

# **Health Care Reform that Works for the U.S. and for the World's Poor**

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*Some 18 million people die annually from poverty-related causes. Insofar as present global institutional arrangements foreseeably and avoidably perpetuate this death toll, affluent countries contribute to the great deprivations suffered by the poor. The Obama administration could substantially reduce this burden by supplementing the rules that govern pharmaceutical innovation. These rules, established by the World Trade Organization's TRIPS Agreement, 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. Choosing this option, the innovator would have to guarantee to make this product available, wherever it is needed, at the lowest feasible cost of production and distribution. 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 health gains.*

## **INTRODUCTION: SEVERE POVERTY PERSISTS ON A MASSIVE SCALE AND COULD BE GREATLY REDUCED AT LOW COST**

The Obama administration's global public health policies are so far a blank canvas, limited only by the interests and imaginations of the holders of high office. This essay seeks to engage their imagination. With substantial popular support and a widespread readiness to rethink national funding priorities, the administration could greatly improve the existing global public health architecture.

A prime example of the administration's fiscal power is the proposed reserve fund for health care, \$634 billion set aside over ten years to pay for the move toward universal health care in the United States. This staggering sum is only the first payment—the costs of badly needed reform are expected to rise over a trillion dollars.<sup>1</sup> Of course, one reason for the high price tag of reform is that providing health care in the United States is expensive. One might wonder how far such an amount would go if it were spread around the globe, especially to countries where needs are greater and costs lower.

The answer is: extremely far. In fact, at about \$63 billion per year, the reserve fund for health care would just about match the aggregate shortfall of the 1.4 billion human beings whom the World Bank counts as living below its \$1.25 per day International Poverty Line.<sup>2</sup> Considering the huge human cost of severe poverty worldwide, \$63 billion annually can hardly seem excessive.

Many more people—some 360 million—have died from hunger and remediable diseases in peacetime in the 20 years since the end of the Cold War than have perished from wars, civil wars, and government repression over the entire 20th century. And poverty continues unabated, as the official statistics amply confirm: 963 million human beings are chronically undernourished, 884 million lack access to safe water, and 2500 million lack access to basic sanitation.<sup>3</sup> 2000 million lack access to essential medicines.<sup>4</sup> 924 million lack adequate shelter and 1600 million lack electricity.<sup>5</sup> 774 million adults are illiterate.<sup>6</sup> 218 million children are child laborers.<sup>7</sup>

Roughly one third of all human deaths, 18 million annually, are due to poverty-related causes, straightforwardly preventable through better nutrition, safe drinking water, cheap re-hydration packs, vaccines, antibiotics, and other medicines. People of color, females, and the very young are heavily overrepresented among the global poor, and hence also among those suffering the staggering effects of severe poverty. Children under five account for over half or 9.2 million of the annual death toll from poverty-related causes.<sup>8</sup> The overrepresentation of females is clearly documented.<sup>9</sup>

With average per capita household income in the high-income countries some 165 times greater than that of the poor at market exchange rates,<sup>10</sup> we could eradicate most severe poverty worldwide if we chose to try—in fact, we could have done so decades ago. Citizens of the rich countries are, however, conditioned to downplay the severity and persistence of world poverty and to think of it as an occasion for minor charitable assistance.

This widespread lack of attention to the world poverty problem becomes morally indefensible once we understand that its human cost is enormous, that its economic magnitude is pathetically small by comparison, and that it has barely diminished during recent periods of healthy global economic growth. This clearly is a problem that any moral person must pay serious attention to.

Those who begin to pay attention often easily content themselves with the thought that we simply cannot avoid world poverty, at least not at reasonable cost. In this vein, many think of the millions of poverty deaths each year as necessary to avoid an overpopulated, impoverished, and ecologically unsustainable future for humanity. While this view once had prominent academic defenders,<sup>11</sup> it is now discredited by abundant empirical evidence across regions and cultures, showing that, when poverty declines, fertility rates also decline sharply.<sup>12</sup> Wherever people have gained access to contraceptives and associated knowledge and have gained some assurance that their children will survive into adulthood and that their own livelihood in old age will be secure, they have substantially reduced their rate of reproduction. We can see this in the dramatic declines in total fertility rates (children per woman) in areas where poverty has declined. In the last 55 years, this rate has dropped from 5.67 to 1.68 in East Asia, for instance, and from 3.04 to 1.46 in Portugal and from 3.18 to 1.79 in Australia.

In economically stagnant poor countries, by contrast, there has been little change over the same period: total fertility rates went from 5.50 to 5.36 in Equatorial Guinea, from 7.11 to 6.52 in Mali, from 8.12 to 7.19 in Niger, and from 6.09 to 6.47 in Sierra Leone.<sup>13</sup> The correlation is further confirmed by synchronic comparisons. Currently, the total fertility rate is 4.63 for the 50 least developed countries versus 1.60 for the more developed regions, and 2.45 for the remaining countries.<sup>14</sup> The complete list of national total fertility rates also confirms a strong correlation with poverty and shows that already some 80 of the more affluent countries have reached total fertility rates below 2,<sup>15</sup> foreshadowing future declines in population. Taken together, these data provide overwhelming evidence that poverty reduction is associated with large fertility declines.

These data also discredit the claim that we should accept world poverty for the sake of the environment which would be gravely damaged if billions of presently poor people began consuming at the rate we do. The short-term ecological impact of eradicating world poverty would be dwarfed by its long-term ecological impact through a lower human population. Eradicating poverty with all deliberate speed would make a huge contribution to an early peaking of the human population which would bring enormous ecological benefits for the rest of the third millennium and beyond. At current projections, massive eradication of severe poverty can achieve, by 2100, a declining population of 7 billion human beings as compared to a still rising population of 10-14 billion otherwise. It should also be noted that the short-term harm from poverty eradication is often overstated. It is true that, if the poorer half of humankind had an additional 1 percent of global household income (i.e., 4 percent instead of 3 percent) at market exchange rates, then their ecological footprint would expand. But it is also true that the richer half of humankind would then have 1 percent less (i.e. 96 percent instead of 97 percent) of global household income with a consequent contraction of their much larger ecological footprint. There is still a net harm to the environment as ecological footprint per unit of income tends to decline with rising income. But this effect is very small compared to the long-term ecological benefit of poverty eradication. And it can be avoided by small incremental reductions in the ecological burdens the more affluent produce.

#### **WHAT DO WE OWE THE WORLD'S POOR, AND WHAT ARE THE GROUNDS OF THESE OBLIGATIONS?**

Having disposed of the claim that world poverty is a necessary evil, we more affluent confront the question what, and how much, we are duty-bound to "sacrifice" towards reducing severe poverty worldwide. Most of the more affluent believe that these duties are feeble, that it is not very wrong to give no help at all. Against this view, some philosophers have argued that the affluent have positive duties that are quite stringent and quite demanding: if people can prevent much hunger, disease, and premature death at little cost to themselves, then they ought to do so even if those in need are distant strangers. Peter Singer famously argued for this conclusion by likening the global poor to a drowning child: affluent

people who give no aid to the hungry behave no better than a passer-by who fails to save a drowning child from a shallow pond in order not to muddy his pants.<sup>16</sup>

One problem with Singer's view is to work out how much an affluent person is required to give when there are always yet further urgent needs she might help meet. On reflection, the assumption of such a cut-off point seems odd. It seems more plausible to assume that, as an affluent person expands her assistance, the moral reason to give even more becomes less stringent. We tend to talk in binary terms, to be sure, about whether some effort is morally required or else beyond the call of duty. But there is no plausible formula that would allow us to compute, from data about a person's financial situation, exactly how much she is required to give toward helping those to whom an extra dollar would bring much greater benefit.

Still, as she keeps giving, the moral reasons to give yet more do become weaker, less duty-like and more discretionary. The strength of these moral reasons may fade in this way on account of three factors. First, the needs of the poor may become less urgent. Second, giving an extra dollar becomes more of a burden as the donor's income declines. Third, what she has given continuously builds a case that she has already done a lot. These three factors are not in precise harmony. The relevance of the third factor is sensitive to whether her current financial situation reflects the fact that she has already given a lot. Singer and his followers have no algorithm for assessing the relevance of these factors or for determining with any precision whether someone has done her duty or not. Nonetheless, they have a plausible case for concluding that we ought to relieve life-threatening poverty so long as we can do so without giving up anything really significant.

Other philosophers have challenged the terms of this debate and, in particular, the shared suggestion that people in affluent countries are as innocent in regard to world poverty as Singer's passer-by is in regard to the child in the pond. This challenge can be formulated in different ways.<sup>17</sup> One can question the legitimacy of the existing highly uneven global distribution of income and wealth, which has emerged from a historical process that was pervaded by grievous wrongs (genocide, colonialism, slavery) and has left many of our contemporaries without a fair share of the world's natural resources or an adequate equivalent. One can criticize the negative externalities affluent populations are imposing upon the world's poor: greenhouse gas emissions that are spreading desertification and tropical diseases, for example, or highly efficient European fishing fleets that are decimating fish stocks in African waters.<sup>18</sup>

One can also critique the increasingly dense and influential web of global institutional arrangements which foreseeably and avoidably perpetuates massive poverty. It does so, for example, by permitting affluent states to protect their markets through tariffs and anti-dumping duties and through export credits and huge subsidies to domestic producers that amount to some \$300 billion annually in agriculture alone. It does so by requiring all WTO members to grant 20-year monopoly patents, thereby causing important and cheaply mass-producible new medicines to be priced out of reach of a majority of the world's population. The existing international institutional order also fosters corrupt and oppressive government in the poorer countries by recognizing any person or group holding

effective power — regardless of how they acquired or exercise it — as entitled to sell the country's resources and to dispose of the proceeds of such sales, to borrow in the country's name and thereby to impose debt service obligations upon it, to sign treaties on the country's behalf and thus to bind its present and future population, and to use state revenues to buy the means of internal repression. This practice of recognition is beneficial to many a putschist and oppressive ruler, who can gain and keep political power even against a large majority of his compatriots and thereby greatly enrich himself at their expense. This practice is also beneficial to affluent countries which can, for instance, buy natural resources from an African ruler regardless of how he came to power and regardless of how badly he rules. But this practice is devastating for the populations of such countries by strengthening their oppressors and also the incentives toward coup attempts and dictatorial rule. Bad governance in so many poor countries (especially those rich in natural resources) is a foreseeable effect of the privileges our international order bestows upon any person or group that manages to bring a country under its control.

The common conclusion suggested by these various considerations is that the moral challenge world poverty poses to the affluent is not merely to help more, but also to harm less. They are not merely failing to fulfill their positive duties to assist and protect, but also violating negative duties: the duty not to defend or take advantage of an unjust distribution of holdings, or the duty not to contribute to or take advantage of unjust international practices and institutional arrangements that foreseeably and avoidably keep billions trapped in life-threatening poverty.

A violation of the latter duty presupposes that it is reasonably possible for the affluent collectively to shape the international practices and institutional arrangements they design and uphold to be more poverty-avoiding. This presupposition is hard to deny in regard to the examples just provided: it is reasonably possible for us *not* to deplete African fish stocks, *not* to distort world markets through massive subsidies and other protectionist measures that hamper exports from poor countries, *not* to insist on pharmaceutical monopolies that deprive the poor of access to cheap generic versions of advanced medicines, *not* to recognize and arm rulers who oppress their poor compatriots and steal their resources. Insofar as alternative, more poverty-avoiding practices and rules are reasonably available, the existing international practices and global institutional order must count as unjust and their continued imposition as a harm done to the world's poor.

There is no agreement on how much inequality and poverty just international practices and institutional arrangements may maximally engender. But no precise answer to this question is required for concluding that existing levels of poverty and inequality are excessive. When the basic human rights of a large proportion of humanity are avoidably unfulfilled, then international practices and institutional arrangements must count as unjust insofar as they contribute to this human rights deficit. Especially the more powerful countries then have a responsibility to reform these practices and institutional arrangements so as to make them more human-rights compliant—a responsibility that falls, in the last analysis, upon these countries' citizens. None

of us can reform international practices and institutions single-handedly, to be sure, but we can work politically toward such reform and we can also make individual efforts to protect poor people from the effects of the unjust arrangements imposed upon them. Such efforts, though active, are required by our negative duty not to harm: insofar as one contributes to and benefits from the imposition of unjust arrangements, one is responsible for a share of the harm these arrangements cause unless one takes compensating action that prevents this share of the harm from materializing.<sup>19</sup>

#### FOCUSING DIRECTLY ON GLOBAL HEALTH

How, then, should the Obama administration go about reforming the global institutional architecture? I noted at the outset the 18 million deaths each year from poverty-related causes. Using the World Health Organization's Global Burden of Disease (GBD) studies, we can break down this figure into some of the more prominent categories of mortality. In 2004, there were about 57 million human deaths. The main causes highly correlated with poverty were (with death tolls in thousands): diarrhea (2163) and malnutrition (487), perinatal (3180) and maternal conditions (524), childhood diseases (847—measles is about half), tuberculosis (1464), malaria (889), meningitis (340), hepatitis (159), tropical diseases (152), respiratory infections (4259—mainly pneumonia), HIV/AIDS (2040) and sexually transmitted diseases (128).<sup>20</sup>

This huge death toll would come down if global poverty were reduced. But it is also possible to make substantial progress against the GBD directly: Existing huge mortality and morbidity rates can be dramatically lowered by reforming our system of funding for the research and development of new medical treatments. 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 health care spending—certainly nothing on the order of magnitude of the proposed reserve fund for health care. In fact, on any plausible accounting, which would take note of the huge economic losses caused by the present GBD, the reform I propose would actually save money. Moreover, it would distribute the cost of global health care spending more fairly across countries, across generations, and between those 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 US 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 reasons 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 enable innovators to apply for patents that entitle them to forbid others to produce or distribute the innovative product and to waive this entitlement in exchange for a licensing fee. The result of such market exclusivity is an artificially elevated sales price that, on average, 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 temporary market exclusivity. Once the patent expires, competitors can freely enter the market with copies of the original innovation and consumers need thus no longer pay a large 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 12 percent per annum, a 10-year effective patent life generates 72 percent, and a 15-year effective patent life 85 percent, of the profit (discounted to present value) that a permanent patent would generate.<sup>21</sup> 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 patent-protected mark-ups.

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 thus 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 TRIPS Agreement.<sup>22</sup> 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.<sup>23</sup>

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 perhaps 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 have relentlessly pursued the globalization of uniform intellectual property rights—with devastating effects, for instance, on access to second-line AIDS therapies and hence 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,<sup>24</sup> through *governmental programs* such as the US President's Emergency Plan for AIDS Relief (PEPFAR), 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.<sup>25</sup>

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 be collected and efficiently 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.

#### SEVEN FAILINGS OF THE PRESENT PHARMACEUTICAL INNOVATION REGIME

The quest for such a systemic solution can 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 near 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 very high above the cost of production before increased gains from enlarging the mark-up are outweighed by losses from reduced sales volume. With patented medicines, mark-ups in excess of 1000 percent are not exceptional.<sup>26</sup> When such exorbitant mark-ups are charged, only a few of the poor can have access through the charity of others.

*Neglect of Diseases Concentrated among the Poor.* When innovators are rewarded with patent-protected mark-ups, diseases concentrated among the poor—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 mark-up. There is no prospect, then, of achieving high sales volume and a large mark-up. 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 gap, alluding to only 10 percent of all pharmaceutical research being focused on diseases that account for 90 percent of the GBD.<sup>27</sup>

*Bias toward Maintenance Drugs.* Medicines can be sorted into three categories: Curative medicines remove the disease from the patient's body; maintenance drugs improve well-being and functioning without removing the disease; preventative medicines reduce the likelihood of contracting the disease in the first place. Under the existing patent regime, maintenance drugs 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 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 patent-protected mark-ups. Even greater costs are due to the deadweight loss “on the order of \$200 billion” 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.<sup>28</sup>

*Counterfeiting.* Large mark-ups also encourage the illegal manufacture of fake products that are diluted, adulterated, inert, or even toxic. Such counterfeits often endanger patient health. They also contribute to the emergence of drug-specific resistance, when patients ingest too little of the active ingredient of a diluted drug to kill off the more resilient pathogenic agents. The emergence of highly drug resistant disease strains—of tuberculosis, for instance—poses dangers to us all.

*Excessive Marketing.* When pharmaceutical companies maintain a very large mark-up, they find it rational to make extensive efforts to increase sales volume, often by scaring patients or by rewarding doctors. This produces pointless battles over market share among similar (“me-too”) drugs as well as perks that induce doctors to prescribe medicines even when these are not indicated or when competing medicines are likely to do better. With a large mark-up it also pays to fund massive direct-to-consumer advertising that persuades people to take medicines they don’t really need for diseases they don’t really have (and sometimes for invented pseudo diseases).<sup>29</sup>

*The Last-Mile Problem.* While the present regime provides strong incentives to sell even unneeded patented medicines to those who can pay or have insurance, it provides no incentives to ensure that poor people benefit from medicines they urgently need. Even in affluent countries, pharmaceutical companies have incentives only to sell products, not to ensure that these are actually used, properly, by patients whom they can benefit. This problem is compounded in poor countries, which often lack the infrastructure to distribute medicines as well as the medical personnel to prescribe them and to ensure their proper use. In fact, the present regime even gives pharmaceutical companies incentives to disregard the medical needs of the poor. To profit under this regime, a company needs not merely a patent on a medicine that is effective in protecting paying patients from a disease or its detrimental symptoms. It also needs this target disease to thrive and spread because, as a disease waxes or wanes, so does market demand for the remedy. A pharmaceutical company helping poor patients to benefit from its patented medicine would be undermining its own profitability in three ways: by paying for the effort to make its drug competently available to them, by curtailing a disease on which its profits depend, and by losing affluent customers who find ways of buying, on the cheap, medicines meant for the poor.

## A STRUCTURAL REFORM: THE HEALTH IMPACT FUND

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 pay-for-performance mechanism in the form of the *Health Impact Fund*.<sup>30</sup> The HIF is a proposed global agency—financed mainly by governments—that would give pharmaceutical innovators the option to register any new product. They would guarantee to make it available, wherever it is needed, at the lowest feasible cost of production and distribution. In exchange, each registered product would, during its first ten years on the market, participate 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.<sup>31</sup>

The requisite health impact assessment could be conducted in terms of quality-adjusted life years (QALYs), a metric that has been deployed for about two decades by academic researchers, insurers, NGOs and government agencies. The assessment would rely on clinical and pragmatic trials of the product, on tracing (facilitated by serial numbers) of random samples of the product to end-users, and on statistical analysis of correlations between sales data (including time and place of sale) and target disease burden.

In view of the great cost (\$200 to \$1300 million) of bringing a new medicine to market, and to take advantage of economies of scale in health impact assessment, the annual reward pools should be at least \$6 billion (which is about 5 percent of current global spending on pharmaceutical research). If all countries were to join up, each would need to contribute about 0.01 percent of its gross national income (GNI). If countries representing only a third of the global product participated, each would need to contribute a still-modest 0.03 percent of its GNI—mitigated by massive cost savings their governments, firms and citizens would enjoy from low-cost HIF-registered medicines. If it were found to work well, the HIF could be scaled up to attract an increasing share of new medicines.

To provide stable incentives, the HIF would need guaranteed financing some 15 years into the future to assure pharmaceutical innovators that, if they fund expensive clinical trials now, they can claim a full decade of health impact rewards upon market approval. Such a solid guarantee is also in the interest of the funders who would not want the incentive power of their contributions to be diluted through skeptical discounting by potential innovators. The guarantee might take the form of a treaty under which each participating country commits to the HIF a fixed fraction of its future gross national income (GNI). Backed by such a treaty, the HIF would automatically adjust the contributions of the various partner countries to their variable economic fortunes, would avoid protracted struggles over contribution proportions, and would assure each country that any extra cost it agreed to bear through an increase in the contribution schedule would be matched by a corresponding increase in the contributions of all other partner countries.

The HIF has five main advantages over conventional innovation prizes, including advance market commitments and advance purchase commitments. First, it is a structural reform, establishing an enduring source of high-impact pharmaceutical innovations. Second, it is not disease-specific and thus much less vulnerable to lobbying by firms and patient groups. Third, conventional prizes must define a precise finish line, specifying at least what disease the sought 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 yet to be encouraged. Since sponsors lack this knowledge ahead of time, their specifications are likely to be seriously suboptimal: they may be too demanding, with the result that firms give up the effort even though something close to the sought medicine is within their reach, or they may be insufficiently demanding, 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.<sup>32</sup> The HIF avoids this problem of the finish line by flexibly rewarding any new registered medicine in proportion to its global health impact. Fourth, formulated to avoid failure and in ignorance of the true cost of innovation, specific prizes are often much too large and thus overpay for innovation. The HIF solves this problem by letting its health impact reward rate adjust itself through competition: a high reward rate would correct by attracting additional registrations (producing an increase in the number of registered medicines) and an unattractively low reward rate would correct by deterring new registrations (producing a decrease in the number of registered medicines). Fifth, the HIF gives each registrant powerful incentives to promote the optimal end-use of its product: to seek its wide and effective use by any patients who can benefit from it.

Because HIF-registered medicines would be cheaply available everywhere, there would be no cheating problems as commonly attend any differential pricing schemes aimed to make a medicine more affordable to poor patients or in poor countries. The HIF's global scope also brings huge efficiency gains by diluting the cost of innovation without diluting its benefits.

There is no space here to discuss the design of the HIF in greater detail.<sup>33</sup> So let me conclude by sketching how it would, without revision of the TRIPS Agreement, provide systemic relief for its seven failings outlined above.

*High Prices* would not exist for HIF-registered medicines. Innovators would typically not even want a higher price as this would reduce their health impact rewards by impeding access to their product by most of the world's population. The HIF counts health benefits to the poorest of patients equally with health benefits to the richest.

*Diseases Concentrated among the Poor*, insofar as they contribute substantially to the GBD, would no longer be neglected. In fact, the more destructive among them would come to afford some of the most lucrative research opportunities for biotechnology and pharmaceutical companies.

*Bias toward Maintenance Drugs* 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 firms to deliberate about potential research projects in a way that is also optimal for 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.

*Wastefulness* would be dramatically lower for HIF-registered products. There would be no deadweight losses from large mark-ups. There would be little

costly litigation as generic competitors would lack incentives to compete and innovators would have no incentive to suppress generic products (because they enhance the innovator's health impact reward). Innovators might therefore often not even bother to obtain, police, and defend patents in many national jurisdictions. To register a medicine with the HIF, innovators need show only once that they have an effective and innovative product.

*Counterfeiting* of HIF-registered products would be unattractive. With the genuine item widely available near or even below the marginal cost of production, there is little to be gained 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, incentives to develop me-too drugs to compete with an existing HIF-registered medicine would be weak. And 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 strong 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 unprofitable markets, pharmaceutical companies would, moreover, have incentives to work with one another and with national health ministries, international agencies and NGOs toward improving the health systems of these countries in order to enhance the impact of their HIF-registered medicines there.

This essay is meant to express three important points to guide the imagination of the Obama administration as it engages in an effort to reform American healthcare. First, in parallel to the institutional order of a country, global institutional arrangements have a profound effect on the welfare of people everywhere. Second, the present rules governing the world economy, designed and imposed to serve powerful corporate and political interests, could be adjusted in minor but highly effective ways to better serve the interests of all. Third, small changes to the rules that incentivize pharmaceutical research and development would produce large health gains in poor and affluent countries—gains that, over time, would easily cover the economic cost of the scheme. Creating the Health Impact Fund would be a large step toward fulfilling the new president's inaugural pledge to “wield technology's wonders to raise healthcare's quality and lower its cost.”<sup>34</sup>

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<sup>1</sup> Ceci Connolly, "Obama Proposes \$634 Billion Fund for Health Care," *Washington Post*, February 26, 2009, [www.washingtonpost.com/wp-dyn/content/article/2009/02/25/AR2009022502587.html](http://www.washingtonpost.com/wp-dyn/content/article/2009/02/25/AR2009022502587.html)

<sup>2</sup> The World Bank counts the members of a household as poor just in case the cost of its consumption per person per day has less purchasing power than \$1.25 had in the US in 2005. See Thomas Pogge, *Politics as Usual* (Cambridge: Polity Press, forthcoming), ch. 3. There, I calculate that, at market exchange rates, the aggregate shortfall of the 1.4 billion people who in 2005 lived below this international poverty line was about 0.15 percent of the global product, or \$70 billion per annum. See also the critique of the Bank's method of tracking poverty in chs. 3 and 4 of *Politics as Usual*.

<sup>3</sup> FAO, "Number of Hungry People Rises to 963 Million," press release, Rome, December 2008, [www.fao.org/news/story/en/item/8836/icode](http://www.fao.org/news/story/en/item/8836/icode); UNDP, *Human Development Report 2006* (Basingstoke: Palgrave Macmillan, 2006), p. 174; WHO and UNICEF, *Progress on Drinking Water and Sanitation: Special Focus on Sanitation* (New York and Geneva: UNICEF and WHO, 2008), [www.wssinfo.org/en/40\\_MDG2008.html](http://www.wssinfo.org/en/40_MDG2008.html), pp. 30 and 7.

<sup>4</sup> Fogarty Center for Advanced Study in the Health Sciences. "Strategic Plan: Fiscal Years 2000–2003." Bethesda, Md.: National Institutes of Health, n.d. [www.fic.nih.gov/about/plan/exec\\_summary.htm](http://www.fic.nih.gov/about/plan/exec_summary.htm).

<sup>5</sup> UN-Habitat, *The Challenge of Slums: Global Report on Human Settlements 2003* (London: Earthscan, 2003), p. vi; UN-Habitat, "Urban Energy," [www.unhabitat.org/content.asp?cid=2884&catid=356&typeid=24&subMenuId=0](http://www.unhabitat.org/content.asp?cid=2884&catid=356&typeid=24&subMenuId=0).

<sup>6</sup> UNESCO Institute for Statistics, "Literacy Topic," Dec. 1, 2008,

[www.uis.unesco.org/ev.php?URL\\_ID=6401&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201](http://www.uis.unesco.org/ev.php?URL_ID=6401&URL_DO=DO_TOPIC&URL_SECTION=201).

<sup>7</sup> See ILO, *The End of Child Labour: Within Reach* (Geneva: International Labour Office, 2006), p. 6.

<sup>8</sup> Roshni Karwal, Policy Advocacy and Partnerships for Children's Rights, 2008, [www.unicef.org/policyanalysis/index\\_45740.html](http://www.unicef.org/policyanalysis/index_45740.html).

<sup>9</sup> UNDP, *Human Development Report 2003* (New York: Oxford University Press, 2003), 310–330; UNRISD, *Gender Equality: Striving for Justice in an Unequal World* (Geneva: UNRISD/UN Publications, 2005); Social Watch, *Unkept Promises* (Montevideo: Instituto del Tercer Mundo, 2005), available at:

[www.socialwatch.org/en/informeImpreso/tablaDeContenidos2005\\_adv.htm](http://www.socialwatch.org/en/informeImpreso/tablaDeContenidos2005_adv.htm).

<sup>10</sup> In 2005, annual household income per capita was about \$130 among the 1.4 billion whom the World Bank counts as poor, versus \$21,400 among the 1 billion then living in high-income countries (World Bank, World Development Indicators database).

<sup>11</sup> Garrett Hardin, "Lifeboat Ethics: The Case Against Helping the Poor," *Psychology Today* 8, no. 4 (1974): 38, 40–43, 123–124, 126.

<sup>12</sup> Amartya Sen, "Population: Delusion and Reality," *New York Review of Books* 41, no. 15 (1994): 62–71.

<sup>13</sup> [esa.un.org/unpp/index.asp?panel=2](http://esa.un.org/unpp/index.asp?panel=2).

<sup>14</sup> *Ibid.*

<sup>15</sup> [www.cia.gov/library/publications/the-world-factbook/rankorder/2127rank.html](http://www.cia.gov/library/publications/the-world-factbook/rankorder/2127rank.html)

<sup>16</sup> Peter Singer, "Famine, Affluence, and Morality," *Philosophy & Public Affairs* 1, no. 3 (1972): 229–243.

<sup>17</sup> See Thomas Pogge, *World Poverty and Human Rights*, 2nd ed. (Cambridge: Polity Press, 2008), pp. 205–210.

<sup>18</sup> The predatory fishing practices of heavily subsidized European fleets in West African waters are described, for instance, in Sharon Lafraniere, "Europe Takes Africa's Fish, and Boatloads of Migrants Follow," *New York Times*, January 14, 2008.

<sup>19</sup> See Thomas Pogge, “Severe Poverty as a Violation of Negative Duties,” *Ethics and International Affairs* 19, no. 1 (2005): 55–84, especially pp. 60–62, 68–75.

<sup>20</sup> WHO, *The Global Burden of Disease: 2004 Update* (Geneva: WHO Publications, 2008), p. 54, table A1.

<sup>21</sup> 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 after they have been on the market for six years or so, and this strengthens the reasons for limiting patent life.

<sup>22</sup> Trade-Related Aspects of Intellectual Property Rights.

<sup>23</sup> 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.

<sup>24</sup> 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.

<sup>25</sup> A prize is a specific reward offered for the development of a new medicine that meets certain specifications. It need not take the form of a cash payment. The successful innovator may also be rewarded by subsidizing the sale of (advance market commitment), or by buying at a pre-set high price (advance purchase commitment), a certain large number of doses of a new medicine that meets certain specifications. Or the successful innovator may be granted an extension on any of its other patents.

<sup>26</sup> In Thailand, Sanofi-Aventis sold its cardiovascular disease medicine Plavix for 70 baht (\$2.20) per pill, some 6000 percent above the price at which the Indian generic firm Emcure agreed to deliver the same medicine (clopidogrel). See Oxfam, Investing for Life, Oxfam Briefing Paper, November 2007, p. 20, [www.oxfam.org/en/policy/bp109\\_investing\\_for\\_life\\_0711](http://www.oxfam.org/en/policy/bp109_investing_for_life_0711).

<sup>27</sup> See Global Forum for Health Research, *The 10/90 Report on Health Research 2003–2004* (Geneva: GFHR 2004), also available at [www.globalforumhealth.org](http://www.globalforumhealth.org).

<sup>28</sup> Personal communication from Aidan Hollis, based on his rough calculation. See also Aidan Hollis, “An Efficient Reward System for Pharmaceutical Innovation,” (working paper, Department of Economics, University of Calgary, 2005), [econ.ucalgary.ca/fac-files/ah/drugprizes.pdf](http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf), p. 8, 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.”

<sup>29</sup> See the special issue on disease mongering, Roy Moynihan and David Henry, eds., *PLoS Medicine* 3, no. 4 (2006): 425–65.

<sup>30</sup> See [www.healthimpactfund.org](http://www.healthimpactfund.org) for details about the team and its work, which have been generously funded by the Australian Research Council, the BUPA Foundation, the European Commission, and the Canadian Social Science and Humanities Research Council. A special issue of the journal *Public Health Ethics* (vol. 1, no. 2, 2008) 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.

<sup>31</sup> Ten years corresponds roughly to the profitable period of a patent: Under TRIPS, WTO members 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. Because some patents may outlast the reward period, HIF registration requires the registrant to offer a royalty-free open license for generic versions of the product following the end of the reward period.

<sup>32</sup> For an excellent discussion, see Aidan Hollis, “Incentive Mechanisms for Innovation” (IAPR Technical Paper, 2007), [www.iapr.ca/iapr/files/iapr/iapr-tp-07005\\_0.pdf](http://www.iapr.ca/iapr/files/iapr/iapr-tp-07005_0.pdf), pp. 15–16.

<sup>33</sup> See Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (Incentives for Global Health 2008), freely available at [www.healthimpactfund.org](http://www.healthimpactfund.org).

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<sup>34</sup> Barack Obama, Inaugural Address, January 20, 2009,  
[www.pic2009.org/blog/entry/president\\_obamas\\_inaugural\\_address](http://www.pic2009.org/blog/entry/president_obamas_inaugural_address).