The Health Impact Fund: Boosting Pharmaceutical Innovation Without Obstructing Free Access

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In an earlier piece in these pages,[1] I described the health effects of the still massive problem of global poverty: The poor worldwide face greater environmental hazards than the rest of us, from contaminated water, filth, pollution, worms, and insects. They are exposed to greater dangers from people around them, through traffic, crime, communicable diseases, sexual violence, and potential exploitation by the more affluent. They lack means to protect themselves and their families against such hazards, through clean water, nutritious food, satisfactory hygiene, necessary rest, adequate clothing, and safe shelter. They lack the means to enforce their legal rights or to press for political reform. They are often obliged by dire need or debt to incur additional health risks, by selling a kidney, for instance, or by accepting hazardous work in prostitution, mining, construction, domestic service, and textile and carpet production. They lack financial reserves and access to public sources of medical knowledge and treatments, and therefore face worse odds of recovering from disease. Mutually reinforcing, all these factors ensure that the poor bear a hugely disproportional burden of disease—especially of communicable, maternal, perinatal, and nutritional conditions—and a hugely disproportional share of premature deaths: One third of all deaths each year, 18 million, are from poverty-related causes. These much greater burdens of morbidity and premature mortality in turn entail large economic burdens that keep most of the poor trapped in lifelong poverty.

This cycle of mutually reinforcing poverty and disease can be broken by reducing or eradicating severe poverty. I have argued that this can be done effectively by reforming various features of existing global institutional arrangements that—beneficial to the affluent and maintained by them—contribute greatly to the persistence of poverty.[2] But it is also possible to make substantial progress against the global burden of disease (GBD) more directly: Existing huge mortality and morbidity rates can be dramatically lowered by reforming the way the development of new medical treatments is funded. I will sketch a concrete, feasible, and politically realistic reform plan that would give medical innovators stable and reliable financial incentives to address the diseases of the poor. If adopted, this plan would not add much to the overall cost of global healthcare spending. In fact, on any plausible accounting, which would take note of the huge economic losses caused by the present GBD, the reform would actually save money. Moreover, it would distribute the cost of global healthcare spending more fairly across countries, across generations, and between those

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lucky enough to enjoy good health and the unlucky ones suffering from serious medical conditions.

Medical progress has traditionally been fueled from two main sources: government funding and sales revenues. The former—given to universities, corporations, other research centers and governmental research facilities such as the U.S. National Institutes of Health—has typically been *push* funding focused on basic research. Sales revenues, usually earned by corporations, have mostly funded more applied research, resulting in the development of specific medicines. Sales revenues, by their nature, constitute *pull* funding: An innovation has to be developed to the point of marketability before any sales revenues can be realized from it.

With medicines, the fixed cost of developing a new product is extremely high for two reasons: It is very expensive to research and fine-tune a new medicine and then to take it through elaborate clinical trials and national approval processes. Moreover, most promising research ideas fail somewhere along the way and thus never lead to a marketable product. Both factors combine to raise the research and development cost per new marketable medicine to somewhere around half a billion dollars or more. Commencing manufacture of a new medicine once it has been invented and approved is cheap by comparison. Because of this fixed-cost imbalance, pharmaceutical innovation is not sustainable in a free market system: Competition among manufacturers would quickly drive down the price of a new medicine to near its long-term marginal cost of production, and the innovator would get nowhere near recovering its investment.

The conventional way of correcting this market failure of undersupply is to award innovators intellectual property rights that entitle them to bar competitors or to charge them licensing fees. Either way, the result of such monopolies is an artificially elevated sales price that enables innovators to recoup their initial investment through selling products that, even at prices far above marginal cost, are in high demand.

Monopolies are widely denounced by economists as inefficient and by ethicists as an immoral interference in people's freedom to produce and exchange. In regard to patents, however, many believe that the curtailment of individual freedom can be justified by the benefit, provided patents are carefully designed. One important design feature is that patents confer only a temporary monopoly. Once the patent expires, competitors can freely enter the market with copies of the original innovation and consumers need thus no longer pay a high mark-up over the competitive market price. Temporal limits make sense, because additional years of patent life barely strengthen innovation incentives: At a typical industry discount rate of 11% per annum, a 10-year effective patent life generates 69% of the profit (discounted to present value) that a permanent patent would generate and a 15-year effective patent life 83% of that profit.[3] It makes no sense to impose monopoly prices on all future generations for the sake of so slight a gain in innovation incentives.

During the life of the patent, everyone is legally deprived of the freedom to produce, sell, and buy a patented medicine without permission from the patent holder. This restraint hurts generic producers and it also hurts consumers by depriving them of the chance to buy such medicines at competitive market prices. But consumers also benefit from the impressive arsenal of useful medicines whose development is motivated by the prospect of monopoly rents.

When everyone has access to vital new medicines as needed, the loss may seem to be dwarfed by the benefit. But billions of human beings are too poor to afford medicines at monopoly prices and therefore cannot share the benefit of a patent regime. This benefit of pharmaceutical innovation thus cannot be used to justify to them that they should be cut off from medicines at competitive market prices.

This moral point was largely respected so long as strict patent rules were mostly confined to the affluent states while the less developed countries were allowed to have weaker patent protections or none at all. The situation changed in 1994, when a powerful alliance of industries (software, entertainment, pharmaceuticals, and agribusinesses) pressured the governments of the richest states to impose globally uniform intellectual property rules as enshrined in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The poorer states agreed to institute TRIPS-compliant intellectual property regimes in order to qualify for membership in the World Trade Organization, which (they were then promised) would allow them to reap large benefits from trade liberalization.[4]

The global poor have a powerful objection to the pharmaceutical patent regime imposed on them by the world's governments: If the freedom to produce, sell and buy advanced medicines were not curtailed in our countries, then the affluent would need to find other (for them possibly less convenient) ways of funding pharmaceutical research. Advanced medicines would then be available at competitive market prices, and we would have a much better chance of getting access to them through our own funds or with the help of national or international government agencies or nongovernmental organizations. The loss of freedom imposed through monopoly patents thus inflicts on us a huge loss in terms of disease and premature death. This loss cannot possibly be justified by any gain that monopoly patents may bring to the affluent. However morally compelling, this objection is ignored by the more affluent states, which relentlessly pursue the globalization of uniform intellectual property rights—with devastating effects, for instance, on the course of the AIDS epidemic.

The world responds to the catastrophic health crisis among the global poor in a variety of ways, with the usual declarations, working papers, conferences, summits, and working groups, of course, but also with efforts to fund delivery of medicines to the poor through *intergovernmental initiatives* such as 3 by 5,[5] through *governmental programs* such as the U.S. president's Emergency Plan for AIDS Relief, through *public-private partnerships* like the Global Alliance for Vaccines and Immunization and the Global Fund to Fight AIDS, Tuberculosis and Malaria, and through medicine donations from pharmaceutical companies, and with various efforts to foster the development of new medicines for the diseases of the poor, such as the Drugs for Neglected Diseases Initiative, the Institute for One World Health, the Novartis Institute for Tropical Diseases, and various prizes, advance market commitments (AMCs), and advance purchase commitments.[6]

Such a busy diversity of initiatives looks good and creates the impression that a lot is being done to solve the problem. And most of these efforts are really doing good by improving the situation relative to what it would be under TRIPS unmitigated. Still, these efforts are not nearly sufficient to protect the poor. It is unrealistic to hope

that enough billions of dollars will be collected to neutralize the cost imposed on the world's poor by the globalization of monopoly patents. And it is even more unrealistic to hope that such billions will reliably and efficiently be spent year after year. It makes sense then to look for a more systemic solution that addresses the global health crisis at its root. Involving institutional reform, such a systemic solution is politically more difficult to achieve. But, once achieved, it is also politically much easier to maintain. And it preempts most of the huge and collectively inefficient mobilizations currently required to produce the many stop-gap measures, which can at best only mitigate the effects of structural problems they leave untouched.

The quest for such a systemic solution should start from an analysis of the main drawbacks of the newly globalized monopoly patent regime.

High Prices

While a medicine is under patent, it will be sold at the profit-maximizing monopoly price, which is largely determined by the demand curve of the affluent. When wealthy people really want a drug, then its price can be raised quite high above the cost of production before increased gains from enlarging the markup are outweighed by losses from reduced sales volume. With patented medicines, markups in excess of 1000% are not exceptional. At such monopoly prices, the poor can have access only through the charity of others.

Neglect of Diseases Concentrated among the Poor

Under a monopoly patent regime, such diseases—no matter how widespread and severe—are not attractive targets for pharmaceutical research. This is so because the demand for such a medicine drops off very steeply as the patent holder enlarges the markup. There is no prospect, then, of achieving high sales volume *and* a large markup. Moreover, there is the further risk that a successful research effort will be greeted with loud demands to make the medicine available at marginal cost or even for free, which would force the innovator to write off its initial investment as a loss. In view of such prospects, biotechnology and pharmaceutical companies predictably prefer even the trivial ailments of the affluent, such as hair loss and acne, over tuberculosis and sleeping sickness. This problem of neglected diseases is also known as the 10/90 problem, alluding to only 10% of all pharmaceutical research being focused on diseases that account for 90% of the GBD.

Bias toward Symptom Relief

Medicines can be sorted into three categories: Curative medicines remove the disease from the patient's body, symptom-relieving medicines improve well-being and functioning without removing the disease, and preventative medicines reduce the likelihood of contracting the disease in the first place. Under the existing monopoly patent regime, symptom-relieving medicines are by far the most profitable, with the most desirable patients being ones who are not cured and do not die (until after patent expiration). Such patients buy the medicine week after week, year after year, delivering vastly more profit than would be the case if they derived the same health benefit from a cure or vaccine. Vaccines are least lucrative because they are typically bought by governments, which can command large volume discounts. This is highly regrettable, because the

health benefits of vaccines tend to be exceptionally great, as vaccines protect from infection or contagion not merely each vaccinated person but also their contacts. Once more, then, the present regime guides pharmaceutical research in the wrong direction—and here to the detriment of poor and affluent alike.

Wastefulness

Under the present regime, innovators must bear the cost of filing for patents in dozens of national jurisdictions and then also the cost of monitoring these jurisdictions for possible infringements of their patents. Huge amounts are spent in these many jurisdictions on costly litigation that pits generic companies, with strong incentives to challenge any patent on a profitable medicine, against patent holders, whose earnings depend on their ability to defend, extend, and prolong their monopoly rents. Even greater costs are due to the deadweight loss "on the order of $200bn" that arises from blocked sales to buyers who are willing and able to pay some price between marginal cost and the much higher monopoly price.[7]

Counterfeiting

Very large markups also encourage the illegal manufacture and sale of medicines. Even when such illegal drugs are pharmacologically fully equivalent, they reduce innovator profits and thereby undermine research incentives. When they are not fully equivalent (e.g., diluted, adulterated, inert, or even toxic), they endanger patient health. This danger exists wherever patients take very expensive medicines.

Excessive Marketing

When pharmaceutical companies can maintain a very high markup, they find it rational to make extensive special efforts to increase sales volume by influencing physicians' prescription patterns. This produces pointless battles over market share among similar ("me-too") drugs as well as gifts that induce doctors to prescribe medicines even when these are not indicated or when competing medicines are likely to do better. With a large markup it also pays to fund massive direct-to-consumer advertising that persuades people to take medicines they do not really need for diseases they do not really have (and sometimes for invented pseudo diseases).[8]

The Last-Mile Problem

While the present regime provides strong incentives to sell the affluent patented medicines they do not need, it provides no incentives to ensure that poor people benefit from medicines they do need. On the contrary, when a medicine's target disease continues to thrive among the poor, then more of this medicine can be sold to the affluent and at higher prices. A company does not profit from ensuring that poor patients have cheap access to its medicines and take such medicines in the right doses, at the right times, for the appropriate length of time. As a result, even medicine donations often do more harm than good as poor compliance renders target diseases more resistant to the medicine in question. The emergence of highly drug resistant disease strains—of tuberculosis, for instance—poses dangers to us all.

All seven drawbacks can be greatly mitigated by supplementing the patent regime with a complementary source of incentives and rewards for developing new medicines. With an international interdisciplinary team, I have been detailing such a mechanism in the form of a *Health Impact Fund* (HIF).

This proposed fund is a global agency, underwritten by governments, that offers to reward the patentee of any new medicine, during its first decade or so,[9] with annual payments proportional to this medicine's demonstrated global health impact. Registering a medicine with the Fund is voluntary for the patentee and requires a concession affecting its price. This concession may be specified in two ways or as a disjunction of both. The patentee might be required permanently to waive claims to market exclusivity on a medicine worldwide, enabling generic competition that would drive the medicine's price down to near long-run marginal cost of production.[10] Or the innovator might be required, during the specified reward period, to sell the medicine at a similarly low price (designated by the HIF) and then afterward to offer zero-priced licenses of relevant technology required for manufacturing and selling the product. Either way, innovators would gain for each of their new medicines the option of forgoing monopoly rents in favor of an alternative path that would provide ample rewards for the development of new high-impact medicines without excluding the poor from their use.[11]

With the HIF in place, pharmaceutical innovators would analyze possible research projects under two competing scenarios. Under scenario 1, the firm would seek the optimal exploitation of its monopoly powers: It would patent the medicine in the optimal set of jurisdictions, take optimal steps to enforce and extend its patent rights, and optimally price and market the medicine to affluent consumers and their physicians. Under scenario 2, the firm would seek the optimal exploitation of its HIF entitlements: It would take optimal steps to ensure that the medicine is widely and effectively used by any patients who can benefit from it. Some potential products might be viable under only one of these scenarios: Products tackling hair loss or acne would be unprofitable on the HIF track whereas products combating tropical diseases are unprofitable on the monopoly track. By contrast, medicines for HIV/AIDS or heart disease might be viable on either track, and with such drugs the innovator's decision will depend on the expected magnitude and perceived reliability of HIF rewards.

A standing HIF reward option can be described as a *comprehensive* AMC.[12] The novelty is that the reward is not disease specific and therefore much less vulnerable to lobbying by firms and patient groups. Conventional AMCs[13] and prizes must moreover define a precise finish line, specifying at least what disease the medicine must attack, how effective and convenient it must minimally be, and how bad its side effects may be. Such specificity is problematic because it presupposes the very knowledge whose acquisition is to be encouraged. Because sponsors lack this knowledge ahead of time, their specification is likely to be seriously suboptimal, even if they are single-mindedly devoted to the goal of improving public health. Such suboptimality can take two forms. The planners may be too demanding with respect to at least one parameter, with the result that firms give up the effort even though something close to the sought medicine is within their reach. Or the planners may be insufficiently demanding with respect to some parameter(s), with the result that firms, to save time and expense, deliver a medicine that is just barely good enough to win even when they could have done much better at little extra cost.[14]

The proposed Health Impact Fund, by contrast, simply offers to reward

any new medicine that works, in proportion to how well it works, provided only that the innovator makes the price-lowering concession. Let me sketch how such a fund would provide a systemic solution to the seven problems.

Diseases concentrated among the poor, insofar as they substantially contribute to the GBD, would no longer be neglected. In fact, the more destructive ones among them would come to afford some of the most lucrative research opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies currently enjoy.

Bias toward symptom relief would be absent from HIF-encouraged research. The HIF assesses each registered medicine's health impact in terms of how its use reduces mortality and morbidity worldwide—without regard to whether it achieves this reduction through cure, symptom relief, or prevention. This would guide biotechnology and pharmaceutical companies to deliberate (under scenario 2) about potential research projects in a way that is also optimal in terms of global public health—namely, in terms of the expected global health impact of the new medicine relative to the cost of developing it. The profitability of research projects would be aligned with their cost effectiveness in terms of global public health.

High prices would not exist for HIF-registered medicines, and innovators would typically not even wish for a higher price on their HIF-registered medicines. The reason is that a higher price would greatly reduce a drug's health impact rewards by impeding access to this drug by the very poor who make up about half the human population. On the HIF track, health benefits to the poorest of patients count equally with health benefits to the richest.

Wastefulness would be dramatically lower for HIF-registered medicines. There would be no deadweight losses from high markups. There would be little costly litigation as innovators would welcome generic competitors who, by increasing access to the medicine, would boost the innovator's health impact reward. Given this situation, innovators might often not even bother to obtain patents in many national jurisdictions. To register a medicine with the HIF, innovators need show *only once* that they have a patentable product.

Counterfeiting would be much less attractive for HIF-registered medicines. With the genuine item widely available near marginal cost of production, much less profit can be made from producing and selling fakes.

Excessive marketing would also be much reduced for HIF-registered medicines. Because each innovator is rewarded for the health impact of its addition to the medical arsenal, innovators get no reward for switching patients over to a new drug that is no better than its predecessor. Its patentee would consequently never register it with the HIF. Innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as such marketing results in measurable therapeutic benefits for which the innovator would then be rewarded.

The last-mile problem would be mitigated because each HIF-registered innovator would have incentives to ensure that patients are fully instructed and properly provisioned so that they make optimal use (dosage, compliance, etc.) of its medicines, which will then, through wide and effective deployment, have their optimal public health impact. Rather than ignore poor countries as unlucrative markets, pharmaceutical companies

would, moreover, have incentives to work together toward improving the heath systems of these countries in order to enhance the impact of their HIF-registered medicines there.

Elaborating the details of such a scheme is obviously a complex undertaking. It requires specification of the reward mechanism: definition of an appropriate metric for the GBD, determination of a monetary reward per unit of GBD reduction, rules for allocating the GBD among the various diseases, ways of collecting sufficient data to assess ex post the global burden each disease imposes and to make plausible baseline projections some years into the future, rules for allocating specific disease burden reductions among HIF-registered innovators, adequate mechanisms for curbing corruption and gaming, and special rules for incremental innovations and for the phase-in period. Another aspect of the design concerns the agency administering the reward mechanism and the arbitration procedures for settling conflicts about the interpretation and application of the rules. A third design aspect concerns morally plausible and politically feasible rules for funding the scheme. With support from the Australian Research Council, the BUPA Foundation, and the European Commission, our team is hard at work on detailing workable solutions to these challenges. Our work is documented, with some time lag, at www.incentivesforglobalhealth.org.

Notes

1. Pogge T. Montréal Statement on the Human Right to Essential Medicines. *Cambridge Quarterly of Healthcare Ethics* 2007;16:97–108.
2. Pogge T. *World Poverty and Human Rights*, 2nd ed. Cambridge: Polity Press; 2008.
3. Patent life is counted from the time the patent application is filed. Effective patent life is the time from receiving market clearance to the time the patent expires. My calculation in the text assumes constant nominal profit each year. In reality, annual profit may rise (due to increasing market penetration or population growth) or fall (through reduced incidence of the disease or through competition from "me-too drugs" developed by competing firms). For most drugs, sales decline steeply after they have been on the market for 6 years or so, and this strengthens the reasons for limiting patent life.
4. The promise was broken as the high-income countries continue to sabotage the export opportunities of poor countries through protectionist tariffs and anti-dumping duties as well as through huge subsidies and export credits to their domestic producers.
5. Announced in 2003, this joint WHO/UNAIDS program was meant to provide, by 2005, anti-retroviral treatment to 3 million (out of what were then estimated to be 40.3 million) AIDS patients in the less developed countries. In fact, it extended such treatment to about 900,000.
6. A prize is a specific reward offered for the development of a new medicine that meets certain specifications. It can be in the form of a cash payment or in some other form, for instance, the extension of a patent on another medicine that is in high demand by affluent patients. An AMC is a promise to subsidize the sale of a certain large number of doses of a new medicine that meets certain specifications. An advance purchase commitment is a promise to buy, at a preset high price, a certain large number of doses of a new medicine that meets certain specifications.
7. Personal communication from Aidan Hollis, based on his rough calculation. See also Hollis A. An efficient reward system for pharmaceutical innovation; 2005:8 at www.econ.ucalgary.ca/fac-files/ah/dragprizes.pdf (retrieved 2008 Jul 16), where he quantifies the deadweight loss in the region "of $5 bn – 20 bn annually for the US. Globally the deadweight loss is certain to be many times this figure, because in many markets drug insurance is unavailable and so consumers are more price-sensitive."
8. See the special issue on disease mongering, Moynihan R, Henry D, eds. *PLoS Medicine* 2006;3:425–65.
9. This corresponds roughly to the profitable period of a patent: Under TRIPS, members of the World Trade Organization must offer patents lasting at least 20 years from the patent filing date, which is typically many

years before the medicine receives market clearance after clinical trials.

10. See note 2, Pogge 2008:ch. 9.
11. For further details, see also Pogge T. Medicines for the World. *Sur: Revista Internacional de direitos humanos*; 2008:8. Additional work by team members is available at www.yale.edu/macmillan/igh/e-library.html. A special issue of the journal *Public Health Ethics*; 2008(1):2 features critical discussions of the proposal by Gorik Ooms and Rachel Hammonds, Thomas Faunce and Hitoshi Nasu, Devi Sridhar, Michael Selgelid, Aidan Hollis, and Michael Ravvin.
12. Hollis A. The Health Impact Fund: A useful supplement to the patent system? *Public Health Ethics* 2008;1(2):123–33.
13. The only existing AMC thus far—funded by Italy, the United Kingdom, Canada, Russia, Norway, and the Gates Foundation—is for vaccines against pneumococcal disease, a major cause of pneumonia and meningitis among the poor.
14. For an excellent discussion, see Hollis A. Incentive Mechanisms for Innovation. IAPR Technical Paper; 2007:15–6. Available from www.iapr.ca/iapr/files/iapr/iapr-tp-07005_0.pdf (retrieved 2008 Jul 16).