatever tool is used to measure the therapeutic benefit of the product.<sup>16</sup> We assume here, without intending to limit the discussion, that the insurer measures health benefits in terms of QALYs. Generally, it may be difficult to capture all of the relevant health benefits in terms of QALYs, so we assume that the insurer is able to make some adjustments for other relevant benefits of the products. However, in the discussion that follows, we assume that there is some tool for assessing the value created by new drugs; we will use QALYs as the shorthand for this tool. The second type of risk relates to the insurer's accuracy in measuring the number of QALYs (or benefits) provided by the product.

#### A. RISK RELATING TO THE AVERAGE REVENUES PER QALY

One type of risk is that the insurer, for some reason, cuts back on payments to drug manufacturers, across the board. We know that this risk exists in price-based markets. For example, in recent years, both Germany and Greece have required across-the-board price cuts for pharmaceuticals supplied to the public system.<sup>17</sup> Generally, in any

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16. A QALY, or Quality-Adjusted Life-Year, is a measure used by insurers and health economists to measure health outcomes in a way that allows comparison across individuals and conditions. See HOLLIS & POGGE, *supra* note 13, at 9. An extra year in full health is 1 QALY; an extra year in imperfect health is worth less than 1 QALY. Using various techniques, health economists have developed estimates the weights that are appropriate for different health states. QALYs create a common currency for evaluating health interventions, since one can directly compare different outcomes: for example, one might compare an intervention that saved 3 people from death, giving them on average 10 years in excellent health (30 QALYs) against an intervention that enabled 40 people to have move from frequent dialysis to less frequent dialysis over five years (0.1 QALYs per person per year times 5 years times 40 people = 20 QALYs). Without QALYs, it would be impossible to make a fair comparison between the two interventions. QALYs enable insurers to decide how to allocate scarce resources.

17. Diana Ognyanova, Annette Zentner & Reinhard Busse, *Pharmaceutical Reform 2010 in Germany: Striking a Balance Between Innovation and Affordability*, 17 EUROHEALTH, no. 1, 2008, at 11, 11-13. <http://apps.who.int/medicinedocs/documents/s20965en/s20965en.pdf>; Sotiris Vadoros & Tom Stargardt, *Reforms in the Greek Pharmaceutical Market During the Financial Crisis*, 109 HEALTH POL'Y 1, 1-2 (2013) <http://www.hche.uni-hamburg.de/de/Bilder/newsletter/Vadoros-Stargardt-2013---Reforms-in-the-Greek-pharmaceutical-market.pdf>.

system constrained by budgets—which is common in public insurance systems—there is a risk that the insurer will decide to reduce the level of payments. This may occur for very different reasons. If the state suffers a financial crisis, it may be forced to reduce the relevant budget. Alternatively, the budget may become constrained by an influx of new, valuable drugs, which create budgetary pressure for price reductions of other drugs. In any case, in a world of fixed (and sometimes unpredictably varying) budgets, there is no certainty that a given drug will be funded at the expected level.

Reward systems face a similar problem. Typically, they are designed with a fixed or quasi-fixed budget. They are subject to the risk of the reward stream being reduced unexpectedly because of government budgetary shortfalls, and to the risk that new drugs will use up some of the rewards anticipated by others. An international reward system, in which multiple governments participate, may create additional risks in the sense that there are more chances for a given government to reduce funding; but it can also mitigate risks through diversification of funding sources and less dependence on a single government's budget.

A low reward per QALY may also occur if products registered with the reward scheme have higher than expected health benefits. If there is a fixed reward payout and the system allocates the reward proportionally between products according to the number of QALYs generated by each, then, by construction, the reward per QALY must be smaller. This, however, does not necessarily increase risk to the participating firms, since the total amount paid out is constant. This has attractive properties as a form of insurance to the industry. For example, if research productivity decreases, there will be fewer products competing for the fixed rewards, and hence the reward per product will increase. On average, the revenues of firms will be protected because the rewards remain unchanged. In a price-based system, lower productivity results in fewer products developed, lower profits for the firms, and, ultimately, lower investment.

Considering all these risks, it is not apparent that reward systems are more likely to face uncertainty in the average revenues per QALY than the price system.

*B. RISKS RELATING TO THE MEASUREMENT OF HEALTH BENEFITS*

Both the reward and price systems make revenues contingent on health benefits, but apply different systems of measurement. The price system uses pre-approval clinical trials as the basis for estimating health benefits per unit of the drug; the reward system does the same, while allowing for adjustments based on evidence of how the drug is used and what the benefits are in practice.

We need to start with understanding risk. The first way of assessing the risk of a reimbursement system is to think of the risk as variance of reimbursement from the perfectly informed market outcome. We could think of the “perfectly informed market outcome” as the stream of revenues that would have been captured by the firm if patients, doctors, and payers had perfect knowledge about the clinical effects and other effects of the product and all its alternatives, and there were no other distortions in the market. While no pharmaceutical market looks like this, the “ideal” market can be a useful benchmark.

Firms are assumed to have a preference for predictability, but they are not better able to assess what the perfect “market” would do compared to what the regulator would do. Firms also have a preference for higher expected revenues. Managers in companies are risk averse, and their preferences should influence the decisions of the firm, resulting in the firm seeking to avoid risk.<sup>18</sup>

By construction, a system in which there is on-going measurement about the clinical effects of the product must get closer to the “perfectly informed market outcome” than a system that relies only on measuring outcomes in the context of clinical trials before registration. Thus, by our first measure of risk, the reward system appears to be superior to the price system.

An alternative measure of risk is whether the firm obtains a predictable stream of revenues from the product. The problem here is tying down the notion of predictability. Let us assume that the prediction of revenues is made at the time the product enters into Phase 3 trials.<sup>19</sup> In this case, our measure of risk is the variance from the prediction made at that stage. Would either kind of revenue stream

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18. Risk aversion is a technical term indicating that preferences are such that an individual would prefer a certain payment of a given value.

19. Clinical trials involving humans are classified into three types. Phase 3 trials are the last stage and generally involve a large number of subjects.

have less variance from the prediction? Of course, the main risk in this case is the performance of the product in the clinical trials. Compared with this risk, risks concerning exactly how the product is reimbursed are secondary. However, let us assume that the pharmaceutical firm has an unbiased view of the likely success of the product if approved.

Let us then consider which type of reimbursement of the product creates more risk, in the sense of being closer to the unbiased expectation of the firm. By construction, the price system is designed so that price is based on the performance of the product in the clinical trials. To the extent that the actual performance of the product varies from that in the clinical trials,<sup>20</sup> basing reimbursement only on the clinical trial results creates more risk. Essentially, the sample in the clinical trial is smaller than the sample in the population, and the distribution of characteristics among the clinical trials' subjects will differ from the distribution of characteristics among the population of patients who will use the drug. This automatically means that the risk of errors in the estimate of the product's actual value must be greater in the price system.

How does this impact the firm? Assuming that reimbursement entities are seeking to limit utilization when prices exceed value, a product that is priced too high will be under-utilized and likely under-perform financially, unless and until the firm lowers prices to more realistically reflect value to patients. A product that is priced too low will under-perform financially, relative to its true value, unless and until a firm can raise prices. In an environment where reimbursements are ridge, either up or down, errors in the estimates of a product's actual value will lead to systematic financial underperformance.

Firms are not the only participants in the system that are exposed to risk. The insurer—in many cases a government agency—and patients also face risk in any system. Insurers also have an interest in budget stability, which prize systems allow for, since the annual payout is less subject to fluctuations than in a price system, particularly when the reward fund is fixed in size and completely predictable. Insurers in the price system are potentially harmed because deviation of the actual effectiveness from the measured effectiveness may result in the risk of paying too much or too little for a given treatment.

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20. Sean R. Tunis, Daniel B. Stryer & Carolyn M. Clancy, *Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy*, 290 JAMA 1624, 1625 (2003).

As noted above, the consequences of paying too much for a given treatment may include avoiding utilization of a health improving intervention, which undermines the objectives of the insurers (and consumers) of the product. The consequence of paying too little for a given treatment is to inadequate incentives for R&D, which also undermines the objectives of the insurers (and consumers) seeking to support innovation. At least in regards to these considerations alone, both sides—firms and insurers—have lower risk in a prize system that matches rewards to outcomes than in a price system that is based upon information from pre-approval clinical trials. The total annual payout by the insurer fluctuates unpredictably in the price system, and this creates risks for both payers and firms.

In a prize system, there is greater stability of the total annual payout, but there will be unpredictability with regard to the investment return for a particular innovative product, due to two factors, namely the emerging evidence regarding the value of the product in use and its utilization, and the degree of competition from others providing innovations that are rivals for prize fund money. Neither of these factors is unique to the prize system, since both exist also for the price system. There are some differences, however. In the price system, rival drug developers have incentives to develop me-too products that use similar mechanisms to achieve similar results, without technically infringing on patent protection. This often constitutes a significant risk in the price system, as the new me-too products may significantly erode the innovator's market share. Under the prize system described above, there are fewer incentives to develop products that simply match existing outcomes, and so the risk for that particular type of competition has been reduced.<sup>21</sup>

What does this mean for measurement? Measurement in a prize system needs to be, at least, no worse than in the price system.

### III. MORAL HAZARD

A second problem that can arise from imperfect measurement of health outcomes in prize systems is moral hazard.<sup>22</sup> A common

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21. James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHIC.-KENT L. REV. 1519, 1524 (2007).

22. Moral hazard is a result of situations where an individual or company does not bear the consequences of its actions. For example, the individual or company might have a tendency to take more risk because the costs will not be fully felt by the risk-

argument against the pay-for-performance mechanism is the potential for firms “gaming” the system. If measurement is imperfect, pharmaceutical companies could manipulate the process either through exaggerating the per unit value of their products or through exaggerating the number of patients who benefit from the product.

Moral hazard is common in medicine. For example, Marshall *et al.* examined the performance of health care in the United States and found that surgeons were hesitant to perform on high-risk patients because even one death could have a high impact on a surgeon’s performance rates.<sup>23</sup> In this case, because mortality data was used as an indicator for quality of clinical care, there was room for a reactive gaming response.<sup>24</sup> “Complete specification of targets and how performance will be measured almost invites reactive gaming.”<sup>25</sup> In a system where rewards are based on health outcomes, pharmaceutical companies might be incentivized to game the system. For example if drug rewards are based on the number of deaths averted, companies could try to game the system by incentivizing providers to only administer drugs to “low-risk” patients so that death would not be linked to the drug, and in turn show better health outcomes even though a high-risk patient may have benefited more from the treatment. An example of this could be administering chemotherapy only to patients known to have a very high survival rate instead of those that have a lower survival rate but could still benefit from the treatment. Unfortunately, no performance indicator can be assumed to remove gaming completely. Performance measurement tools used in the prize system should have a level of transparency and ambiguity as to not invite gaming, according to Bevan and Hood.<sup>26</sup> They argue that a level of ambiguity in measuring targets will reduce gaming.<sup>27</sup> Using the

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taking party. In particular, moral hazard is a problem when one side has greater information than the other (i.e., information asymmetry). In the case of pharmaceuticals this may lead to demand for the product exceeding what is expected under normal market conditions. This results in a welfare loss to society because the cost of the drug exceeds the benefit to the patients.

23. See MARTIN MARSHALL ET AL., DYING TO KNOW: PUBLIC RELEASE OF INFORMATION ABOUT QUALITY OF HEALTH CARE 87, 96 (2000).

24. See *id.* at 95-96.

25. Gwyn Bevan & Christopher Hood, *What's Measured is What Matters: Targets and Gaming in the English Public Health Care System*, 84 PUB. ADMIN. 517, 533 (2006).

26. *Id.* at 533-34.

27. *Id.* at 533.

above example, if the measurement were based on something a bit more ambiguous such as health outcome instead of mortality, the surgeons might have been less likely to avert procedures on high-risk patients.

Here, it is important to acknowledge that opportunity for gaming is present in the price system. The question is whether the opportunity for moral hazard is any greater in the prize system than in the price system.

In the price system, payers (regulators, insurers, governments) will be motivated to devalue the innovation while innovators will overstate the value of the drug. The payer will be tempted to grant a much lower valuation of the innovation in order to reduce the price that must be paid. Decreasing the price too much will diminish incentives for innovators. On the other hand, innovators will want to exaggerate the value of the product in order to obtain a higher price. They will be tempted to hide information about the product, or to pitch the advantages of the product in the most appealing light.

Recent attempts by pharmaceutical companies to hide, deny, or minimize negative outcomes associated with drugs suggest misaligned interests of pharmaceutical companies with those of increasing health outcomes.<sup>28</sup> The quality of published literature is constantly being scrutinized due to biases and motivations outside of the public good. As noted in the *Tragedy of the Commons*, individual profit maximization may endanger public good.<sup>29</sup> For example, in 2000, Pfizer published information regarding the safety and efficacy of the drug Celebrex in *The Journal of the American Medical Association*, which showed that, when used for six months, the drug reduced the incidence of gastrointestinal complications.<sup>30</sup> However, Pfizer failed to release the second half of the study, which showed that, in the following six months, nearly all incidence of gastrointestinal complications was associated with patients on Celebrex, thereby

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28. See Mayer Brezis, *Big Pharma and Health Care: Unsolvable Conflict of Interest Between Private Enterprise and Public Health*, 45 *ISR. J. PSYCHIATRY RELATED SCI.* 83, 84 (2008).

29. See Garrett Hardin, *The Tragedy of the Commons*, 162 *SCIENCE* 1243, 1244 (1968).

30. John Abramson & Barbara Starfield, *The Effect of Conflict of Interest on Biomedical Research and Clinical Practice Guidelines: Can We Trust the Evidence in Evidence-Based Medicine?*, 18 *J. AM. BOARD FAM. PRAC.* 414, 415 (2005).

negating the findings shown in the first study.<sup>31</sup> As such events demonstrate, the current price system creates strong incentives for companies to alter or hide evidence to increase monetary gain and market share at the cost of patient outcomes and safety.<sup>32</sup>

Another form of potential moral hazard in the price system is “disease mongering,” when external sources convince people that they are sick in order to expand the market share of a product. Trivial conditions such as normal ageing could be incorrectly categorized as osteoporosis, leading individuals to think that they need some treatment. In doing so, companies claim rewards by “benefiting” patients who never needed the treatment in the first place. For example, someone with abdominal discomfort could be diagnosed with irritable bowel syndrome. The person would then proceed to take the treatment and be “cured” when in reality the treatment was never needed.

The vulnerability of the prize system to these types of moral hazards relates to the quality of measurement. With accurate measurement, the prize authority would know how many people were treated, what the typical response to treatment was, and the likely counterfactual outcomes for those patients. It is necessary to know not just the outcome, but also the counterfactual outcome, i.e. what the outcome would have been in the absence of the treatment, to assess the value of the treatment given. Of course, this is ambitious. But the prize system, in its exposure to moral hazard, resembles the price system.

The area of most concern for prize systems is that poor people are protected from some exploitation by their poverty. Innovative pharmaceutical companies have few incentives to get very poor people to take a drug to cure a disease they do not have, because they acquire small or zero profits from selling to such people. With a prize based on health impact, companies might find it attractive to try to sell large volumes of drugs to poor people who can afford the generic price, but who do not really need any medicine. In the absence of good measurement, such a strategy would be profitable, but bad for people taking those drugs. In principle, people in developed countries are already vulnerable to such over-medicalization, as they are convinced to take unneeded drugs, which generate profits for the industry. However, people in developed countries are *relatively* well protected

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31. *Id.*

32. See Brezis, *supra* note 28, at 84.

from abuse through laws, regulations, and comprehensive health care systems: the poor and uneducated in developing countries would present an easier mark. Thus, a key requirement for prize systems is to ensure that the measurement is good enough in developing countries to ensure that poor people do not become the prey of unscrupulous practices to sell unneeded drugs. Good quality measurement of health benefits would solve the problem since firms would be motivated to sell products only to patients who could actually benefit from them.

From the above discussion it is clear that the potential for moral hazard will be present regardless of whether we are to examine the prize system or the price system. However, the prize system would need to pay special attention to measurements where there is a potential for excessive sales to poor people becoming an income source without corresponding benefits to the patients.

#### IV. CONCLUSION

Delinked reward systems have been challenged as presenting insuperable difficulties in implementation because they rely on measuring and rewarding pharmaceutical companies for actual health outcomes. As this paper has shown, however, other systems of paying for pharmaceuticals, including the familiar system in which insurers assess the effects of drugs before they agree to insure them, also require measurement, and make the revenues of pharmaceutical companies, as well as the expenses of insurers, explicitly dependent on these measurements. Delinked reward systems can reduce risk for both innovative pharmaceutical companies and insurers, and achieve better outcomes for patients at the same time.