

The Health Impact Fund: A Useful Supplement to the Patent System?

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The Health Impact Fund has been proposed as an optional, comprehensive advance market commitment system offering financial payments or ‘prizes’ to patentees of new drugs, which are sold globally at an administered low price. The Fund is designed to offer payments based on the therapeutic impact of the drugs or vaccines, so that innovators will have efficient incentives to develop drugs that maximize health gains. Consumers would have improved access to such drugs because of low prices.

Introduction

This brief paper examines how an optional system of rewards—the Health Impact Fund (HIF)—could supplement the system of patent-based exclusivities which currently forms the basic incentive for private investment into pharmaceutical research and development (R&D).¹ The core idea is that innovative firms would have an option—they could either exploit the exclusivity rights inherent in the patent without restriction on their pricing, or sell their product at an administered low price while being compensated with supplementary payments over the course of several years based on the therapeutic impact of their innovation. Such a system would require substantial funding from high-income country governments. However, it would also create a powerful incentive for R&D investment into drugs for the diseases which affect lower-income countries, while ensuring access at affordable prices for those products.

In this paper, I begin by summarizing the strengths and weaknesses of our current systems of incentivizing research and development, including patents, research grants and Advance Market Commitment (AMC). I then examine how the proposed system would operate and how it could usefully supplement the system of patent exclusivity. Ravvin (2008) provides an excellent discussion of why such a system is needed.

What is Wrong and What is Right with Current Systems of Incentivizing R&D?

There are two widely used mechanisms designed to increase the amount of useful R&D: patents and research

grants. It is important to understand what they do well, as well as their failings, in order to be able to see whether there might be opportunities for complementary mechanisms which would be useful particularly for stimulating R&D into medicines for neglected diseases.

Patents

A patent offers the patentee the power of applying in court to use the power of the state to exclude anyone else from using the innovation disclosed in the patent, for some period. Following the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), patent rights are very similar in most countries, with a term of 20 years now standard. The implementation of patent laws still varies somewhat across countries. Patents are extremely important in pharmaceutical markets, since pharmaceutical innovation is expensive, with estimates of the cost per new drug launched at over \$1 billion. At the same time, generic drugs are generally not distinguished in any important characteristics from branded drugs, and are, when they enter, typically quickly able to capture the dominant share of sales. Thus, without patent protection, innovative firms would be unable to recoup the cost of R&D.

Patents have a number of very attractive properties. First, they impose all the risk of R&D on the firm that invests in R&D. Thus, if a firm makes a poor choice of how to invest its money—in a drug that is ineffective or unsafe or for some other reason unprofitable—it does so at no cost to the public. Second, the party that has the most information about the prospects for successfully developing a product or process is the one that makes the investment decision. This is an efficient allocation of responsibility, and avoids outcomes in which resources

are squandered on projects that are unlikely to come to fruition or are unimportant to consumers. Third, under the patent system the incentives to invest are proportional (though not perfectly) to the expected value to consumers of the innovation. This is because the patentee's profits as a monopolist of the product will be related to the price at which it can sell the drug and the quantity sold, which are in turn dependent on its value to consumers.

Patents also have some important weaknesses as instruments for promoting valuable innovation. The chief problem is that there are many innovations which would be socially valuable, but for which the profits to be obtained through a patent are inadequate to make investment in R&D privately profitable for the patentee. There are at least three types of innovation in pharmaceuticals for which the profits are not commensurate with the social value:

- (A) Innovation that has most of its payoff in the far future, outside the twenty-year protection of the patent. Such innovation includes much basic research.
- (B) Innovation for which patent protection would be of too narrow scope to prevent effective competition. For example, an innovation consisting of the demonstration of a new use for an existing drug might have great social value, and yet not have effective protection through the patent system if the patentee were unable to prevent consumers from buying a generic version of the drug and then using it for the new use.
- (C) Innovation into pharmaceuticals mainly consumed by very poor people. The use of life-saving pharmaceuticals by the very poor is likely to have social value far above the price the very poor can pay.

This is essentially just the converse of the point that patents are effective because profits are related to social value: the problem is that patents are not *perfectly* related to social value and there are some important areas where they fail badly in this respect.

The second main problem created by the patent system is that when it is working well, it allows the patentee to charge a price above the competitive price. (If the price were no higher than the competitive price, then there are no profits being earned and no point in having a patent.) A price above the competitive level, however, implies efficiency losses, since some people who value the product at above its cost of production are unable or unwilling to buy it at the higher price. Economists generally refer to this as a 'deadweight' loss since there is no compensating benefit: there is strictly a loss in value to society. In the jargon of pharmaceutical activism, high

prices hinder 'access' to life-saving drugs so that sick people go untreated.

A third problem with the patent system—especially in pharmaceutical markets—is that it engenders a great deal of litigation. The litigation is not productive and is to a large extent rent-seeking: the payoff from being able to maintain a monopoly on a blockbuster drug is so large that extending the exclusivity rights by even a day may be worth millions of dollars to a firm. The high stakes lead to expensive legal battles, the costs of which reduce the incentive to invest in drug development in the first place.

Research Grants

The system of research grants may be thought to fill in some of the lacunae in R&D incentives of the patent system. It can address cases in which there is perceived to be a wedge between social value and patentee profits, by providing an infusion of cash to a university or corporation doing research believed to be valuable. In particular, it seems designed to address the difficulty the patent system has in providing any reward for basic research.

Unfortunately, there are difficulties with research grants, which largely relate to incentives and information. The informational problem is that the decision to direct the grant is made by the grantor, who likely does not have the best information on the expected value of different projects. In a sense, research grants resemble a system of central command and control over research investment, compared to patents, which resemble a market in that decisions are made by agents on the basis of their private information. The incentive problem with research grants is that innovators who have received a research grant have relatively weak incentives to finish the research and turn it into a commercializable innovation in the market: they cannot usually profit substantially from this. (This is not to say that such researchers have no incentives to succeed in their research: but a commercial firm is motivated by desire for success in the same way *and* the desire for profits. Since greed appears to be a very powerful motivating force, it is of course desirable to harness it to the greatest extent possible.) Thus research grants, while of tremendous importance, have limitations. Collectively, the patent system and research grants are a very successful set of incentive mechanisms for research and development, but it appears that there may be scope for other complementary mechanisms.

Advance Market Commitment

In this section, I examine how Advance Market Commitment may complement patents and research grants.

Advance Market Commitment are generally feasible only for products in a late stage of development, when the technical characteristics of the product can be described, and as of early 2008 there is one Advance Market Commitment espoused by several countries for a pneumococcal vaccine and funded to the tune of \$1.5bn. While AMCs are generally believed most suitable for vaccines, as I will describe later, this system can be broadened to apply to other pharmaceutical products as both Thomas Pogge (2005) and I (Hollis, 2005) have proposed.

The AMC is relatively well understood and is thoroughly explored in Kremer and Glennerster (2004), the Tremonti report (2005) and the World Bank's framework document for a pilot AMC (2006). The essence of the AMC is that funds are committed in advance to make payments to any firm that can produce and sell a qualifying drug or vaccine. The total amount of funds is set in advance, and once the money is used up, the AMC is finished. To qualify, the product has to meet a certain 'Technical Product Profile' also determined in advance, relating to the efficacy and safety of the vaccine or drug. The payments made to the firm under the AMC are set at a payment per unit, less the price the firm charges to governments. For example, if the AMC guarantees a payment of \$9 per vaccine delivered, and the firm charges governments \$2 per unit, the AMC would pay the firm \$7 per unit. The seller can choose its price, but whatever price it chooses must remain the same following the termination of the AMC. Thus, the firm must balance the gain from a low price—increased sales during the period of the AMC—with the loss from a low price following the AMC.²

The AMC can thus be seen as a simple contractual arrangement. The funders are agreeing in advance to pay \$x per unit sold in exchange for the seller agreeing to hold its price fixed over a certain number of years. The seller need not enter into this agreement, but could simply exploit its patent exclusivity as profitably as possible, selling its products at whatever price it could obtain. The funders, on the other hand, are obliged to pay the contracted amount for any vaccine that meets the technical requirements, if the company agrees to the terms.

The AMC has some very attractive properties as a supplement to the patent system. Most importantly, it increases the incentive to invest in research into a specific vaccine or drug. This increase is due to the fact that the total payment per unit under the AMC is likely to be much larger than the market price for the product. Firms only receive the supplementary payment if they are successful in developing a qualifying product that is sold widely, so the risks of product development and commercial sales remain squarely with the innovator, which is, as discussed

above, efficient. The larger the total amount of the fund, and the higher the guaranteed payment per unit, the stronger the incentives for developing a vaccine or drug become. The AMC can set the payment parameters to create incentives that align with funders' willingness to increase the speed of development. If the parameters are set appropriately then, according to models of the AMC, it will be a cost-effective way of saving lives.

The AMC system is intended to spur competition, in the sense that multiple firms may develop a qualifying vaccine. Given the pricing structure, it is not clear that this would occur. The first firm into the market has the strongest incentives to set a low price, since the time until the end of the AMC is then at the maximum. Moreover, the lower its price, the less attractive competitive entry is, since a later entrant would have to at least meet its price or undercut it to obtain significant sales. A late entrant obtains relatively little benefit from the AMC but is still constrained by the price it sets during the AMC. Therefore the incentives for later entrants are relatively weak, and the prospects for competition accordingly dim.

There are also some problems with AMCs. The most striking problem is that it is necessary, in advance of a given vaccine being developed, to describe its technical profile. This automatically limits the flexibility of the AMC: if a vaccine is very close to good enough, it gets nothing, even if it is the only product available. Similarly, if the product exceeds the technical standards, there is no flexibility to pay a higher total price. For products whose technical characteristics can be predicted in advance, this is not a significant problem: it is likely that for most vaccines, the technical characteristics may become known while the product is in late-stage development, as appears to be the case with pneumococcal vaccines. However, for many other products, this is a much more significant problem, as the technical characteristics of unknown products cannot be forecast accurately.³

Thus, AMCs can only be applied to a rather limited set of products: the most likely candidates are vaccines in late-stage development, since the technical characteristics of such products can be described relatively well at that stage.⁴ Vaccines are more suitable than other pharmaceutical products because their side effects tend to be less problematic: for other drugs, side effect profiles are often only known following stage III clinical trials. If AMCs can achieve rapid commercialization of such vaccines, then they will very effectively save lives. It is no criticism of AMCs that they are specialized to a particular function—but it does raise the question of whether there is a more general version of AMCs that is not limited in

the same way: it is exactly this kind of mechanism that I discuss in the next section.

Health Impact Fund (HIF)

The essence of the HIF is that governments (and perhaps other donors) establish a pot of money, which can be used for payments every year to firms with a patented pharmaceutical product (including vaccines), which they agree to sell at an administratively determined low price. The amount paid to the patentee is based on the measured health impact achieved because of the product, compared with the previous state of the art. Health impact could be measured in terms of Quality-Adjusted Life Years (QALYs), a standardized measure for assessing health interventions.⁵ Thus the health impact of a drug could, for example, be approximated as the number of units sold times the estimated incremental QALY benefit per unit.

The chief strength of this system is that it creates an *incentive to develop new medicines* with large measurable health impacts, where the incentive is independent of the wealth of the consumer, while *enabling access at low prices*. That is to say, the system is automatically ‘needs-driven’. It empowers innovators to use their private information to determine R&D investments, and does not require bureaucratic prioritization of needs or identification of research gaps. The system is intended to be optional, so that innovators can choose between it and exploitation of their patent exclusivity rights.

Like a standard AMC, and like exploitation of exclusive rights under the patent system, the HIF would pay out over a period of years. For example, a new pharmaceutical product might earn payments from the HIF every year for its first 10 years of use.⁶ An extended payment period is important since it smoothes the payment stream and offers an incentive for innovators to promote their products to ensure that they are widely used by those whom they can benefit. In this respect the HIF differs from a patent buy-out. It is also different from a patent buy-out in that the patentee retains all intellectual property rights, but gives up the freedom to charge a monopoly price. Instead, the HIF would determine a price at approximately the variable cost of manufacturing, so that the patentee would earn profits chiefly from the payments made by the HIF, rather than from high prices charged to consumers.

The HIF would require annual committed funding at levels on the order of \$2bn–\$10bn, and this funding would have to be committed many years into the future. The reason for this size is that if the Fund’s payments were too small, it would be unable to attract a variety of

products, and would be unable to benefit from economies of scale in estimating actual health impacts. It would also require an administrative branch to annually estimate the incremental health impact of each product.

Funding

The optimal amount of funding for the proposed HIF has not yet been determined, and would in part depend on some important details in the plans. There are two ways of fixing the amount to be paid out under the system: either the price per incremental QALY would be fixed in advance, leaving the total budget indeterminate; or the total amount to be paid out would be fixed in advance, with the payment per QALY prorated.

In the case of a fixed price per QALY, firms would be justly skeptical as to the ability of the HIF to obtain sufficient resources from donor governments to meet its commitments. Donor governments would also be understandably reluctant to enter into any commitment which would create an unlimited financial liability. Therefore this approach appears improbable.

With a fixed budget, the payments could be prorated so that the payment per QALY would be set equal to the budget divided by the total QALYs saved. For example, suppose that the HIF had a budgeted amount to pay out of \$2bn. Then, if 4,000,000 QALYs had been saved by all firms that had opted into the HIF, each firm would obtain a payment of \$500 per QALY saved by its own product. This means, of course, that the payment each firm receives is dependent not only on the performance of its own product, but also on the performance of all other products included in the HIF scheme.

How large an amount is reasonable for annual disbursements from such a fund? In principle, the HIF system could conceivably be very large, with annual payments sufficient to provide an appropriate return on several new drugs each year: perhaps \$10bn–\$20bn annually. This would of course give it tremendous power. If it were smaller, say \$2bn annually, it would still be able to incentivize development and commercialization of new pharmaceutical products with high health impacts but little commercial value under the patent system, though at a much lower rate. Therefore it is not necessary to determine in advance the ‘theoretically correct’ amount of funding. One possible strategy, in this context, is to start with a relatively modest annual commitment, and then to expand this if it appears to be successful.

It is important here to note that the net cost of the HIF system would be lower than its budget because it would include some drugs that would otherwise have high prices. To the extent that there were extra costs, they

would have the benefit of increasing the incentives for valuable innovation.

One of the concerns arising from this system is that the payments for one drug are necessarily dependent on the therapeutic effects of other drugs in the system, since all drugs are in effect competing for the limited funding available. Thus, for example, if a perfectly effective vaccine for HIV/AIDS were introduced, it could suck up a large share of the available funding, leaving other products with very small payments. However, in the absence of breakthrough drugs such as completely effective vaccines, the risks in this mechanism are considerably reduced by the fact that there is the possibility of substitution from the HIF mechanism to and from exploitation of patent exclusivity. If the payments fall too low, the HIF will not attract other drug products, which will instead be sold at monopoly prices. This will allow the payments on products remaining in the HIF to be higher. In effect, because of the possibility of substitution, the riskiness of the HIF payments is considerably reduced.

Estimating the QALY Impact

An important requirement to make such a system effective is the creation of an Independent Assessment Committee (IAC), which would be authorized to estimate, for the purpose of determining payments, the incremental health impact of a given medicine. In reaching such a determination, the IAC would examine evidence presented by the patentee, other independent evidence brought forward by governments, and evidence from its own investigations. Since predictability is important for investors, it would be very important for the IAC to use a transparent process for determining rewards, in which the expected method of determining rewards was well understood by outside observers. To be sure, this would be difficult at first but would likely improve over time as the IAC accumulated cases. For any given drug, it would probably be necessary initially to use information from clinical trials to estimate its therapeutic impact; after the drug had been in use for some time, it might be possible to use epidemiological studies to refine these estimates. It might be possible to obtain information on how the product was being used in order to increase the precision of the estimated health effects.⁷

There are considerable theoretical difficulties in using QALYs or other measures of health impact. For example, one must determine a discount rate to be applied when the benefits of a pharmaceutical—such as a vaccine—extend many years into the future. There are difficulties in evaluating the contributions of individual firms when two products have complementary effects on

health. For example, a combination antiretroviral therapy depends for its effectiveness on multiple drugs: in this case how is one to determine the individual contribution of each when additive separability fails? There are also difficulties in determining the health impacts of pharmaceuticals for the case of infectious diseases, since, for example, inoculating one person makes it less likely that other people will be exposed to the disease. The IAC would have to grapple with these and other problems in evaluating the health impacts of pharmaceuticals, and would require an effective monitoring and reporting system. It is important to note that pharmaceutical companies trying to price their drugs with patent exclusivity face exactly the same difficult questions when they are trying to decide on the profit-maximizing price.

The measurement of the health impacts of a drug is a task whose difficulty should not be underestimated. It is well known that in countries that use QALYs in cost-effectiveness analysis (typically to inform decisions by insurers to fund particular drugs), the QALY evidence that is presented is frequently of questionable value and is generally very difficult to compare. However, what is important is that this kind of approach is already being taken, which implies, in turn, that it is feasible to estimate the QALY impact of a medicine for the purpose of deciding whether and how it will be rewarded. Selgelid (2008) offers a valuable discussion of some of the types of problems that are likely to occur when trying to attribute health impact to a particular drug.

Despite these difficulties, estimates of QALYs are possible and by definition would represent the best possible estimate of the health impact of a given product. Since health impact is the objective that it is desirable to reward, and QALYs are arguably the best measure of health impact, it makes sense to use QALYs as a basis for payments made by the HIF.

Given that the IAC will inevitably make mistakes in evaluating QALYs, the question is whether this is an insurmountable obstacle to the usefulness of an HIF. Perhaps the best way to answer this is to ask whether other schemes for rewarding pharmaceutical innovation are more accurately able to reward valuable contributions: in the patent system, it is well known that prices do not perfectly reflect the health impact of drugs. There is no reason to expect that the HIF would be less effective than prices in making rewards conditional on measurable social benefits of an innovation. Given that, by construction, the payments are to be conditioned on the best available measure of health impacts, the HIF should be successful in adding value as an optional incentive mechanism to reward pharmaceutical innovation.

Properties of the HIF Mechanism

The HIF mechanism is to the greatest extent possible *dependent on competition and markets* rather than on arbitrary decisions. The amount of payments due to each innovator is determined by competition for the fixed budget of the HIF. Innovators compete by developing and promoting drugs which improve human health.

With a limited HIF budget whose disbursement is entirely based on the estimated health impact of each drug, firms would have an incentive to focus their efforts on those interventions which would lead to the greatest expected health impact per research dollar expended. Because the incentive to invest in R&D on a pharmaceutical product is proportional to its health impact under the HIF mechanism, the limited dollars of the HIF are automatically directed to those products of the greatest expected importance, which is a very attractive feature.

Since the HIF is optional, firms will only submit innovations to the HIF on which they expect to earn greater profits from HIF payments than from unconstrained use of patent exclusivity.⁸ This considerably mitigates the risks firms face from competition for the HIF budget: if the payment per QALY drops too low, some firms will choose to exploit their patent exclusivity, instead of accepting payment under the HIF. In turn, this increases the payment per QALY for those firms that remain in the HIF system. Note that this effect also works in the other direction.⁹ Thus the system *automatically* adjusts itself: the Independent Assessment Committee would not need to determine a rate per QALY.¹⁰ What is more, this automatic adjustment has the desirable property that the payment under the HIF system is proportional to the health impact at a rate approximately consistent with that of profits under the patent system, because of substitution by firms across the two systems.¹¹

One of the most attractive features of the HIF approach is that it would encourage many highly productive lines of R&D, which are currently not seen as profitable because the patent system does not yield effective protection from imitation or because consumers are indigent. For example, one of the potentially serious obstacles faced by drug companies is that even when they obtain a patent for a new use of an existing drug, they may not be able to stop generic companies from selling the drug.¹² Thus, the incentives under the patent system to explore new uses of existing drugs are relatively weak. Under the HIF approach, a firm that has obtained a patent for a new use of an existing drug—perhaps one initially patented by a different firm, or one that had been generically available for many years—and could show that some proportion of sales of the drug was for the new use, would be able

to receive payments on this basis. It need not prevent sales by other firms, which is the mechanism used by the patent system, since the basis of payment would be the use of the drug. Similarly, firms could earn substantial profits by developing drugs that would be consumed mainly by poor people, a strategy that is less attractive without the HIF.

Administrative Matters

Should there be geographic or disease category limits?

Given limited funding, it would be most useful to direct rewards toward the so-called Type II and III diseases—diseases that are prevalent mainly in low and medium income countries, and for which no viable market exists in high-income countries—since those are the ones for which patent exclusivity creates the weakest incentives for research.¹³ This is, of course, a strategic decision. Poor people in low-income countries are just as much in need of drugs for Type I diseases (those with a common global distribution), such as cancer, diabetes and hypertension, as of drugs for the infectious diseases which particularly plague them. However, a reward fund with annual payments of a few billion dollars would have relatively little effect on incentives for innovation into global diseases, but could be very important in stimulating research into Type III diseases.

This, in turn, suggests a simple mechanism: payments should be available under the HIF only when the patentee offers a low price for the registered product *in all countries*. In that case, firms with drugs for Type I would tend not to apply to be compensated under the HIF system, since they would have to forgo the large profits available in high-income countries. Firms with products with relatively small markets in high-income countries, and large markets in low-income countries, however, could find the HIF payments attractive. Thus, ironically, by opening up the system to allow for any drug in any country to be eligible for reward payments, only firms with drugs treating chiefly Type III diseases would be likely to apply.

An alternative approach would be to base the payments on measured health impact of the drugs in low- and medium-income countries only, and to require low prices only in those countries. In that case, any drug, whether treating a Type I, II or III disease, would be eligible. Firms with Type I drugs could easily wish to take advantage of such payments and to the extent that they did, they would effectively reduce the available funding for Type II and III disease drugs. Since it appears that Type II and III diseases are those in most urgent need of research, this approach is unattractive. It also creates problems of parallel trade, which need not occur with the global approach. What

is more, under the global system, all countries have the opportunity to benefit from low prices on the drugs sold, although in practice it seems unlikely that there would be substantial sales in high-income countries.

The appealing result here is that the simplest rule—a global approach—is also the one that gets exactly the desired results—more incentives for drug innovation for the diseases that currently present the least attractive commercial targets for research.

What innovations deserve payments under an HIF?

An important technical problem for such a system is that the IAC would need to determine a baseline for calculating the incremental health impact of a given drug. One possible solution is to make the reward conditional on the increase in QALYs from the prior state of the art. However, this approach may need refinement: for example, it may be desirable to compare the outcome under the innovation with the state of the art 2 years before the innovation was approved for commercial use, in order to allow for payments to multiple parties in case of simultaneous development of comparable products.

Preventing gaming and rent-seeking

There are three ways of gaming this kind of system. The innovating firm can attempt to increase the estimate of the QALYs per unit of the product sold; it can attempt to increase the estimate of the units sold (but not the actual number of units sold); and it can artificially increase the number of units actually sold. These are the only three margins on which the firm can artificially influence its payments under the HIF scheme, and I discuss them below.

Evidently, given the difficulty of evaluating the health impact per unit of a product, patentees will make every effort to present their product's effectiveness in the most positive light. Unscrupulous firms might even attempt to bribe members of the IAC to overestimate the product's effectiveness. The best response to this is undoubtedly transparency. If data from clinical trials and other evidence on the effectiveness of pharmaceuticals in different settings is made public, the IAC will be able to benefit not only from the advice of its own experts, but also from comments made by others. Since firms will compete for payments, the more one firm gets paid, the less there is available for other firms. Thus, each will have an incentive to point out weaknesses in the claims made by its rivals.

Attempting to inflate the *estimate* of the actual number of units sold is likely to be relatively difficult. The IAC should, however, rely on a variety of information sources to determine quantities sold, including data from

pharmacies, manufacturers, wholesalers, governments and, where available, from independent data collection agencies.

The third problem is that innovators have an incentive to inflate the actual sales of the product. If the innovator expects an HIF payment of \$10 per unit sold, it may heavily promote the product, even for off-label uses of dubious value. In such a situation, the HIF might end up rewarding improper use of the product. The IAC can mitigate this kind of abuse by surveys of use of the products, with the payments adjusted accordingly.¹⁴ Another way innovators could stimulate sales volumes would be through pricing below the administered low price, or subsidizing purchases by wholesalers. This is a problem commonly faced by insurers, who face the problem of insured consumers claiming false losses or even causing losses for the purpose of being reimbursed by the insurer. Thus, the HIF would be required to be prudent in assessing claims by manufacturers and to undertake active assessments of how products were actually used.

Notably, the incentives for counterfeiting would be somewhat reduced if drugs were sold at low prices.

Treatment of drugs for rare diseases

Because the HIF would make payments dependent on estimated health impact in a population, the incentives would be weak for drugs for rare diseases. There are two possible responses to this. The first is that exploitation of exclusivity rights under the patent system would still be an option. Therefore the HIF proposal, while it does nothing to assist in the treatment of rare diseases and conditions, does nothing to harm them either. An alternative response might be to set aside a portion of funding only for those pharmaceutical innovations that addressed diseases and conditions with low prevalence. However, one of the attractive features of the HIF system is its simplicity, and so for this reason, I would not favor including set-asides for special purposes.

Funding sources

Incentives for Global Health has suggested an international treaty to form the basis of a funding arrangement between countries, where financial contributions would be based in some way on per capita income. However, no such treaty would strictly be required—merely willing funders, exactly in the way that the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) is supported by a number of governments without any international treaty. It is also conceivable that other charitable foundations might choose to participate, at least to kickstart the system.

The size of the HIF does, however, present a serious obstacle: in order to make the fund credible, countries will need to commit substantial funding far into the future. Some of the contributions might be made up by lower health care costs and lower expenditures on pharmaceutical products—since any product under the HIF scheme would be available at low prices.

Litigation and patent expense

One of the problems observed in the patent system is that it engenders a great deal of costly and unproductive litigation. This is true in pharmaceutical markets particularly because obtaining a few days of extra exclusivity can be worth millions to the patentee, who will therefore be willing to use the patent system to obtain even trivial extensions in patent protection. So it is important to consider carefully what effect the HIF system might have on patent litigation.

The HIF system offers considerable advantages in terms of litigation, if it is designed so that there is a fixed period during which the patentee is eligible for payments (e.g., 10 years). Such a system would reduce the opportunities to ‘evergreen’, since additional patents would not offer the firm any ability to extend its payments. In case the firm developed a minor improvement, it could receive payments for the minor improvement, but the payments would be proportional to the significance of the improvement.

Summary

The essence of the HIF proposal is to develop a scheme in which incentives are well aligned with health needs. Under the HIF scheme, firms would have an incentive to develop and promote products that improve health, since their profits would be perfectly correlated with health impact. They would have an incentive to work with public health agencies to promote their product and to ensure that it was rationally used. They would have an incentive to develop products that cured consumers, instead of maintenance products. They would have all of these incentives because the payments under the HIF would be conditional on the measurable effects of their product on health.

In many ways, the HIF closely resembles a system of pharmaceutical insurance where the insurer sets a price that is dependent on the incremental health impact of the drug, much as proposed by Faunce and Nasu (2008). However, it is not designed to be a universal system of insurance covering all drugs—instead it is likely to have particular application to important drugs, which are, for

a variety of reasons, such as the poverty of the likely consumers, not particularly profitable under monopoly pricing.

The HIF approach is guaranteed to set a reasonable rate of payment for innovative medicines, because of substitutability between the exploitation of exclusivity rights under the patent and payments under the HIF. This possibility of substitution ensures that no matter what innovations arise, there will be a reasonable return available under the HIF. The HIF approach also largely solves some technical problems related to the limited protection granted by the patent system, because it is not necessary to be able to exclude imitators in order to receive payments. Most importantly, the HIF approach can be used to create new incentives for R&D into drugs that will be accessible to the poor, because it treats human lives as equal—unlike the uncomplemented patent system, which encourages R&D into the diseases of the rich—while enabling access.

Notes

1. This paper draws heavily from Hollis (2007a, b).
2. It is not really clear what sort of results these incentives will create. According to the Tremonti report, the intention was to get prices close to variable cost of production; but the system proposed in the later Framework Document is not really consistent with this aspiration. A firm might simply choose a very low price—perhaps zero—to maximize its sales during the AMC. Following the AMC, it is not clear how the AMC administrator would ensure that the price stayed unchanged.
3. In principle, the problem of having excess specificity required in the terms of the AMC could be solved somewhat by giving more discretion to the AMC administrators, to award more or less to a given product if it exceeded or fell short of the technical specifications. But more discretion in the hands of administrators leads to more uncertainty for firms, unless the administrators’ discretion is limited by applying a rule that ties the reward to some objective measure of health impact.
4. Ironically, products that are in late-stage development are exactly the products that require the least incentives, since the innovating firm is already close to having a commercializable product.
5. Other measures are also possible, though clearly the Health Impact Fund administrators would have to pick just one. For example, typically the burden of disease is measured in DALYs or Disability-Adjusted Life-Years, which assume that if a person’s death were

prevented, he or she would live to an age of roughly 80 years. This particular assumption, along with others relating to the weights imposed on various ‘disabilities’, in my opinion make the DALY a less appealing measure of health impact. Michael Selgelid (2008), however, suggests that the DALY approach might be preferable for the purposes of the HIF in estimating the relief from the burden of disease.

6. One of the attractive features of the HIF is reduced patent litigation expenses so that innovators’ profits can be reinvested or returned to shareholders. If the payments are set for a fixed number of years following registration and commercialization of the product, there will be much less benefit from frivolous patenting or from litigation.
7. There are similar difficulties here as in the Cost-Effectiveness Assessment and Tender model proposed by Faunce and Nasu (2008), although in the case of the HIF, it would be necessary only to measure effectiveness, not cost.
8. Since the HIF is optional, it creates new opportunities for pharmaceutical firms to earn profits, and thus has the potential to obtain their support, as observed by Pogge (2008).
9. This is not to suggest that firms could switch a given innovation back and forth from the HIF to exploitation of high prices under patent exclusivity. There appears to be no reason to exclude a firm from switching from patent exclusivity to the HIF; however, patients who had started on a course of therapy based on a low price would be harmed by a sudden increase in price if the firm removed its product from the HIF mechanism and hiked the price to the monopoly level. Therefore the HIF would have to require adequate notice for products that were to be removed from the HIF system.
10. The rate per QALY would in effect be established automatically simply through a division of the budget of the fund proportionally by QALY. Note that this is quite different, in terms of difficulty, from most insurance schemes that have to arbitrarily determine some cutoff price per QALY, above which the insurer is unwilling to accept the drug into the formulary.
11. There would likely be some difficulty for firms to estimate how large payments would be in the early years of the HIF; without any experience of such a fund, it would be difficult to form expectations. This suggests that it might be useful to provide some minimal guarantees of payment per QALY in the initial years of the HIF.
12. This is only a ‘potentially’ serious problem in that we don’t know its magnitude—we simply don’t

observe innovations that are not developed, and so we don’t know what innovative uses of older medicines might arise if firms had incentives. I cite in Hollis (2007a) the case of DCA, an older product with potentially significant cancer-fighting properties, for which there appears to be no commercial incentive to run clinical trials.

13. World Health Organization (2006) describes Type III diseases as overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). As the report noted, such diseases have historically been the subject of very little R&D investment. The same applies also to Type II diseases, which are those prevalent chiefly (but not overwhelmingly) in developing countries.
14. IMS Health and perhaps other organizations conduct such surveys in developed countries: but this would clearly be a challenging task in most developing countries.

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