The Health Impact Fund

Making New Medicines Accessible for All

A Report of *Incentives for Global Health*

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Executive Summary

The Health Impact Fund (HIF) is a new proposal based on two simple insights: (1) privately funded pharmaceutical R&D responds to incentives, and (2) new drugs can have a much larger impact if their prices are low. At present, the most profitable research efforts are not the ones most needed to alleviate the global burden of disease. And high prices often put new drugs out of reach of most of the world’s population.

The HIF seeks to correct both of these failings by offering to reward any new medicine, if priced at cost, on the basis of its global health impact. Any firm receiving marketing approval for a new medicine would be offered a choice between (a) exercising its usual patent rights through high prices or (b) registering its product with the HIF. Registration would require the firm to sell its product worldwide at an administered price near the average cost of production and distribution. In exchange, the firm would receive from the HIF a stream of payments based on the assessed global health impact of its drug. The HIF is, in other words, an optional pay-for-performance scheme for new pharmaceuticals.

Innovative companies would benefit from this new option because they could profitably introduce important new medicines that are needed mainly by patients who cannot pay high prices. Patients—especially those in the developing world—would benefit through access to new drugs at low prices. By supporting the HIF, citizens and governments in all countries would reap large cost savings on medicines as well as substantial reductions in the human and economic burdens of disease.

The chief problems with the present system governing the development and distribution of medicines are well known: despite relatively low manufacturing costs, patented medicines are often very expensive and are therefore unaffordable for most people; and diseases concentrated among the poor attract little or no pharmaceutical research. As a result of both factors, the disease burden among the poor is, avoidably, very high. Many diseases of the poor are communicable and expose all of humanity to the risk of new and virulent strains. These problems are further aggravated: by patients who, often deterred by high prices, fail to complete a full course of treatment; by lack of access to competent medical staff who would ensure that medicines are taken correctly; and by counterfeiters, often attracted by high prices, who may dilute a medicine’s active ingredients. In addition, competitive marketing and litigation costs reduce the return from innovation, and make it a less attractive investment.

Each of these problems has provoked ideas and initiatives by academics, NGOs, governments, and international agencies. By supporting both innovation and real access, the Health Impact Fund extends the best of these ideas into one comprehensive, unified solution that makes substantial progress toward a rational system of developing and distributing worldwide the pharmaceuticals we all need.

This book explains how the HIF would work and why the world needs it. Chapter 1 provides a summa-
2 THE HEALTH IMPACT FUND

The next four chapters examine in detail how the HIF would operate. Chapter 2 discusses the proposed mechanism for deciding how much each innovative drug would earn based on its assessed health impact. Chapter 3 shows how health impact can be measured while also examining the difficulties such measurement would have to overcome. Chapter 4 explores the HIF’s governance and administrative structure. Chapter 5 considers the commitment of funding partners.

The following four chapters explore the rationale for the HIF. Chapter 6 constructs a moral argument, based on widely recognized human rights, for implementing the HIF. Chapter 7 shows how the HIF would help address the important "last mile" problem of ensuring effective distribution and use of pharmaceuticals in poor countries. Chapter 8 shows, from an economic perspective, how the HIF would usefully supplement the patent system, and Chapter 9 examines the relationship between the HIF and other proposed reforms. Chapter 10 summarizes the above and shows how this new mechanism can be brought into being.

The HIF is a work in progress, to be further perfected and completed with the help of many stakeholders. This book’s objective is to show that, and how, the existing rules governing the development and distribution of new medicines can be improved upon in ways that would dramatically enhance global public health. The Health Impact Fund is a feasible complement to the existing regime. Governments have decisive moral reasons to implement the HIF and citizens have decisive reasons to urge their governments to do so.

Most countries are unable to institute the HIF single-handedly. But governments can make a conditional commitment to participate if enough others are also willing. Given a threshold participation of states representing about one third of global income, the founding partner states can commence the Fund at a cost of 0.03 percent of their respective gross national products. The Fund would then become operational within three years and be enhanced thereafter as experience warrants. There is little to lose, much to gain, and no time to waste.
I. The Health Impact Fund: A Summary Overview

THE HEALTH IMPACT FUND: PAY-FOR-PERFORMANCE

The goal of pharmaceutical innovation is improved health. The Health Impact Fund will give innovative firms an option to be directly rewarded based on their contribution to this goal, without impeding access through high prices. It will thus be able to achieve the twin goals of stimulating pharmaceutical innovation in the most important therapeutic areas and enabling widespread access.

The integrated solution the HIF provides is global in scope. Many innovative firms have found it difficult to make money in poorer countries because the low prices required to generate substantial sales in those markets made it impossible to charge high prices to wealthier people in those and other markets. The HIF eliminates this problem by requiring a uniformly low price worldwide, while offering innovative companies direct payment based on the health impact of their innovations, no matter where the health impact occurs.

This approach will make it profitable to develop medicines for heretofore neglected diseases as well as medicines with global impact. And these medicines will be sold at low prices all over the world, while still generating a return for the shareholders of innovative pharmaceutical companies.

The essence of the proposal is to offer firms a share of a fixed fund for each of ten years, in proportion to the share of health impact of their registered product out of all registered products. For example, if all registered products were estimated to have saved twenty million “Quality-Adjusted Life Years” (or QALYs), a registered product which had saved two million of those QALYs would receive ten percent of the fund. This calculation would be performed every year, and each registered product would receive a payment based on this approach for ten years following market approval. In exchange, the firm would agree to sell its product worldwide at a specified low price, roughly equal to the average cost of manufacturing, and to offer a royalty-free open license for generic versions of the product following the ten-year reward period. Firms could choose whether to register any particular product for health impact rewards or to exploit their monopoly pricing privilege in the usual way.

Capitalism has improved the lives of billions of people … But it has left out billions more. They have great needs, but they can’t express those needs in ways that matter to markets. So they are stuck in poverty, suffer from preventable diseases and never have a chance to make the most of their lives. Governments and nonprofit groups have an irreplaceable role in helping them, but it will take too long if they try to do it alone. It is mainly corporations that have the skills to make technological innovations work for the poor. To make the most of those skills, we need a more creative capitalism: an attempt to stretch the reach of market forces so that more companies can benefit from doing work that makes more people better off.

Bill Gates
THE HEALTH IMPACT FUND

Funds for the HIF will be provided by partner countries that agree to support it. The greater the support provided to the HIF, the more effective it will be in encouraging widely accessible innovations. The system can be scaled up as larger amounts of funding become available, but a reasonable starting level would be six billion dollars per year. At this scale, the HIF could support the development of about two new drugs per year, sustaining a stock of about twenty medicines.

The HIF is designed to use market forces to set the rate of payment made to innovators: the more patented medicines are registered with the HIF, the lower would be the payment for any given health impact. Market forces will also determine sales volumes of registered medicines without the monopoly price distortions that are otherwise typical of pharmaceutical markets. In many countries today, pharmaceutical pricing is to a large extent controlled by governments. The HIF would employ a method for determining payments to innovators that is more transparent and less subject to influence than the mechanisms used by state and private insurers today. And unlike systems in which research is funded directly, the HIF would not intervene at any stage in funding research: it would only reward successfully developed products based on their assessed impact. Difficult decisions about which molecules should be explored and tested, and how to allocate research funds among particular illnesses would be left to firms with a financial stake in the decision. The HIF is thus more market-oriented and less prone to creating distortions than are existing systems of financing pharmaceutical innovation. It pays strictly on the basis of performance.

WHY THE HEALTH IMPACT FUND IS NECESSARY

The global pharmaceutical industry should serve two critical needs: to create new medicines that are important to global health, and to enable people all over the world to access these products once they are developed. A system that promotes innovation without also ensuring access is cruel to those who are excluded from medicines by high prices. And achieving low drug prices is of little value if the most urgently needed remedies are not being developed.

The Health Impact Fund is specifically designed to address both those needs by rewarding pharmaceutical innovators directly on the basis of health impact, while requiring low prices to enable access. In addition, the HIF will create incentives for manufacturers to engage in facilitating the appropriate distribution of their products in poor as well as in wealthy countries, since improved (appropriate) use will increase the rewards they earn. Since the HIF will reward health impact on anyone in the world at an equal rate, innovators will find it profitable to develop medicines to treat even the poor – especially given that among them the greatest health impacts are waiting to be realized.

Our current systems of innovation are not fully achieving the needs of patients or even of investors in the pharmaceutical industry. They encourage drug firms to spend too much on developing minor modifications of existing drugs and on competitive marketing and patent litigation, instead of focusing their efforts on the innovations that would have the largest global health impact. This is not what patients need, it is not what the research scientists want, and it does not seem to be creating the returns that investors demand. Firms are responding to the incentives they face, and doing the best they can given those incentives. Under the present system, firms have incentives:

1. to focus on the diseases of the people who can pay a lot of money when they get sick, even though those diseases tend to have many available treatments already, and the incremental health gains are typically small;
2. to extend the monopoly position of existing patented medicines by incremental changes; and
3. to duplicate other firms’ blockbuster medicines by creating “me-too” drugs.

Of course, while those activities have some value, they may not have much effect on the overall health of the world’s population.

The Health Impact Fund will offer innovators the option to be rewarded for global health impact, even
if most of the people consuming their products are poor and can only afford medicines priced near cost. This opens up a range of diseases and treatments which so far have been of only marginal interest to investors, since under the current system they have little prospect of benefiting from sales to the poor. The HIF will thus benefit investors, researchers, and wealthy and poor patients alike. Of course, these benefits come at a cost: governments and private foundations will have to finance the Fund for it to be able to reward innovators.

Currently, diseases concentrated among the poor are “neglected diseases.” An example is human African trypanosomiasis (sleeping sickness) with about sixty thousand infections reported annually and perhaps ten times as many going unreported. Diagnosis of this disease is difficult, and current treatments have severe side effects and involve frequent infusions at a clinic.

There has certainly been welcome progress in addressing neglected diseases, much of it due to an increase in charitable contributions. PPPs (private-public partnerships) have successfully enhanced the rate of development of new drugs in the absence of significant new government incentives, through contributions from pharmaceutical companies and philanthropic foundations. Despite these laudable efforts, the attention of pharmaceutical companies naturally continues to be focused on products which can be profitable to them. Unfortunately, while the poor are numerous, they cannot pay very much for drugs. It is therefore typically unprofitable to develop drugs for diseases concentrated among the poor. There are other obstacles as well: in the absence of well-developed primary care systems, diagnosis may be incomplete or absent; and distribution systems may be expensive, effectively impeding both demand and supply. For all these reasons, some pharmaceutical firms have shunned altogether the diseases of the poor.

With respect to drugs for global diseases, which affect people all over the world, manufacturers of patented products tend to set high prices which exclude some buyers, both in rich and in poor countries. Differential pricing between rich and poor consumers, between or within countries, is difficult: arbitrageurs will try to buy the good cheaply and resell it at the higher price. Even without parallel trade, there is a network of international price comparisons which makes it hard for firms to charge different prices in different countries or within the same country. But then, if the innovator firm sets a high price even in poor countries, its sales volume will be low and it may face a risk of compulsory licensing or of bad public relations.

Firms operating in other markets don’t usually face such problems. Few would demand that Siemens sell its refrigerators at low prices to the poor, but many people believe that Sanofi Aventis should sell its drugs at low prices to poor patients. Such atypical demands are directed at the pharmaceutical industry because this industry is in the business of saving lives. Under the prevailing rules, these ethical demands are in conflict with the for-profit nature of pharmaceutical firms, which have a legal responsibility to their shareholders.

These problems can be solved only through a mechanism such as the Health Impact Fund, which aligns the mission of pharmaceutical firms, to promote public health, with their responsibility to make money for their shareholders. The HIF is not a system which looks to the pharmaceutical companies for philanthropy: instead the idea is to offer them the opportunity for market-based rewards for the contribution their products make to improving global health.

We need a bolder effort to solve the global problem of drug pricing. Prescription drugs are truly global products today, and we need a global strategy to get the most benefit from new medications for all of the people of the world. Specifically, it’s time for developed nations, recognizing their shared interest in bringing better treatments to market, to find ways to fairly share the cost of new drug treatments.

Mark McClellan – Commissioner of the US Food and Drug Administration 2002–2004

The HIF would not merely stimulate the development of medicines that are unprofitable in its absence. Products such as Plavix (which helps prevent heart attacks and strokes) could offer therapeutic
value throughout the world, and yet their sales tend to be concentrated in the wealthiest countries due to relatively high prices. If rewarded under the HIF, such products could see enormously expanded sales volumes because of lower prices. Depending on the scale of funding of the HIF, this could be a more profitable way of selling such drugs—and it would be of tremendous value to patients all over the world.

**PROPERTIES OF THE HEALTH IMPACT FUND**

The HIF approach to solving problems of innovation and access is straightforward: pay directly for what is valuable, and don’t ration access on the basis of artificially high prices. This simple and intuitively compelling approach has many attractive characteristics.

- The mechanism of the HIF is designed to give incentives for innovation, the strength of which is proportional to the social value of the innovation, as measured by health impact. No other approach to paying for innovation has this desirable property. The patent system places a value on an innovation based on people's willingness to pay, which, for essential medicines, is closely related to their ability to pay. As a result, the patent system rewards innovation which addresses the health needs of the wealthy much more than those of the poor. The HIF redresses this imbalance and motivates firms to invest in research with the greatest impact on health.

- The HIF eliminates the need for high prices, which is of course a significant obstacle to making important drugs accessible to the poor. The savings from low drug prices, however, will accrue to everyone.

- The low price of HIF medicines reduces the incentives for counterfeiting, which is a blight on pharmaceutical markets, especially in developing countries. Counterfeit drugs harm not only manufacturers, but, when they fail to contain the correct amounts of the relevant active ingredients, may also harm patients and, in the case of communicable diseases, people everywhere (by causing development of disease-resistant strains).

- The HIF is ethically attractive because it solves the problem of obtaining innovation without blocking access through artificially high prices.

- The HIF is scaleable: if it works well, it can be expanded by increasing the amount of funding available.

- The HIF has a clear objective and straightforward rules. It requires relatively little administrative discretion.

- Because the HIF is an optional system, there is an automatic adjustment mechanism to ensure that the payments it makes are reasonable relative to the profits earned on other drugs not registered with the HIF: if payments get to be too high, more products will be registered with the HIF and payments will fall as funds are spread over more products. The reverse effect operates if payments fall too low. This not only limits the risks of insufficient payments faced by firms that register their products with the HIF, it also curtails the risk faced by funding partners of excessive payments.

- The HIF addresses the “last mile” problem of getting drugs to the poor who need them. While the present regime provides strong incentives to expose affluent people to patented medicines they do not need, it provides no incentives to ensure that poor people benefit from medicines they do need. However, in the HIF system, registrants will be financially motivated to encourage appropriate use of their products among both the rich and the poor, since the amount of health impact will in part depend on the number of people using the medicine effectively.

- The citizens of the wealthier countries benefit not only directly from lower drug prices and a greater industry focus on achieving actual health impact, but also indirectly from improved health in developing countries which has global benefits in terms of economic growth and reduction in the development and spread of harmful pathogens.

- The HIF can reduce expenditures by pharmaceutical companies on promotional activities and litigation. To the extent that pharmaceutical companies can reduce such wasteful competitive expenses, they will obtain higher profits and will
be more strongly motivated to innovate and to register their products with the HIF.

It is instructive here to compare the HIF to the Advance Market Commitments (AMCs) espoused by the G8 finance ministers. What makes the HIF different is that (1) it applies to all kinds of pharmaceutical products that improve human health, and not just a particular prespecified vaccine for a neglected disease; (2) it doesn't require a body of experts to set a price, since the reward paid under the HIF arises endogenously from choices by firms about which products to register in the HIF; (3) it can offer incentives for R&D at an early stage because it isn't exclusive about the products that can be registered; and (4) it rewards the innovator not by subsidizing sales but on the basis of the health benefits this medicine actually brings to patients. For supporting R&D on specific vaccines, AMCs are an effective mechanism. But for pharmaceuticals generally, the HIF is arguably the best mechanism for inducing innovations that will be widely accessible.

In summary, as a mechanism for incentivizing innovation and access to essential medicines, the HIF has a unique combination of advantages which the succeeding chapters lay out in greater detail.

THE HIF IS NOT CHARITY FOR THE DEVELOPING WORLD

In the wake of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which has introduced stronger pharmaceutical patent protections into the less developed countries, much greater attention has come to be focused on the deplorable health care situation of the world's poor: the three-quarters of humanity currently unable to afford patented medicines. Many – including some of those who have pushed hardest for or benefited the most from the much-strengthened intellectual property regimes, the United States, Bill Clinton, and Bill Gates, for example – have adopted the cause of improving the health of the world's poor and are directing billions of dollars to it. Many others have developed interesting and promising ideas about how this can best be done. Is the Health Impact Fund another such idea?

Yes, and no. Yes, because, properly funded, the HIF would make a huge difference to what health care the world's poor have access to. It would have this effect in three main ways. The poor will have immediate access to some new high-impact medicines that would otherwise sell at high, patent-protected prices. The poor will have immediate access to some other high-impact new medicines that would otherwise not have been developed. And the poor will greatly benefit from a newly created motive of pharmaceutical firms: to ensure appropriate use of their products.

No, because the HIF has corresponding benefits also for the affluent. They too will be able to purchase at low prices some new high-impact medicines that would otherwise sell at high prices. This difference will be most obvious to individuals who lack complete drug insurance. But even for people with drug insurance, the lower prices of HIF-registered drugs will result in lower insurance premiums and national health system expenditures.

The affluent will benefit alongside the poor also from the existence of new medicines that would not otherwise have existed. It is likely that, in the short term, these medicines will mostly treat communicable diseases of the developing world. But, so long as these diseases are very poorly controlled there, they pose a substantial danger to all humankind. It is in everyone's interest that the diseases of the poor not be treated with half-measures that lead to drug resistance and new virulent strains, but that they be fully understood and, if possible, eradicated. In the medium to long term, once the "low-hanging fruit" in treatments for tropical diseases has been picked, the HIF is likely to become more focused on supporting innovation for global diseases.

The affluent will also benefit greatly from a realignment of pharmaceutical companies' interests with actual health impact. After all, the interest of affluent people is not in maximizing their medicine consumption as measured in dollars, but to make rational use of medicines toward achieving better health. Pharmaceutical companies have an enormous influence on the practice of health care in afflu-
ent countries through the diseases they research, the remedies they develop, their influence on the prescription patterns of doctors, and their interactions with national health systems, insurance companies, and legislators. In exerting this influence, these firms are obviously motivated by maximizing their profits. And wouldn’t it be good for all – rich and poor alike – if these firms’ profits on some of their more important medicines were precisely aligned with the health impact these products actually achieve?

The HIF is not then about affluent people or countries helping poor people or countries, but a crucial addition to the established system governing the development and distribution of medicines. Being optional for innovators, the HIF will initially produce some very important medicines for diseases concentrated among the poor – medicines whose development is not lucrative under the present regime. But in the medium term, the HIF will attract high-impact medicines for global diseases and conditions: those that will make a great difference to the health of rich and poor alike.

With Voltaire one might say that not creating the HIF is worse than a crime, it is a blunder. But we believe that it would be a crime as well. In both rich and poor countries today, poor people—and even people who think they are wealthy enough until they get sick—are unable to purchase the drugs they need because the price is too high. This is not an accident. Patents create monopoly power, which enables the patentee to push prices up as long as the loss in profits from lost sales is smaller than the increase in profits from higher prices. Given the enormous disparities in incomes between and within countries, this means that profit-maximizing companies are forced to deny people access to life-saving medicines in order to meet their obligations to shareholders. That is a hard decision: but if the HIF were created, no one would have to make that decision. Firms would increase their profits by treating more people, rather than the other way around.

An astonishing feature of the HIF is that this realignment of incentives needn’t cost more. Wealthy people are already paying for pharmaceutical R&D through the high prices they pay for drugs, or the high insurance premiums and taxes to support government health systems. The HIF reduces the amount consumers pay for drugs through high prices, premiums, and taxes, and takes about the same amount through taxes to be paid on the basis of health impact. Here the HIF takes advantage of the fact that allowing poor people to purchase a drug at marginal cost does not increase the cost to be borne by anyone else. The costs of R&D have to be covered somehow, but obliging firms to cover these costs through high prices that will lead people to die is deeply, morally, wrong. The HIF offers a workable, practical solution to this important moral dilemma.

How the Health Impact Fund Would Work

This section briefly describes how the Health Impact Fund would actually work. A more detailed account of all these aspects is given in chapters 2–5 of this book.

Granting Payments

The Health Impact Fund would have a fixed pool of money to pay out annually. Each year, this amount would be disbursed, and each firm would receive a...
share of the pool equal to the share of assessed health impact of its registered medicines. When assessing health impact, the HIF would essentially estimate the difference between (1) the actual health status of people who consumed the registered product and (2) the estimated health status of those people, had they not had access to the registered product, or to any other products introduced less than two years before the registered product. (The HIF would also take into account effects due to decreased transmission of communicable diseases.) That is, the HIF will estimate the incremental health impact of each product registered with it, setting the baseline at the set of technologies two years before the registered product became available. This incremental health impact will be estimated each year for ten years during which the firm will be eligible for payments, and in each of those years, the firm will receive a share of the available funds. If agreed by funding partners, the size of the fund could be expanded automatically if the payment per unit of health impact dropped below a predetermined floor.

To be eligible to register a product under the HIF reward scheme, a company must hold a patent (on the product) from one of a set of patent offices specified by the HIF. It can then register its product with the HIF and will then be rewarded on the basis of the product’s global health impact in its first ten years following marketing approval. To register a product with the HIF, the company would be required to:

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

A company could seek preregistration clearance from the HIF to ensure that its product is suitable for HIF registration. Some products might be unsuitable—for example, if a drug were about to become generically available, the HIF would not wish to pay for health impact of a slightly different version of the same product.

### Assessing Health Impact

It would be necessary to summarize the health impact of each product registered with the HIF using a single measure. The standard measure of health impact is the Quality-Adjusted Life Year, or QALY. A drug that extended a person’s life by ten healthy years would be recognized as having created ten QALYs. The health impact of a medicine will be considered to have occurred at the time the medicine was consumed; so the entire ten years of extra life would be rewarded even if some of these years fall beyond the end of the medicine’s specific reward period. Health impact would be evaluated without regard to wealth or income, and aggregated globally, to assess a drug’s total health impact in each year.

Assessing QALYs is difficult, and it would take a great deal of data to be able to make such evaluations credible. The essence of the assessment process involves obtaining evidence on the incremental effect on health of the average consumer of the registered product. When the registered product simply displaces some existing medicine, the analysis is relatively straightforward. But typically a medicine’s QALY impact would be more complex, arising from an improved therapeutic profile, from increased use due to a lower price, and from more effective use due to better prescription and patient instruction practices.
The Health Impact Fund, as described in chapter 4, would have a substantial department specializing in undertaking continuous evaluation of the health impacts of registered medicines. This would be an expensive feature of the fund. However, not only would this provide the most reasonable way of determining the “reward” for a given drug, it would also create an extremely valuable resource in practical prescribing, since the actual health impact of drugs would be better understood. It would also provide vital data for the promotion of development generally, by poor-country governments, international agencies, NGOs, development aid ministries, etc.

Funding

The HIF would require substantial government funding, including initial commitments of at least six billion dollars per year. (The net incremental cost to the partner countries would, however, be a fraction of this, since there would be substantial savings from paying low prices on new, patented medicines registered with the HIF.) Partner countries would have to commit to financial support for at least twelve years into the future at any time, so that innovators would have some assurance about the payments they could expect to receive. An ideal structure would involve countries committing a fixed share (perhaps 0.03 percent) of their annual gross national income, so that the HIF would grow in proportion to their economies. Such an approach would also ensure a kind of parity between the contributions of funding partners and lead to a larger scale of funding than any partner would achieve on its own.

It is helpful to put the proposed size of the HIF in the context of annual expenditures on drugs. To do this, let us assume that countries representing one-third of the global product agree to underwrite the HIF. (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.) On this assumption each country would need to contribute 0.03 percent of its gross national income (GNI) in order to reach the minimum $6 billion Fund size. For affluent countries with GNI per capita of around $40,000 per annum, committing...
0.03 percent of GNI would constitute a contribution of $12 per citizen per year— as compared to average annual per capita expenditure on pharmaceuticals of $413 in the OECD countries (2005). The actual net cost of the HIF to OECD citizens would be well below $12 because of the savings they would realize on HIF-registered drugs that, without the HIF, would cost much more. These small net costs are associated with much larger benefits. They would stimulate the development of widely accessible new medicines that greatly reduce morbidity and premature mortality worldwide, would thereby improve global economic performance, and would also reduce dangers from heretofore neglected diseases.

The contributions of funding partners would initially grow over the course of three years to the target level. The reason for having a lower funding level initially is that the number of drugs in the system would initially be smaller, and would increase as more new drugs were registered with the HIF. Contributions would remain at the target level thereafter. If a country were to decide to leave the system as a funding partner, its commitment would require it to continue to contribute over a period of years, though at a declining rate each year. This commitment would be necessary to provide innovators with assurance that after they register their product the HIF will have sufficient funds to meet its obligations.

**Administration and Governance**

The administrative structure of the HIF would consist of three main branches: the technical branch, the assessment branch, and the audit branch. The technical branch would determine standards for how health impact was to be assessed, so that there would be consistent expectations across countries and across diseases about data and how it would be interpreted. The assessment branch would apply those standards to the observed data, and assess the health impact of each registered product. The audit branch would check the integrity of this process.

The Board of Directors of the Health Impact Fund would bear ultimate responsibility for overseeing this process. As such, it would need to have the support of the funding partners, and so the composition of the Board would naturally include representatives of each contributing country, presumably with a voting representation based on their contribution share. It might also be suitable to include other stakeholders on the Board.

**THE HEALTH IMPACT FUND: DIRECTIONS FOR PROGRESS**

The Health Impact Fund offers an integrated approach to solving problems of innovation and access to medicines, and along the way addresses many other important issues in pharmaceutical markets, including neglected diseases, counterfeiting, and excessive marketing expenditures. The remainder of the book explains in much more detail how the HIF would work (chs. 2–5) and why it is attractive (chs. 6–9).

This book is a work in progress meant to invite the views and perspectives of the wide variety of stakeholders who would be affected by the implementation of the HIF. Governments, pharmaceutical companies, and citizens should carefully consider this proposal. Their challenges and confirmations, refinements and support will be essential in further progress on the HIF idea.

Ultimately, the HIF can become a reality only if it receives financial support from governments. Since most countries will want to participate only if others share the financial burden, a sensible approach to making progress is for countries to agree to offer financial support conditional on the participation of enough other countries. For example, countries could commit to become founding partners in the Fund at a rate of 0.03 percent of GNI once countries representing one third of global income have made a like commitment.
I2 THE HEALTH IMPACT FUND

NOTES

1. Over the last five years (July 2003 – July 2008), the Dow Jones Industrial Average has risen by 25%. In contrast, the Pharmaceutical Index (DRG) is down by 4% over the same period.


4. An arbitrageur is a person who takes advantage of price differentials between individual markets.

5. In fact, some insurers have successfully used “no-cure, no-pay” arrangements with drug manufacturers in which the payments to the manufacturer is conditional on the actual success of the product. This obviously requires monitoring similar to the assessment process of the HIF. (See, for example, Moldrup 2005, Hughes, Tunnage, and Yeo 2005.)


7. OECD (n.d.).