

2. Reward Mechanism

The Health Impact Fund pays rewards for registered products over a fixed number of years. The funds paid out in any given year are divided between the registered products in accordance with the health impact each product has achieved in this year. Details about the entry, exit and patent status of products as well as the attribution of health impact are discussed against the background of a variety of design options.

INTRODUCTION

The essence of the HIF mechanism is that innovators are rewarded in proportion to the measurable net health impact of their innovations. The HIF would have a predetermined reward fund available for distribution to innovators in any given year. Each year, registrants of eligible innovations would receive payment in proportion to their share of the health impact created by all eligible innovations.

This mechanism creates incentives for innovation that are efficient in the sense of maximizing health impact for a given amount of payments by aligning the interests of the innovator with society's interest in public health. The HIF incorporates Arrow's (1963, p. 964) prescription for "ideal insurance" in which the healthcare provider receives payment "in accordance with the degree of benefit," though it also modifies it, since firms must compete to obtain these payments from the HIF. This competition, together with the fact that the HIF is an option, ensures that the payments made to innovators are fair and reasonable.

There are many ways that the reward mechanism might be specified, and it is difficult to determine which design option is to be preferred in advance of further engagement with stakeholders. To help fix ideas and to provide a more concrete starting point for discussion, we offer a reasonably detailed sketch of one plausible reward mechanism in the next section. We then describe and discuss alternative design options.

Motivation is the art of getting people to do what you want them to do because they want to do it.

Dwight D. Eisenhower

SKETCH OF A REWARD MECHANISM

Firms can choose to register a drug in the HIF system at any time. Generally, the firm will decide at or before the time of market approval in major markets. The registrant is the firm that owns or has licensed all the patents required to manufacture and sell the product.¹ Registrants of eligible innovations will receive in each of the first ten years following the initial market approval of their product, a payment based on the estimated incremental global health impact of the product as determined by the Health Impact Fund for that year. This payment would be $S \times F$, where

S is the estimated Health Impact of that product divided by the sum of the estimated health impacts for all products eligible for reward in that year;

F is the fixed amount of the HIF available for disbursement in that year.

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Payments would in no case exceed a ceiling per Quality-Adjusted Life Year (QALY), the level of which is yet to be determined. (In order to protect registrants, this ceiling could be lowered by the HIF only if prospective innovators are given ten years advance notice.)

Following the ten year payment period, the HIF is entitled to offer royalty-free limited licenses in all jurisdictions, of all patents required to manufacture and sell the product, limited to use in manufacturing and selling the product. This would enable generic competition following the ten year payment period from the HIF.

In some cases, the registrant may face generic competition. When there is such competition, the HIF will include any health impact attributable to sales of generic versions some product when calculating its estimated health impact.

In cases in which the registrant has shown and obtained approval for a new indication of an existing product, *S* will be based on the estimated health impact for that product in its new indication. Such a new indication would be eligible for rewards for five years.

In exchange for these payments, the registrant would be required to supply its product at an administratively determined price in all countries where the product is legal and is needed.

These payments and the relevant conditions are discussed in more detail below.

Eligible Innovations

Eligible innovations include (1) new drugs that achieve approval in the jurisdictions in which they are sold, and which are protected by patents in at least some set of major patent offices;² and (2) new, approved indications for existing drugs when the new indication is patented. If the product is not generically available, the patentee of a new use for an existing product will not be eligible for payments unless it agrees to sell the product at cost, as described below.³

The HIF has discretion to refuse to allow registration of medicines that have been previously marketed in a slightly different version, if the older version is generically available or if the HIF expects that it soon will be.

Obligations of Drug Registrants

Payment by the HIF to a registrant will entail certain obligations on the part of the registrant. To register a product with the HIF, the company is required to:

1. make a good faith effort to obtain market clearance wherever the product is needed;
2. preauthorize the HIF to seek market clearance for the product wherever the registrant has failed to do so and to subtract the cost of this effort from the registrant's next health impact reward payment;
3. sell the product at a low price, no higher than the long-run marginal cost of production and distribution as determined by the HIF, wherever the product is legal and needed; and
4. preauthorize the HIF to sublicense the relevant patents to generic firms who would supply it wherever the registrant fails to provide an adequate supply;
5. provide sales data and other evidence required by the HIF for assessing the product's global health impact during the reward period;
6. pay a yearly registration fee calculated to cover the costs of health impact assessment; and
7. preauthorize the HIF to sublicense the relevant patents to generic firms following the end of the reward period.

A company may seek pre-registration clearance from the HIF to ensure its product's suitability for HIF registration. Some products are unsuitable—for example, if a drug is about to become generically available, the HIF ought not to pay for health impact of a slightly different version of the same product.

Health Impact

As discussed in more detail in chapters 3 and 4, the Assessment Branch will estimate the incremental health impact of each product or new use globally. The health impact will be estimated each year during the payment period (ten years for new products and five years for new uses), with the health impact understood in terms of the attributed incremental

health impact of the intervention in each year of the payment period, for all approved indications.⁴ For interventions that affect the patient only (that is, for non-communicable diseases), the effect would be assessed in terms of the estimated lifetime of the individual. For interventions with externalities (that is, for communicable diseases), the effect will be assessed for the estimated lifetime of the individual who consumed the product, and for a fixed period (for example, ten years) for all other indirectly affected individuals.

The incremental health impact of a given product is defined by the difference between the actual health and a baseline. The baseline is conceived as the expected health level of consumers of the product being assessed, given the set of pharmaceuticals available, their approved indications, and their prices, at the time when the product was first commercially marketed or two years prior to that (with the firm to choose), excluding the new product and any others sold exclusively by the same registrant. The motivation for allowing the baseline to be specified in this manner is that it is frequently the case that firms develop similar drugs at the same time in the wake of some significant clinical or biomechanical advance. If two similar drugs are in simultaneous development, the two-year lag in the baseline will allow both drugs to obtain similar payments per unit.⁵

Thus, at the time that a new product registered with the HIF is introduced, the HIF will essentially take a “snapshot” of the state of care for people whom the product is intended to treat (or, if requested by the registrant, a snapshot of the state of care of such people two years prior to the registration of the drug) and set that as the baseline. Given that there will likely be a fairly small set of drugs introduced to the HIF each year, this approach seems more feasible than trying to keep a constant review of the state of care for all diseases every year.

All innovations developed by the registrant and currently eligible for payments from the HIF will be excluded from the baseline for that registrant. Thus, a firm would find it profitable to introduce incremental improvements on its own products registered with the HIF without the risk of cannibalizing payments. However, if a firm developed a product which

was slightly superior to a different firm’s product, the baseline would include the different firm’s products and in this case, the reward for the incremental improvement would simply be based on the incremental health impact realized.⁶

The fact that a given firm’s products are excluded from the baseline means that it will be more profitable for a single firm to offer two similar products than for two firms to offer the same two products. In turn, this implies that firms may wish to merge to take advantage of this relationship. In a way, this is similar to the fact that firms with similar products in markets without the HIF may wish to merge to prevent costly marketing and price competition between their products, since this undermines the profitability of both firms. Antitrust laws are designed to prevent mergers when they harm consumers by increasing prices. However, with products on the HIF, there would be no price effect on consumers, and only an impact on how much of the HIF payments the merged firms could capture. Thus, antitrust laws would typically fail to stop such mergers. This seems to suggest that the HIF might have to specify that when firms merged, the baselines applicable to their products would not change.

In cases in which there are synergistic effects between two different registered products, each product will receive a supplementary payment. The supplementary payment for each product will be half the normal payment for the estimated synergistic health impact. If only one product is registered with the HIF, and the other is not registered, the product registered with the HIF will be eligible for its entire incremental effect on health, including any synergistic effect. The treatment of synergistic effects is discussed more fully below.

The Administered Price

The HIF will set an administered permissible price range for wholesale sales of all products registered with it, with all sales of the product to be between the permitted maximum and minimum prices. This price range would be determined at that time for the entire payment period, and might be automatically adjusted through the use of an inflation index.⁷ The

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administered price range will be listed for each product on the HIF website, so that any buyers can know that the product should be available in that price window, and will therefore be encouraged to report sales outside that range.

The maximum of the administered price window would be set by the HIF at a level intended to mimic average manufacturing and distribution cost, that is, the level at which one would expect generic firms to be able to compete. The minimum of the window would be set at approximately marginal cost of production and distribution, that is, the economically efficient level. In defining this window, the HIF would have to rely at least in part on expert engineering assessments or possibly quotations from contract manufacturers. The registrant would in general always prefer a wider window for pricing. The actual choice of price within the window will depend on the elasticity of demand, the marginal cost of production, and the expected size of the payment made by the HIF per unit sold. In general, the larger the size of the HIF payment per unit and the greater the elasticity, the lower is the profit-maximizing price. In setting the administered price, the HIF must rely at least in part on expert engineering assessments, or possibly quotations from contract manufacturers.

The purpose of setting a *minimum* price is to help reduce the risk that the product is not used appropriately. For example, the registrant might give the product away in hopes of increasing its reward from the HIF through achieving higher volumes of products shipped. At the same time, if the price were too low, patients might be apt to waste the product, potentially causing environmental harm. In cases in which patients are too poor to purchase the product even at marginal cost, and yet the product is essential to the person's health, there is of course a rationale for subsidy. The question is, who should offer the subsidy? Here we think there is a suitable role for a third party such as government or an NGO to purchase the product on behalf of indigent patients.

Registrants would, however, be permitted to contract with wholesalers and distributors to achieve low retail prices for registered products, provided that the retail price did not fall below the minimum.

A Ceiling on Payments

In order to protect the interests of donors in case of inadequate take-up of the HIF mechanism, the HIF will set a maximum payment per QALY. Determining how high this ceiling should be is beyond the scope of this chapter. However, some sense of the possible range is indicated by the prices that countries have been willing to pay for healthcare improvements in the past. For example, interventions which cost less than \$50,000 to \$100,000 per QALY are often described as being cost-effective (Ubel et al. 2003). At the other end of the spectrum, antiretrovirals that cost \$350–500 per QALY have been considered expensive in a developing country context (Jamison et al. 2006).

When it is possible for pharmaceutical innovators to develop new pharmaceuticals at costs which are much lower than the ceiling price per QALY, we can expect that they will do so and that the actual payment per QALY will in fact be much lower than the ceiling. If pharmaceutical innovators believe that the ceiling is so low that they can always earn more profits outside the HIF, the HIF will find that it has no take-up.⁸

One consideration in setting this ceiling is that it should probably be relatively high because it is paying for innovation only temporarily, while the innovation itself will be available permanently. Thus, assuming continued use of the innovation, the true *average* payment per QALY attributable to the innovation will always be lower than the ceiling.

Intellectual Property

A key feature of the HIF is that it does not require any substantial changes to the structure of intellectual property or licensing, and largely mimics the structure of the patent monopoly system. Suppose, for example, that a firm requires its own patents plus those of three other parties to market a drug. In the current system, it will have to obtain licenses from the other parties. The same will hold in the HIF system. If a firm develops a new use for an existing product, it will have to make mutually agreeable arrangements with the patentee if the manufacture of the product is

covered by a patent, whether in the HIF system or in the patent monopoly system.

There are, however, several respects in which the structure of the HIF differs from that of the patent monopoly system. First, the incentives to challenge patents will be relatively weak, since generic companies will find themselves competing not against a firm with high prices, but against a firm with low prices. If the registrant sold the product at a price below the generic average cost of manufacture, generic firms would find entering such a market unprofitable until the end of the payment period, at which time the patents would be openly licensed. This approach would thus largely eliminate the wasteful litigation which consumes a great deal of the resources of pharmaceutical companies under the present system.⁹

Second, patentees will be unable to obtain disproportionate increases in profits through evergreening in the HIF. In the current system, small modifications to existing products may extend the monopoly profits. In the HIF system, small modifications are rewarded with small payments. This would diminish incentives for firms to use the patent system strategically.¹⁰

Third, firms will be able to make use of patents issued for new uses when those new uses are recognized as new indications. At present, patentees are largely unable to capture the benefits of performing clinical trials to demonstrate efficacy and safety of existing (older) medicines for new indications, leading arguably to inefficient use of our pharmaceutical armament. The problem is that a patent for a new use may not allow the firm to exclude other firms from selling the product, since neither the manufacturer nor the pharmacist necessarily knows how the product will be used.¹¹ However, the HIF reward mechanism does not require exclusion: it only requires the patentee to provide evidence that the existing drug was in fact used for the new indication.

Finally, note that the HIF fixes the period of rewards at ten years for new products and five years for new indications. In the current system, the period of exclusivity tends to vary considerably, depending on how long clinical trials and the approval process takes. Since a drug which has longer clinical trials is not inherently a less valuable drug, the current

system is flawed in this varied period of exclusivity. The HIF system simply offers a reward period of ten years, regardless of the length of patent exclusivity. This may, in some cases, lead firms to choose to use the HIF rather than monopoly pricing, if their expected patent protection under the current system is relatively short. In this respect the HIF provides a superior system of incentives.

Cumulative Innovation

An important feature of innovation is that it is often cumulative. This creates complex patenting and licensing requirements. As discussed above, the HIF essentially leaves all those requirements unchanged. However, it does change the way that cumulative innovation is rewarded, since relatively minor improvements are rewarded with relatively small payments. This should be seen as a positive feature of the HIF system, since limiting payments for small innovations enables larger payments for clinically important innovations.

Which Products Would This System Suit?

An important feature of the HIF reward mechanism is that it provides the largest rewards for those products with the largest health impact. However, since the system is optional, firms will choose to register their product with the HIF only if this leads to earnings higher than those expected from sales at unconstrained prices. Firms will find the HIF system most attractive for products with high health impact but low profitability under the current system. These are likely to include products that can bring substantial health benefits to people who are poor or located in countries where the patent protection is weak. Thus, this system automatically offers the strongest incentives exactly for those products for which monopoly exploitation under the patent system is most inadequate. This set of potential products is likely to be dominated by drugs and vaccines which are targeted primarily at poor, uninsured people, as those products are likely to have large health impact, but low profitability under monopoly pricing.

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I have always believed deeply in the need to offer more protection to weaker victims of globalization; and as diseases cross frontiers—in fact we now speak of the “sovereignty of disease” over that of States—our globalized world response must always remain ultimately focussed on human beings.

Pascal Lamy

An important aspect of the HIF system is that it is global in nature and offers equal rewards for a life saved anywhere in the world. That is quite different from the rewards earned by unconstrained pricing, which tend to be much higher for drugs which are primarily sold in affluent countries than for those primarily sold in poorer countries. Therefore, it is likely that in the near future, the “low-hanging fruit” is likely to consist mainly of treatments for tropical and contagious diseases, which have tremendous health importance but which have so far attracted relatively little investment from pharmaceutical companies. However, especially in the medium to long term a wide range of products and new uses can be expected to benefit from the HIF.

A Registration Process

It is possible that not every product meeting the registration requirements for the HIF would really be suitable. For example, suppose that a firm has developed and sold an important product at monopoly prices for many years. It expects this product to become generically available in most countries in the near future. It then develops a slightly modified version of the same product, using a different formulation, which it seeks to register with the HIF. The low price of the new HIF-registered product would substantially increase access (compared to the baseline level of access), and the firm would be entitled to substantial payments on this basis, even though low-priced generic versions of the older product would have been launched globally soon after. This is a case in which the HIF clearly should not grant significant payments to the innovator, since the innovation is really not significant, and yet the proposed terms of how payment is to

be determined allow some scope for firms to abuse the system.

To avoid such abuses, the HIF should be granted some discretion in permitting registration of new products. Ideally, firms would seek an early decision from the HIF as to whether it would accept registration of a given new product. In cases in which the new product offered no meaningful expected health impact compared to other products in the firm's portfolio, or where the firm had shown a pattern of abuse of the system, the HIF should be able to advise the firm that its product cannot be registered.

In general, the HIF should be designed to minimize discretion as the amount of payments made for any product (see chapter four for further discussion of this point). However, because of the variety of circumstances the HIF is likely to encounter, and the limited amount of funds it would be able to pay out, it is important to minimize the extent to which unduly rigid rules enable firms to abuse the system and obtain payments for patented products which embody innovations of marginal, if any, value in terms of health impact.

DESIGN OPTIONS

The mechanism described above is one of several plausible options for designing the reward mechanism of the HIF. In this section we discuss some alternative designs.

The “Price” per QALY

The system proposed above makes the “price” per QALY—or the amount which each registrant is rewarded per QALY assessed—endogenous. There are possible alternatives, discussed below, including setting a fixed payment per QALY, or something in between.

There are several useful features of the endogenous price per QALY mechanism. First, it relies on the market to set the price for health impact. It is clear that the HIF administrators cannot know what “price” per QALY is actually required to stimulate meaningful investment in innovation, so that stipulating in advance any particular “price” per QALY

would be arbitrary and counterproductive. If the decision to enter the HIF system is left up to firms, they will rely on their private information about the probability of success of developing a given innovation and the costs of doing so. That is, as in any market setting, the “price” will be determined by the interaction of agents using private information. In addition, because the rate of payment per QALY generated is created in a system in which firms have the option to exploit their patent rights outside the HIF system, the “price” will be within the range which is available in the patent system for a given health impact.¹² Thus, by relying on this market mechanism, the HIF administrators can automatically generate a level of reward per QALY which is consistent with firms’ costs and which is consistent with the expected rewards which are available for other drugs under the patent system.¹³ Thus, it is important to recognize that the reward mechanism employed by the HIF is not a regulatory one in which some administrative body determines the reward: it is a competitive one, in which the reward is determined by the measured health impact of each product.

The mechanism employed by the HIF is not a regulatory one in which some administrative body determines the reward: it is a competitive one, in which the reward is determined by the measured health impact of each product.

A second benefit of fixing the total amount of payments per year is that it removes discretion from the HIF regarding how much it should pay out. This is useful, since it is a simple way of committing to investors that the HIF will not try to skimp on the payments made, and of assuring funding partners that the HIF will not over-estimate health impact to increase the total payments made.

Third, by fixing the total amount of payments per year, the funding partners have no uncertainty regarding the extent of their financial obligations.

Finally, the fixed amount of payments means that firms in the system are forced to compete for payments. This in turn implies that there is a benefit to monitoring other firms’ claims about health impacts. Firms with products which had a claim to a substan-

tial proportion of the HIF payments would have the largest incentive to undermine the claims of the other firms—they might do so by providing information to the HIF.

Unfortunately, a system with fixed total payments, and an endogenous amount of reward per QALY, imposes risks on registrants: their payment is dependent on the number of QALYs created by other registered medicines. Registrants would therefore prefer a fixed reward per QALY if it were set high enough. A fixed reward per QALY would eliminate some of the uncertainty inherent in the system described above, in which each firm receives a share of the HIF allocation. Since, all else being equal, firms dislike uncertainty, anything which increases their ability to forecast future profits would be helpful for them.

However, removing risk from registrants only imposes it on funders. If there is a fixed price per QALY, then the funding partners to the HIF must bear the risk of making larger contributions than they expect in case registered drugs create more QALYs than anticipated, in aggregate.

A further option would be to set a guaranteed minimum level of reward per QALY. This would go some way to reducing the risks to innovators, and if the minimum reward per QALY were set sufficiently low, there would be relatively little risk of exceeding the HIF budget. However, it is in exactly those circumstances where the minimum reward was relevant that the budget would be exceeded. The minimum price therefore has similar characteristics as a fixed price, in that it transfers risk from the pharmaceutical innovators to the sponsors of the HIF.

To reduce risks for funding partners and registrants, the HIF could set a fixed reward per QALY and then limit the number of products eligible for payments from the HIF. If the payments on expected health impacts from products already in the HIF system were getting close to the available funds, the HIF would be made unavailable to other products until there was more space in the system. This approach would ensure that existing registrants could count on continued payments at the expected rate per QALY, while firms with products not yet in the system would face much larger risks, since they would be either in or out, and could be out of the system even if (or be-

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cause) they had a product with substantial health impact which could not be rewarded at the established level given the size of the HIF.

An intermediate solution would be to design a risk-sharing arrangement such that the risk of inadequate payments for registrants was balanced with the risk of unexpectedly large obligations for donors. Such a system might involve increasing the total rewards paid out at some predetermined rate if the total QALYs achieved by all registered products exceeded some number.¹⁴ Provided that the schedule of the price per QALY was defined in advance, the price would be endogenous. Such a system could allocate the risks more efficiently between funding partners and registrants, though possibly at some cost in terms of the attractive characteristics of having a fixed reward pool described above. These issues are discussed further in chapter 5.

If firms express concern that a fixed reward pool exposes them to excessive risk, it is perhaps most suitable for governments to address these risks directly through other funding mechanisms, such as direct grants for early-stage research.

A Dollar Ceiling on Total Payments per Product

Given a fixed payout from the HIF each year, firms face the risk that some product may be developed which has such a large impact—for example, a cheap and effective malaria vaccine—that it captures virtually the entire HIF payment stream over the course of many years. While donors to the HIF might be delighted with such an outcome, the risk of this occurring will tend to deter innovators from entering the system. One possible response to this problem is to limit the proportion of the Fund that a single product can capture in any given year. For example, the HIF could limit the total payments for any product in a given year to at most 50 percent of the fund's payout or to a fixed amount. By limiting the payment for a “blockbuster” product, developers of other less therapeutically important products would have greater assurance that they would be adequately rewarded for their innovations.

This approach would reduce risk and encourage entry. Its main drawback would be that incentives for firms to pursue the most important pharmaceutical advances would be weakened.

The Duration of the Payment Period

In the proposal sketched in above, ten years was fixed as the time period for a new product to be rewarded, and five years was proposed for new indications. These durations are somewhat arbitrary. Ten years is intended to replicate roughly the typical period of exclusivity of new products under the patent system, given that the approval process is so lengthy for new pharmaceuticals. The shorter period of five years for new indications is shorter only because it is likely that, in general, it will be considerably less expensive and less risky to show a new indication than to develop a new product (Ashburn and Thor, 2004). In the former case, the product has already been developed and shown to be safe, and all that is required is evidence that the product is effective in the new indication. Either of these periods can be lengthened or shortened.

The length of the HIF payment period is, notably, not as important as the duration of patents under the patent system. The reason is that a shorter period of payment in the HIF will typically result in higher payments per product in each year, as fewer products are eligible for payments in each year. Thus, a shorter period for HIF payments would be compensated by higher payments during each year.¹⁵ Assuming an equal number of products were registered with the HIF each year, the average payments per product would remain the same. (This is not true with the patent system, in which shortening the twenty-year patent duration would cause a significant reduction to the incentives for innovation, since prices would not increase.)

One benefit of extending the payment period is that the HIF requires that the registrant offer a royalty-free license on all patents required for the manufacture and sale of the product, limited to use in manufacturing and selling that product, following the payment period. This is inconvenient, since it introduces a licensing requirement that would be

absent if the payment period were sufficiently long, as eventually all the relevant patents would expire.

The longer the payment period, the stronger the incentives the registrant has to invest in promoting their product. It is well known that it takes several years for new drugs to achieve widespread acceptance, since it takes time for doctors and patients to learn about the effects of the product.

On the other hand, a shorter period reduces the amount of monitoring required by the HIF, thus reducing its costs of administration. A payment period of eight years instead of ten would reduce monitoring costs by twenty percent. A shorter period also increases the amount of payment in the early years, which can be important for investors.

An important feature of the length of the payment period is that it does not depend on patent status. Thus, even if all relevant patents expire in the sixth year of the payment period, the registrant may continue to obtain payments, although in that case generic competitors might make a significant proportion of the sales of the product. However, this means that the HIF would be paying rewards for a product which would have been available at generic prices in any case. This suggests another option: the duration of the payment period could be shortened in cases in which all relevant patents have expired. Since patents are national in character, this would imply that rewards would only be paid in those countries in which a valid patent protected the product. However, this option seems unappealing since then it forces the innovator to apply for patents in *all* countries, including those without a pharmaceutical manufacturing industry. In addition, it would typically be very difficult for the HIF to determine whether patents in various countries would in fact be found valid if they were challenged. Finally, it should be recognized that since the HIF payments are based on incremental health impact of an innovation, it should not really matter whether the duration of the relevant patents is more or less than ten years from the initiation of commercial sales. Unlike the regular implementation of the patent system, the HIF mechanism is designed to reward innovators based on value created.

Synergistic Effects

The discussion above suggests that, when there are beneficial synergistic effects from two separate medicines eligible for payments from the HIF, the two products should split the benefits of the synergistic impact equally between them for the purpose of determining how large a reward should go to each. There are other possible ways of dividing the synergistic impact. For example, the second firm to develop its product could be awarded all the benefit. Such an arrangement, however, might lead to undesirable delays in the introduction of new products.

In most cases, such synergistic effects would be between one product registered with the HIF, and one or more products or services not registered with the HIF. How the HIF deals with such cases is important and difficult. Suppose there are two perfectly complementary products, *A* and *B*, which together have a given health impact and which individually have no health impact at all. Under the current system, the owners of these two products would in general be motivated to come to an agreement to jointly market the products, and to share the sales proceeds. Suppose instead that product *a* (sold by firm *A*) were registered with the HIF, and *b* (sold by firm *B*) were not. How should the HIF calculate the incremental health impact of *a*? *B* would naturally choose a high price for its product, knowing that *A* would set a low price. *A* would suffer from this, since its profits would be reduced owing to reduced sales (because of the high price of *b*) and hence reduced health impact. *A* might even be willing to pay *B* to reduce the price of *b*.

Consider further an even more troubling possibility. Suppose that *a* and *b* were products that normally would be sold only in rich countries, and that the joint product was not normally be suitable for the HIF. However, given the perfect complementarity between the products, the profit-maximizing strategy would be to charge monopoly prices for *b*, and to obtain supplementary payments from the HIF for *a*. In this case, the profits of *B* would be larger than the profits of *A*. (If the profits of *A* were larger, then this would be a suitable candidate for the HIF to begin with.) To make this strategy work, *B* would therefore most likely have to pay *A*. Such a situation would certainly be

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a concern for the HIF, since it would mean that firms could use the HIF as strictly a supplementary reward for a combination drug which would be priced at a monopoly level. This would defeat the purpose of the HIF and must be avoided. A reasonable rule would be to require that firms which register their products with the HIF be prevented from receiving compensation from other firms. However, payments could flow in the opposite direction, since firms with products registered with the HIF may reasonably wish to lower the prices of other complementary drugs.

Similar concerns arise in cases in which *a* and *b* are owned by the same firm, where drug *a* but not drug *b* is registered with the HIF. In this case, drug *a* would not be credited with any synergies with drug *b*, since it would be assumed that the firm was being fully compensated by high prices for drug *b*. If in fact the firm was not charging high prices for *b*, it would be benefited by registering *b* with the HIF as well. In that case, the firm would obtain the benefit of all synergies between *a* and *b*.

Voluntary Licensing

Under the system proposed above, the drug registrant retains exclusivity rights in its product, but accepts an administered price in exchange for payments from the HIF. An alternative approach would instead require that the registrant offer a voluntary license with a zero royalty for any generics to produce the product. Assuming a competitive generic drug industry, such licensing would lead to prices roughly equal to the average cost of production and distribution.

There are a number of reasons for preferring a system in which the registrant must forgo only pricing freedom, rather than giving up the exclusivity rights created by the patent.

First, the licensing approach would require registrants to forgo some intellectual property protection, which is not necessary as long as the registrant is willing to sell the product at the administered price. In some cases, the intellectual property arrangements may be complex, and licensing may therefore be difficult. In other cases, the intellectual property may have many applications, and the patentee might prefer not to grant an open license for its use.

Second, in cases where the generic drug industry is not competitive—as is the case in many countries—licensing to generics would fail to achieve the goal of low prices. If competition is ineffective in reducing the price to near cost, registrants would benefit from high prices and still receive reward payments from the HIF. Competition may fail to be effective for a variety of reasons:

- a. Competition can take a long time to push prices down. Generic firms need to ramp up their manufacturing capacity and obtain the approval of regulatory authorities, which can take years.
- b. In many countries, generic competition does not lead to low prices because of other distortions (including insurance) in pharmaceutical markets.
- c. For many products (such as complex biologics and some vaccines), generic versions simply don't exist, or there are very few generics, even when patents do not obstruct entry.
- d. Even if generic competitors have access to patented technologies, they may be significantly disadvantaged if they lack access to unpatented trade secrets or supplies of an essential ingredient.

Thus, generic competition will not always lead to low prices. There are some situations in which generic competition might, however, be more effective in achieving low prices. In particular, generic producers may sometimes have lower costs which are simply not revealed unless competition occurs. On balance, however, direct price control seems like a more effective way of ensuring low prices than open licensing.

Third, the fact that the HIF is optional introduces additional considerations in favor of price control rather than open licensing. If the HIF mandated open licensing rather than price controls, every product for which no generic competition was anticipated even given open licensing of the relevant patents would register for HIF rewards. There are many such products. Many firms producing very expensive biologic drugs, for example, have no generic competitors because of the complexity of the manufacturing process. Since these expensive products would have no generic competition, they could be registered with the HIF and would benefit not only from the usual

high prices, but potentially also from HIF rewards. In this case, much of the money paid out by the HIF would be a supplementary payment for high-priced products, leaving less for rewarding other products.

Entry/Exit Options

Should firms be permitted to enter or exit the HIF system at any time? One possible design option would allow entry only at the beginning of commercial marketing of the product, without any escape option. However, this would clearly lead to less take-up of the system, particularly for firms which were uncertain of how the HIF would work.

Allowing delayed entry appears attractive, but it is possible that firms with effective patent protection of less than ten years would then exploit their patent rights as long as possible and then switch over to the HIF. This is not a desirable outcome. One possible rule in such cases is to reduce the payment period by some multiple of the length of delay of entry into the HIF system. (The multiple would be a number greater than one.) For example, assuming a multiple of two, if a firm decided to proceed initially outside the HIF system for two years, when it entered the HIF system it would be eligible for payments only for six (ten less two times two) years.¹⁶

If a firm wished to withdraw its product from the HIF system, it would be permitted to. However, the non-exclusive license of relevant patents, data, and other know-how used for the manufacture and sale of the drug would remain with the HIF, which the HIF could sub-license following the end of the ten-year payment period. Thus, even if a firm withdrew after five years, the HIF could still enable generic competition at the end of ten years. This rule is designed to prevent firms with longer patent protection registering with the HIF, accepting payments, and then withdrawing after nine years and six months to take advantage of extended exclusivity under its patent.

Interim Payments

Many people have expressed the argument that the risks in pharmaceutical research are so high that the HIF mechanism could be improved by providing

interim payments to innovators upon the achievement of specific technical goals. (For example, the company might be paid an interim payment following successful approval of Stage II clinical trials.) While such interim payments are highly attractive to innovator companies, and may be extremely important in enabling companies to invest in valuable research projects, the HIF should avoid such payments. Governments that wish to sponsor such technical prizes and research grants should continue to do so.

As Peter Drucker (2006, 132) has pointed out, “information-based organizations need concentration on one objective,” which, in the case of the HIF, is accurate measurement of health impact. Research grants or bonuses based on the achievement of specific technical goals are fundamentally not in the mandate of the HIF, which will be more effective if its function is as simple as possible.

SUMMARY

The reward mechanism of the Health Impact Fund is designed, fundamentally, to make the payments to innovators dependent on the health impact achieved by each registered product. However, it also needs to balance a number of other considerations in pharmaceutical markets, including allocating risk appropriately, minimizing double payment to firms which try to obtain both monopoly prices and payments from the HIF, correctly rewarding registered products which are complementary with other products, and limiting the discretion available to fund administrators.

The HIF is an optional, global pay-for-performance scheme for new medicines. Its design is intended to align incentives for innovators with the common goal of reducing the global burden of disease. All the innovations it rewards will be cheaply available wherever they are needed. The HIF uses a market mechanism to determine the rate of payment per unit of health impact, letting firms compete for the available reward moneys. This makes the reward rate self-adjusting in a way that assures innovators of an appropriate rate of return and the funding partners of the cost-effectiveness of the HIF itself.

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NOTES

1. The registrant need not be the innovator but must own or have licensed all the relevant intellectual property.
2. The HIF might require at least one patent issued by a patent office qualified as an International Searching and Examining Authority under the Patent Cooperation Treaty, and could require that the patentee had made an international application, which would be the subject of an international search.
3. If the registrant of a product registered with the HIF registered a new use during the payment period of the product, the registrant may obtain payments based on the old indications as well as the new indication during the initial payment period, and payments based on the new use only (if within the five year period) following the expiration of the initial period. For example, if a firm registered its drug with the HIF for the treatment of heart attacks, and 8 years later received approval for a new indication to treat strokes, it would receive payments based on measured health impact for all approved indications until year 10, and in years 11–13 would receive payments based on the effects of the product for the treatment of strokes only. The registrant will receive payments based on its own sales as well as on sales made by generics during the later period.
4. For clarification, when measuring the health impact of a vaccine given in year 5, the measured health impact would be the estimated decrease in disease burden over the lifetime of the vaccinated individual because of that vaccination in year 5. However, vaccinations given in year 11 would not be eligible for any payment.
5. The two-year baseline lag is somewhat arbitrary. If the baseline lag is too large, (1) it becomes increasingly difficult to assess the state of technology and access at that date, and (2) it may induce imitation. Imitation is not desirable if it does not lead to better health outcomes. On the other hand, if the baseline lag is too short, innovators could be significantly short-changed. For example, suppose that two similar products are introduced to the market on two subsequent days. And suppose that the second product is slightly better and is therefore able to dominate the market. Since the first product obtains small sales, it would obtain only small revenues under any system. In the absence of the baseline lag, the second product would obtain a very small payment per unit, since it would be compared to the first product. Thus, the collective payments would be relatively small. In contrast, with the baseline lag, the second product would be found to have a relatively large health impact, leading to much larger payments.
6. In this case, the later entrant would in effect cannibalize the payments to the first firm, since it would reduce the payments to that firm if it succeeded in capturing some market share for its product. However, the later entrant would likely prefer to exploit its monopoly rights under the patent system, since it would typically receive rather small payments from the HIF if its product was only incrementally better than the first product.
7. Since inflation varies between countries, the inflation index chosen should reflect the countries in which the registrant expected the product to be manufactured.
8. Note that in such a situation the HIF will simply not spend much money.
9. Weak incentives for litigation may also present problems. The HIF should avoid making payments to firms for products not embodying innovations which are significant in improving health outcomes. The registration process discussed in this chapter would be an important screen to prevent abuses of this sort.

10. Note that firms could continue to make use of minor innovations: for example, a minor modification of a product registered with the HIF might be sold outside the HIF at a monopoly price – but it would be competing against the much lower priced similar product registered with the HIF.
11. For example, if a researcher discovered that 500 mg of acetaminophen per day was adequate to stop the progression of Alzheimer’s disease, and conducted the clinical trials to show this, she could certainly obtain a patent on this use. However, she would likely be unsuccessful in charging a price for acetaminophen higher than other manufacturers; and she could not stop other firms from selling acetaminophen which might be used in the patented way.
12. Note that while the price per QALY in the HIF is similar to that outside of the HIF, this does not mean that the rewards for a given innovation are the same with and without the HIF. Without the HIF, the reward for a new drug which treats primarily the poor will be low, because the reward is not based on health impact. With the HIF as an option, such a drug would be registered with the HIF, increasing the reward for its development.
13. See Hollis (2007b) for a technical analysis of this point.
14. For example, suppose that the total reward pool was set at \$6bn, provided the QALYs achieved by all registered medicines totaled no more than a pre-determined threshold of 60m. However, the reward pool would automatically increase by $\sqrt{Q/T}$ (where Q indicates QALYs achieved and T indicates the threshold) if $Q > T$. Thus, if 80m QALYs were achieved, the total reward pool would increase by about 15% (or by precisely $\sqrt{80 / 60} - 1$) to \$6.9bn. Such an approach leads to increasingly smaller payments per QALY the more the threshold is exceeded. Of course, funding partners would need to agree on a mechanism for increasing their contributions in years in which such excesses occurred.
15. A shorter duration would also suggest a higher ceiling on the payment per QALY.
16. The period of payments cannot generally be dependent on the remaining duration of the patent, since there will usually be a number of patents outstanding in different jurisdictions, all of which may have different expiry dates.

