

5. Financing the Health Impact Fund

The Health Impact Fund will require substantial funding to benefit from economies of scale in its operation and long-term commitments from funding partners to assure investors of future revenue streams. The level of annual funding should be set at a level which benefits from economies of scale in measurement and administration and allows at least two new drugs per year. A mechanism for setting relative contributions across funding partners is suggested. Risk-sharing between funding partners and HIF registrants may give stronger incentives for innovation and participation.

INTRODUCTION

Core funding for the HIF will be provided by states which agree to become funding partners. A small number of states can commence the HIF while allowing other states to join the agreement at any time. By joining the HIF, a state undertakes a pre-structured commitment that matches the commitments undertaken by the other contributing states. Whether they are funding partners or not, states can, alongside other non-state contributors, make unstructured payments into the HIF at any time, as will be further described below.

The specifics of the pre-structured commitment that funding partners undertake match the details of the reward mechanism described in Chapter 2. Chief among these specifics are the following.

THE COMMITMENT TERM OF THE FUNDING PARTNERS

The commitment term should at least equal the length of time during which HIF-registered products are rewarded. A somewhat longer period is desirable so that potential innovators have advance notice with regard to the funds that will be available during the reward period. Since the bulk of R&D expenses are incurred in the final few years before market clearance (clinical trials), a commitment of two years beyond the reward period should be sufficient to satisfy this requirement. Thus, with a reward period of 10

years, the commitment term of the funding partners should be specified at about 12 years.

ANNUAL CONTRIBUTIONS BY THE FUNDING PARTNERS

The annual financial contributions to the HIF by the funding partners would ideally be proportioned to their ability to pay. It may be best to fix these obligations in terms of states' gross national incomes (GNIs) in the current or preceding year. Thus, if one member state's GNI is 3.7 times that of another, the contribution assigned to the former would be 3.7 times that assigned to the latter. There are three main advantages to this simple approach. First, the contributions of the various countries are automatically adjusted in a way that tracks their shifting fortunes — fast-growing countries automatically assume a larger share while countries declining income find their burden alleviated. Second, this method pre-empts protracted struggles over contributions such as those that have occurred within the United Nations.

Third, allocating financial obligations in this way facilitates the gradual scaling up of the Fund on the basis of income shares (discussed below), since each country would be assured that its contributions will be matched by a corresponding increase in the contributions of all other member states. This way, any country providing $1/n$ of the HIF's core funding will understand that each additional dollar it agrees to contribute will raise the money the HIF has available to promote global health by n dollars — or by even

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more thanks to economies of scale achievable in the HIF's administration. If contribution increases were left to ad hoc negotiations, by contrast, then each additional dollar a country agreed to contribute would add only this one dollar to the coffers of the HIF. This mechanism also eliminates uncertainty related to exchange and inflation rates, as each partner's contribution is denominated in its own currency.

It may be argued that the contribution schedule should be progressive with respect to income per capita, so that more affluent countries would contribute a higher proportion of their GNI than poorer countries. But such progressivity would make the HIF a much harder "sell" in the more affluent countries. And poor countries are already favored to some extent insofar as they contribute less on a per capita basis even while the health of their citizens is given equal weight. It is also important that the HIF should reflect, and be seen to reflect, a genuine commitment by all the funding partners who maintain it. The large avoidable excess of morbidity and premature mortality in this world is not just a problem of the poor countries, whose people bear most of this burden, nor just a problem of the affluent countries which will bear much of the financial costs of the HIF. Rather, it is a common global problem, and all countries ought to contribute to its solution in accordance with their means.

For the very poorest countries, the cost of HIF membership may be a serious deterrent. These countries might simply decline to join and then enjoy the benefits of the scheme without sharing its cost. It would be highly desirable, however, for these countries to be full partners in supporting the HIF and in making it work. Though they contain 37 percent of the world's population, the 53 countries the World Bank currently lists as "low-income" account for only 1.3 percent of global income. Their partner contributions to the HIF would therefore be quite low – around \$30,000 to \$200,000 per million population – and, if needed, could easily be subsidized by wealthier states or other donors.

THE HIF BUDGET

As the large costs of developing a new medicine require correspondingly large incentives and as the

costs of administration and health impact assessment should not be excessive relative to the reward payments, a reasonable minimum funding level for the HIF is around \$6 billion or roughly 0.01 percent of global income. This amount can be compared with the 5-year budget of PEPFAR recently announced at around \$10bn per year, and funded only by the United States. \$6bn is easily affordable if countries accounting for one third of global income were willing to join the partnership, as each partner country would then need to commit only 0.03 percent of its GNI. This initial commitment rate might be lower (assuming wider participation in the partnership) or it might be higher (assuming smaller participation). The following discussion assumes a 0.03-percent initial commitment rate for purposes of illustration.

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The \$6-billion budget is justified by a goal of enabling the HIF to maintain a reasonable portfolio of drugs. It should maintain at least 20 registered drugs at a time, implying that on average two new drugs are registered each year. A portfolio of 20 drugs with an average of two new drugs per year would mean that the rates of payment per QALY would be reasonably smoothed over time, since each product would share the payout with 19 other products. Ensuring some degree of predictability over time with respect to the expected payment per QALY is desirable in order to mitigate the risks involved in registering a product with the HIF.

With 20 drugs being rewarded at any given time, a HIF with \$6 billion annually would have \$300 million available per drug per year. Assuming that the production costs of HIF-registered drugs are covered by the selling price agreed at registration, this \$300 million would need to cover three kinds of expenses. The largest of these arises from the need to recoup the R&D costs of the company as amortized over the 10-year reward period. DiMasi, Hansen and Grabowski (2003) claim that, taking account of the risk of failure, pharmaceutical companies must spend

about \$0.8 billion on R&D for each drug they bring to the point of marketing approval. They also assert that pharmaceutical firms work with a real discount rate of 11 percent. (This rate is used to inflate R&D expenses incurred before marketing approval and also to deflate the recovery of such expenses through earnings occurring after marketing approval. Thus, a \$90 expense incurred a year before marketing approval is considered to be equivalent to \$100 at the time of marketing approval.) Based on these two assumptions, HIF-registered products must obtain payments averaging \$170 million per year, over ten years (starting at the end of the first year), merely to offset average R&D costs of \$1-billion.

This leaves \$130 million per drug per year. This amount must offset the company's selling, general and administrative (SG&A) expenses, including the cost of required submissions to the HIF demonstrating health impact. While SG&A costs for HIF-registered drugs might be lower than those for high-priced drugs under patent, these costs of selling a drug worldwide would still be substantial. Those \$130 million per drug must also compensate the firm for the expenses incurred by the HIF for administration and global health impact assessment. Such assessment expenses would be largely or wholly covered by registration fees paid by registrants to the HIF. Still, registrants must be able to cover these fees out of the rewards they receive from the HIF; and so it is appropriate here to include these costs which, with 20 registered drugs, would likewise be substantial. (Recall that the registrant's costs of production are covered by the price that it charges for the drug.)

A firm could earn greater profits (over and above those implied in the assumed 11-percent real discount rate) with a HIF-registered product if it succeeded in developing an effective product for less than a billion dollars, in reducing its SG&A costs, or in capturing a larger than 1/20 share of annual HIF reward payments. However, on average, a budget of \$6 billion appears to create a payout large enough to support approximately two new drugs a year. If the average costs of R&D and/or SG&A are in fact lower than here assumed, then a budget of \$6 billion might over time end up supporting more than two drugs a year. If average costs are higher, this budget would over time

end up supporting fewer. A recent analysis purportedly by a "Big Pharma" company estimated the cost of developing a new drug for a neglected tropical disease to be in the range of \$300m, which is well below the DiMasi *et al* estimates, possibly because there are low-hanging fruit to be plucked, or possibly because the cost of clinical trials in developing countries are likely to be considerably below those used in the DiMasi *et al* analysis (McCaughan 2008).

A further consideration supporting a \$6-billion minimum annual allocation to the HIF appeals to the cost of performing credible health impact assessments. There are likely substantial economies of scale to be realized by increasing the number of registered medicines under assessment. For example, the costs of developing an appropriate methodology, which is the function of the Technical Branch described in Chapter 4, is independent of the number of drugs being assessed. Similarly, assessments in different countries may be performed more efficiently when there are more medicines under review.

Given such substantial economies of scale, a poorly funded HIF would face a dilemma. If it performed credible global health impact assessments, then the cost of these assessments would become excessive relative to the net health impact rewards the HIF pays out on their basis. Yet, if it limited assessment costs to some reasonable proportion of total reward payments, then the assessments could become unreliable and even subject to manipulation.

A HIF budget of \$6 billion would suffice to avoid this dilemma as the costs of assessment and administration could be kept around a reasonable 10 percent of the HIF's annual budget and still be large enough, at \$600 million annually, to support a credible operation.

In sum, then, \$6 billion annually seems a reasonable minimum. Were the HIF to be funded at a level substantially below \$6 billion, then it would not generate a smooth and adequate flow of new high-impact medications and would also have to devote too much of its funding to administration and assessment expenses.

Looking above this minimum, there is no "optimal" budget for the HIF. The larger it is, the more drugs it could sustain in its portfolio, and the larger

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the incentive effects it would have on R&D. However, there appear to be benefits from having a larger portfolio of drugs, both in terms of increasing predictability about rates of payment for firms, and in terms of exploiting economies of scale in assessment. An appealing feature of the HIF is that, as it grows larger, it will tend to displace drugs from high pricing, leading to savings for patients and insurers. Thus, the net costs of increasing the budget are likely to be far less than the increase in the budget. (This point is discussed further in Chapter 8.)

A simple example can illustrate the point. Suppose the developer of an important new medicine could – charging a patent-protected high price – sell annually 7 million packages to affluent patients at \$50 each and thereby earn \$315 million (\$45 per package) over production costs. Suppose further that, were the same medicine sold worldwide at cost, it would serve a much larger patient population. In this scenario, affluent patients stand to gain \$315 million (\$45 on 7 million packages) annually from at-cost pricing. If the HIF, by offering the prospect of a \$315 million annual reward, induced the firm to register its product, the net cost to the public would therefore be much lower. The HIF might pay out \$315 million in taxpayers' money, but affluent patients (or their national health systems and insurance companies) would save \$315 million. Therefore, it would effectively cost the public nothing to include the four-fifths of humanity who cannot now afford patented medicines. If the increased production runs enabled by higher sales volumes reduced the cost of production, the net cost to the affluent would be negative. In addition, there would be worldwide gains in productivity due to the reduced burden of disease as well as the prospect of eradicating some communicable diseases (which now proliferate among those too poor to be promising targets for pharmaceutical sales).

COMMENCEMENT OF FUNDING

As it takes several years to develop new medicines and bring them to market, the HIF need not be funded at full strength from the beginning. Nonetheless, the phase-in should be fairly rapid because companies are likely to have some recently patented

and also some partially developed products that they would want to register soon after the HIF's commencement. Too slow a phase-in is also undesirable if it signifies lack of commitment to potential registrants. The dollar-per-QALY ceiling (discussed in Chapter 2) insures against overpayment should early uptake be poor. And reward funds unspent in an early year – or indeed in any year – could simply be rolled over into the subsequent 10 years. In this way, no money would be wasted if the aggregate health impact achieved by all registered medicines in some year were insufficient to exhaust reward funds available.

A reasonable phase-in schedule might call for the funding partners to contribute one-half of their standing contribution in the first year and three-quarters in the second year of the HIF's operation. At an initial commitment rate of 0.03 percent, each initial funding partner would then contribute 0.015 percent in the first year, 0.0225 percent in the second year, and 0.03 percent in the third and subsequent years.

Other countries may be invited to join the HIF in later years on the same phase-in terms. This seems reasonable in light of the fact that any money they contribute in their first two years as funding partners could not have been counted on by the registrants who are rewarded in these two years.

LEAVING THE FUNDING PARTNERSHIP

Countries joining the HIF at inception might be uncertain to some extent about how well it will work. They will be more likely to join if there is an exit option. But if countries were allowed to exit the HIF at any time, its failure would be assured as innovators would not take seriously the opportunity to register their products without reasonable assurance of the envisioned rewards.

This dilemma can be resolved by including the option of a phased withdrawal. Countries would have the option to withdraw from the partnership by winding down their commitment at the rate of 10% per year, following an announcement period of 2 years. Thus, if a country had a commitment of 0.03% of GNI annually to the HIF, and wished to

withdraw, it would be required under the terms of the agreement to contribute this amount for the next two years, and then an amount declining by 0.003% of GNI a year over the following ten years, after which its commitment would be zero. During the ten-year drawdown period, the amount committed by that country would be segregated, and paid only on the basis of health impact by products that were registered with the HIF before the drawdown period commenced.

SHARING THE COST OF THE HIF BUDGET

The suggested minimum amount of \$6 billion per annum is quite small for states — not much more than the annual development assistance provided by the Netherlands, for example. Even affluent countries with low population number — Australia, Switzerland, Norway — could fund such a commitment by themselves. But, in light of the goal that the HIF should gradually be expanded, early buy-in by many states is much to be preferred.

Global income is currently nearly \$60 trillion. Thus, if all countries were to join the HIF, each of them would need to contribute 0.01 percent of its GNI in order to reach the minimum \$6 billion per annum. With countries representing half of global income participating, each funding partner would need to commit 0.02 percent of its GNI to reach the minimum \$6 billion per annum. And with countries representing one third of the global product as funding partners, the corresponding contribution percentage would be 0.03. This one-third target is very easily reached if the HIF is joined either by the United States or else by all or nearly all member states of the European Union.

One can put the cost of the HIF in perspective by comparing its initial annual cost of \$6 billion to global spending on pharmaceuticals which, in 2008, is expected to be about \$735 billion. Given population growth — as discussed in Appendix B — global expenditures on pharmaceuticals seems likely to continue to rise. Total health-care spending is much larger still, around 10–15 percent of GNI in affluent countries — \$2,000 billion in the US alone. And, as

discussed above, the cost of the HIF would not be incremental spending on medicines, but would often merely change the way a pharmaceutical innovation is paid for.

Assuming the HIF works well, the contribution percentage could gradually be increased, and funding would, of course, also increase through real GNI growth in the partner countries as well as through the accession of new funding partners.

COPING WITH UNCERTAINTY

The HIF is to reward pharmaceutical innovators each year in proportion to the health impact their registered medicines have achieved in this year. This requires relating a fixed amount of money to a varying health impact (which we here express in terms of QALYs). A simple solution is to divide each year the available funds over the registered pharmaceuticals in proportion to their health impact in this year. This solution has various advantages outlined in chapter 2, in particular that no dollar-amount per QALY needs to be specified in advance. A scheme structured in this way will lead innovators to adjust the supply of rewardable pharmaceutical innovation through decisions about whether or not to undertake potential research efforts, and through decisions about whether to register a new medicine with the HIF.

If the aggregate health impact of all registered medicines is small in any year, the HIF is protected against excessive pay-outs through the dollar-per-QALY ceiling already discussed. But there is an inverse problem: what if the global health impact achieved by all registered medicines is very large in a given year? This prospect is very agreeable, of course, from the standpoint of global health. But this prospect might also reduce the attractiveness of the HIF to innovators, deterring potential research efforts and making firms less willing to register their products with the HIF.

One possible solution to this problem is insurance. The Health Impact Fund could negotiate an insurance contract that would commit a consortium of insurance companies to guaranteeing a minimum dollar-per-QALY rate in exchange for a fixed premium. Or individual companies could negotiate such

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insurance contracts for their HIF-registered products. A draw-back of this solution is that, in light of the considerable uncertainty involved at least in the early years, the premiums would be high and thus would reduce substantially the net rewards received by registered innovators, with detrimental effects on incentives. In addition, there are problems of moral hazard which render insurance probably infeasible since, with insurance, the HIF would be perceived to have no incentive to control the amount of QALYs attributed to the registered products.

Another solution to the problem of inadequate rewards would be for the HIF to underwrite a minimum \$-per-QALY rate by tapping into funds assigned to future years. But allowing the HIF to run such deficits would reduce committed funds available for future pay-outs and would thereby — rather than solve the problem of reduced incentives — shift this problem into future years.

A third solution would be to transfer some of the uncertainty from pharmaceutical innovators to the funding partners. Obviously, both sets of actors are averse to financial uncertainty in their relations with the HIF. Pharmaceutical innovators have a strong interest in predictable rewards, such as a fixed payment per QALY assessed. They already face great uncertainties relating to research, testing, patenting, obtaining market clearance, and marketing of a new medicine. The funding partners contributing to the HIF, on the other hand, have a strong interest in predictable outlays, specified perhaps as a proportion of GNI as suggested above. They will be less willing to make a 12-year commitment to an international scheme the more uncertainty there is about how much this commitment will cost.

Liked neither by the funding partners nor by innovative firms, the uncertainty nonetheless has to be borne by someone, and the more one set of actors is shielded from it, the more must be imposed on the other set of actors.

There are three reasons for imposing some of the uncertainty on the funding partners. First, countries are generally better able than companies to absorb financial risk and uncertainty. This is especially true with respect to small- and medium-sized companies, including those located in developing countries

— companies that account for a large proportion of pharmaceutical innovation and whose innovative efforts the HIF is intended to encourage. But it is true even for the very largest of pharmaceutical companies, because the HIF payments they receive could constitute a significant fraction of their profits. While HIF payments might initially constitute about one percent (and eventually much more) of Pfizer's \$50 billion in annual revenues, state contributions to the Health Impact Fund would be only a small fraction of one percent of the government budget of each partner country. Therefore, it is easier for states to cope with a cost overrun than it is for pharmaceutical firms to cope with a corresponding shortfall.

Second, there is an important asymmetry: insofar as uncertainty is imposed on innovators, and things go badly for them because the collective health impact of all registered medicines is unexpectedly large, such innovators suffer an unmitigated loss of anticipated reward revenue. By contrast, insofar as uncertainty is imposed on countries and things go badly for them because the collective health impact of all registered medicines is unexpectedly large, such states suffer a mitigated loss: they are required to make a supplemental payment to the HIF, but they also benefit from a larger than expected decline in the burden of disease, from larger than expected cost savings on patented medicines, and from larger than expected economic gains from better global public health.

Third, insofar as uncertainty is imposed on companies, they will factor an extra risk premium into their decision making. This will cause them prudently to forgo some research efforts of more marginal expected profitability, and the HIF will then achieve less health impact for its \$6 billion annual cost than would be the case if less uncertainty were imposed on companies. This in turn is undesirable for the funding partners which, by absorbing more of the uncertainty, could make the fund more cost-effective.

Powerful as these considerations are, they do not show that governments should shoulder all of the uncertainty by agreeing to a rigid dollar-per-QALY floor. Such a rigid reward mechanism would lose a desirable informational feature discussed in Chapter 2, namely that a scheme under which the dollar-per-QALY rate varies inversely with supply provides

valuable information about the cost of innovation on a per-QALY basis and thereby allows the member states to reach better-informed decisions about how to structure and how richly to fund the HIF. These advantages can be preserved through sharing of uncertainty between governments and registered innovators, as discussed in Chapter 2.

The decision as to whether member states are willing to accept a commitment that involves the risk of paying somewhat more than expected is ultimately a political one. There are, however, some advantages that could be realized if the commitment of states to the HIF were sufficiently flexible to help mitigate the uncertainties faced by innovators. However, there are also other, less open-ended ways to mitigate such uncertainties, including by making contributions to early-stage research.

EXPANDING THE HIF OVER TIME

An important aspect of the HIF is that, if successful, it can be expanded, enabling ever more products to be registered. Growth in the size of the HIF can occur in various ways.

One dimension of growth is firmly locked in: as partner states enjoy real growth in GNI, their contributions to the HIF increase apace.

A second dimension of growth is the accession of additional countries as funding partners. This could be a very substantial source of growth if (as we assumed) countries accounting for two-thirds of global income initially opted not to join. Such accessions might easily double the size of the HIF from \$6 billion to \$12 billion or more annually.

A third dimension of growth is an increase in the contribution percentage. (In order to reassure potential innovators, the contribution percentage cannot be decreased except in the special case of departing partners as described above.) The funding partners have an opportunity to observe the HIF in operation and, in particular, to learn at the end of each year the reward rate of dollars per QALY for that year. If the reward rate is near the maximum, then there is little urgency in raising the contribution percentage. If the reward rate is much lower — signalling that the HIF is producing particularly good value for the money

invested in it — then this could serve as a signal to expand the HIF's size. The terms of the HIF might be written so that low payments per QALY in any given year would trigger official consideration of an increase in the contribution percentage for subsequent years. The decision about whether to increase the percentage, and by how much, would obviously be made by the funding partners. Here it seems reasonable to weight the votes of the larger contributors more heavily (though perhaps not quite in proportion to their contribution) and to require a substantial supermajority of these weighted votes for any increase to become effective. Such a conservative structure also has the advantage of making it easier for states to agree to join the HIF in the first place.

A fourth way in which annual HIF pools can increase over time is through sponsors other than member states. The HIF should invite such other potential sponsors large or small, to contribute as well: foundations, corporations, and individuals, for example, and also governmental and non-governmental organizations, non-member states, and sub-national governments. Such additional sponsors can make a similar 12-year rolling commitment. Or, alternatively, they may make a one-time contribution. Such casual contributions could be collected into an endowment in order further to stabilize expectations that funding will continue to be available long-term and perhaps also to smooth out fluctuations in the reward rate. Over time, a pattern of casual funding may emerge and strengthen the innovation incentives. Nonetheless, the funding partners' reliable long-term commitments for a 12-year period are crucial for the success of the scheme. And sponsors — especially states — should therefore be strongly urged to join the Health Impact Fund as full funding partners rather than to remain outside as casual sponsors.

A fifth, less significant way in which annual HIF payments may increase over time is through a reduction in the HIF's net operating expenses. These expenses consist — simplifying slightly — of fixed costs, incurred regardless of the number of registered products, and variable costs, rising somewhat less steeply than number of registered products. The variable costs should be estimated in advance and charged to the registrants as user fees (thereby dis-

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couraging the registration of low-impact medicines whose assessment would be disproportionately costly). As the HIF grows, its assessment expenses per registered medicine will fall. This will result in higher net gains (reward payments minus registration fees) for registrants and will therefore strengthen the incentives the HIF provides.

CONCLUSION

The last four chapters have given a detailed sketch of how the Health Impact Fund might work. The point of this sketch was to show that the HIF is possible, along the lines here suggested. Attentive readers will have found things to disagree with. Such disagreements are welcome as they will make it possible to improve the specification of the HIF and of the arguments in its favor. The viability of the HIF does not

depend on each and every detail of our description. We invite constructive critique that is mindful of the urgency of the problem and of the great promise of the solution we have outlined.

Having described the HIF, we will proceed in the next four chapters to present the most important arguments in its favor. We will show how the HIF can be justified in moral and specifically in human rights terms, how it is uniquely capable of reducing the last-mile problem of delivering minimally adequate health care to the world's poorest populations, how it relates to a simple reliance on the patent system, and how it stacks up against alternative ideas for improving global public health.