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Product-Development Partnerships and the Health Impact Fund*

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Abstract: Product development partnerships (PDPs) have become a central component of the war on neglected diseases. PDPs typically consist of a formal partnership between a not-for-profit organization focused on developing treatments for neglected diseases and one or more for-profit pharmaceutical companies. This paper explores how the role of such PDPs may be enhanced through the proposed Health Impact Fund (HIF), particularly in terms of increased sustainability, better controls on price, and enhanced incentives to distribute products developed through PDPs.

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1. INTRODUCTION

In the past few years, product development partnerships (PDPs) have become a central component of the war on neglected diseases. PDPs typically consist of a formal partnership between a not-for-profit organization focused on developing treatments for neglected diseases and one or more for-profit pharmaceutical companies. Partnerships of this new type have only sprung up over the last 15 years or so, but they have already attracted substantial funding from governments and foundations – especially the Bill and Melinda Gates Foundation (BMGF) – and have begun to repay these investments by developing new treatments for important medical conditions for which treatment options had previously been woefully inadequate.

This paper considers how the role of such PDPs may be enhanced through the proposed Health Impact Fund (HIF). The HIF proposal is for an international fund that would directly incentivize the development of new medicines by offering to reward them according to their health impact if they are sold everywhere at or below their cost of production. While they have broadly similar purposes in terms of the kinds of medicine they seek to develop and make widely accessible, the HIF and PDPs are not so much substitutes as complements: each works better with the other than on its own.

We begin by describing the key problems that have led to the recent popularity of both PDPs and the HIF proposal. Next we review the development of PDPs and their operations, considering what obstacles they face in reaching their goals of developing and distributing drugs primarily for the benefit of poor people in need of new and effective treatments. We then describe the HIF proposal and discuss how its structure is complementary to PDPs.

2. THE PROBLEM

Pharmaceutical research and development (R&D) appears to be on a trend of declining productivity, with increasing R&D expenditures resulting in a decreasing number of new chemical entities being brought to market. This trend

is naturally a matter of immense concern since pharmaceutical innovation has delivered great benefits. Given the natural evolution of new infectious diseases, including different variants of influenza and HIV, and the seemingly inevitable increase in antibiotic resistance of existing pathogens, standing still is losing ground. So it is essential that we have efficient, productive research laboratories that can respond to these new threats to human health as well as to the many older medical conditions for which adequate treatments are still lacking.

It is also noteworthy that R&D spending by private corporations is focused on the diseases that promise the highest expected profitability. This means that — very high prospective therapeutic benefits notwithstanding — innovators tend to under-invest in cures and treatments for diseases concentrated among the poor. This is a foreseeable result of how we reward pharmaceutical innovators, who are of course aware that they typically cannot obtain high prices for delivering even vital drugs to poor patients.

Given that the R&D process is lengthy and expensive, pharmaceutical companies cannot be expected to create new treatments with little reward. The WHO report, Public Health: Innovation and Intellectual Property Rights, outlines the stages of development for a pharmaceutical product.[1] First, there is basic research that may lead to the discovery of a useful product. At this point, a patent is filed for the new product, and the first phase of testing will occur. This is followed by two more phases of testing on patients before a marketing application is filed. These testing phases take years to complete, and there is a great deal of attrition throughout this development chain. As a result, the developer will often incur huge expense for a product that never even reaches the market. After a regulatory review of the marketing application is filed, the drug may be available for purchase. The development of a single product is estimated to cost the developer an average of 800 million dollars after considering the costs of both successes and failures.[2] Pharmaceutical companies spend large amounts on R&D in anticipation that they will earn back even larger amounts by charging high prices for their products; rarely will a product be developed for limited financial

[1] See WHO (2006, p. 65ff).
[2] Adams and Brantner (2006).

gain. Ridley states that expected sales of about $200 million per year are reasonable to incentivize innovation for a product, and naturally the interest of drug companies increases with the potential of the market above this point.[3]

Poor people typically do not represent an attractive market opportunity for a for-profit drug company because their ability to pay for new drugs is limited. Developing countries account for over 80% of the world's population, yet only 10% of global pharmaceutical sales occur there.[4] These lower sales do not indicate better health; on the contrary, developing countries account for well over 80% of the global burden of disease as a much larger proportion of their citizens suffer from communicable diseases and diseases of poverty.[5]

In this context, commercial drug companies have largely avoided investments in developing treatments for diseases primarily affecting the global poor, such as malaria and tuberculosis, because such medicines have no substantial market in the developed world. Commercial drug company managers have a fiduciary duty to shareholders to maximize the return on equity and are therefore reluctant to fund clinical trials of drugs that – however likely to be medically significant – are expected to be unprofitable. Considering the extent of the investment required it is unsurprising that the developing world has been neglected by this industry, and it is unrealistic to expect for-profit companies, who are responsible to shareholders and stakeholders, to allocate the needed funds in a sustainable way.

3. PRODUCT-DEVELOPMENT PARTNERSHIPS

In the face of a general decline in productivity and weak private incentives to invest in innovation targeting some very important diseases, governments and private foundations have made substantial investments in research that attempts to address the gap. But pharmaceutical companies themselves have the crucial

[3] Ridley (2004, p. 5).
[4] WHO (2006, p.15).
[5] WHO (2006, p.3).

advantages of substantial expertise, technological capacities, and large libraries of potentially interesting compounds. So it was natural for partnerships to arise between governments or foundations and for-profit pharmaceutical companies. The difficulty was that for-profit companies wanted to be able to earn a return on their investment, while governments and foundations were especially interested in ensuring that the prices of products were low enough to enable widespread use in poor countries.

A key innovation in developing these partnerships was identifying how pharmaceutical companies could be rewarded for their participation, in a way that also allowed the "public" partner to achieve its goals. Modern product development partnerships have typically satisfied the divergent goals of their partners by splitting the market for the product into a commercial one, left to the industry partner, and a humanitarian one, in which some arrangement was made to achieve wider access, usually through at-cost pricing or through licensing to competitive producers.

Thus, over the last few years, several important PDPs have been established, and some have been successful in delivering products to market. The most substantial PDPs, according to the amount of funding received, are the International AIDS Vaccine Initiative and the Medicines for Malaria Venture (MMV), which are both funded at close to $100m annually. MMV has an extraordinarily large portfolio of products at different stages of development. Unlike a traditional drug company, which has a portfolio of drugs in different therapeutic areas, MMV is focused only on malaria. This approach would create undesirable risk for a for-profit company; but it is efficient for MMV because its advisory committee has the opportunity to compare many different prospective products and to choose a portfolio optimized to achieve success in addressing medical needs. Most other PDPs have a focus on one or two therapeutic areas, a feature that distinguishes them from private companies and offers a strategic advantage for development work.

While PDPs are similar in their goals, they differ in how they are structured, possibly reflecting diverse national laws, diverse funding arrangements, and

diverse states of knowledge in the various disease areas which shape expectations for how the public and private partners will cooperate. For example, Aeras and MMV are legally independent organizations, while the Malaria Vaccine Initiative operates within the Program for Appropriate Technologies in Health. Some PDPs have their own laboratories, while others rely on contract research or on the private partner.[6]

PDPs have been extraordinarily active in the last few years. In 2007, according to the G-Finder survey, PDPs obtained funding of over $450 million. The vast majority of this amount was directed toward development of drugs and vaccines for HIV/AIDS, malaria and tuberculosis.[7]

One of the potential reasons for the appeal of these organizations, according to Moran et al is that they offer funders a way to support a diversified portfolio of development efforts.[8] A small bilateral aid agency cannot manage many different large drug development projects – but with relatively low administrative costs, it can participate in several PDPs, each of which has several molecules under consideration at any time. The important exception to this is the US-government's National Institutes of Health, which directs substantial funding toward neglected disease research and does have the financial and administrative capacity to manage its own large portfolio of sponsored research.

These partnerships are likely to be one of the more important sources of new medicines for historically neglected diseases over the next few years.

4. OBSTACLES TO EFFECTIVE PDPs

In this section, we note some of the obstacles PDPs face in achieving their goals. Since this discussion cannot be comprehensive, the interested reader is referred to Taubman (2004) for a fuller analysis of problems related to contracting and

[6] Moran et al (2010, p.116).
[7] Moran et al (2010, p.117).
[8] Moran et al (2010, p.120).

distribution. As discussed in Section 6, the HIF could help provide meaningful solutions to some of these obstacles.

4.1 Ensuring adequate and sustainable funding

Phase III clinical trials require substantial funding. As Jim Connolly, President and CEO of Aeras has recently observed, the costs of drug development, even in a non-profit setting, run into the "tens if not hundreds of millions of dollars".[9] The need for such large investments entails the risk of a product being stalled at the proof-of-concept stage by an unwillingness to pay for an adequate clinical trial. A non-profit partner may find it difficult to obtain sufficient funding for a large trial that, at some risk of failing to obtain satisfactory results, could conclude product development.

This challenge to sustain funding is heightened by the time mismatch between funding provision and the clinical trial timetable:

> Most product development for the developing world is underfunded and relies on short-term grants – very hand to mouth. Running a 10- to 15-year development program when you are funded year to year is a hopeless way to make products. A number of groups have been set up to examine how to do this better.[10]

One reason why R&D funding for developing-world diseases is problematic is that very little of it comes from sustainable private investment motivated by predictable market returns: private investment in this area was only 11.3% of the global total, driven mostly by Corporate Social Responsibility.[11] Private partners are not contributing presumably because they expect relatively little gain from most of the products under development. Approximately 90% of the contribution thus comes from governments and foundations, whose resources and funding priorities may vary from year to year.

[9] Nature Reviews Drug Development (2010).
[10] Mary Moran, quoted in Novartis (2010, pp. 4-5).
[11] Moran et al (2009, p. 54).

One positive point here is that about half of all funding for PDPs comes from the Bill and Melinda Gates Foundation, which has significant resources and has shown an enduring commitment to neglected diseases. Some commentators argue that this reliance on a single funding source may be a liability;[12] the emergence of additional long-term funding would certainly be a welcome development.

4.2 Ensuring a low sales price

PDPs seek to ensure that the products they help develop are sold at low prices in developing countries. However the implementation of this commitment faces three challenges.

i) Contracting

The contractual requirements for ensuring low prices are complex. The contract, written at the time the parties are beginning development of a product, must anticipate contingencies many years in the future, following the development of one or more products.

The difficulty of writing contracts given the uncertainty inherent in a product research program gives rise sometimes to rather vague terms. For example, Taubman quotes contracts stating that the industry partner agrees to make all products developed under the agreement "available for purchase in the developing countries of the world at a reasonable price" or "to use commercially reasonable efforts to develop the product candidate."[13] Commercial reasonableness, of course, is something more easily defined by the industry partner, and in this case it most likely indicates that decisions should be justifiable to shareholders.

[12] See Mossalios (2010).
[13] Taubman (2004, pp. 15, 16)

As with other situations where contracts are complex and require flexibility with respect to unknown and unknowable contingencies, a key requirement for successful contracting is trust. To the extent that the relationship is based on trust and the expectation of an ongoing partnership, the contracting parties can leave some parts of the contract incomplete, and make suitable arrangements as needed. The financial muscle and credibility of the BMGF as a funder of many PDPs is therefore relevant to their successful operation.

ii) Monitoring compliance

A second problem with low sales price requirements is that the public partner may lack effective mechanisms for monitoring compliance. This will be true whether the product is sold at some low price related to the cost of production or licensed out for generic production. Monitoring compliance with a requirement of, say, pricing at the cost of production will not be easy since the public partner is not likely to be in a position to investigate the costs of production. Similarly, monitoring compliance with a failure to license the product extensively may be difficult if the private partner can show reasonable objections to certain licensees, such as a failure to meet good manufacturing practice. Alternatively, the private partner may license the relevant patents but fail to effectively transfer trade secrets concerning manufacturing process. That is, monitoring compliance with access terms is complicated, since observing the relevant underlying conditions is difficult – it requires the public partner to have access to information that would normally be available only to the private partner. That said, the private partner will typically be motivated by CSR concerns and then price and license in a manner consistent with that goal.

iii) Enforcing compliance

A third problem with low sales price requirements is that the public partner may lack a mechanism for effectively enforcing compliance. Typically the public partner may be granted some right to sub-license the technology if the private partner fails to obtain regulatory clearances or to market the product in relevant countries. However, in case the private partner has failed to do any of these things, it may be costly for the public partner to do them instead, and the public partner may have no means of penalizing the private partner for failing to

comply with all the terms of the contract. Generally, the public partner may lack leverage to affect the behavior of the private partner once the product has already been developed. One way of addressing this problem is for there to be the potential for continuing partnership benefits.

4.3 Incentivizing effective regulatory submissions

Even if contractual issues have been successfully addressed, and the product has passed clinical trials, there are obstacles created by a requirement that the private partner is not allowed to make profits from selling and delivering the product to people in developing countries. Whether the contract requires cost-based pricing, or licensing to generics, the structure of most PDP contracts limits the profitable exploitation of the product in developing countries. The problem is that it generally takes additional investment to sell a product in a country. For example, a product will typically need to achieve regulatory approval through a process that can be time-consuming and costly relative to the potential gains. This approval process is intended to ensure the safety and efficacy of a pharmaceutical product before it is released for use in the market.

Unfortunately, some very poor countries, which typically face the largest burden of disease from neglected tropical diseases, lack local regulatory capacity to approve products.[14] Regulatory approval tends to follow decisions in developed countries, even though a product intended for a variant of a disease in one country may be of little value against a different local variant. Approval should be related to the context of the market including local culture and socioeconomic factors.[15]. For products that are not approved in developed countries, possibly because of lack of a market in those countries, developing countries will have to conduct regulatory assessment independently. Thus, one should not take regulatory approval for granted, nor assume that it will be easy or inexpensive to obtain.

[14] WHO (2006, p. 80).
[15] WHO (2006, p. 80).

The prospect of profits, however, motivates companies to make efforts to move their products through the regulatory approval process. Similar incentives are relevant for corporate efforts to have drugs included in state insurance program formularies. If the product is to be sold at a non-profit price who is motivated to invest in obtaining regulatory approval? Firms are motivated, to some extent, by the opportunity to benefit from a successful implementation of a "corporate social responsibility" program, but this kind of motivation only goes so far. A more significant problem arises if the product is sold only as a generic, since each generic firm will hope that another generic producer will spend resources to obtain approval.

The lack of incentives to push products through regulatory approval can lead to delays. While such delays may be related to slower regulatory approval times, it is likely that incentives to get products approved also play a part in these delays. An interesting example of this problem is the use of paromomycin for the treatment of visceral leishmaniasis (VL). This antibiotic has been unpatented for decades, and its effectiveness against VL has been known since the 1960s. Small clinical trials in India and Kenya demonstrated the effectiveness of the treatment.[16] Nonetheless, paromomycin was not registered as a treatment for VL in East African countries, and it was not until 2004 that DNDi starting running trials to demonstrate its effectiveness for this purpose. As of 2010, the trials are ongoing, and the product is still not approved for this use in East African countries.[17] Paromomycin was approved for use against VL in India in August 2006, following clinical trials conducted by IOWH.[18]

4.4 Incentivizing post-approval promotion

In developed countries, drugs rely on the marketing efforts of the manufacturers to achieve substantial sales. Such marketing efforts include, inter alia, "Phase IV"

[16] Thakur et al (1992).
[17] See DNDi's webpage on Combination Therapy (VL in Africa), last accessed September 30 2010 at http://www.dndi.org/portfolio/combination-therapy-africa.html.
[18] See IOWH's press release dated November 6, 2007, last accessed September 30, 2010, at http://www.oneworldhealth.org/press_releases/release/pr_1227120528.

trials to demonstrate the clinical properties of the drug, and the briefing of physicians to inform them of the properties of the drug. In developed countries, we often observe that once a product is genericized, total prescriptions fall, because there is a reduction in promotional activities. In general, as Kieff (2001) has observed, pharmaceutical products do not achieve market penetration without the effort of the seller, and this effort is motivated by the potential for profits. A requirement to sell at a no-profit price creates little incentive to engage in costly activities designed to increase sales volumes or effective use.

The example of paromomycin is again relevant here. Recall that paromomycin was approved for use in India in 2006. Hasker et al (2010) conducted a study of the management of VL in rural primary health care services in Bihar, India, in 2008. They do not show any patients being treated with paromomycin at that time – only alternative treatments were in use. As of late 2010, IOWH is continuing to conduct a Phase IV study to examine how the product is being deployed in rural areas, with the goal of getting the product listed in India's public health program, and paromomycin is still limited to that trial.[19] Thus the roll-out of paromomycin for VL in India has yet to begin, more than four years after product approval. This is certainly not intended as a criticism of IOWH, which is continuing to invest in and bring to market a valuable treatment for a terrible disease – but it seems plausible that with greater resources the process of getting the product to market might have been expedited. In particular, it seems likely that a company with a profit motivation and more substantial capacities might have helped the government to accelerate a decision to adopt paromomycin in the public health program.

Generally, we can expect that if no firm can make substantial profits by expanding the use of a given drug – or if its efforts to expand usage are vulnerable to free-riding by other companies that do not invest in similar efforts – there will be little investment in activities that increase usage.

[19] A Phase IV study is a clinical trial conducted following product approval.

To be sure, these obstacles are serious, but not necessarily fatal: no system will be perfect, and if there are enough gains from a partnership because of the complementary assets each partner brings, the partnership will still be attractive. Indeed, billions of dollars committed to PDPs in the last few years show that some funding partners have been willing to make substantial investments despite the obstacles. But this fact should not detract us from the attempt to design a structural reform that, by addressing these obstacles in a more systematic way, would stimulate even larger efforts especially from the private partners.

5. THE HEALTH IMPACT FUND

The Health Impact Fund (HIF) promotes a new way of stimulating pharmaceutical research to encourage the development of pharmaceuticals that best improve health worldwide. The HIF is designed to reward companies based on the actual health improvements that result from the use of their product, and, in this way, encourages companies to focus on the health impact of their product. This promotes accessible and low-cost pharmaceuticals that reach both developed and developing nations, the latter of which have been largely neglected thus far by the pharmaceutical industry.

Pharmaceutical companies invest significant resources into the development of a product in exchange for patent exclusivity of the product once it reaches the market. As a result, innovation is primarily driven by the amount of profit a product can expect to earn once it reaches the market. This profit in turn depends on there being a large number of patients to whom the product can be delivered at a high mark-up. Pharmaceutical companies prosper by catering to the affluent; and they would be violating their responsibilities to their shareholders if they purposefully served poor patients at the expense of their bottom line. As will be discussed in greater detail later in this chapter, development of pharmaceuticals thus neglects diseases that predominantly affect the poor in favor of diseases that promise to provide the company with greater profits.

When a pharmaceutical company expects that it won't be able to cover its R&D expenses by charging high prices for a product, then it won't develop this product. The rules governing pharmaceutical innovation thus are designed as if readiness to pay for a product were an accurate measure of value. But this is plainly not so. It is morally unacceptable that people in developing countries suffer needlessly from treatable or under-researched diseases merely because they lack the funds to exert effective market demand. Respecting companies' responsibilities to their shareholders, the proposed HIF is a mechanism for ensuring that companies have sufficient financial incentives to realize any highly cost-effective health gains that they can realize through developing and promoting new products.

The HIF is designed to expand the scope of profitability to include products with the greatest potential to heal; the HIF will reward innovators based on the ultimate health impact of their products. Under the HIF, firms make the most profits by creating medicines that do the most to improve health and by ensuring access to these new medicines and to already existing ones. The HIF would offer patentees the option – no obligation – to forego conventional profits, enabled by patent protection, in exchange for a reward based on the health impact of their new medicine. By "opting-in" to the HIF mechanism, a firm would be agreeing to sell its product worldwide at cost, and in exchange for foregone profits, the firm would receive payments from the HIF based on the product's assessed health impact. Companies would then be motivated to make any and all cost-effective efforts to enhance the health impact of their product: by facilitating wide access and proper use. In this way, the HIF would benefit both developed and developing nations: without touching patent rights, the HIF would ensure real access to pharmaceutical products in developing nations and substantial savings to insurance providers and private payers in developed nations.

The HIF will be financed mainly by governments. This expense is not trivial – a minimum of $6 billion annually is expected. But the HIF will ultimately result in massive health improvements and cost savings worldwide. Those who are uninsured or live in developing nations will gain access to life-saving drugs. Even insured patients in developed countries are limited by what their insurer

will pay for; with the HIF system, these drugs will be priced at the lowest feasible cost of manufacture and distribution. While providing large benefits to the developing world, this scheme also provides cost savings to wealthy countries by offering the same low prices everywhere in the world. These costs savings, in turn, help pay for the fund, so that its net cost would be much smaller than its nominal price tag of $6 billion annually – and this is not even counting the massive economic benefits from improved health worldwide. HIF participants will be compensated for innovation based on the actual health impact of their product, which is a measure of years of life extended by the product while taking into account the quality of years lived. The HIF is a pay-for-performance scheme with rewards based on actual health benefits.

The HIF would also benefit pharmaceutical companies. Leaving untouched the existing R&D incentives generated by the patent system, it would provide an additional stream of revenue for these companies should they choose to register some of their products. Pharmaceutical innovators will not be punished for developing drugs that benefit developed countries, and pharmaceutical companies may choose to be rewarded through the current patent system, but now these companies will also have the option of profitably engaging in the development of drugs that benefit developing nations. This system may also provide an additional reward to these companies by providing them a cost-free means to improve their public image through the development of life-saving drugs for poorer countries. Additionally, research scientists of these firms will be relieved to be working for an enterprise that encourages them to focus on addressing the most important diseases and not merely those with potential remedies that can be sold at high prices to the affluent.

The HIF involves a scheme to develop products that provide the greatest health impact without harming existing pharmaceutical development incentives. This scheme has the potential to save millions of lives worldwide, while lowering prices for all payers. The HIF is thus intended to be a lasting, structural mechanism to incentivize pharmaceutical innovations that will continuously track the more serious threats to human health.

6. THE HIF AND PDPs

The HIF can help address many of the obstacles faced by PDPs discussed in Section 4 above. We can divide these obstacles into three categories: those relating to inadequate and uncertain funding streams; those relating to problems of contracting; and those relating to inadequate incentives for product roll-out and promotion. To see how the HIF can effectively operate in conjunction with PDPs, consider a PDP designed so that all products developed inside it will be registered with the HIF, with any reward payments to be divided according to an agreed rule.

First, financing problems would be eased as the HIF would be offering rewards that would otherwise be unavailable. This would help encourage private partners to invest more in PDPs and would also bring public partners rewards that they could use for supporting future research. The HIF would, in particular, create a long-term, sustainable source of funding that would be particularly attractive for PDPs since it wouldn't require high prices. Instead of collecting money project by project, PDPs would have some capacity to predict revenues based on registered medicines.

Second, consider the problems of contracting: writing the contract, monitoring it, and enforcing it. If a PDP agrees from the outset that any products developed from the partnership are to be registered with the HIF, the contracting problem is greatly reduced. Monitoring of price-setting or licensing would be performed by the HIF as one of its key functions. (Indeed, insofar as higher prices reduce sales, the private partner may not even wish for a higher price in developing countries as this would diminish its stream of rewards based on total health impact.) Administratively, a PDP is not set up to engage in monitoring prices or licensing terms in countries all over the world – but the HIF would be doing this job in any case.

Enforcement would also be easier to manage because the HIF has a financial relationship with the registrant. That is, the HIF is in a stronger position to enforce compliance because (a) it has the ability to withhold payments to the

partners and (b) the HIF is designed as a continuing agency, so that the firm would find it unattractive to try to cheat on the contract, recognizing the possibility of harm to its relationship with the HIF in the future.

Third, the HIF would stimulate efforts to get products approved, insured, and sold, since the partners would receive rewards on the basis of actual health impact. Because the HIF rewards firms for health impact, firms will find it profitable to address effectively the obstacles to achieving regulatory approval in order to get their products to the developing world as quickly as possible. Of course, efforts by a firm will not always be a solution – particularly since, as observed above, there is a shortage of expertise in many governments to work through the regulatory process in a timely manner. Similarly, efforts to promote effective use of a drug will be difficult in environments where there are major barriers to health care delivery, such as insufficient clinics and doctors. However, the HIF would provide some motivation for firms to attempt to overcome barriers to the effective distribution and optimal use of their product. So while the HIF's design will not be a panacea for the problems of distribution, it will move matters in the right direction.

PDPs, of course, offer something that the HIF does not: direct funding for research before a product has been developed. The HIF, because it is designed to reward successful product development, leaves all the risks of research with the organizations that invest in it. A critical problem in all drug development relates to decision-making capacity: drug development is extraordinarily expensive, risky, and the stakes keep getting larger. The initial development of a compound and in vitro analysis may cost relatively little; but as it proceeds through subsequent rounds of clinical trials, to demonstrate both safety and efficacy, the costs keep increasing. Phase III trials often cost in the range of $100 million. PDPs help to diffuse some of this risk through a partnership between private and public funders. In effect, PDPs offer a way to help direct research funding towards projects that appear to be socially valuable. Even with the HIF in place, it seems unlikely that there will be a perfect allocation of funding across diseases and conditions, and so there will be a continuing need of mechanisms such as

PDPs that direct research funding to high-need areas, create efficiencies in drug development through knowledge exchange, and spread risks across partners.

7. CONCLUDING COMMENTS

Product-development partnerships have become extremely important in the search for new medicines, particularly for the so-called neglected diseases. In this short paper, we have considered the feasibility of complementarities between PDPs and the Health Impact Fund. It is apparent that these different mechanisms address different needs, and have the potential to complement each other. PDPs offer special benefits through direction of research, efficiencies in the development process, and risk sharing, while the HIF offers solutions in terms of contracting, financing, and motivating production and distribution of successfully developed products.

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