# **Access to Medicines**

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I would pay three million to go into space, says the banker to his attorney. — I wouldn't go if you paid me, the latter laughs, for me the French Riviera is quite exciting enough.

Ah, I would pay a million for an extra year of life, the elderly tourist effusively tells his lover. — We have never had even a hundred dollars, the Cambodian teenager replies, we are a large family.

Markets are highly efficient mechanisms for ensuring that outcomes track people's different preferences. This is illustrated by the first story, which suggests how markets can achieve a miraculously apt match-up of people to vacations or, more generally, commodities. Markets can be similarly efficient in achieving an apt match-up of people to jobs.

But markets can be problematic, too, as the second story suggests. Channary rents out her body for a few dollars, often suffering violence and abuse. She will be HIV positive in a few years and, unable to afford advanced AIDS medicine, she will die in her early twenties. The tourist will enjoy quality medical care in his home country and will have quite a few extra years beyond his parents' life expectancy. Though fifty years older than Channary, he will outlive her by a decade.

Some see no moral problem here. They may judge that, when Channary is renting out her body, she is choosing her most preferred option. If she lacked this opportunity, she would be worse off. And if she rents out her body while knowing the risks, then why should others have to bail her out later when, like so many girls before her, she gets sick?

But consider the situation, seven years after their encounter, when he gets his coronary bypass while Channary is losing her battle with AIDS. The cost of his surgery is 200 times that of an annual supply of the antiretrovirals she needs. It is wonderful, of course, that he can be given more healthy years of life. But is it right that she is left to waste away, and to die at 23?

There are two related points here. Looking to the future, we might ask whether the market-produced outcome tracks what matters. At \$150 per year (Rimmer, 2008), Channary cannot afford the antiretrovirals she needs to survive. Does her access to this medicine really matter less than all the other things on which such an amount, or more, is actually spent? Is an extra year of life

for her really less important than my jet ski rental or my dinner at the revolving restaurant?

Looking to the past, we should question the economic distribution that conditions decisions and market allocations. Channary indeed prefers to rent out her body seeing her younger siblings cry for food and her mother from despair. But how come she is trapped in such an awful set of options? She was born into a poor family in a country that had suffered decades of devastation. Cambodia was drawn into the Vietnam War, which ended in 1975 with a victory for Pol Pot and the Khmer Rouge. Having killed about one-fifth of the population in four years, they were ousted by Vietnamese forces in 1979, but, with support from China, the US, the UK and the UN, the Khmer Rouge continued to wage a devastating civil war that left Channary's family in perpetual destitution. None of this can be viewed as her responsibility. It is hard to find fault even with her parents, who worked hard all their lives to get by. They did have five children, to be sure, but with high infant mortality and the lack of social security for old age, one can hardly fault them for that. And they could not have foreseen, of course, her father's early death from typhoid fever.

A market system can put poverty to good uses. It is a good thing that those who, for whatever reason, tend to use resources poorly should become poorer as a result and thus get fewer resources to waste. This is good because more scarce resources will then be controlled by people using them well. And it is good also because, under such a system, people have incentives to improve their performance.

But these thoughts must be balanced against two other considerations. The penalty should not be hugely disproportionate. The man who wasted heating oil last year, and the woman who overspent her credit card—let the market constrain them to cut back their spending. But this should not lead to their freezing or starving to death or

being compelled to accept slavery or servitude to secure their survival.

The other balancing consideration concerns side effects of the penalty. When a person becomes poor, others often lose as well. And these others may bear no responsibility for his decisions, as when workers lose their job through their employer's bankruptcy. To be sure, looming deprivations of the innocent—the agent's children, for instance—sometimes increase the incentives to exercise proper care. This may justify the loss of advantages, such as the children's riding lessons. But a parent's bankruptcy should not lead to serious disadvantages for his children, such as loss of food or basic education, or being exposed to serious health hazards or lack of basic medical care.

This latter balancing consideration applies also to governments. The poverty of Channary and her family is surely due in part to bad government: by Prince Norodom Sihanouk, US-backed strongman Lon Nol, the horrific Khmer Rouge, and the current regime dominated by Hun Sen. But Channary shares no responsibility for the bad policies of these rulers, and there is little evidence that her dire poverty teaches some useful lesson to Cambodia's political elite. Channary and her family do not deserve their fate. They ought not have to live like this

The 'ought' in this last sentence expresses an impersonal *ought*—not one that addresses others who may be in a position to protect Channary and her family. And so it may be easy to agree—yes, her life ought not to be wasted like this. It's easy to agree because the statement does not ask anything from anyone.

But then, on reflection, it is hard to deny that the statement has moral implications for us. To deny this, one must reject all routes from the impersonal to the personal *ought*. There are at least three such compelling routes.

The first route involves a comparison of what is at stake for her with what is at stake for us. I have already made one such comparison between an extra year of life for her and my jet ski rental. If such an extra year of being well and with her family is hugely more important than my lake ride, then how can I decide to rent the jet ski and let her be without the medication? This line of thought has been followed by many. In a famous article, Peter Singer (1972) developed it in a utilitarian spirit. Henry Shue (1980) invoked the priority of rights: we ought to protect the basic rights of others if we can do so without endangering the fulfillment of our own basic rights. Shue's argument has exerted great influence on later debates about internationally recognized human rights and their counterpart duties. It is now widely accepted among international lawyers, ethicists, international civil servants, and the general public—if not yet among affluent governments—that human rights impose not merely negative duties not to violate these rights, but also positive duties to protect and promote them.

The second route has also been alluded to already. Channary's situation grows out of an historical process in which we are deeply entangled: the Vietnam War, the establishment of Lon Nol, the continued support for the Khmer Rouge. We may have no share of responsibility in any of this; so reparation for past wrongs is not at issue here. The point is rather that the situations and prospects of all of us are deeply shaped by one common history that has given some of us a start like Channary's and others vastly superior options and opportunities. Perhaps such huge inequalities could have come about without injustice. But, in fact, they did not. Our common history is deeply pervaded by the most grievous wrongs. And these wrongs taint the huge inequalities this history has resulted in. To be sure, it makes no sense to say that we inherit responsibility for crimes others have committed, even if they were our ancestors and even if they acted for our benefit. But if we rightly disown responsibility for such historical wrongs, then how can we lay claim to the fruits of these wrongs? How can we accept and forcefully defend the great advantages from birth that an unjust historical process has arbitrarily bestowed upon us without addressing the severe deprivations this same unjust process has arbitrarily imposed upon others?

The third route will be further discussed in what follows. Historically accumulated, the huge inequalities of the present manifest themselves also in the rules that govern our interactions. The most advantaged have both the power and strong incentives to shape these rules so as to entrench and expand their advantage. This phenomenon is plainly visible in many countries—in the United States, for instance, where contributions to political campaigns can buy legislative outcomes. Such laws, structuring the US economy, have between 1979 and 2005 expanded the national income share of the top 1 percent of the population from 10 to 22 percent (Saez and Piketti, 2008: Table A3), while slashing the share of the bottom half from 26 (WIDER, 2007: 4664) to 13 percent (Roney, 2007). In global rule-making, the phenomenon is even more plainly visible. Shaped by the wealthier countries, current international rules contribute to massive deprivations among the disadvantaged and are therefore unjust. Those responsible for the design and imposition of these rules are not merely failing to protect human rights, but are actively violating them. This is true according to our governments' own Universal Declaration of Human Rights which, in its Article 28, affirms that 'everyone is entitled to a social and

international order in which the rights set forth in this Declaration can be fully realized.' By imposing an international order in which especially social and economic rights foreseeably and avoidably remain massively unfulfilled, the more powerful states are violating the human rights of billions. As citizens of these states, we ought to work toward reform or else compensate for these harms insofar as we either contribute to the design or imposition of such unjust rules or benefit therefrom.

## Ш

Channary's life is typical of many lives lived among the poorer half of humankind: short lives blighted by hunger, disease, violence, servitude, and frequent deaths among one's family and close friends. Most of us in the more affluent countries never meet any of these people. But we know of them, and wish we could help. But how could we possibly help so many?

This common reaction fails fully to appreciate that the problem, though unimaginably large in terms of human suffering, is in fact tiny in economic terms. Relative to the World Bank's more generous \$2/day poverty line, the global poverty gap—the aggregate shortfall of the 40 percent of humanity reportedly living below this line—is barely \$300 billion annually, well under 1 percent of the gross national incomes of the high-income countries.2 A program that would bring a source of safe drinking water to the billion people without one, and sanitation to the 2.6 billion now without, is estimated to cost about \$7 billion annually (UNDP 2005: 93). And similar figures have been calculated for health care. The cost of implementing current and new vaccines in the 75 least-developed countries is \$2 billion annually (Jarrett, 2008). And it would cost \$51 billion annually to fund a broader foreign aid scheme that, by enabling all countries to spend each year at least \$38 per person on health, would facilitate minimally adequate public health systems for 52 of the poorest countries and their 2.3 billion citizens (Ooms and Hammonds, 2008).

How large are these amounts, really? Spreading the expense over us citizens of the affluent countries, who number just over 1 billion, makes the maths simple. The comprehensive vaccination program would cost each of us \$2 annually. And supporting minimally adequate public health systems in all countries would cost each of us \$50 per year—one movie ticket every three months or so.

While there are many laudable initiatives by international agencies, affluent governments, nongovernmental organizations, and public-private partnerships toward alleviating the health emergency among the poorer half, these initiatives, even taken together, are nowhere near sufficient. In fact, most of this effort is neutralized by countervailing forces also emanating mainly from the more affluent countries.

Exerted through the International Monetary Fund, persistent pressures on poor countries to reduce their government spending on health, education, and food subsidies are one such countervailing force (Ooms and Hammonds, 2008, also Stiglitz 2002). Another is the brain drain, which each year deprives poor countries of thousands of badly needed nurses and doctors and of the schooling and training these health workers had received at public expense (Eyal and Hurst, 2008). A third example is conventional arms exports worth tens of billions annually, which facilitate tyrannies as well as wars and civil wars especially in the resource-rich poor countries.<sup>3</sup> Then there are trade and investment rules that permit wealthy countries unfairly to advantage their own firms through huge subsidies that, for many poor countries, undermine or destroy what would otherwise be their best export opportunities. The wealthy countries have also been making a concerted effort to ease their energy shortage through biofuels, without regard to the hunger and starvation predictably resulting from higher food prices.

A sixth example is the notorious TRIPS Agreement<sup>4</sup> which—at the behest of the software, pharmaceutical, entertainment, and agricultural businesses-the Clinton Administration made a condition of WTO membership. This Agreement has devastating effects especially through its requirement that states grant 20-year product patents on new medicines, where previously patent protections had been weak or nonexistent in the developing countries.<sup>5</sup> The US intellectual-property offensive has since been continued through a series of bilateral free-trade agreements that include additional 'TRIPSplus' provisions. These enable patent holders to extend, or 'evergreen,' their monopolies and they also discourage, impede, and delay the manufacture of generic medicines in many other ways: through provisions on data exclusivity, for instance, and through restrictions on and political pressures against the effective use of compulsory licenses (Pogge 2008a: 225).

The TRIPS Agreement globalizes a monopoly patent regime that, by suppressing generic competition, keeps the prices of advanced medicines very much higher than the long-run cost of production. It thereby foreseeably excludes the global poor from access to vital medicines for the sake of enhancing the incentives to develop new medicines for the affluent. How can the imposition of such a regime be justified to the global poor?

Some say that the Agreement cannot be unjust because it was freely accepted by the governments of the poor countries. But how free were these acceptances?<sup>6</sup> And how representative were the acceding governments—which included Suharto, Mugabe, Sani Abacha, Mobutu Sese Seko, and Burma's SLORC junta—of the interests of the people they were ruling? Moreover, the fact that a government, even a democratically elected one, freely decides to impose certain rules on its country's population does not show these rules to be just. How then can the fact that two, or three, or even 151 governments agree to impose certain rules on all their countries' populations remove the possibility that these rules are unjust?

Another popular defense of the TRIPS Agreement justifies it by appeal to a natural right of inventors to control the product of their labors. If you take some of your wood and shape it into a wheel, then surely this wheel is yours to use or to sell at a price of your choosing. Likewise, if a pharmaceutical company takes some of its chemicals and converts them into a medicine effective against tuberculosis, then surely it owns this medicine. Doesn't it?

The argument's conclusion is ambiguous. If the company wanted to lay claim to the particular molecules it had synthesized, few would deny its claim. The TRIPS Agreement, however, allows this company to assert a property right not merely over what it has produced out of its chemicals, but also over what others may produce out of their chemicals. Once the company has patented its claim in the various national jurisdictions, others living there are no longer free to do what they were free to do before: to use their own chemicals to produce the molecules in question. A natural right so to constrain what others may do with their own materials is surely strange, as our homely analogue makes plain: why should the fact that you made the first wheel entitle you to saleable veto powers—for exactly 20 years!—over others' making wheels out of their own materials?

Conceived as natural rights, akin to the right not to be killed or tortured, such veto powers are bizarre. They can, however, be plausible elements in a useful scheme of law: rewarding innovators encourages innovations. But this appeal to usefulness runs into difficulties when we employ it to justify the patent regime to the global poor. They can present two powerful objections against it. They can object that such rewards are unfair because the affluent enjoy crushing advantages in the innovation race. And they can further object that the patent regime gives most of them nothing in return for the freedom it deprives them of. If the freedom to produce, sell and buy advanced medicines were not curtailed, then the affluent would need to find other ways of stimulating pharmaceutical research. But advanced medicines would then be available at competitive market prices, and the poor would have a much better chance to get access to

such medicines through their own funds or with the help of national or international government agencies or nongovernmental organizations. The suppression of such free trade cannot be justified as beneficial to the poor who suffer and die as a result. Nor can the harms they suffer be said to be outweighed by the benefits the Agreement brings to affluent patients and pharmaceutical companies.

By globalizing our pharmaceutical patent regime, we affluent have made this regime more useful to ourselves: by reducing parallel imports and by compelling the wealthier citizens of developing countries to contribute more to pharmaceutical research and development (R&D). But we have thereby also imposed a very costly loss of freedom on the global poor: cutting off poor patients from their generic drug supply and exposing billions of vulnerable people to heightened risk of death and disease (Pogge 2008b). The TRIPS Agreement and its imposition are plainly unjust and will, in terms of the magnitude of harm caused, number among the largest human rights violations in history.

#### Ш

To mitigate the injustice, a complement to the current patent regime has been proposed: the Health Impact Fund. This proposal is much discussed in this special issue: by Aidan Hollis, Michael Ravvin, and Michael Selgelid—who, like myself, are part of an international team elaborating this proposal—and also by Thomas Faunce and Hitoshi Nasu, Gorik Ooms and Rachel Hammond, and Devi Sridhar. Let me therefore briefly sketch the basic idea.

Financed mainly by governments, the Health Impact Fund (HIF) would offer any firm that brings a new pharmaceutical product to market the option to forgo monopoly pricing in exchange for a reward based on the global health impact of the new medicine. By registering a drug with the HIF, a firm agrees to sell its product globally at a price that is set no higher than cost. In exchange, it receives, for a fixed number of years, reward payments based on the product's assessed global health impact. The firm may patent a HIF-registered product anywhere it likes, but must sell it everywhere, during the reward period, at the designated price. It must also agree to offer, after the reward period, zero-priced licenses of relevant technology required for manufacturing and selling the product.

If adequately funded, such a global reward mechanism would greatly reduce the harmful effects of the patent regime and bring additional benefits besides. Rewarding actual health benefits to rich and poor alike, the HIF

would create a rush to develop drugs for diseases concentrated among the poor. These diseases have been greatly neglected, because the poor offer no viable market for monopoly-priced medicines. With the HIF, traditionally neglected diseases such as tuberculosis, malaria and tropical diseases would rise to afford some of the most lucrative research opportunities.

Under the patent regime, the most profitable patients are those who never get well and do not die. Thus, symptom relieving drugs are the most attractive to develop. The HIF avoids this bias. It rewards on the basis of actual health impact regardless of whether this is achieved through vaccines, cures or symptom relief.

The HIF is designed to facilitate wide availability of effective drugs at low prices that are further reduced through economies of scale. And each participating firm will share this aim: by making its HIF-registered products widely and cheaply available, it enhances access by the poor and thereby greatly magnifies its reward payments.

Such firms will also take other steps to overcome the last-mile problem: to ensure that their HIF-registered products are widely and optimally used. Currently, patentees have little incentive to care about what happens to their drugs beyond the point of sale. What is worse, patentees benefit when their target disease proliferates among noncustomers and thus have no incentive to fight this disease at the population level. On the HIF track, by contrast, a firm would maximize its reward through an early and complete defeat of the target disease. Working toward this goal, such firms would find it profitable to collaborate—with local governments, NGOs, international agencies, and one another—toward improving health infrastructure in poor countries so as to make their HIF-registered products optimally effective there. It has often been said that, even if the right advanced medicines were cheaply available everywhere, most people in poor countries would still go without. But this point cannot defend the current regime (Sridhar, 2008). The poor need both medicines and health professionals, that is true. But what follows from this is not that neither need should be met, but that both should be. The HIF is designed to achieve this.

To profit under the current regime, innovators must file for patents in dozens of countries and then monitor these jurisdictions for possible patent infringements. Huge amounts are spent in all these countries on costly litigation that pits generic companies, inclined to challenge any profitable patent, against patentees, whose earnings depend on their ability to defend, extend, and prolong their monopoly rents. Even greater costs are due to deadweight losses that arise from blocked sales to buyers who are willing and able to pay more than marginal

cost but not the much higher monopoly price. All this waste, which globally costs hundreds of billions of Dollars each year, would be avoided for new drugs registered with the HIF.

When prices are vastly higher than the cost of production, criminals have strong incentives to produce counterfeit drugs that endanger the health of patients everywhere. Such incentives would be weak or nonexistent in the case of HIF-registered medicines whose prices would be much lower.

Monopoly-inflated mark-ups and profit margins also stimulate aggressive marketing efforts that often work by rewarding doctors and scaring patients. Such efforts can be wasteful, resulting for instance in pointless battles over market share among similar 'me-too' medicines. Such efforts can also endanger patient health, as when massive direct-to-consumer advertising persuades people to take medicines they don't really need for diseases they don't really have—and sometimes for invented pseudo diseases (Moynihan and Henry, 2006). On the HIF track, where each innovator is rewarded for the actual global 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. There would be no reason then aggressively to market a me-too drug against an existing HIF-registered medicine—or indeed to develop such a duplicative drug in the first place. Innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as this effort results in measurable therapeutic benefits to patients who otherwise would be taking an inferior drug or none at all.

Adding the HIF as a complement to the current patent regime would go a long way toward correcting its injustice to the poorer half of humanity. It would stimulate a concerted effort to address their specific health needs through the development and effective distribution of cheap new medicines that would otherwise not have existed or have cost much more.

The HIF would also bring considerable gains to the more affluent. We, too, would benefit from the availability of advanced drugs at low prices. We would benefit from reducing the threat posed by drug-resistant disease strains, which are now predictably incubated among patients too poor to complete their course of treatment (witness MDR and XDR tuberculosis—Selgelid, 2007). We would benefit from more health-driven marketing, a reduced threat from counterfeit drugs and a greater emphasis on cures and vaccines.

The HIF would be advantageous also to the biotechnology and pharmaceutical industries. They would gain a wide range of new profit opportunities without losing any of the opportunities now open to them under the patent regime. HIF registration is optional. A firm would register a new product with the HIF when it expects health impact rewards for serving all patients worldwide to be larger than monopoly rents from serving affluent patients alone. By underwriting this standing option, the HIF would enable such firms profitably to promote their professed goal of working for a healthier world and profitably to improve their public image which current high mark-ups and neglect of the poor have left in tatters.

Creation of the HIF would require a long-term forward commitment in the amount of at least a few billion Dollars per year, which only governments could credibly make. Such a commitment is necessary, because firms deciding about a research project today must be assured that its success would actually be rewarded, after the new medicine receives market clearance, with the full set of annual health impact payments. The cost of such a commitment to taxpayers is partly offset by a reduction in the waste due to litigation, 'me-too' battles, and deadweight losses. Substantial reductions in global morbidity and premature mortality would also reduce health-care expenditures and the huge economic losses now resulting from millions of potentially productive people being debilitated or killed by disease.

A great advantage of the HIF is that it can be smoothly scaled up as experience warrants. How this can be done depends on the details of the reward mechanism. If innovators are guaranteed a certain amount per unit of health impact, this reward rate could be gradually increased. Such increases would accelerate new drug registrations with the Fund and would also increase the reward for each such new drug. Another design option is for governments to guarantee fixed annual amounts 15 years into the future, with the pool for each year to be divided among HIF-registered medicines in proportion to their assessed health impact in that year (Hollis, 2008). Here the size of the annual pool could be gradually scaled up over the years.

These two design options differ in how they allocate the inevitable burden from uncertainty about how much health impact HIF-registered products will achieve in aggregate. The former option imposes more of the uncertainty on governments and less on pharmaceutical innovators. I think this is tolerable. If the HIF stimulates more successful innovation than expected, governments will be obliged to spend more taxpayer money. But taxpayers will then also enjoy greater health gains with consequent economic benefits. There are also intermediate design options that split the burden from uncertainty between governments and pharmaceutical innovators. With even division, if the aggregate health impact of HIF-registered products is, say, 1.44 times what was expected, govern-

ment contributions would be multiplied by 1.2 and the reward rate divided by 1.2.8

It would be simplest for states joining the HIF to contribute each year in proportion to their gross national income. If states accounting for half the world's social product contributed, each state would pay about 0.02 percent of its GNI for a \$5 billion annual commitment. In the case of the high-income countries, this would work out to about \$7 annually per citizen.

The HIF would not merely alleviate a great injustice. It would also be a highly efficient means for promoting global public health, development, and economic equity and growth. But to do all these good things, the HIF must be carefully designed so that it would actually work. This requires a full specification, including the fund's administrative design, its funding rules, the requirements it imposes on registrants, its health impact measurement methodology, its algorithm for calculating reward payments, and its safeguards against corruption and gaming. Once this is accomplished, we will face an even larger, political task of publicizing the proposal and of convincing governments and citizens worldwide of its merits and practicability. The odds may be low, but the stakes are so high as to command the attempt.

### IV

The essays in this volume illuminate different aspects of the access to medicines crisis engulfing the global poor. Writing from a practical political perspective, Devi Sridhar describes what she calls the 'space' for reform of the relevant global agreements. By space, she means political opportunities that enterprising actors can seize to improve access to medicines. She focuses on two sets of actors: governments of developing countries, and citizens with their civil society organizations especially in the more affluent countries. Citing the well-known 'Green Room' procedures for WTO negotiations, as well as Thomas Pogge's discussion of imbalances in expertise and bargaining power, she argues that developing country governments can more effectively shape trade agreements by forming coalitions. Citizens, in turn, can form pressure groups in support of access to medicines, especially during election periods. Sridhar concludes by noting that although these tactics succeeded in producing the 2001 Doha Declaration on TRIPS and Public Health, they have been underused since, and opposing actors have used the time to erode the coalition as well as the 'Doha Declaration' it achieved.

Matthew Rimmer assesses the argument in favor of incorporating the 2001 Doha Declaration on TRIPS and

Public Heath, as officially interpreted by a 2003 WTO General Council Decision, into the main corpus of WTO law. The 2003 Decision allows the production and export of medicines to a developing country that has issued a compulsory license for, but lacks the capacity to manufacture, this medicine. Rimmer examines this regime through its implementation in Canada, one of the first developed countries to have adopted the relevant legislation in national law, and he traces the path of Rwanda's application to Canada for production of a HIV/AIDS drug. Noting that the Rwandan case is the only one in the world to have resulted in the manufacture and export of a medication under the 2003 decision, Rimmer criticizes the Canadian regime. In particular, he notes that the Canadian regime is more restrictive than the outlines established by the WTO, and that it imposes on generic manufacturers onerous negotiation requirements that are plainly biased toward brand-name drug companies. Rimmer's assessment holds that the Canadian-Rwandan example does not offer sufficient evidence to support the claim that the 2003 Decision is successful in enabling manufacture for export.

Vaccine markets in rich and poor countries have diverged sharply over the past 20 years. Stephen Jarrett argues that this divergence represents a failure to uphold the universal right to health. The factors causing this divergence prominently include the increased cost of new biotechnologies. This is regrettable, given that some new vaccines, against polio for example, are clearly superior to their predecessors. In other cases, the WHO is unable to recommend adoption of vaccines in developing countries for lack of data on the burden of disease there; pharmaceutical companies in turn are reluctant to study the burden of disease without assurances that their costly research will be rewarded by official vaccine adoption. Calling the prevention of disease a 'global responsibility', Jarrett asserts that a 'toolbox of incentives' should be relied upon to address the twin problems of insufficient developing-country funding and inadequate research into the burden of disease outside the affluent countries.

Michael Ravvin evaluates various proposals for reforming or complementing the intellectual property regime established by the TRIPS Agreement. This regime has resulted in several areas of concern, namely, high prices, neglected diseases, deadweight losses, bias toward symptom relief, duplication of existing drugs, counterfeiting, excessive marketing, and the last-mile problem. With specific comparison to two proposals that have been implemented to some degree-Priority Review Vouchers and Advanced Market Commitments—Ravvin claims that the Health Impact Fund offers a politically feasible, efficient, and sustainable way of increasing the availability of important new medicines at reliably low prices. An optional supplement to the patent system, this Fund would reward registered medicines on the basis of their effects on the global burden of disease (GBD).

Following on Ravvin, Aidan Hollis further explores the benefits and drawbacks of the Health Impact Fund that he has elaborated with others. Hollis describes this proposal as an extension of Advanced Market Commitment (AMC) and which work by promising prespecified large subsidies to the first firm able to supply a drug that meets a certain technical profile. AMCs therefore spur innovation toward that precisely prespecified profile. Hollis acknowledges that AMCs are suitable in some cases, such as vaccines that can be well defined in advance. The narrowness of AMCs, however, also means that they will fail to stimulate the development of drugs that don't precisely match the technical profile. In light of this, Hollis considers the properties and requirements of the Health Impact Fund. This mechanism replaces the technical profile of the AMC with a general requirement to reduce the burden of disease, measured perhaps in Quality-Adjusted Life Years (QALYs). Firms would designate particular products to participate in the scheme. These products would be sold at a HIF-mandated low price at or near cost, and the firm would then be rewarded in proportion to the health impact of its products. Hollis believes that, given sufficient funding, the HIF could effectively increase innovation compared to the uncomplemented patent system, while also providing widespread access to the new drugs.

Michael Selgelid discusses a number of critical challenges for the proposal of a Health Impact Fund. Why should the Fund offer rewards only for the health impact achieved by the purveyors of new medicines, rather than also for the health gains realized by those who distribute off-patent medicines, provide nutritional supplements, or improve drinking water and sanitation? Selgelid argues that the scope of the funding should be extended to cover other health-relevant interventions as well. He then takes up the challenges of health impact measurement. Here a key theoretical difficulty concerns additive separability: Where illness and health improvements have several interacting causes, there is even in theory no correct allocation of causal contributions. Thus, if factors A and B together cause/prevent 100 deaths and if A alone would have caused/prevented 40 and B alone would have caused/prevented 20, then there is no correct way of determining how many of the 100 should be attributed to each cause. Selgelid concludes by stressing the practical difficulties arising from the paucity of population health data for many developing countries.

Addressing the flaws of a global system of pharmaceutical access and innovation that has been shaped by what they call 'market fundamentalism', Thomas Faunce and Hitoshi Nasu propose a Cost-Effectiveness Assessment and Competitive Tender model. This model would seek to implement in an international treaty the kind of expert-based system for allocation of public health funds that currently exists in Australia and New Zealand. The treaty would set out technical criteria for determining which therapies are safe and cost-effective, and based on these principles would link expert-determined therapies to national public funding. The authors argue that, because such a model does not attempt to replace or reform the current patent system, it is politically more realistic than alternatives such as the Medical Research and Development Treaty (Medical R&D Treaty) and the Health Impact Fund.

Some commentators have recently insisted that development aid is a form of economic colonization and should therefore be curtailed in favor of fair trade. Gorik Ooms and Rachel Hammonds resist this conclusion, arguing that development aid for health is an entitlement of developing countries rather than string-laden charity from donors. Ooms and Hammonds argue that customary international law now includes an obligation to offer the international cooperation needed to realize human rights such as the right to health in the developing world. All countries thus have an obligation to cooperate in the realization of the core content of the human right to health on a global scale—in achieving a basic level of health that many countries have not yet attained. This requires increased health expenditures from both developed and developing countries. Such new monies could be deployed through the Health Impact Fund and a Global Health Fund that would enable every country to achieve minimally adequate health care for all its citizens.

Keith Horton focuses on a dilemma transnational medical agencies face when supplying aid to people in developing countries. Sometimes, supplying such aid risks producing significant negative effects, due to the wrongdoing of other agents or agencies. How should one respond to such risks? In particular, should one take account of risks that arise from the wrongdoing of others in the same way in which one takes account of such risks arising more directly from one's own actions, or from natural forces? Or do risks of negative effects that arise from the wrongdoing of others demand a different response? Horton articulates and discusses a number of reasons favoring an affirmative answer to this last question.

Finally, Nir Eyal and Samia Hurst offer a proposal for an ethically sound means of combating the brain drain of physicians from rural to urban areas and from de-

veloping to developed countries. They argue that public medical schools in such areas should consider switching their curriculum to what they call 'locally relevant medical training'. Currently, most physicians throughout the world are trained to an 'international' standard of medical practice: they are taught to use cutting-edge medical techniques that typically were developed in Western countries for use with expensive technologies. Eval and Hurst contend that, with this standard, physicians learn medical techniques that are not specifically suited to their local areas and are encouraged to migrate to where such techniques dominate. The international standard contributes to the brain drain. The authors propose that medical schools train physicians with techniques better suited to rural areas and developing countries. For instance, such schools might teach how to glean more information from a physical exam—a skill that a doctor with access to MRI machines might not need. In time, locally relevant medical training can develop into a specialty of medicine, similar to family practice, and in doing so allow for both increased prestige and career development opportunities for its practitioners. Their proposal, argue Eyal and Hurst, also avoids excessive breaches of rights to education and occupational choice and to free movement, and lacks some of the pitfalls associated with many other proposals to combat brain drain.

Composing this Special Issue has been a long process that began well before our symposium at the 8<sup>th</sup> World Congress of Bioethics, Beijing, in August 2006. Throughout this time, the collaboration with the authors has been exceptionally rewarding, both personally and intellectually. Together, we must also thank this Journal's editors, Angus Dawson and Marcel Verweij, as well as Matt Peterson, for providing very helpful comments on the entire text. We are also most grateful for generous support from the ANU Centre for Applied Philosophy and Public Ethics, from the Australian Research Council, and from the BUPA Foundation.

#### Notes

- But often overlooked, as the affluent prefer to credit their affluence solely to themselves and prefer also to attribute the persistence of poverty exclusively to national and local factors that are domestic to the societies where poverty persists.
- 2. Defined in terms of annual income or consumption expenditure with the purchasing power that \$785.76 had in the US in 1993, this poverty line corresponds today to \$1,170 in the US (www.bls.gov/CPI/) and to around \$300–500 in most poor countries. The World Bank's much more prominent \$1/day poverty corresponds to half these amounts.

- 3. A recent example is the Second Congo War (1998-2003), which killed over 5 million. Conventional arms sales from affluent to less developed countries average about \$27 billion annually, of which the US supplies about 38 percent and the UK about 6 percent (Congressional Research Service, 2007: 48).
- 4. Trade-Related Aspects of Intellectual Property Rights.
- 5. Before 2005, Indian law allowed only patents on processes, none on products. As a result, India's thriving generic pharmaceuticals industry, inventing new processes for manufacturing known medicines patented elsewhere, cheaply supplied such medicines for poor patients throughout the world's poor regions. 'But when India signed the World Trade Organization (WTO) Agreement on intellectual property in 1994, it was required to institute patents on products by Jan. 1, 2005. These rules have little to do with free trade and more to do with the lobbying power of the American and European pharmaceutical industries. India's government has issued rules that will effectively end the copycat industry for newer drugs. For the world's poor, this will be a double hit—cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs' (New York Times, 2005). Being among the poorest countries, Cambodia has until 2016 to institute the required patent regime. But because Cambodia lacks pharmaceutical manufacturing capacity, it is unclear whether cheap generic versions of advanced medicines will be available to its population in the interim. In any case, prices for advanced medicines are set to rise even in the poorest countries, well beyond the generic price level that proved too high for Channary and her family.
- 6. Signing on to the WTO Agreement may be a poor country's best option. But, as in the case of Channary selling her body, a poor country's set of options may be greatly restricted by unjust rules or past wrongs that are not the country's responsibility.
- 7. It is true, poor patients can often afford only one or a few doses and thereby contribute to the emergence of drug-resistant strains of the disease. But such resistance rarely becomes widespread before patent
- 8. More generally, one can specify in advance, for each year, the expected aggregate health impact from HIFregistered products, H, along with the expected aggregate reward payment for that year, P, and the resulting reward rate r = P/H. If H turns out to be greater than expected by a factor of n (with n > 1), one can then preserve the correctness of the equation by multiplying P by  $n^e$  and dividing r by  $n^{(1-e)}$  (with 0 < e <1). When  $e = \frac{1}{2}$ , the burden is shared equally between

- governments and innovators; the example in the text illustrates this case. If *e* is fixed above  $\frac{1}{2}$ , governments absorb more of the burden. If e is fixed below  $\frac{1}{2}$ , innovators absorb more.
- 9. We hope to have a preliminary blueprint ready by the time this special issue appears. It will be available at www.incentivesforglobalhealth.org.

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