

The Health Impact Fund and Price Determination

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The Health Impact Fund and Price Determination*

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This paper is intended to stimulate discussion on how the Health Impact Fund can ensure that registered drugs achieve the greatest possible health impact.

Abstract: The Health Impact Fund, like other similar proposals, requires a mechanism to ensure that products being rewarded on the basis of health impact are available to people in need at the lowest possible prices. This discussion paper explores possible mechanisms for enabling access, considering price controls; generic licensing; and systems of tendering for production.

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1. INTRODUCTION

What is the best way of ensuring low prices for medicines when the innovators are rewarded separately for health impact? Several proposals for “prize funds” have been made in recent years, including the Health Impact Fund (Hollis and Pogge, 2008), the “Priority Medicines and Vaccines Prize Fund” proposal made by Barbados and Bolivia¹, and the U.S. Medical Innovation Prize Fund Act of 2007 (S. 2210) introduced by Senator Sanders. All of these proposals essentially attempt to reward pharmaceutical innovation in a way that is separate from, and hence does not raise, the price of the innovative medicine. In each there is a fixed fund which pays innovators based on measured health impact, and then the patented drug is to become available at the cost of manufacturing.

This paper examines how one might best obtain low prices and high availability for innovative medicines in the context of such proposals, and particularly in the case of the Health Impact Fund (HIF). Some proposals have included open licensing to enable immediate generic competition. While this seems intuitively attractive, generic competition is not always effective at achieving low consumer prices, particularly outside the United States. Open licensing also creates new complications related to the licensing of patents and other related know-how which may be difficult to resolve. Thus, Hollis and Pogge (2008) suggested an alternative mechanism, in which no licensing would be required; but the “registrant” or supplier of the product would be subject to price controls on the registered product.² This mechanism creates other problems, such as estimating the true cost of production and ensuring that the best technologies are in fact being employed.

Product-development partnerships (such as the International AIDS Vaccines Initiative and the Institute for OneWorld Health) face similar issues in establishing access conditions for the products developed.³ Typically PDPs may allow the private partner exclusive, unrestricted rights in developed countries and limited rights in developing countries. The access conditions in PDP contracts may require generic licensing or they may require the private partner to make the product available in developing countries on non-profit terms. Taubman (2004) provides a very

¹ See http://www.keionline.org/misc-docs/b_b_igwg/prop3_pmv_pf.pdf.

² This is similar to the approach adopted for “Advanced Market Commitments” which have somewhat comparable properties.

³ For additional information on PDPs, see Kettler and Towse (2002).

thoughtful examination of the different kinds of contracts and their advantages and disadvantages, which provides helpful background to this paper. However, optimal access conditions under PDPs and a reward mechanism such as the HIF differ in an important way, since under a mechanism such as the HIF, the private innovator is motivated to expand access, while the non-profit terms imposed on private partners in PDPs are unlikely to provide much motivation. Thus, one should not simplistically assume that enabling access would require the same mechanisms in the HIF as in PDPs.

This document considers four different mechanisms which could be used to obtain low prices for products registered with the HIF:

A. Price controls based on estimated production costs

This is the mechanism that was proposed in Hollis and Pogge (2008). Here the registrant would retain a monopoly in the production and sale of the registered product, but would be limited to a maximum price determined by the HIF on the basis of estimates of the cost of production, which could be adjusted over time to reflect advances in manufacturing technology.

B. Open licensing

This is essentially the mechanism in the prize fund proposal made by Bolivia and Barbados. Here the registrant would have to grant zero-price licenses for all patents, data and know-how needed for competitive supply of the registered product to all firms which met quality and data-reporting standards. Generic producers including the registrant would compete to make sales in a way that would likely resemble what is observed in genericized markets today.

C. Price controls based on tendered bids to produce

In this mechanism, the registrant would have the exclusive right to sell the registered product, but it would source the product through tenders from competitive generic manufacturers. It would then be required to sell the product at the same price it purchased it, plus a mark-up for distribution

costs determined by the HIF. This is similar in terms of production to open licensing, but the registrant would maintain the exclusive right to distribute the product. The generic producers would have limited licenses of all relevant intellectual property.

D. Option approach

In this mechanism, the registrant would be given the option of choosing between B and C. Since the registrant cannot earn profits on the sale of the drug in either case, but must earn profits only through the health impact rewards, the registrant would wish to choose the mechanism that would lead to the greatest measurable impact on health.

The HIF would be forced to use A and B in some particular situations. In case of insufficient competition in manufacturing, neither B, C, nor D will achieve the desired low prices in all circumstances. If the HIF believed that there was likely to be a failure of competition to deliver achievable low prices, it might have to impose solution A. In other circumstances, B would be the only possible mechanism. In particular, the HIF is intended to be able to reward discoveries of new uses of existing, generically available drugs. In such situations, open licensing is already *de facto* present, and other solutions are not feasible.

In the follow sections, we first describe the different methods in greater detail. We then introduce the key issues which can help to decide which mechanism is best for price determination. It is clear that there is no “perfect” mechanism and that the choice between them will involve complex trade-offs.

2. FOUR MECHANISMS TO CONTROL PRICE

This section describes the four possible mechanisms in greater detail.

2.A. Price controls based on estimated production costs

The approach suggested in Hollis and Pogge (2008) is for the Health Impact Fund to set a maximum price for sales of any registered product, based on estimates of the cost of production

and transportation. This maximum could be based on expert engineering assessments or quotations from contract manufacturers. Estimates would be obtained at the beginning of the reward period, and could be revised over time to reflect new production methods or changes in raw material costs. This approach is similar to cost-of-service regulation of utilities and suffers from some of the same problems.⁴ What distinguishes this approach from cost-of-service regulation is that the registrant obtains profits from health impact-based rewards, which changes its incentives concerning pricing and, by extension, cost reduction. In particular, the registrant may be motivated to charge prices below the ceiling if such price reductions sufficiently increase sales and if the health impact reward per unit sold is sufficiently high; it will also be incentivized to invest in cost reduction.

2.B Open licensing

The open licensing system is easy to describe in brief, although likely more complicated to use in practice. The HIF would require, as a condition of registering a drug, that the registrant ensure that all patents relevant to the manufacture or sale of the product are available for that use through an open license. The license might stipulate certain terms, such as requiring that any generic firms manufacturing or selling the product meet specific standards with respect to quality of manufacturing and sales practices and that they maintain detailed records of all sales made.

Barbados and Bolivia (2008) proposed a prize mechanism in a short document to the World Health Organization-sponsored Intergovernmental Working Group. The proposal suggests a “Priority Medicines and Vaccines Prize Fund” which would essentially be similar to the HIF, though with some important differences. The proposal suggests that “The prize awards will be divided among competitors on the basis of the relative impact of the products on health outcomes.” The Barbados and Bolivia proposal, which was developed with assistance by Knowledge Ecology International, requires that “In order to make claims on the prizes, the winners must grant licenses to all patents, data and know-how needed for competitive supply of the final products.” This proposal is the open licensing approach. This is also the approach proposed by Hollis (2004) and Pogge (2005).

Such an approach, if it worked well, could have many potential benefits. Generic manufacturers, with their low per-unit costs and manufacturing economies of scope across

⁴ For a discussion of some of these problems, see Armstrong and Sappington (2007).

products, would compete against one another to sell registered products, and this competition would tend to drive prices down. Assuming that effective generic competition existed, this approach would require little regulatory oversight.

Some of the questions relating to the implementation of this approach relate to determining how to deal with questions of what constitutes adequate disclosure of know-how; how to deal with product liability issues; and how to address patent infringement claims by third parties. Presumably each generic producer would be responsible for obtaining the regulatory approval required to sell the product in each country.

2.C Price controls based on tendered bids to produce

A third approach is for the HIF to issue a call for tenders for production on behalf of the registrant. The registrant would be obliged to provide a zero-priced license of all patented technologies to the winner or winners for the period of the tender, as in the case of open licensing.⁵ The winner would produce the product on behalf of the registrant, who would then be responsible for distribution. The registrant would then face a price ceiling equal to the tender price plus an appropriate mark-up for distribution costs.⁶ The registrant could participate in the tender if it wished, but would have no special rights or privileges in the tender process.

The tendering process could be repeated annually or less frequently depending on the technologies involved.⁷ Tenders could also be for fixed amounts or could be geographically restricted, so that each would be for production adequate to supply a given area.⁸ The registrant would indemnify the producer of the medicine against any patent infringement claims for any technologies covered by the patents held or licensed by the registrant.⁹ The registrant would

⁵ The registrant might also have to temporarily license its patents for the purpose of testing production by firms wishing to bid in the tender.

⁶ The distribution costs allowed would be transportation costs and financing costs of holding the stock during transportation. This would have to be estimated by the HIF. Unlike manufacturing, however, distribution costs tend not to vary much between drugs, so that obtaining estimates of distribution costs need not be particularly difficult.

⁷ Some products – particularly biologicals – require long production runs which would make frequent switching between producers more costly.

⁸ Having multiple producers would help to make tenders more competitive in the future, since multiple firms would develop expertise in manufacturing the product, and would also help to ensure security of supply.

⁹ In effect, the producer would have to specify, at the time of registration, a product made using a process or set of processes against which the producer would be indemnified. The producer could still be liable for lawsuits relating to the technologies used to produce the medicine, if those technologies were different from the ones supplied by the registrant. Suppose, for example, that two different production processes existed for the patented drug, and that the registrant had patented only one process. A second, lower cost process was patented by a second firm. If the

indemnify the producer against any product liability claims based on the properties of the registered medicine.¹⁰

The registrant would be responsible for obtaining marketing approval in each country for its product. Registrants might lack the expertise to distribute and market their products in some countries and could form relationships with other companies to co-market the registered product in particular locations as desired.

In effect, this approach is similar to open licensing in terms of manufacturing, but generic manufacturers would sell the product only to the registrant, rather than to wholesalers and retailers. The registrant would then control the distribution of the product.

In some situations inadequate competition in tendering might lead to high tendered prices. The HIF could therefore retain the right to impose price controls based on estimates of manufacturing cost when it considered that competition in tendering was insufficient. In these cases, the registrant would produce the product itself (or sub-contract its production) and the HIF would determine the maximum price it could charge for the product.

China uses a tender process with retail price controls for generic drugs which is similar to the mechanism proposed here. The approach used is a central procurement auction in each province so that the purchasers obtain the lowest competitive price (Watanabe and Luwen). Mark-ups of fixed percentages are allowed in the wholesale and retail sectors, although most drugs are sold through hospitals.¹¹

Tenders are not always optimal, but in cases of large-scale procurement, they seem to be an effective way of obtaining low prices. New Zealand, for example, has been successfully using a tender system to procure generic drugs for many years.¹² Many governments use tender contracts to arrange for competitive supply of high volume generic pharmaceuticals. In Canada, Saskatchewan's tender system has historically obtained the lowest retail generic drug prices in the country (Hollis, 2009).¹³ IMS Health reports that tenders are becoming increasingly common as a way for payers "to encourage price competition" since in many cases competition is being

producer used the second process, it might face claims of patent infringement from the second firm, for which it would not be indemnified by the registrant.

¹⁰ The producer could still be liable for product liability claims in case of manufacturing defects.

¹¹ The percentage mark-ups which are permitted encourage hospitals to prescribe expensive drugs. This kind of result is of course problematic for the HIF regardless of the pricing mechanism used.

¹² There are problems with using tender systems to procure generic drugs when these systems under incentives to challenge patents. However, this problem does not arise in the current case.

¹³ Of course, these tenders are for very small markets; the HIF would require tenders for much larger markets.

diverted to allowances and rebates to pharmacies, rather than price reductions which are passed through to payers.¹⁴ The winners of these contracts, of course, are likely to be manufacturers with both breadth and scale to fulfill high-volume contracts at low cost.

2.D Option approach

Another mechanism is for the registrant would be given a choice between B and C. Since the registrant cannot earn profits on the sale of the drug in either case, but must earn profits only through the health impact rewards, the registrant would wish to choose the mechanism which would lead to the greatest measurable impact on health. (To ensure that the registrant was unable to earn profits in either case, it might be desirable to prohibit the registrant from manufacturing the product itself.)

It is helpful to think about the first three mechanisms according to the control exercised by the registrant: given the open licensing mechanism, the registrant loses control over how its product is manufactured, distributed, and marketed to wholesalers and pharmacies. Given price controls with tendering, the registrant loses control only over how its product is manufactured, but retains control over distribution and marketing to wholesalers and pharmacies. Given price controls based on assessed manufacturing cost, the registrant maintains control over all aspects of manufacturing and distribution except the maximum price at which the product is sold.

We now consider how these different approaches are likely to affect costs, mark-ups, innovation, and the generic industry, focusing on mechanisms A, B and C, and examine mechanism D only later.

3. KEY ISSUES

In this section, we introduce the key issues that are important to consider in evaluating the choices between the four mechanisms. The issues considered include costs, mark-ups, strategic

¹⁴ “A trend toward centralized contracting will benefit those generics manufacturers with a broad portfolio and low-cost manufacturing base. Companies with the breadth and scale to fulfill high-volume contracts by payers are most likely to succeed in this environment. Payers are turning to contracting as a way to encourage price competition. For example, in Germany, 68 percent of generics sales are now covered by payer contracts. The Netherlands has adopted a similar system that has led to steep discounts for generics, ranging from 55 to 93 percent.” IMS HEALTH (2008).

behavior, administrative ease, consistency, the effect on the generic industry, and incentives to innovate.

3.1 Effects on costs

In this section, we consider efficiency of production and distribution, rather than final prices paid by buyers of the registered medicines. There are four types of costs which can be affected by the choice between open licensing and price controls with tendering: manufacturing costs, regulatory costs, distribution costs, and administrative costs, and we consider these in turn.

3.1.1 Manufacturing costs

Manufacturing costs include two major components: the production of the bulk active pharmaceutical ingredient or API, and the production of pills incorporating the API. In some cases these two steps may be united. In markets for patented medicines, the monopolist will typically produce the APIs itself or contract this production out. In markets for generically available medicines, the APIs are typically produced by specialized bulk chemicals producers, who then sell the APIs to downstream generic manufacturers. Typically there are relatively few producers of a given API because of economies of scale in production, although there may be many firms with the technological capability of producing the given API. Under the open licensing approach, this industry structure would likely continue. Under the tendering system, manufacturers of pills would likely have to negotiate with producers of APIs in order to bid into the tender system. There are typically more producers of finished drugs than of APIs for a given molecule.

Manufacturing costs can be affected by economies of scale, learning by doing, or cost-reducing innovation.

A production technology has “economies of scale” if it is cheaper to produce greater volumes in one facility than to spread out the same amount of production between different plants. Depending on the size of tender contracts and the technologies involved in production, there could be economies of scale in having a smaller number of firms engaged in production. However, for most products, this effect is unlikely to be very important, since if economies of scale were large, one would simply expect, with open licensing, that a few firms would

eventually dominate in production. However, when economies of scale are important, the small number of competitive producers may result in high mark-ups, as discussed below.

Learning-by-doing refers to the increased efficiency in production which occurs as a firm's accumulated production increases. Some learning-by-doing is proprietary – i.e. the efficiencies acquired do not readily transfer to other firms – while in other cases there are important spillovers as learning spreads between firms. To the extent that learning is proprietary and tenders are large and long, learning-by-doing will be greater in the tendering approach. If tenders are short, usually won by different firms, and learning is proprietary, the tendering approach will inhibit efficiencies.

Innovations which reduce manufacturing costs are likely to occur under mechanisms A, B, and C, but it is difficult to predict how the magnitudes would differ across the different mechanisms. In each case, there are incentives for cost-reducing innovation. If there is only one producer, as in A, the relative incentive for investing in innovation is strong, since the gains from cost-reduction are captured completely by the firm. With many producers, as in open licensing, there are more sources of cost-reducing innovation, and a single generic firm which introduces the innovation may be able to capture a large share of the market, at least temporarily. The economics literature does not make clear predictions as to whether monopolies or competitive industries tend to be more effective in generating cost reducing innovation. Certainly, there seems little reason to think that there would be a substantial difference in manufacturing costs between B and C as both mechanisms involve competition in manufacturing.

Manufacturing costs may also vary because of different quality standards. If one type of arrangement leads to lower quality products, there would be a trade-off between the price reduction and the lower quality.

3.1.2 Regulatory costs

The key regulatory costs relate to obtaining market approval for a drug. In most countries, there are separate pathways for regulatory approval for innovative and for generic drugs. Typically there is a substantial process for approval of the innovative drug which involves demonstration of efficacy and safety. There may be a separate process for demonstration of cost-effectiveness. And typically there is an abbreviated marketing approval process for generic drugs, which need

only demonstrate bio-equivalence.¹⁵ Bio-equivalence studies are generally not very costly, although for some drugs they may be more complex and expensive. Especially for biologics, regulatory costs of approval of generic versions may be substantial. Regulatory costs will be incurred both by participating firms and by regulatory agencies; in many cases the agencies will charge user fees to the firms. This does not eliminate the costs of regulatory approval, but it means that the costs are transferred to the firms, which must then be compensated, ultimately, through higher mark-ups on the products they sell.

There may also be regulatory requirements relating to approval of the facilities in which a product is manufactured. These costs, however, appear to be relatively low, owing to relatively lax standards for inspection of manufacturing facilities.¹⁶

Mechanisms A and C would likely to lead to lower regulatory approval costs than mechanism B, since the registrant would be the sole seller of the drug in each country. No bio-equivalence tests would be required, and no approval process for separate generics. While regulatory costs for generic producers is typically not very large, if generics expect there to be fierce price competition, even small entry costs may deter entry, leading to less competition.

3.1.3 Distribution costs

Distribution involves moving the product from the location of manufacturing to the retailer, which in most cases is a pharmacy, clinic, or hospital. (In many developing countries, pharmaceuticals are also sold through other retailers including unlicensed shops.) It seems likely that the costs of the retailer are unaffected by the choice between A, B, and C. To the extent that the product moves through a typical wholesaler, costs also seem unlikely to be affected. The costs of the manufacturer or registrant may however be affected, since it would not have to duplicate the supply chain. However, in some countries the registrant may lack an effective distribution system, in which case it would have to rely on subcontracting through wholesalers or other manufacturers. The difference in costs is not likely to be substantial in most settings.

¹⁵ For simple products, demonstrating bio-equivalence can be done by showing that the generic drug leads to equivalent doses of the API in the bloodstream.

¹⁶ Harris (2008) reports that the FDA has inspected only 75 of the 714 Chinese drug plants that export to the United States in the last five years.

3.1.4 Administrative costs

Mechanism A requires the HIF to obtain third-party estimates of manufacturing costs which could be expensive. Mechanism C requires that the HIF administer tenders for production. This would entail some administrative costs which would be avoided in case of open licensing. However, mechanisms B and C both require generic manufacturers to engage in assessments of their willingness to participate, which itself creates substantial administrative costs for the firms which participate or seriously consider participation in the market. The total costs of administration, including those incurred by manufacturers and the HIF, would however be unlikely to be very substantially different.

3.2 Mark-ups over cost

Firms exercise market power through marking up their prices over the costs of production. Given constant costs, higher mark-ups will lead to higher prices for consumers. Mark-ups occur at a variety of levels: manufacturer, distributor, and retailer. Mark-ups over variable costs may be justified by the necessity to cover fixed costs, and in cases where an insufficient mark-up is available, the firm may simply decide not to offer the service at all. For example, it is common to justify mark-ups over variable costs for innovative drugs as providing an incentive for firms to invest in research into new drugs. Pharmacies which are not rewarded with a suitable mark-up may decide not to carry a product.

As a general rule, mark-ups increase when competition is weak, though this depends on the particular conditions of each market. We begin by considering mark-ups by manufacturers.

3.2.1 Manufacturer mark-ups

Manufacturer mark-ups in pharmaceutical markets are not surprisingly related to the number of competitors. For example, the 1998 Congressional Budget Office report on generic drugs shows data from 112 molecules which had become genericized in the United States.¹⁷ Of those 112 molecules, 34 molecules had between one and five generic competitors, while only 4 molecules had over 20 competitors. The average generic price/brand price ratio was 61% for the products with few generics, and 39% for the products with the most generic competitors. The first inference to draw from this data is that competition is not as effective in price reduction in

¹⁷ See Chapter 3, Table 5 of Congressional Budget Office, 1998.

markets with relatively few competitors, exactly as economic theory predicts. This is also consistent with evidence from other drug markets.

The second observation to make is that there are many products which do not attract many generic competitors. This is true even in very open markets, such as the US, with well developed generic industries. As the data in the CBO report shows, of the 112 molecules studied, 34 had between one and five generic competitors, suggesting less robust competition. The United States has relatively high generic penetration, but a recent study by Danzon and Furukawa (2008) found that 26% of molecules with no known patent obstacles had no generic competition at all. As Danzon and Furukawa note, 26% was the lowest rate in the countries they studied: other countries had higher rates of markets without generic competition. They suggest that “Slower generic entry abroad reflects both regulatory obstacles and weaker economic incentives.”

The Canadian Patented Medicines Price Review Board reported that in Canada in 2005 there were 134 drugs representing about C\$800m in sales volume (or about 4% of total prescription drug sales) without generic competition.¹⁸ Of these drugs, according to the Board, 88 had exact counterparts in other countries; and of those 88 products, 79 were also single-source in some other OECD countries. Thus, contrary to the general preconception, generic competition is not inevitable just because of a lack of patent barriers. Canada has a relatively well-developed generic industry, with substantial generic manufacturing operations in the country. Thus, the failure of generic manufacturers to compete in these markets probably reflects the costs of developing competitive products and of obtaining regulatory approval.

It is likely that a substantial share of biologics now on the market, including many oncology products, may have few or no generic competitors in many countries even following expiry of all relevant patents, as the costs of regulatory approval may be prohibitive, especially in smaller drug markets.

In addition, it is important to recognize that even in markets which ultimately have many generic competitors, there are often significant delays in the entry of generic competition. Again, this is not a universal condition, but for the most part we would expect slower generic entry in national markets for drugs with smaller sales volumes.

¹⁸ Patented Medicines Price Review Board, 2007. For total expenditure data, see Canadian Institute for Health Information (2008).

For the most important products with the largest sales, generic competition tends to be relatively effective because of the presence of many competitors; unfortunately, this is not a universal condition, and for many products in many countries, there is no competition at all despite the absence of patent barriers, and for even more products, the competition is at best anemic with just two or three firms sharing a market. This is likely to be an important problem since the effects of weak competition on price tends to be high prices.¹⁹

Given that there are currently many products with zero or few competitive generic manufacturers in well developed markets with clear pathways for generic approval, the lack of competition from generics is likely to be even more pronounced in smaller, less developed countries with small markets and poorly established regulatory procedures. It is not appropriate to assume that just because generic competition works relatively well in the United States it is uniformly successful, or that just because generic competition has worked well for some drugs it works well for all drugs.

These observations about generic competition have two implications for the HIF. First, it would be a mistake to rely exclusively on generic competition to ensure low wholesale prices in all circumstances. Competition will simply fail to deliver low prices in many cases because of insufficient competitors. This is not to claim that competitive generic production never works to lower price – only that it sometimes does not work. Second, the fact that some products are likely to have weak competition will induce strategic behavior from innovators, undermining the HIF, if open licensing is always used. The problem is that if the innovator company knows that its product will not attract generic competition even if the patents are openly available to be licensed, the company can register with the HIF, charge the usual monopoly price uninhibited by generic competition, *and* collect health impact rewards. The HIF would therefore have to use some alternative mechanism to control this sort of behavior – either refusing to pay rewards or requiring the firm to set a lower price for its product. This would have to be done on a case-by-case basis, drug-by-drug and country-by-country, as there might be competition in some jurisdictions and not in others.²⁰

¹⁹ Markets vary in their dynamics, and a simple count of the number of actual competitors may be inadequate to reflect competition. In some cases, the threat of potential competition can induce competitive pricing.

²⁰ One reason for different levels of competition in different countries is that countries have different rules for permission to market a drug, and in some countries the timeline for drug approval, even of generics, is slow.

Mechanism C suffers from some of the same problems in generic competition but helps to alleviate others. Each generic competitor does not need to obtain regulatory approval. Instead, the registrant obtains that regulatory approval and then sells the approved product, manufactured under contract by the firm or firms that won the tender. This increases the production volume for each manufacturer, which is likely to increase the willingness of manufacturers to compete to win the tender. If it is worthwhile entering and competing in the largest market given open licensing, it will be even more worthwhile to compete to win the tender. Tendering can help to stitch together the internationally fractured market which typifies current generic markets and leads to limited generic competition in smaller markets.²¹ The gains in market size are even more significant since the tender can be designed so that the tender winner obtains the entire market, and does not share it with anyone.

Tendering is not, however, likely to be a cure-all. As noted above, particularly for the most complex drugs and biologics, it may be difficult to ensure adequate competition even for a tender to supply global demand. For biologics, it may be possible to require the registrant to make the relevant cell-line available to firms that wish to tender for production. However, differences in manufacturing technique may lead to differences in the final products which will render them not bio-equivalent. This suggests that there may need to be a back-up mechanism of price controls when tendering fails to elicit adequate competition.

The proposed back-up mechanism is that the registrant faces price controls and must produce (or sub-contract production of) the drug. This mechanism is not easy to apply when the standard protocol is open licensing, since there may be some countries in which there is adequate competition, and other countries in which there is not. It is likely that there will fail to be effective generic competition in some countries for any given product. A price ceiling would have to be set up for those countries only. Such a price ceiling could act as a collusive device for generic manufacturers in other countries.²²

Even when many generic firms enter a market, competition between them will not always drive prices down. It is commonly observed that competitive behavior between firms with homogenous products is inhibited by repeated interactions: instead of competing on price, they may simply match prices with each other. As a general rule, collusion is more likely to occur

²¹ Perhaps a better way of reducing regulatory costs for generic entrants would be international harmonization of standards and the creation of a global agency for all drug approvals.

²² Price ceilings often create a convenient “focal point” for collusion between competitors.

when firms face each other repeatedly, compete in various markets, and when prices are transparent. With open licensing, each transaction, pharmacy by pharmacy, allows for repeated interactions which make collusion easier to sustain than in tendering, which is characterized by large, infrequent bids. The problem of collusion becomes particularly severe if there are few firms participating in the market. On the other hand, tendering arguably allows for more transparency in prices²³, which makes collusion easier to sustain.

One of the key aspects of the HIF approach is that the registrant earns profits from sale of the product to consumers who benefit from it. Depending on the price elasticity of demand and the health impact on patients who are deterred by high prices from purchasing the drug, the registrant may find it profitable to sell the product in some countries at prices below the maximum price, i.e. making a loss on sale of the product which is more than recouped by larger health impact rewards. This would, however, inhibit effective competition given open licensing, and generic firms might well have weak incentives to compete when facing a highly motivated supplier who was willing to sell at under the cost of production.

In summary, open licensing seems less likely than tendering to create vigorous generic competition in smaller countries for non-blockbuster drugs, leading to higher mark-ups in production. For blockbuster drugs in large countries, either approach to competition is likely to lead to similar outcomes.

3.2.1.1 Mark-ups when the Registrant is the Monopolist. Mechanism A might lead to higher or lower mark-ups in the price of the product, over the lowest feasible production cost. Under Mechanism A, the administered price ceiling might be set too high or too low, compared to the lowest average cost of manufacturing. If set too low, it would almost certainly lead to complaints by the registrant and re-evaluation by the HIF. If set too high, given the flexibility to price below the ceiling, the registrant would have no reason to dispute it. Thus, one might expect only one type of error to persist.

Although the price ceiling could therefore be set too high, this will not necessarily lead to high prices. The registrant would want to take advantage of an excessively high ceiling only in specific circumstances. It would price high in jurisdictions where the price elasticity of demand was relatively low, i.e. wherever there was widespread insurance. And it would price high for

²³ That is, the winning bids must be public, and hence known to competitors.

products with relatively low health impact rewards – but of course those products would typically not be registered with the HIF in any case. In contrast, in the places with the most sensitivity to price, and for the products with the greatest impact on health, the registrant would have more incentive to drop the price below the ceiling. Thus, while one could expect higher mark-ups under Mechanism A, these mark-ups would likely have relatively benign effects on public health. A more technical discussion of these points is provided in Appendix A.

Another important issue to consider is that in the context of the Health Impact Fund, if there are mark-ups by the registrants, this reduces the size of the reward needed to induce firms to register their products with the Fund. The intuition for this point is easy to understand. If registrants expect to earn additional direct profits on the sale of their registered products, this reduces the amount firms need to earn through rewards to make registration attractive. This implies that if registrants expect to earn “excess” profits earned by through mark-ups above cost, a lower rate of reward per QALY will be adequate to induce registration, which in turn will allow for a larger set of products to be registered given the same total available reward pool. In this case, there is a trade-off between the price at which each product is sold and the number of products registered and therefore available at low prices. Notably, this is only true if it is the registrants who capture the benefit of mark-ups over manufacturing cost. If the mark-up is captured by generic firms (because of insufficient generic competition), prices are higher but there is no reduction in the required reward needed to make registration attractive.

3.2.2 Distribution and retail mark-ups

Distribution and retail costs tend to be composed mainly of fixed costs, with limited variable costs. The mark-up for the distributor needs to be adequate to cover both fixed and variable costs, on average, which implies that distributors must charge mark-ups above variable cost. In order to sustain such mark-ups, retailers need to have some market power, which is typically achieved by geographic separation of one retailer from others. Sick consumers, and especially those who are insured and do not face the full cost of the medicine they are buying, tend not to want to bear the travel costs of going to a more distant pharmacy; in many cases there are national laws preventing advertising of pharmaceutical prices, which also inhibits comparison shopping.

Distribution and retail mark-ups can be a substantial portion of retail pharmaceutical prices, especially for generic drugs. Exhibit 1 of Danzon and Furukawa (2008) shows distribution costs across a variety of countries, ranging from 18% to 43% of the retail price. These are listed for all pharmaceuticals and do not include dispensing fees, which typically add more than 10% to the price of a generic drug. The share of the retail price accounted for by distribution in Danzon and Furukawa also omits rebates and discounts paid by competitive manufacturers to pharmacies. (This latter omission is particularly important. Danzon and Furukawa list the Canadian distribution margin as 27%. However, when accounting for rebates paid to pharmacies, the average net manufacturer price is less than 50% of the retail price for generic drugs in Canada, even excluding dispensing fees (Hollis 2009).) The implication is that the mark-up at the retail level can be over 100% of the manufacturer's net price.

In many countries, mark-ups on generic drugs are extremely high relative to the ex-manufacturer price because the competition is between generic manufacturers to get their product into the pharmacy, but this does not lead to low retail prices. Danzon and Furukawa 2008 show (Exhibit 6) that in other OECD countries, generic prices are considerably higher than in the US: from 8% higher in France to 116% higher in Mexico. This may in part be due to higher-cost distribution systems, but is likely also a result of higher mark-ups.

Cameron et al (2009) examine mark-ups over the FOB price for drugs. They show that the retail price in a number of developing countries was typically from around 30% to 300% above the FOB price (Table 7). This implies that, consistent with pricing and mark-ups in other countries, between 25% and 75% of the price paid by the consumer relates to the costs of distribution and the accompanying mark-up by retailers and wholesalers. In the public systems, not surprisingly, Cameron et al find that final prices tended to be considerably lower. This could be because of lower distribution costs in public systems, or because of smaller mark-ups by distributors.

A recent report by Srivastava (2008, p. 40) describes the situation in India: "The high number of [generic] competitors may encourage price competition. In the current environment, however markups are not well regulated which results in high private sector retail prices. This implies that affordability will continue to be a problem for low income individuals unless regulation is improved, and well designed insurance schemes are put in place." A recent report of Working Group A of the Taskforce for Innovative International Financing for Health Systems

notes that “Drugs are a critical element of health services but are often unavailable through public outlets and have to be purchased through frequently unregulated outlets, and at substantial price markups.”²⁴ A recent New York Times article reports “Drug companies usually sell artemisinin combination therapy at \$1 to governments but \$4 to private wholesalers. By the time it reaches village level, it may cost 10 to 40 times as much as old drugs.”²⁵ Evidently, mark-ups by retailers and by manufacturers are both important.

The implication is that we ignore the mark-ups entailed in distribution at our peril: we need to take seriously *both* manufacturing *and* distribution costs. If there is scope for distributors to exercise market power, what kind of mechanism will effectively control the final price? This is, of course, exactly the critical problem, and what the data above show is that open licensing – which is essentially what we have in markets post-patent expiry – does not automatically lead to low retail prices in all markets.

Mechanism B will likely fail to minimize mark-ups by distributor and retailers, since it relies on exactly the same mechanisms as we currently observe for generic drug sales, but it is likely to be relatively successful in ensuring that pharmacies and other distributors can access drugs at low ex-manufacture prices. Ultimately, while pharmacies and other distributors are happy to pay a low price to the manufacturer, in terms of health impact what matters is that the product is available to people in need at low retail prices.

One possible solution is of course for governments to control distributor mark-ups. Unfortunately, it is not optimal for the HIF or for governments simply to decree maximum mark-ups for HIF-registered products. The problem is that such a policy may simply lead distributors not to stock the product: achieving low prices without availability of the product is not of much benefit to anyone. So it is important to ensure that retailers earn enough from a product to make it worth their while to stock it. It is, however, difficult to know exactly how much of a mark-up a given retailer requires – in general, this will depend on the retailer’s costs and the profitability of alternative products.

What effects would Mechanisms A and C have on distributor mark-ups? The key difference is that a monopoly supplier can contract with retailers over mark-ups. The supplier

²⁴ Taskforce for Innovative International Financing for Health Systems, Report of Working Group 1: “Constraints and Costs” dated 11th March 2009, p. 3, available at <http://www.internationalhealthpartnership.net/pdf/IHP%20Update%202013/Taskforce/london%20meeting/new/Working%20Group%201%20First%20Report%20090311.pdf>

²⁵ D. McNeil, “Plan tries to lower malaria drug cost.” *New York Times*, April 17 2009.

maximizes health impact rewards by maximizing sales. This means that the supplier must balance low retail prices with wide availability. The supplier has a variety of tools which it can use to achieve this. First, the supplier may choose a low wholesale price, as described above. Second, the supplier may impose contractual restraints on the maximum retail mark-up. Third, the supplier may print the maximum retail price on the product.

The monopoly supplier of the product, in general, is likely to be better able to judge what approach to use to control retail prices than would a regulatory authority, and in the case of the HIF, the registrant is motivated to maximize sales of the product, since each additional unit sold earns the registrant additional reward payments. Volume will be maximized through permitting an optimal mark-up – one which creates a low final price to consumers while also giving distributors adequate incentives to stock the product.

In many cases, of course, the supplier might not find it worthwhile to contract over the mark-up to be charged – possibly it would be too costly to contract or to monitor retailer behavior.²⁶ In that case, the situation with respect to the retail mark-up is, however, no worse than if there are multiple generic firms supplying the product. However, with multiple generic firms vying to place competing products in the pharmacy, it will not be possible to contract for a price ceiling. Suppose, in this situation, that an individual generic supplier attempts to impose a retail price ceiling. If the ceiling is binding, it must reduce the profits of the pharmacy, which will therefore switch to a different generic supplier without any price ceiling. In contrast, if there is only one supplier to the pharmacy, it can impose a price ceiling credibly. (Of course, it should be recognized that imposing an optimal price ceiling requires considerable information on the part of the supplier -- but it will be possible to do better or no worse than in the presence of multiple generic suppliers.)

While contracting to control mark-ups is feasible, it is difficult to know how effective it would be in practice. Generally, of course, contracting to control mark-ups is not necessary, since in most non-pharmaceutical markets consumers are not insured, and there is no supplementary reward payment being made to the supplier. Thus, we would not normally expect to observe such contracts, though they do certainly exist.

²⁶ The supplier might sell to a wholesaler who would, in turn, sell the product to pharmacies and other retailers, making it particularly difficult for the supplier to monitor and enforce maximum resale prices.

Maximum retail prices are stipulated in contracts in developing countries, such as India²⁷ and in developed countries, by firms such as Apple. The fact that such contracting takes place between manufacturers and retailers does not, of course, mean that it is feasible or profitable in every circumstance. The point is that we do observe such contracting in some circumstances. (In the United States, setting a maximum mark-up was illegal until 1997.²⁸)

In summary, monopoly supply with tendering to set a price ceiling seems likely to be more effective in controlling distribution mark-ups than open licensing, at least for retail buyers. The same is not true when buyers are large and well-informed, as they can use their buyer power to obtain low prices, even with open licensing. For example, one would imagine that governments with centralized purchasing would continue to use tender contracts to force manufacturers to bid aggressively in a situation with open licensing. However, given open licensing, we can expect other buyers to face high prices at the pharmacy. Using centralized tendering can protect those consumers and allow the registrant to maximize its health impact reward payments by contracting for optimal mark-ups by pharmacies and other retailers.

It thus appears that tendering (Mechanism C) is likely to result in lower prices for consumers than open licensing (Mechanism B) because of enhanced competition at the manufacturer level and superior incentives at the retailer level, but does require the HIF to set an appropriate mark-up to pay for wholesaling costs. It is difficult, however, to be sure about how large the difference would likely be. Sole-supplier manufacturing and distribution (Mechanism A) is attractive for similar reasons but less attractive because of the difficulty of ensuring that the manufacturer has the lowest feasible costs of production. It is difficult to make the judgment on how the pricing would turn out since we have no experience with suppliers who face incentives like those created by the HIF.

3.3 Effects on pharmaceutical innovation

Registrants with the HIF will earn profits through health impact-based rewards. Therefore each individual firm will have the strongest incentives to engage in research and development if the

²⁷ For example, Reil Electricals of India stipulates Maximum Retail Prices to its dealers (<http://www.reilindia.com/doc/mrp.pdf>). Also see Subhomoy Bhattacharjee & Deepshikha Sikarwar “Contract manufacturing to be taxed at source”, *Economic Times* (India), 4 August 2006.

²⁸ The prohibition on setting a maximum retail price was overturned by the Supreme Court in *State Oil Co. v. Khan*, 522 U.S. 3 (1997). There may be some countries in which it is still illegal to set a maximum retail price.

system of pricing and distributing drugs leads to the greatest volume of sales. Let us suppose that mechanism X results in higher retail prices for many products, leading to reduced global health impact, compared to mechanism Y. Given the structure of the HIF, with rewards based on the share of health impact achieved, if all products have a proportional reduction in health impact because of higher prices, then the effect on incentives for innovation of X rather than Y should be approximately zero. If, under mechanism X, some products are affected more by high prices than others, then there will be a corresponding distortion in incentives. The direction of the distortion depends on which party captures the high prices. If it is the registrant that is benefiting from a higher mark-up, that will tend to increase incentives for registrants in that position; if it is retailers or other manufacturers who are benefiting from the mark-up, the effect will be to discourage innovation because of reduced earnings for the innovator. Thus, the likely effects on pharmaceutical innovation of the choice of pricing mechanism are complex.²⁹

3.4 Effects on the generic industry

Mechanisms B and C are likely to have similar effects on the generic industry, since both involve production by generic companies (if generics win the tender). However, price controls with tendering involve distribution by or for the registrant rather than by competitive generic firms. The effect on generic firms of this is unlikely to be significant. The expected scale of the HIF is initially a stock of about 20 drugs at any given point, which is a tiny fraction of global drug sales. To put it into context, with total rewards of \$6bn per year, the HIF rewards would represent less than 1% of global drug revenues. Whether the HIF used B or C, or even A, would not plausibly have a material effect on generic drug manufacturers. If, ultimately, one approach resulted in a lower price to consumers, there would be a cost somewhere in the system, either to manufacturers, wholesalers, or retailers. Arguably, the key measure of success should be whether the product is available to consumers (where needed) at low prices, rather than whether one part of the industry or another is enriched.

²⁹ One argument for open licensing that has sometimes been advanced is that it more readily enables follow-on innovation, such as heat-stable versions of a medicine. Whether or not that is true for the most extreme versions of open licensing, it does not appear to be true for the Barbados and Bolivia proposal, which requires that innovators grant “licenses to all patents, data and know-how needed for competitive supply of the final products” and not for the supply of other products which are derivative.

Large-scale contracts may inhibit competition by excluding producers of smaller scale. However, since the vast majority of generic production would continue to relate to products which were not registered with the HIF, there would still be a route for smaller firms to enter into the generic industry, where they could grow until able to compete effectively for the large-scale contracts issued by the HIF. Furthermore, consortia of smaller generic firms might also bid jointly, where the production capacity of a given firm was insufficient.

James Love has criticized mechanism A as excluding the generic industry from production, thus diminishing the opportunities for generic firms to benefit from economies of scale and scope.³⁰ These concerns do not appear to be relevant. If economies of scale in the manufacture of the medicine are important, then having a single manufacturer reduces cost, and allowing open licensing with several competing manufacturers increases cost. Economies of scope do not appear to be likely to be affected by the choice of method. If there are significant economies of scope in production, then even under mechanism A the registrant will contract out production to another firm to benefit from those economies. The idea that the lack of production of a given product or small set of products registered under the HIF would significantly increase the average costs of other products made by generic manufacturers seems far-fetched, as there are literally thousands of medicines being produced generically and medicines registered with the HIF would represent a tiny share of total medicines, most likely less than one percent.

3.5 Technical problems of implementation

3.5.A Price controls

This approach has been criticized as being too vulnerable to manipulation, and possibly too rigid to allow for price decreases which would likely arise from competitive manufacturing. Manufacturing costs typically fall for pharmaceuticals over time, but the path of manufacturing costs for a particular product may be difficult to predict. This suggests that there would be a need to revisit the permitted price ceiling at least periodically. However, it is likely that the price ceiling established by the HIF would be incorrect, and, as suggested above, the errors would tend to be one-sided, leading to higher ceilings than are optimal from the perspective of global health. However, as discussed above, and in Appendix A, the price which firms would choose need not

³⁰ See blog by James Love, November 20 2008, at <http://www.keionline.org/blogs/2008/11/20/impact-of-hif-on-generics/>

necessarily be at the ceiling, and would, for products with large health impacts and significant consumer sensitivity to price, be set below the ceiling.

3.5.B Open licensing

Open licensing would eliminate the need for the HIF to make judgments about the cost of manufacturing, although, as described above, it might not necessarily lead to lower retail prices. The simplicity of not having to determine prices does not, however lead to an elimination of administrative difficulties. In particular, open licensing would require the HIF to become involved in administering intellectual property rights.

In many situations, the licensing of patents could be expected to work well. However, licensing of the required patents may be difficult to arrange in every situation. For example, it may not be clear which patents, exactly, are in fact required. For example, suppose that there were two known technologies for manufacture of the product, and that patents for both were held by the registrant. Would the registrant be required to license both technologies? What if one technology offered lower costs of production? These kinds of issues could lead to the need for the HIF to become engaged with matters relating to patents.

In other circumstances, ensuring that there is a complete transfer of (unpatented, and therefore undisclosed) know-how may be difficult to verify, making it difficult to know whether the firm has in fact complied with the open licensing requirement.³¹

In yet other circumstances, licensing may lead to infringement liability issues. For example, it is common for patentees to dispute whether a given a product is infringing. Would the generic licensees of the registrant's patents be covered from infringement liability with respect to patents held by third parties? (If those generic firms are earning a mark-up on the sales they make, it seems reasonable that they should also bear some of the infringement liability risk.)

Other problems that can be envisaged include ensuring that the patented technology is used *only* for competitive supply of the registered product and not for any other purpose. For example, suppose that a given drug has both human and veterinary uses. The license could be

³¹ Rob Weissman has suggested that compulsory licensing cases from the past show that there are few complications in licensing, and that evidence from past compulsory licensing cases is adequate to show that these kinds of issues are really not that problematic. Undoubtedly, with appropriate support from governments, many issues could be ironed out. However, pharmaceutical companies are extremely active in pursuing available advantages through patent litigation and I see no reason to imagine that this would change under the HIF.

expected to cover only the human uses of the drug, but the registrant might be concerned about the possibility of unlicensed veterinary sales.

Open licensing also creates problems of knowing how many units of the medicine were actually shipped. The license would have to require that licensees provided complete reports to the HIF about sales volumes. Obtaining full information from competitive suppliers is clearly more difficult than obtaining information from a single supplier who is motivated to provide such reports. Generic suppliers do not earn rewards and are not necessarily motivated to provide complete information about sales volumes, particularly if there is any risk of such information being used by competitors. Underreporting is unlikely to be a major issue, however.

A more significant problem with open licensing is that the registrant has its name associated with a product whose quality it cannot in any way control. Suppose, for example, that the registrant has promoted a given product which it developed, but that a generic manufacturer with inadequate quality controls introduces some poorly made product which leads to sickness of the consumers. The registrant would find itself connected with this unfortunate outcome, even though it was not responsible, and its reputation could be damaged and it might face litigation. Firms might well hesitate to register products with the HIF if they feared reputation pitfalls such as this. Even if the firm's reputation was not harmed, it seems likely that the product's reputation would be harmed, reducing the potential earnings from health impact-based rewards.

3.5.C Price controls with tendering

Mechanism C has a combination of the problems created by A and B. Like A, it requires that the HIF become involved in estimating distribution costs. This is a less onerous task than estimating both distribution and manufacturing costs, but is not without difficulty. Like B, it requires some licensing of intellectual property, although the licensing is more restricted since the licensees (generic manufacturers) sell their product only to the licensor (the registrant). This means that the licensees would likely be covered for infringement liability with respect to third party patents.

The problem of poorly manufactured product becomes even worse in this case, in some respects. If the registrant is responsible for distributing a generic product which turns out to be unsafe, the registrant is certainly vulnerable to reputational damage and liability claims. However, in this case the registrant also has the ability to test the product to ensure that it meets

quality standards. (This would not be an unusual situation: it is very common for pharmaceutical firms to contract out production to a specialized manufacturer.)

3.6 Consistency

One desirable feature in any mechanism is that it should have consistent properties across different situations, and that the HIF should be able to use that mechanism consistently. It is clear that it is preferable to minimize the degree of discretion used by the HIF, in order to provide the clearest possible signals to actual and potential participants in the HIF. One consideration here is the HIF will be forced to use open licensing in cases in which rewards are being granted for new uses of generically available medicines. Using open licensing in other situations would permit consistency across different products. However, as noted above, it is also possible that for some products open licensing would likely not create adequate competition between manufacturers to ensure low wholesale prices. These products would likely face price controls under the HIF, and so using mechanism A across other products would enable consistency with the products for which price controls were the only solution. In effect, consistent treatment of all products and new uses may not be feasible.

4. COMBINING OPEN LICENSING, PRICE CONTROLS WITH TENDERING, AND PRICE CONTROLS BASED ON COST

One approach to dealing with the various problems described above would be for the HIF to allow the registrant to choose between Mechanisms B and C (i.e. between open licensing and price controls with tendering). Recall that under the HIF, the registrant has incentives to maximize the effectiveness of the product in order to maximize rewards. Thus, if either B or C is more effective in increasing appropriate use of the product, that is what the firm will wish to choose. If open licensing is likely to lead to wider use of the product by patients who would most benefit, the registrant will choose open licensing; if however the registrant suspects that open licensing would lead to high mark-ups at the retail level, inhibiting sales volume, it may prefer the tendering approach.

Some restrictions would likely be required for this approach to work well. In particular, it might be necessary to restrict the registrant from participating in the market if it chose the open licensing approach. This restriction is motivated by a concern that in some situations the

registrant might expect to be able to dominate that market through control of superior technology or other advantages. If the firm expected that the market for its product would not be competitive in most countries, it might register the product with the HIF, and then proceed to charge monopoly prices as well as earning rewards. This would use up the HIF's scarce reward fund without providing much additional benefit to global health. This problem can be effectively circumvented by requiring that the registrant (and its agents) cannot participate in the market if open licensing is the mechanism it chooses.

There could be a need to employ the back-up mechanism of price controls based on estimated cost of production in some situations in which the HIF concluded that there was insufficient competition to ensure low prices, whether in the open licensing or tendering approach.

5. SUMMARY

This document discusses how several mechanisms that could be employed as a tool to ensure availability at low prices to drugs registered with the Health Impact Fund and other similar proposed systems. There are many complex trade-offs which are difficult to resolve since we do not have the experience with an incentive system such as the Health Impact Fund to enable us to identify the relative magnitude of the different problems that would likely arise, particularly given the varying systems of distribution, procurement and pricing of pharmaceuticals across countries. Clearly there is more research to be done here, with scope for informed commentary from manufacturers, wholesalers, retailers, governments, insurers, and other observers with experience of the operation of pharmaceutical markets.

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APPENDIX A

A registrant obtains profits given by

$$\pi = (p + r)q(p) - c(q(p)) - D$$

where p indicates the price at which the product is sold; r indicates the reward per unit paid by the HIF to the registrant; $q(p)$ indicates the number of units sold (which is a function of the price); $c(q)$ represents the total cost of production, and D represents the (sunk) cost of research and development.

The registrant maximizes profits by choosing p to satisfy

$$(p + r - c') \frac{\partial q}{\partial p} + q = 0$$

where c' indicates the marginal cost of production. This can be re-arranged to show the Lerner Index:

$$\frac{p - c'}{p} = \frac{1}{|\varepsilon|} - \frac{r}{p}$$

where $|\varepsilon|$ indicates the absolute value of the price elasticity of demand. In the absence of the HIF – when $r = 0$ – this becomes the more usual relationship $\frac{p - c'}{p} = \frac{1}{|\varepsilon|}$. Thus, the profit-maximizing mark-up will be lower given the HIF, even without any price setting by the HIF.

The optimal price is given by $\frac{p - c'}{p} = 0$, which will be obtained, for the case of the HIF, only where $\frac{1}{|\varepsilon|} = \frac{r}{p}$. Evidently the price chosen by the registrant, even if not constrained by the HIF, would be lower than the monopoly price. In some cases, it might be below the competitive price $p = c'$. So, given the incentives created by HIF rewards, registrants are likely overshoot or undershoot the optimal price.

A too-high or too-low price may not, however, have such negative effects on welfare as one might usually expect. First, consider the case in which $\frac{1}{|\varepsilon|} < \frac{r}{p}$, so that $p < c'$. This can arise because r is large, which implies that there are large health impacts per unit. In such a situation it may be desirable to set a price below marginal cost in any case. (If price is deterring usage of a

product which significantly improves health, then a subsidy may be warranted.) A price below marginal cost might also occur because of very high elasticity. High elasticity of demand for a health-improving drug implies that lowering price may result in considerable improvements in health by increased volume, again suggesting that a subsidy may be warranted.

Now consider the case in which $\frac{1}{|\varepsilon|} > \frac{r}{p}$ so that price remains above marginal cost. This is a case in which either the elasticity of demand is low (so that further reductions in price have little impact on volume) or the reward payment per unit is relatively small (so that additional volume has little impact on health). The overall implication is that drugs registered with the HIF are likely to avoid a significant loss in welfare from pricing too high even if there is no constraint imposed on their pricing by the HIF.

Notice that this varies from the standard case of monopoly pricing without the HIF since prices are always too high regardless of the medical value of the product.