

A decorative graphic consisting of a grid of grey dots of varying sizes, with several dots highlighted in red. The dots are arranged in a pattern that roughly outlines the shape of a globe or a map of the world.

Getting the Incentives Right: The Health Impact Fund

A Concrete Contribution to Global Justice
and an Innovation in Global Health

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- The human right to health, enshrined in Article 25 of the Universal Declaration of Human Rights, is fundamental because health is an important precondition for the realization of most other human rights.
- Shortfalls in the realization of this human right are highly correlated with poverty: most of today's morbidity and premature mortality are poverty-related. Most poverty is undeserved: at least 80 % of global income variability is explained by a person's initial country and class which profoundly affect human beings from the moment of conception.
- Avoidable health deficits result in avoidable suffering, lack of physical and mental functioning, as well as premature death on a massive scale. Because most of these medical conditions cause economic losses that are much larger than what it would have cost to avoid or adequately treat these conditions, realizing the human right to health would actually *increase* human economic prosperity overall.
- This point is especially obvious in regard to the current international system for encouraging pharmaceutical innovation, whose incentives are only tenuously related to health outcomes. This system is unsustainable as even the wealthiest countries cannot afford skyrocketing health care costs forever. There are huge collective gains waiting to be realized through reform of how we reward the development of new medicines.
- The Health Impact Fund (HIF) is a concrete proposal for how, in the important domain of pharmaceutical innovation, medical costs can be meaningfully tied to therapeutic benefits.



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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 countless deaths among poor people 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 % of global income variability is explained by a person's initial country and class.² 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 per cent of global private wealth³ and six per cent of global household income. Average income in the top 5 per cent of humanity is 9.3 times the global average, while average income in the bottom quarter is 1/32 of the global average. So one person in the top 5 per cent has as

much income, on average, as 300 people in the bottom quarter.⁴

Poverty strongly affects health: Even in affluent European countries, the life expectancy of the poorest groups is considerably below that of the richest. Globally, health disparities are vastly greater as avoidable health deficits are highly correlated with poverty. Most of today's morbidity and premature mortality are poverty-related. Those whose right to health is unfulfilled are overwhelmingly poor. This right, enshrined in Article 25 of the Universal Declaration of Human Rights, is a fundamental human right because health is an important precondition for the realization of most other human rights. Large shortfalls in its realization result in avoidable suffering, lack of physical and mental functioning and premature death on a massive scale. Most of these avoidable medical conditions cause economic losses that are much larger than what it would have cost to avoid them or to treat them adequately. Realizing the human right to health would thus not merely fulfil a preeminent moral responsibility, but also *increase* human economic prosperity overall.

A second, independent problem with the mentioned defence 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 affluent countries should subsidize advanced medicines for the poor. Rather, the question is whether affluent countries may promote the enforcement of temporary monopolies that foreseeably make advanced medicines inaccessible to a majority of humankind.

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 competitive manufacture and sale of generic versions of »their« products. In defence of this practice it has been argued that the manufacture and sale of generic pro-

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 World Health Organization: »WTO and the TRIPS Agreement«, available at www.who.int/medicines/areas/policy/wto_trips/en/index.html.

2. Branko Milanovic: »Global Inequality of Opportunity: How much of our income is determined at birth?«, available at <http://microdata.worldbank.org/lms/index.php/citations/904>.

3. See Credit Suisse, *Global Wealth Report*, p. 3, and *Global Wealth Databook*, both available at <https://responsibility.credit-suisse.com/app/article/index.cfm?fuseaction=OpenArticle&aoid=291405&coid=284071&lang=EN>.

4. 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 Branko Milanovic: »True World Income Distribution, 1988 and 1993: First Calculation Based on Household Surveys Alone«, *The Economic Journal* 112 (2002), 51-92; Branko Milanovic: *Worlds Apart: Measuring International and Global Inequality* (Princeton: Princeton University Press 2005); Branko Milanovic, *The Haves and the Have-Nots: A Brief and Idiosyncratic History of Global Inequality* (New York: Basic Books 2011).

ducts 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.⁵

2. A Question 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.

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 so as to produce more equitable and just outcomes. 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, 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.⁶ Each reward payment would be part of a large annual pay-out – initially perhaps around EUR 4.5 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 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 bring enormous moral gains:

- It would greatly mitigate the most obvious 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).
- 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.
- The HIF would also motivate registrants to ensure that their products are widely available, perhaps

5. And, if there were such a moral right, does it last exactly as long as the local patent law protects it? For a more detailed discussion, see Aidan Hollis and Thomas Pogge: *The Health Impact Fund: Making New Medicines Accessible for All* (Oslo and New Haven: Incentives for Global Health 2008, freely available at www.healthimpactfund.org), chapter 6.

6. 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.

even below the price ceiling, and that they are competently prescribed and optimally used.⁷ 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, people in affluent countries avoid excluding the poor. Including the poor in this way costs nothing because the cost of manufacturing additional doses is covered by their price. The expansion of production may even benefit the affluent through lower unit costs as well as through generally improved global health. The HIF would benefit the 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 receive no reward for mere sales but would profit only insofar as its 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 owes 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 accor-

ding 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 *does* 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. The HIF has been designed in close collaboration 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, the pool is 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,

7. 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. 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.

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.⁸ 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 the US Trade Representative, which can inflict various 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 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 developers of a pre-defined vaccine or other medicine of profitable sales. 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 are inferior in five significant ways:

- (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, by contrast, 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 needs no advance specifications – it simply rewards each registered product according to its health impact.

8. 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).

- (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 at a self-adjusting rate that reflects the innovators' own and accurate assessment of their R&D costs.⁹ A reward rate perceived as rich would decline as a result of eliciting additional HIF-registrations; and a reward rate perceived as puny would increase as a result of discouraging some new HIF-registrations. Such self-adjustment 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 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 and 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 global health.

5. What Next?

To realize these gains, two hurdles must be overcome. 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.¹⁰ Such a treaty might simply commit each partner country to an annual contribution fixed as a percentage of its gross national income.¹¹ If this contribution were fixed at 0.03 per cent, then countries with a combined GNI of EUR 15 trillion would be needed to launch the fund with the desired annual pool size of EUR 4.5 billion.

The financial crisis has unpleasantly demonstrated that regulatory regimes designed in regard to short-term concerns may be unsustainable and cause huge financial and social costs in the medium to long term. This is as true for world health as for global finance. It is high time to work toward structural reforms that secure equitable outcomes in the long term. Answering this challenge, the HIF can be a model for institutional reforms in other domains.

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

10. See Hollis and Pogge 2008 (note 5), 46-47.

11. Another option would be to fund the HIF through a financial transactions tax, a carbon tax, or a global resources dividend.

6. 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? Substantial progress in this regard was made in April 2010 at a collaborative workshop with many health economists and epidemiologists at the National Institute for Health and Clinical Excellence (NICE) in London. But full reassurance of governments and innovators requires conducting »pilots« of the HIF concept. Each 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 scale of the jurisdiction and the prevalence of the target disease, a pilot could be run at a relatively low cost.

A pilot would show whether health impact can be reliably assessed at reasonable cost and also how an innovator firm behaves differently when it is rewarded according to health impact rather than through a markup built into the price of its product. A pilot would also provide practical evidence on the best methods for assessing health impact and provide an opportunity 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 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 net profits would be no less than what they would be without the pilot. The firm's sales would be rewarded differentially: it would receive no reward for patients switched from an equally effective drug, small rewards for patients switched from a less effective drug (e. g. one with greater toxicity and therefore typically lower compliance), and large rewards for patients switched from no treatment at all. The scheme of rewards would be agreed with the firm in advance. Several promising

pilot possibilities emerged from a workshop held in May 2011 at the Rockefeller Foundation's conference centre 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. Each pilot will share with the HIF itself the desirable property that its costs are straightforwardly related to its health impact. The cost of each pilot is unknown in advance, but it is known that, the more it will cost, the more health gains it will have produced.

7. In 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.¹² 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. Were it to work as expected, the medicines it supports would bring enormous health gains, especially in the world's impoverished 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 pharmacological interventions. And they

12. See Thomas Pogge: »The Health Impact Fund: enduring innovation incentives for cost-effective health gains«, in *Social Europe Journal* 5/2 (Winter 2010/2011), 5-9, www.social-europe.eu/2011/01/the-health-impact-fund-enduring-innovation-incentives-for-cost-effective-health-gains/#comments.



would benefit most of all from the diffuse economic effects of a massive reduction in the global burden of disease. For the poor in less-developed countries the HIF would bring significant health gains, especially in regard to neglected diseases which are currently underfunded in pharmaceutical research.

Politicians and potential funders should join forces in initiating suitable pilots and in creating the Health Impact Fund as a global institution that brings justice to global health.



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