

The Health Impact Fund: More justice and efficiency in global health

Thomas Pogge

Abstract

Some 18 million people die annually from poverty-related causes. Many more are suffering grievously from treatable medical conditions. These burdens can be substantially reduced by supplementing the rules governing pharmaceutical innovation. Established by the World Trade Organization's TRIPS Agreement, these rules cause advanced medicines to be priced beyond the reach of the poor and steer medical research away from diseases concentrated among them. We should complement these rules with the Health Impact Fund. Financed by many governments, the HIF would offer any new pharmaceutical product the opportunity to participate, during its first ten years, in the HIF's annual reward pools, receiving a share equal to its share of the assessed global health impact of all HIF-registered products. In exchange, the innovator would have to agree to make this product available worldwide at the lowest feasible cost of manufacture. Fully consistent with TRIPS, the HIF achieves three key advances. It directs some pharmaceutical innovation toward the most serious diseases, including those concentrated among the poor. It makes all HIF-registered medicines cheaply available to all. And it incentivizes innovators to promote the optimal use of their HIF-registered medicines. Magnifying one another's effects, these advances would engender large global health gains.

The Health Impact Fund:

More justice and efficiency in global health

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The Health Impact Fund: more justice and efficiency in global health

1. Introduction

Part of the WTO Treaty, the TRIPS Agreement entitles pharmaceutical firms to protect their innovations with product patents,¹ which suppress generic competition, and then to sell their patented medicines at prices far above the cost of production. By pressing less developed countries to institute and enforce stronger patent protections, the wealthier countries enabled their pharmaceutical firms to profit from sales to the more affluent people in the developing world. As a side effect of this success, poor people are now excluded from many advanced medicines which, without TRIPS, would have been immediately available to them as cheap generics. In order to make sure that affluent people in the developing world contribute to the cost of pharmaceutical research and development (R&D), TRIPS causes grave harms and deaths among poor people in the developing world who cannot afford the large mark-ups charged on patented medicines.

Some defenders of the TRIPS regime contend that it is natural and not unfair that affluent people have all kinds of expensive things that poor people cannot afford to buy. But this contention assumes that the existing distribution of income and wealth is fair. This assumption is highly problematic. Today, at least 80 percent of global income variability is explained by a person's initial country and class (Milanovic 2009). Affecting human beings from the moment of conception, these (dis)advantages are obviously undeserved. And their magnitude has become extreme in the course of a long history pervaded by massive crimes such as slavery, colonialism, and genocide. Today, the bottom two-thirds of humankind have about four percent of global private wealth (Credit Suisse 2010; Shorrocks & Davies 2010, p. 3) and six percent of global household income. Average income in the top five percent of humanity is 9.3 times the global average, while average

¹ Product patents allow the patent holder to veto the manufacture and sale of a patented molecule regardless of how it is produced. Before TRIPS, India granted only process patents, which allow the patent holder to veto merely a specific way of making a molecule (see: WHO, 2011). India is the leading supplier of medicines in the less developed countries.

income in the bottom quarter is 1/32 of the global average. So, one person in the top five percent has as much income, on average, as 300 people in the bottom quarter.²

A second, independent problem with the mentioned defense of TRIPS is that new medicines are not expensive to manufacture. Their high prices are “artificial” in the sense that they are enabled by patents. The question is not whether we should subsidize advanced medicines for the poor. Rather, the question is whether we may promote the enforcement of temporary monopolies that drive up the prices at which they can buy such medicines. This is what our governments have done in our name by insisting that innovators must be enabled, even in the less developed countries, to outlaw and suppress the manufacture and sale of generic versions of “their” product at competitive market prices. In defense of this practice it has been argued that the manufacture and sale of generic products are moral crimes that any just legal system ought to suppress. But the defenders of this view have not managed to provide a convincing argument to show why the fact that one person has made a new product should give her a natural right to bar others from making a like product out of their own raw materials.³

2. A matter of incentives

In view of the difficulty of formulating a convincing natural-law argument, most defenders of TRIPS resort to pragmatic arguments that appeal to the need for economic incentives. Pharmaceutical R&D is expensive and would not be sustainable if innovators could not make a decent profit on their successful innovations. Therefore the prospect of hefty mark-ups, at least for a certain period, is necessary for stimulating the introduction of new medicines. Such mark-ups require blocking access to cheap generic copies of advanced medicines.

² The income data used here were kindly supplied by Branko Milanovic, Lead Economist in the World Bank’s Research Department, in a personal e-mail communication of 25 April 2010, on file with the author. Milanovic is the leading authority on the measurement of economic inequality, and his published work contains similar albeit somewhat less updated information (see Milanovic 2002; Milanovic 2005; Milanovic 2011).

³ And, if there were such a right, does it last exactly as long as the local patent law protects it? For a more detailed discussion (see Hollis & Pogge 2008, ch. 6).

Despite its popularity, this pragmatic reasoning fails for the simple reason that the introduction of important new medicines can be adequately incentivized and rewarded without mark-ups harmful to the poor. Diverse such mechanisms have been discussed in the last decade, at the World Health Organization and in other forums. Let us here focus on one such mechanism that would dramatically improve health outcomes for humankind — not by spending even more money on medicines, but by changing the incentive structure in a way that more equitable and just outcomes are produced. Conceived and critically tested by an international and interdisciplinary team of experts, the Health Impact Fund (HIF) holds out the prospect of massive global health improvements at a net cost that is negligible or even negative.

3. What is the Health Impact Fund?

Financed mainly by governments, the HIF is a proposed pay-for-performance mechanism that would offer innovators the option — no obligation — to register any new medicine or, under certain conditions, also a traditional medicine or a new use of an existing medicine. By registering a product at the time of marketing approval, the innovator would undertake to make it available, during its first 10 years on the market, wherever it is needed at no more than the lowest feasible cost of production and distribution. The innovator would further commit to allowing, at no charge, generic production and distribution of the product after this decade has ended (if the innovator still has unexpired patents on the product). In exchange, the registrant would receive, during those ten years, annual reward payments based on its product's health impact.⁴ Each reward payment would be part of a large annual pay-out — initially perhaps around AUD 6 billion — with every registered product receiving a share equal to its share of the assessed health impact of all HIF-registered products in the relevant

⁴ Health impact can be measured in quality-adjusted life years (QALYs) saved. Giving a patient an additional year in good health is worth one QALY. Appropriate fractions of QALYs are awarded for additional years in less than good health and also for life years in which patients are in better health than would otherwise have been the case. QALY awards for periods longer or shorter than a year are proportionately adjusted. The QALY metric has been refined over the last 20 years and is already extensively used in many contexts, including by public and private insurers for deciding which new drugs to cover.

year. If the HIF were found to work well, its annual reward pools could be scaled up to attract an increasing share of new medicines.

The HIF would greatly mitigate the greatest injustice of the present system by limiting the price of any registered medicine to the lowest feasible cost of production and distribution. This price ceiling would enable the poor majority of humankind to gain immediate access to the fruits of pharmaceutical innovation — either through their own funds or through national health systems, NGOs, international agencies, or insurance programs (all of which would be able to serve more patients more cheaply thanks to much lower medicine prices). In addition, the HIF would foster the development of new high-impact medicines against diseases concentrated among the poor. Pharmaceutical innovators are now neglecting such diseases because they have no realistic hope of recovering their R&D costs from sales to the poor. As a further bonus, the HIF would also motivate registrants to ensure that their products are widely available, perhaps even below the price ceiling, and that they are competently prescribed and optimally used.⁵ Registrants would be rewarded not for merely selling their products, but for making them effective toward improving global health.

If some pharmaceutical R&D were financed through HIF rewards, most of the cost would be borne by affluent populations and people — just like today. But by funding innovation through health impact rewards rather than through patent-protected mark-ups, we affluent avoid the need to exclude the poor. Including the poor in this way costs us nothing because the cost of manufacturing additional doses is covered by the price. The expansion of production may even benefit us through lower unit costs as well as through generally improved global health. The HIF would benefit us affluent also by changing profoundly the marketing and promotion of new medicines. The HIF would pay nothing for the creation or promotion of a “me-too” product that merely takes market share from a competitor’s earlier no-less-effective medicine. And even with a highly superior product, a HIF registrant would make no profit from the sale of its

⁵ A registrant would want to offer its product to poor populations below cost if and insofar as the additional health impact rewards due to reaching additional poor patients are expected to be larger than the loss on the sales price. And a registrant would want to promote the wide and proper use of its product (esp. by those who can benefit the most from it) if and insofar as the additional health impact rewards due to such efforts outweigh their costs.

medicine as such, but would profit only insofar as this medicine were actually made effective toward improving patient health. Thanks to this new incentive, *all* patients would be more likely to receive medicines that will actually improve their condition.

4. The Global Fund, UNITAID, Compulsory Licensing and AMCs – What is the added value of the HIF?

The initiative for and design of the HIF owe much to other global health initiatives, such as the Global Fund, the patent pool initiated by UNITAID, and advance market commitments. The HIF would nonetheless play a unique role that cannot be filled as well by these other approaches. The four initiatives mentioned all fit the label “development aid”: predominantly funded by the affluent, they are designed to benefit poor populations. By contrast, the HIF is jointly funded by rich and poor countries, with each funding partner contributing according to its gross national product. The HIF also benefits rich and poor populations alike through lower drug prices and much greater efforts toward ensuring that medicines are directed to the right patients and used to optimal effect.

While the Global Fund supports large purchases of medicines, it does not aim to incentivize innovation. One might say that its purchases do have an incentive effect: innovators can now expect that, if they develop a high-impact medicine for AIDS, TB or malaria, they will earn money from mark-ups on sales supported by the Global Fund in behalf of poor patients. This is true, but the HIF provides more suitable incentives because its funding is locked in for a longer time period and also because it offers rewards based not on how much a new product can achieve but on how much *more* it can achieve than the current standard of care enjoyed by the various patient groups. The present system provides large rewards to a new medicine that is only slightly better than the treatment that patients would otherwise have had: as buyers (including the Global Fund) switch over to the better medicine, this medicine now comes to earn the entire mark-up. The HIF would reward a new medicine only for the improvement it brings relative to the treatment that patients would otherwise have had. In this way, the

HIF incentivizes innovators to concentrate their efforts to where they can realize the largest *incremental* health benefits. This is not a criticism of the Global Fund, which was not designed as an innovation mechanism. But it shows how the HIF usefully complements the Global Fund by rewarding more accurately the innovation component of new drugs. The Global Fund can then purchase these new drugs without any mark-up. In designing the HIF, we have worked closely with the Global Fund, which is ready to host the HIF in Geneva much like it is now hosting the Medicines for Malaria Venture.

UNITAID has created a patent pool intended to facilitate licensing by pharmaceutical innovators to generic firms, initially limited to HIV/AIDS medicines in specified developing countries and improving access to existing or slightly modified HIV/AIDS treatments. So far, this improvement has typically been tightly limited, excluding the populations of many low- and middle-income countries. The benefits of this pool are likely, over time, to be extended to more countries and more therapies. But the patent pool does not (and is not meant to) stimulate pharmaceutical R&D and therefore does not obviate the need for the HIF. Conversely, the HIF does not obviate the need for the patent pool: even with the HIF in operation, UNITAID's patent pool would continue to be useful for facilitating access by poor people to HIF-unregistered products, including combination therapies.

Similar points apply to compulsory licensing as provided for in the TRIPS Agreement as clarified in the Doha Declaration.⁶ The TRIPS Agreement permits a government to compel a patent holder to license a domestic company to manufacture and sell its medicine, in exchange for a (typically small) licensing fee that is set by the government and paid by the generic manufacturer to the patent holder. The point of compulsory licenses is to enable governments to make important new medicines accessible to their populations. Although compulsory licenses are perfectly legal, they have been issued only rarely — mainly because pharmaceutical companies lobby strongly against them, often by calling upon the support of agencies of their own government (e.g. the office of

⁶ See Article 31 of the 1995 TRIPS Agreement (www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm) and the 2001 Doha Declaration (www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

the US Trade Representative, which can inflict serious penalties upon countries deemed to be hostile to US economic interests presented as free trade principles). Compulsory licenses have given poor patients access to urgently needed medicines; and they might come to do so on a much grander scale if less-developed countries were to combine more effectively against political and economic pressures from the leading pharmaceutical innovator states. But compulsory licenses do have a dampening effect on innovation by creating uncertainty about the extent to which successful innovators will be allowed to profit from their successes. Unlike the HIF, compulsory licenses cannot stimulate innovation (especially against the diseases of the poor), nor can they provide incentives to market and promote medicines for optimal health impact. Even if compulsory licenses were deployed in the best possible way, they would not undermine the need for the HIF.

A leading species of innovation prize, Advance Market Commitments (AMCs) assure profitable sales to developers of a pre-defined vaccine or other medicine. An AMC may legally guarantee, for example, that the first 200 million doses of a new kind of vaccine – if they meet certain specific requirements and are sold into less developed countries at \$3 a dose – are rewarded with an additional subsidy of \$15 per dose. The described AMC would incentivize innovator firms to work hard to collect as much of the \$3 billion prize as possible: by developing a qualifying vaccine more quickly than its competitors and by selling doses of it sooner and faster into the developing world. Though AMCs are more similar to the HIF than the other three mechanisms, they have five significant draw-backs:

1. Each innovation prize targets a specific disease, which is chosen by politicians, bureaucrats, or experts — presumably with an eye to selecting that disease against which the most cost-effective health gains can be achieved. The HIF would let each innovator company decide which disease(s) to target. The latter design is superior because insiders have proprietary information that gives them a much better understanding of how they can reduce the global burden of disease most cost-effectively. Insiders also have powerful incentives to get it right: if they do well in selecting research targets, they will end up with products that will bring

large therapeutic benefits and hence large health impact rewards. Innovation prize designers lack such incentives: they lose nothing by selecting an inferior research target, and lobbying by companies and patient groups may then easily lead them to do just that.

2. Funding of innovation prizes depends on donor willingness, which can easily dry up because the renewals will be for different diseases. Guaranteeing annual reward pools far into the future, the HIF would be a permanent source of pharmaceutical innovation, supporting some 20-30 products at any given time (with 2-3 added and expiring each year). But this advantage comes at a cost: establishing the HIF in the first place is much harder than getting funding for an innovation prize.
3. Innovation prizes must specify rather precisely what is to count as a qualifying innovation. But such a precise “finish line” is difficult to specify optimally in advance of the research that the prize is yet to encourage. Suboptimal specification may lead to no qualifying innovation (with much wasted effort) or to qualifying products that, with a little extra effort, could have been substantially better. The HIF need issue no advance specifications — it simply rewards each registered product according to its health impact.
4. An innovation prize must fix the size of the reward — in the case of an AMC, the size of the subsidy. Since innovators have every reason to conceal and exaggerate the true cost of their R&D, there is a substantial likelihood that an innovation prize, if it motivates successful innovation efforts at all, will pay more than would have been necessary, thereby producing a windfall profit for innovators. HIF rewards would, by contrast, be paid as a self-adjusting rate that reflects innovators’ own and accurate assessment of their R&D costs.⁷ A reward rate perceived as rich would decline as a result of eliciting additional HIF-registrations of newly approved drugs; and a reward rate perceived as puny would increase as a result of discouraging some new HIF-registrations. Such self-adjustment

⁷ This rate might be expressed as a monetary amount per QALY saved.

assures taxpayers that their funds are spent efficiently while also assuring firms that they will earn a decent return on their HIF-registered products.

5. An AMC gives any successful innovator strong incentives quickly to sell doses eligible for the subsidy but no reason to care about what happens to these doses beyond the point of sale. The innovator's earnings are unaffected if some of the sold product is never used, loses its efficacy, is taken by patients who do not benefit from (or are even harmed by) it, or is consumed without adherence to the proper protocol. The HIF, by contrast, would pay according to the product's actual health impact, thereby incentivizing the innovator to take all cost-effective measures toward maximizing this impact: to safeguard freshness, to ensure supply to patients who benefit the most, to instruct medical personnel and patients in how the product is to be taken for optimal effect.

While AMCs can work better than simpler innovation prizes, especially in stimulating the development of new vaccines, the HIF can be much more cost-effective in terms of its impact on patient health.

5. What are the origins of the HIF proposal?

Many people have contributed intellectually and in many practical ways to the development of the HIF proposal. The proposal continues to be explored, improved and refined by the thoughtful suggestions and criticisms of people of various backgrounds. The main way stations that brought the HIF proposal to its present form might be summed up as follows:

1. Abramowicz (2003) first developed a proposal for a reward system with a fixed fund, in which rewards would be based on the proportion of social value created by the innovation, as assessed after the innovation has been commercialized. He considered the possibility that such a system could be (a) mandatory and universal or (b) optional. Rewards were to be conditional on the patentee renouncing patent rights. Abramowicz's lengthy paper (122 pages) built extensively on a 2001 working paper version and analysis of other proposals for prizes for innovation.

2. Love (2003) and Hubbard & Love (2004) proposed the creation of such a mandatory, universal fund with prizes limited to pharmaceuticals (as in Guell & Fischbaum 1995).
3. Hollis (2004) proposed that social value in such a prize mechanism to be measured in QALYs or DALYs, much like the approach taken by the National Institute of Health and Clinical Excellence in the UK and the Australian Pharmaceutical Benefits Scheme.
4. Love (2004) proposed that the period of prize payments could be structured over a fixed number of years, much like US Orphan Drug Act, data exclusivity, etc.
5. Still unaware of any of this earlier work, Pogge (2005) proposed a prize system for drugs that would be voluntary, but without the proportional rewards first suggested by Abramowicz. The paper characterized the ethical properties of such a system. This paper was written during Pogge's year (2003–04) as a research scholar in the Department of Clinical Bioethics at the US National Institutes of Health and was first presented there and at the University of Birmingham (June 2004).
6. Hollis (2005) characterized the economic properties of an optional fund for pharmaceuticals.
7. Hollis & Pogge (2008) described in much greater detail a proposal for an optional fund, in which prices are regulated, but open licensing is not required. This book also describes possible approaches to many other issues of implementation, including determining ownership of the right to rewards, governance structures for the Fund, and methods for determining incremental health benefits. The book was conceived and commenced during a two-week workshop at the ANU (December 2007) at which the name "Health Impact Fund" was coined and in which Hafiz Aziz-ur-Rehman, Christian Barry, Laura Biron, Leila Chirayath, Kieran Donaghue, Jocelyn Finlay, Mike Ravvin, Matt Rimmer, and Michael Selgelid were also participating.

8. Syed (2009) showed that the HIF mechanism need not rely on patents to qualify innovations for rewards.

All persons involved in working on the Health Impact Fund proposal deeply appreciate the important contributions others have made to it. Our concern is not to take credit for, or ownership of these ideas, but to bring them to life for the benefit of humanity. The HIF is still a work in progress, and we continue gratefully to receive all criticisms and suggestions toward refining and improving the proposal toward its realization.

6. Who is supporting the HIF?

The development of the Health Impact Fund proposal has been supported by a ARC Discovery Grant that Pogge led with Judith Whitworth, who was then the Director of ANU's John Curtin School of Medical Research; by a grant from the British BUPA Foundation; by the Canadian Institutes of Health Research; by Yale University's MacMillan Center; and by a grant from the European Commission, which funded a collaboration ("Innova-P2") of teams in seven countries, including India, China, Australia and the Philippines. Many others have given time, thoughts and publicity to the HIF project and specifically to the registered NGO *Incentives for Global Health* (www.incentivesforglobalhealth.org) that is now spearheading the effort to get the HIF on the international political agenda.

IGH is supported by a very distinguished Advisory Board consisting of John J. DeGioia, President of Georgetown University; Ruth Faden, the Philip Franklin Wagley Professor of Biomedical Ethics, Johns Hopkins University and Director of the Johns Hopkins Berman Institute of Bioethics; Paul Farmer, Chair of the Department of Global Health and Social Medicine at the Harvard Medical School, Chief of the Division of Global Health Equity at Brigham and Women's Hospital in Boston, co-founder of Partners in Health, and recipient of a MacArthur Genius Award; Jim Yong Kim, President of Dartmouth College, former Director of the WHO HIV/AIDS department and co-founder of Partners in Health; Paul Martin, former Prime Minister of Canada; Christopher Murray, Director of the Seattle Institute for Health Metrics and Evaluation (IHME), former Executive Director of the WHO Evidence and Information for Policy Cluster and former Director of the

Harvard Center for Population and Development Studies; Baroness Onora O'Neill, member of the UK House of Lords and formerly Chair of the Nuffield Foundation, President of the British Academy and Principal of Newnham College, Cambridge University; James Orbinski, Associate Professor of Medicine and Political Science at the University of Toronto, former International President of Médecins Sans Frontières, accepting the 1999 Nobel Peace Prize on behalf of MSF; co-founder of Drugs For Neglected Diseases Initiative (DNDi) and founder and Board Chair of Dignitas International; Sir Michael Rawlins, Chair of the UK National Institute of Health and Clinical Excellence (NICE); Karin Roth, Member of the German Bundestag (parliament); Amartya Sen, Lamont University Professor at Harvard University, former Master of Trinity College, Cambridge University, and winner of the 1998 Nobel Prize in Economics; Peter Singer, Ira W. DeCamp Professor of Bioethics and named as one of the world's 100 most influential people by Time Magazine (2005); Judith Whitworth, former Director of The John Curtin School of Medical Research and Australian Capital Territory Australian of the Year for 2004; Heidemarie Wieczorek-Zeul, Member of the German Bundestag (parliament) and former Federal Minister for Economic Cooperation and Development (1998–2009); Richard Wilder, Associate General Counsel of the Bill & Melinda Gates Foundation, formerly Associate General Counsel for Intellectual Property Policy at Microsoft and Director of the WIPO Global Intellectual Property Issues Division. Further details about IGH, specifically its Scientific Advisory Committee and its Management Team can be found at www.yale.edu/macmillan/igh/about.us.html.

7. What next?

To realize the enormous potential of the HIF for global health, we must overcome two hurdles. The first is to establish a partnership of countries willing to underwrite the HIF through long-term funding commitments. These are necessary to create stable new innovation incentives. It can take ten years or more for a research project to result in a new medicine approved for sale. It takes another ten years for the innovator firm to collect its annual health impact rewards for this drug. To project its full incentive power, the funding of the annual HIF pools must then be guaranteed at least twenty years out. This would

be a novelty in global health funding: currently, funders at best commit only some three years into the future (as with the Global Fund); and their commitments are soft, that is, statements of intent that are sometimes simply withdrawn (as happened recently with Germany's contribution commitment to the Global Fund).

Is it realistic to expect governments to make binding long-term funding commitments in global health? In the wake of the global financial crisis, governments are especially concerned to spend their scarce funds efficiently. And they would realize, of course, that the incentive power of the HIF would be diminished if potential innovators discounted future rewards by the probability that these will not be actually available for disbursement. Therefore, if governments agree to create the HIF at all, then they are likely to back it with a proper treaty mechanism so as fully to reassure innovators that any successful efforts they make will be rewarded. The treaty would of course include an exit option, but one that involves a substantial lead time as needed to leave innovation incentives undisturbed (see Hollis & Pogge 2008, pp. 46–7). Such a treaty might simply commit each partner country to an annual contribution fixed as a percentage of its gross national income.⁸ If this contribution were fixed at 0.03 percent, then countries with a combined GNI of AUD 20 trillion would be needed to launch the fund with the desired annual pool size of AUD 6 billion.

We are fortunate to have found enlightened backers in some pharmaceutical companies and also in politics. The parliamentary delegation of the German Social Democratic Party (SPD) – including IGH Advisory Board members Heidemarie Wieczorek-Zeul and Karin Roth – has officially endorsed the HIF and also initiated various important seminars on the HIF, including one in the European Parliament (April 11, 2011) that was sponsored by MEP Norbert Neuser and attended by numerous prominent politicians including EU Commissioner for Development Andris Piebalgs. On the basis of this meeting, we expect more outreach to other Social Democratic and Labour Parties in Europe as well as to Green Parties which have also shown an interest in the way the

⁸ Another option would be to fund the HIF through a financial transactions tax, a carbon tax, or a global resources dividend. On the latter, (see Pogge 2008, ch. 8).

current intellectual property regime burdens the world poor populations. And there is considerable political support in other countries as well, including India, where former President Dr. A. P. J. Abdul Kalam has become a friend of the HIF, addressing our last Innova-P2 meeting there on May 12, 2011.⁹

We are currently involved in an effort to win sponsorship for an official side event at the UN General Assembly meeting on non-communicable diseases, September 18-20, 2011, in New York.

8. The need for pilots

The second hurdle is related to the first. Governments will muster the political will to create the HIF only if they are convinced that it would work. In this regard, their main concern is the measurement of health impact. Is it really possible, at reasonable cost, credibly to assess the therapeutic benefits of a new medicine in poor and rich countries around the world? The best way to reassure governments and innovators on this point is to conduct a “pilot” of the HIF concept. Such a pilot would consist of a contractual arrangement in which a firm is rewarded explicitly on the basis of assessed health impact for one product in a single jurisdiction. Depending on the size of the jurisdiction and the volume of drug sales, a pilot could be run at a relatively low cost.

A pilot would demonstrate the feasibility of reliable health impact assessment and show the effect on behavior of rewarding a firm according to health impact rather than through mark-ups. A pilot would also provide practical evidence on the best methods for assessing health impact and opportunities to learn how to write contracts governing rewards based on health impact.

In a suitable pilot, a firm would agree to reduce the price of a newly launched (or existing) product in one jurisdiction, which could be a city, province, country, or region. In exchange, it would receive rewards based on its product’s measured

⁹ See the speech here:

www.abdulkalam.com/kalam/jsp/display_content_front.jsp?menuid=28&menuname=Speeches%20/%20Lectures&linkid=68&linkname=Recent&content=1821&columnno=0&starts=0&menu_image=-&contentsForum=Address%20at%20the%20International%20Conference%20on%20Equity%20and%20Access%20to%20Medicine%20Research%20and%20Information%20System%20%208RIS%29

health impact. The incentives should be designed so that, if the firm appropriately responds to them (enhancing the health impact of its product by safeguarding freshness, focusing on patients who benefit the most and promoting proper adherence to treatment protocol), its profits would be no less than what they would be without the pilot. For example, in the case of an anti-retroviral (ARV), a firm would receive no reward for patients switched from an equally effective ARV, small rewards for patients switched from a less effective ARV with greater toxicity and therefore typically lower compliance, and large rewards for patients who had previously had no treatment at all. The scheme of rewards would be agreed with the firm in advance.

Our preparations for pilots were concentrated around two major meetings. In April 2010, we made substantial progress on the measurement of health impact at a collaborative workshop with many health economists and epidemiologists at the National Institute for Health and Clinical Excellence (NICE) in London. Concrete pilot possibilities were then discussed at a three-day workshop held in May 2011 at the Rockefeller Foundation's conference center in Bellagio with experts in epidemiology, health economics, health outcomes, and trial design from Canada, China, Colombia, India, Mexico, South Africa, the UK, the US, and Vietnam. The latter Workshop settled on the following five desiderata.

1. A pilot must involve a change in practice — ideally in the introduction of a new drug or a reduction in price — that has a measurable impact on health. To be measurable, impact must be substantial and capable of being documented with suitable evidence. If the pilot involves a reduction in the price of an existing drug, the health impact may arise from improved take-up of the drug due to increased volume or due to a shift in take-up toward patients who benefit more.
2. A pilot should be cost-effective from a health or humanitarian perspective, that is, should lead to measurable health improvements at reasonable cost. Here it is helpful that, because the rewards paid to the firm are based on assessed health benefits, their cost-effectiveness is

known in advance. If the firm's efforts to enhance the health impact of its product bear little fruit, the cost of the pilot is correspondingly reduced.

3. A pilot must be feasible in a defined area so that its cost can be controlled by limiting the territory in which data on health outcomes and drug usage must be obtained.
4. A pilot should not undermine market competition. When a firm is rewarded for selling at a low price, it may be able to undercut other firms in the market. This unfairness should be avoided by ensuring that, if a product is already available generically, all firms selling this product are offered the same rewards. Even if the product is not yet available generically, the rewards should be designed so that they do not inhibit generic entry in the future.
5. To demonstrate the feasibility of the HIF, several pilots should be run. There is great international diversity in conditions relevant to health impact assessment, including diversity in the availability, reliability and cost of data, in the prevalence of insurance coverage, in the extent to which medicines are supplied through the private sector, and in the extent to which prescriptions are required. Moreover, medicines themselves differ in various important ways, such as mode of action, time lag, risk of product deterioration, and importance of compliance. A variety of pilots, involving different medicines and diverse locations, would provide much better preparation for the creation of the HIF than any single pilot could.

Two promising pilot projects have emerged from the Bellagio Workshop, and we are now involved in hammering out a specific pilot plan that is acceptable to the company whose product is to be marketed in the new way, to the funder(s) of the health impact assessments and reward payments, and to the relevant political authorities in the pilot jurisdiction.

9. Conclusion: Joining forces for justice in global health

The current international system for encouraging pharmaceutical innovation is highly inefficient because the rewards it offers are only very tenuously related to health outcomes (see Pogge 2011a). This system is unsustainable as even the wealthiest countries cannot afford skyrocketing health care costs forever. The HIF is a concrete proposal for tying cost to therapeutic benefits in the important domain of pharmaceutical innovations. The HIF is not cheap, and its creation therefore involves financial and political risks. These risks can be greatly reduced through appropriate pilots. The paramount task now is to gather financial and political support for a suitable set of pilots, each of which requires a willing firm, a cooperative jurisdiction, funding for the reward payments and funding for the health impact assessment. Fortunately, these pilots have their own intrinsic value by delivering health improvements at reasonable cost. But their potentially much greater value consists in preparing the way for the HIF itself which could be an amazing revolution in global health and a concrete model of a just global institution. If it works as expected, the medicines it supports would bring enormous health gains, especially in the world's poorer areas, even while its net costs would be negligible or (more likely) negative. While funding the HIF, taxpayers would save through reduced expenses on public health facilities, foreign aid, insurance premiums and private drug purchases. They would save expenses for costly hospitalizations averted by timely and effective pharmacological interventions. And they would benefit most of all from the diffuse economic effects of a massive reduction in the global burden of disease. Last and foremost, we would have taken an important step toward global justice by reducing the artificial exclusion of poor people from the fruits of pharmaceutical R&D. We ask politicians and potential funders to help us explore this great opportunity through a set of suitable pilots.

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