A Reform Proposal in Need of Reform

A Critique of Thomas Pogge's Proposal for How to Incentivize Research and Development of Essential Drugs

Sonderholm, J.

Published in:
Public Health Ethics

Publication date:
2010

Document Version
Early version, also known as pre-print

A Reform Proposal in Need of Reform: A Critique of Thomas Pogge's Proposal for How to Incentivize Research and Development of Essential Drugs

Jorn Sonderholm*, Georgetown University

*Corresponding author: Georgetown University, Department of Athletics, Box 571121, McDonough Gymnasium, Washington, DC 20057-1121. Tel.: +(1)202-687-2435; Email: jorn13@gmail.com.

In two recent essays, Thomas Pogge addresses the question of how research and development of essential drugs should be incentivized. Essential drugs are drugs for diseases that ruin human lives. The current incentivizing scheme for such drugs is, according to Pogge, a significant causal factor in bringing about a state of affairs in which millions of people die or suffer from lack of access to essential drugs. Pogge, therefore, suggests a reform plan for how to incentivize research and development of these drugs, and he is of the opinion that implementation of this plan will have a significant positive impact on the global disease burden. This paper is a critical examination of Pogge's reform plan. In the first part of the paper, Pogge's reasons for being dissatisfied with the current incentivizing scheme are spelled out. The reform plan is then presented, and in the final part of the paper, it is argued that the reform plan is flawed at a number of levels.

Introduction

In two recent essays, Thomas Pogge addresses the question of how research and development of medical drugs should be incentivized.[1] He is especially interested in this question with respect to what he calls 'essential drugs'.[2] In Pogge's opinion, such a special interest is warranted by the fact that millions of people in developing countries die each year from diseases for which there either are no drugs or for which effective drugs are so expensive that they are unaffordable for the vast majority of the people who need them. The current way of incentivizing research and development of essential drugs is, according to Pogge, a significant causal factor in bringing about a state of affairs in which so many people die or suffer from lack of access to essential drugs. Pogge, therefore, suggests a reform plan for how to incentivize research and development of essential drugs, and he is of the opinion that implementation of this plan will have a significant positive impact on the global disease burden.

This paper is a critical examination of Pogge's reform plan. In the first part of the paper (the section 'A Free Market, Patents and Essential Drugs'), Pogge's reasons for being dissatisfied with the current way of incentivizing research and development of essential drugs are spelled out. The reform plan is presented thereafter (the section 'Pogge's Reform Plan'). In the final part of the paper (the section 'A Critique of the Reform Plan'), it is argued that the reform plan is unattractive because it, among other things, has little prudential appeal to those who will pay for it, is difficult to implement practically and faces a theoretical difficulty with respect to how producers of ingredients in drug cocktails should be rewarded.

Before proceeding, let me express the hope that the critique presented in this paper is not taken to be a display of lack of appreciation for Pogge's contribution to the area of global health policy. Very few philosophers, if indeed any, have made a contribution to this area as significant and influential as that of Pogge's. Whatever flaws the work discussed in this paper may have, Pogge deserves to be congratulated and respected for his efforts to highlight global health problems and for his constructive attempts to find a solution to them.

A Free Market, Patents and Essential Drugs

It is an expensive, time-consuming and financially risky endeavor to produce new and safe drugs for the market. Advanced chemical research and long clinical trials must be undertaken, and in case both of these prove

doi: 10.1093/phe/php017
Advance Access publication on 3 July 2009

successful, there awaits an often-lengthy approval process. Given that pharmaceutical companies must bear all the costs of the development process, it is no surprise that such companies are reluctant to undertake research and development of new drugs unless the financial prospects of doing so are bright. Without patent rights for pharmaceutical innovations, such prospects would be everything but bright. The reason for this is that as soon as an inventor firm introduces a new innovation in the market, other companies will copy the innovation, and given that these other companies have had no costs in terms of research and development, they will be able to charge a price for the product that is much lower than the one charged by the inventor firm. The market price for the product will therefore very likely be driven down to just above marginal costs of production, and the inventor firm will be unable to recoup its research and development costs. A macroeconomic setup for the buying and selling of drugs that does not allow for innovators to take out patents on their innovations is therefore likely to lead to a market failure of undersupply of pharmaceutical innovations.

Patent rights are a socio-economic tool that creates a temporary monopoly for inventor firms and enables such firms to charge prices for their innovations that are many times higher than the marginal cost of production of the innovations. This allows the inventor firms to salvage their research costs and secure a (sometimes hefty) profit on their innovations. So, in virtue of increasing the financial attractiveness of engaging in the process of producing pharmaceutical innovations, patent rights can be, and often are, instrumental in correcting the market failure of undersupply of pharmaceutical innovations.

However, the introduction of patent rights for pharmaceutical innovations often creates another market failure that consists in the fact that a number of mutually beneficial transactions between seller and buyer do not take place. The relatively high price of a patented drug squeezes certain potential buyers out of the market: namely those buyers who are able and willing to buy the product if it was priced somewhat above its marginal costs of production but cannot afford the product when it is priced at the profit-maximizing level that obtains during the period in which the product is patented.[3] The feature of patent rights that they squeeze out certain potential buyers from the market creates what might be labeled the 'exclusion problem'.[4] According to Pogge, the exclusion problem is morally troubling when it is essential drugs that some group of people is excluded from (Pogge, 2005: 187).

There are two standard solutions to the exclusion problem. One of them commonly goes under the name of 'differential pricing' and is the idea that a patented product is sold at different prices in different geographical locations. In high-income countries, the product is sold at one price whereas it is sold at a lower price in low-income countries. By pricing the product in this way, an inventor firm is, at least in theory, able to get the better of two worlds. High profits on the product are secured in markets with a high buying power without sacrificing the medium to low profits that come from selling the product in markets with a relatively low buying power. In addition to this, the diminished price of the product in low-income countries means that the inhabitants of these countries have an easier access to the product than they would have if the product were priced at the level of high-income countries. For someone who sees the exclusion problem as morally problematic when it comes to essential drugs, this latter feature of differential pricing makes differential pricing a prima facie attractive pricing scheme for essential drugs.

The other standard solution to the exclusion problem goes under the name 'compulsory licensing'. This mechanism bestows a right to governments to issue production licenses for patented innovations (e.g., essential drugs) that are needed to respond to public emergencies.[5] For example, on the assumption that the HIV/AIDS pandemic currently existing in sub-Saharan Africa counts as a public emergency for a number of countries in this region, the governments of these countries can authorize the production and marketing of cheaper generic versions of patented HIV/AIDS drugs on the condition that the authorized generic firms pay a small license fee to the patent holders. The market entry of companies producing generic versions of HIV/AIDS drugs will very likely drive down the price of these drugs to just above their marginal cost of production, and this will in turn ease access to the drugs. For reasons that need not be dwelled on here, Pogge is of the opinion that neither of the standard solutions to the exclusion problem will work.[6]

According to Pogge, there are two other features of the current incentivizing scheme that make it problematic. First, pharmaceutical companies have little economic incentive to try to develop drugs for the so-called 'orphan diseases'. Orphan diseases are diseases that only affect a very limited number of people. This means that the market for drugs for such diseases is very small, and the prospect of making a significant profit on drugs for orphan diseases is therefore bleak. Second, pharmaceutical companies have little economic incentive to try to develop drugs for diseases that mainly affect poor people in developing countries. The buying power of such people is extremely limited, and the prospect of making a significant profit on drugs for such diseases is therefore unpromising. When one focuses on these two features

of the current incentivizing scheme, it becomes evident that the problem with the scheme is not so much that it excludes poor people in developing countries from access to already existing drugs on the market. The problem is rather that the scheme is instrumental in bringing about a state of affairs in which a limited number of drugs that address the needs of these people are introduced in the market.[7] This problem is sometimes called the 'availability problem' (Selgelid, 2008: 134).

Pogge's Reform Plan

Pogge's reform plan consists of three components.[8] First, the results of any successful effort to develop (research, test and obtain regulatory approval for) a new essential drug are to be provided as a public good that *all* pharmaceutical companies may use free of charge. This component of the reform plan will, according to Pogge, dramatically diminish the exclusion problem. Given that new essential drugs can be freely copied by all pharmaceutical companies and introduced in the market, the price of such drugs will most likely drop to a level just above their marginal cost of production.

As Pogge notes, if this component is implemented in isolation, all economic incentive to try to develop new essential drugs will be destroyed (Pogge, 2005: 84). Such an undesirable state of affairs can be, however, avoided by implementing the second component of the reform plan. The idea here is that the inventor firms should be entitled to take out a multi-year patent on any essential drug they invent, and during the life of the patent, the companies should be rewarded out of public funds in proportion to the impact of their invention on the global disease burden.

According to Pogge, this component has several desirable consequences. First, it will generate a strong incentive for any inventor firm to (i) sell its innovative drug cheaply and (ii) allow, and even encourage, other companies to copy the drug (Pogge, 2005: 189).[9] By taking these steps, an inventor firm ensures that its innovative drug will be accessible to an increased number of people in the low-income range, and as a consequence of this, the drug will have an increased effect on the global disease burden.

Second, this component will create a situation in which an inventor firm has incentives to see to it that patients are fully instructed in the proper use of its drug (dosage and compliance). The reason for this is that only by ensuring that its product is used properly can an inventor firm avoid the (for it) unfortunate situation in which its product is widely used but fails to make a significant impact on the global disease burden. Third, this component will bring it about that the poor populations of developing countries constitute a lucrative market for pharmaceutical companies. There would, for example, be strong economic incentives for pharmaceutical companies to try to develop drugs for diseases such as malaria, tuberculosis and pneumonia. Given that these diseases affect a large number of people in the most gruesome of ways, an effective drug for any of these diseases would have a huge impact on the global disease burden. An inventor firm that could produce an effective and safe drug for any of these diseases would therefore be the recipient of a reward of considerable proportions. Fourth, this component has an advantage over the status quo in the sense that it will alleviate the current problem that very little is done in terms of research and development of drugs for orphan diseases.[10]

It should be noted that the fourth consequence of the second component of the reform plan is one that Pogge sees as a moral (as opposed to a prudential) reason for adopting the plan. The third consequence constitutes also, at least in part, a moral reason in favor of implementation of the plan. According to Pogge, it is *morally* problematic that so little is done in order to develop treatments for diseases (malaria, tuberculosis, pneumonia, diarrhea etc.) that cause most of the premature deaths and suffering in the world today (Pogge, 2005: 190).

The main task associated with the second reform component consists in coming up with a set of principles that can guide the reward process. Pogge suggests that when two or more different drugs are alternative treatments for the same disease, then the reward corresponding to their aggregate impact must be allocated among their respective investors on the basis of each drug's market share and effectiveness (Pogge, 2005: 191).[11] As acknowledged by Pogge, things get, however, more complicated when an essential drug is not a single product but a 'drug cocktail' that combines various drugs that have been developed and manufactured by different companies.

The third component of Pogge's reform plan consists in developing a fair, feasible and politically realistic allocation of the costs associated with the second component.[12] According to Pogge, effective implementation of the reform requires that much of its costs be borne by the developed countries. Such countries will have to shoulder around $70 billion per year in new expenditures, but this only amounts to an annual outlay of $70 for each citizen of these countries. To make this increased spending realistic, taxpayers and politicians of the high-income countries need to be given compelling reasons for supporting it. Pogge is of the opinion that his plan can be supported by prudential considerations (Pogge, 2005: 192).[13]

First, the new incentivizing scheme will lead to significantly lower prices for essential drugs for consumers in the high-income countries. Under the current free-market scheme, consumers in these countries pay high prices for essential drugs either directly or through contributions to commercial insurance companies. Second, by giving the poor citizens of developing countries a free ride on the pharmaceutical research conducted for the benefit of citizens in the affluent countries, the latter citizens are building goodwill toward themselves in the developing world by demonstrating in a tangible way their concern for the horrendous public-health problems these populations are facing (Pogge, 2005: 193). Third, the reform plan will create top-flight medical research jobs in the developed countries. Fourth, it will enable these countries to respond more effectively to public-health emergencies and problems in the future by earning them more rapidly increasing medical knowledge combined with a stronger and more diversified arsenal of medical interventions (Pogge, 2005: 193).

A Critique of the Reform Plan

Patents and the HIV/AIDS Pandemic

The most important reason for Pogge's dissatisfaction with the current way of incentivizing research and development of essential drugs is that it creates an exclusion problem. Consider this passage:

> The existing rules for incentivizing pharmaceutical research are morally deeply problematic. This fact, long understood among international health experts, has come to be more widely recognized in the wake of the AIDS crisis, especially in Africa, where the vital needs of poor patients are pitted against the need of pharmaceutical companies to recoup their research-and-development investments. (Pogge, 2005: 184)

There is, however, reason to be skeptical that the HIV/AIDS pandemic in Africa can be used to support the idea that the current reward scheme is problematic because it creates an exclusion problem. Empirical research shows that antiretroviral drugs for HIV/AIDS are not commonly patented in African countries (Attaran and Gillespie-White, 2001). Out of 795 possible instances of patenting (the number of African countries examined in the study (53) multiplied by the number of antiretroviral drugs examined in the study (15)) only 172 (21.6 per cent) are taken out (Attaran and Gillespie-White, 2001: 1887). In every African country there are at least two antiretroviral drugs that are not patented. South Africa lies at one end of the spectrum. Thirteen out of 15 of such drugs have here been patented by pharmaceutical companies. Namibia, Mozambique and 11 other countries lie at the other end of spectrum. In these countries, no antiretrovirals have been patented by pharmaceutical companies. This means that African countries are legally free to copy available antiretroviral drugs on the market and distribute them to their citizens without having to pay *anything* to inventor firms. In light of this, there is not much substance to the suggestion that the HIV/AIDS pandemic in Africa is an example of a situation in which the vital needs of poor patients are pitted against the need of pharmaceutical companies to recoup their research and development interests.

A recent WHO report estimates that just 11 per cent of sub-Saharan African HIV/AIDS patients in the age group 0–49 receive antiretroviral therapy.[14] How many of these patients receive the WHO recommended standard therapeutic regimen consisting of *at least* three antiretroviral drugs is not disclosed.[15] Assuming that the WHO estimate is correct, there is a clear case for saying that an exclusion problem does exist in Africa with respect to antiretroviral drugs. However, if this problem cannot be attributed to the pricing policies of pharmaceutical companies, what is then that generates the problem?

According to Attaran and Gillespie-White, the main problem is the ubiquitous poverty of African countries. These countries simply lack the necessary resources to finance "the physicians, clinics, and infrastructure needed to administer antiretroviral therapy, much less to screen patients for HIV infection, and this has the lamentable result that even in cases in which pharmaceutical companies discount or freely donate antiretroviral drugs, poor African countries still cannot afford to use them. Lack of finance thwarts not only 'expensive' AIDS treatment but even the highly cost-effective use of antiretroviral drugs in preventing pediatric HIV infection at birth (one such drug, nevirapine, is donated by Boehringer Ingelheim but is rarely used in Africa)" (Attaran and Gillespie-White, 2001: 1891).

In an attempt to further underscore the suggestion that the pricing policies of pharmaceutical companies do not, to a significant degree, exclude HIV/AIDS patients in Africa from access to relevant drugs, it is instructive to consider this statement from Dr. Joseph Decosas, director of the South African Aids Training Program:

> Even if you make these drugs available for *free*, the systems to deliver them are not there. Of course we should get the prices down, if only 50 people benefit. But this is not going to make any difference and probably is going to cause distortions to the already struggling African health systems, by forcing new technology when they can't even

> distribute treatments for tuberculosis, which costs $1 a month. HIV in Africa is contracted and spread through a web of causations—economic, developmental, social—and when you start focusing on a single solution, like antiretrovirals, you fail. (Friedman, 2001).

The issue of how poverty and lack of infrastructure constitute a barrier to the delivery of essential drugs to patients in Africa (and elsewhere in the developing world) is one that Pogge addresses in a number of his writings. It is common to think of this issue as the 'last mile problem'. In order for essential drugs to be effective and have an effect on the global burden of disease, they must be delivered over the last mile, all the way to the patients who need them. Pogge is of the opinion that the HIF will create positive incentives for pharmaceutical companies to overcome some of the challenges posed by the last mile problem (Hollis and Pogge, 2008: Chapter 7). To get an understanding of exactly how the HIF will achieve this aim, it is instructive to consider these passages:

> If systemic shortcomings in the health sector were adversely affecting the widespread accessibility of its HIF-registered drug, a pharmaceutical company might well be prepared to provide financial and other support to a SWAp [Sector Wide Approach] designed to address these problems, though the company would understandably be focused on issues relating to the distribution of its own product (Hollis and Pogge, 2008: 75).

> HIF registrants can be expected to have a strong interest in supporting efforts aimed at: identifying key factors that prevent the acquisition of knowledge about appropriate use of medicines leading to changed behavior of health care workers and patients; determining how information on poor-quality drugs can best be communicated to the general public; identifying which strategies are most effective in encouraging health care providers in both the public and private sectors to adhere to standard treatment guidelines; developing simple tests that can be used by community health workers, dispensers or drug sellers to detect counterfeit drugs; and identifying how best to conduct improved drug use information, education and communication campaigns for consumers (Hollis and Pogge, 2008: 77).

I do not, however, see how pharmaceutical companies en bloc have the positive incentives described here. It is quite likely that a given pharmaceutical company in a given context has (perverse) incentives to contribute to the deterioration of the public health infrastructure in a given country. If the general improvement in this respect is facilitated and paid for by a given pharmaceutical company, then the expensive efforts of this company also make other companies' products more effective. This means that these other companies will receive higher reimbursement from the HIF, which in turn means that the company that has worked for the general improvements will receive a smaller reimbursement (this inference is based on the assumption made by Hollis and Pogge that there should be no fixed rate per 'unit of health improvement' (2008: 18)). The overall reimbursement per year by the HIF should be spread out evenly among the products that have a positive impact on the global burden of disease. So, imagine that company A has a product in country x and that company B also has a product in this country and that its product has a significantly higher potential for health improvement than the product of company A. Imagine also that company A has another product in another country that has a huge potential for health improvement and that company B has no other product than the one it has in x. In this scenario, company A has very little financial incentive for contributing to the general improvement of the health infrastructure in country x.

Prudential Appeal

This point of criticism concerns the prudential appeal of Pogge's plan. The point requires some examples to get under way. First example: (a) is a drug that immediately reduces the symptoms of diarrhea in infants and keeps the symptoms at bay for up to four weeks. It is successful in 40 per cent of cases and comes in the form of two pills that cost $2 to produce. (b) is a drug that immediately reduces the symptoms of diarrhea in infants and keeps the symptoms at bay for up to four weeks. It is successful in 90 per cent of cases and comes in the form of a powder that needs to be dissolved in 25 cl of clean water that should be drunk by the infant. The production cost of (b) is one-fourth of that of (a).

Second example: (a) is a treatment for malaria. It is successful in 40 per cent of cases and comes in the form of two pills that must to be taken with an interval of 24 hours. The production cost is $2. (b) is a treatment for malaria. It is successful in 90 per cent of cases and comes in the form of two pills that must be taken with an interval of 24 hours. (b) requires cold storage (i.e., requires storage at refrigerator temperature) and has a production cost that is one-fourth of that of (a).

Third example: (a) is a treatment for tuberculosis. It is successful in 40 per cent of cases and comes in the form of two pills that must be taken with an interval of 24 hours. The production cost is $2. (b) is a treatment for tuberculosis. It is successful in 90 per cent of cases and comes in the form of a liquid that needs to be injected

into a specific vein in the arm (this is quite important, so a nurse is required to do the injection). The production cost is one-fourth of that of (a).

These examples describe scenarios in which it is very likely that the producers of (a) will receive a higher reward than the producers of (b). This is so because (a) is likely to have a greater impact on the global disease burden than (b). This stems from the fact that the effectiveness of (a) does not require things that are quite often lacking in developing countries and that (b) requires in order to be effective (clean drinking water, infrastructure (harbors, roads, railways, storage facilities, a reliable electricity grid) and educated health personnel are examples of such things).[16] So, geographic, industrial and educational features of the regions in which people with diarrhea, malaria and tuberculosis commonly live contribute in a very tangible way to the relatively small reward that produces of (b) will receive under Pogge's reform plan.[17]

Pharmaceutical companies that are driven by the profit motive will soon realize that the economic prospects of developing high-tech essential drugs aimed at the medical needs of the populations in developing countries are meager.[18] As a result, they will predictably reorient at least some of their research and development efforts toward low-tech drugs. There will also predictably be an emergence of new pharmaceutical companies that have as their only focus the development of low-tech essential drugs that address the medical needs of the populations of developing countries.

These are developments that will be welcomed by Pogge. There is, however, a question with respect to what prudential reasons there are for citizens in developed countries to support a reform plan that results in these developments. As far as I can see, there are very few such reasons. It is true that the emergence of this new niche of drug development will likely create new jobs, but the funding for these jobs will come from the fund that pays for the second component of the reform plan, and as Pogge himself has stressed, it is the developed countries that must shoulder 'much of the costs' associated with the setting up of this fund (Pogge, 2005: 192). So, most of the resources that are needed to pay for these new research jobs in the developed countries is being provided by the developed countries themselves. No new capital (or only very little) flows, in other words, into the economies of these countries, and in case some of these new niche pharmaceutical companies are situated in a developing country, economic resources are flowing from the developed countries into the developing ones.

There might, however, be other prudential reasons for implementing the plan. Perhaps the existence of these niche pharmaceutical companies within the developed countries will result in these countries gaining useful medical knowledge that would be to the benefit of their citizens. This cannot be ruled out, but if the objective is to create new medical knowledge for the benefit of the citizens of developed countries, resources are not best spent by funding research that is hindered in the sense that it must yield an output that is effective under the geographic, industrial and educational conditions that commonly obtain in developing countries. Research undertaken for the benefit of citizens of developed countries would be much more likely to succeed if it was allowed to develop drugs that require for their effectiveness *all* the technological, educational and financial resources that exist within the healthcare systems of developed countries.

Pogge is right that diseases can spread quickly nowadays (think of SARS) and that some diseases that have their origin in developing countries today exist in the developed world (think of West-Nile Virus that is spread by mosquitoes in many areas of the southern United States). In light of this, it is indeed reasonable for developed countries to seek to acquire medical knowledge that enables them to deal with the health-threats posed by diseases such as these. However, from the perspective of taxpayers in the developed world, there are few prudential reasons for funding research and development of drugs that are geared toward being effective in the developing world. The vast majority of taxpayers in the developed world have advanced technological and educational resources available to them, and cures for diseases such as SARS and West-Nile Virus (and HIV/AIDS) are most likely to be found if researchers are allowed to look for drugs the effectiveness of which presupposes the availability of these resources.

What about Pogge's argument that implementation of the reform plan will result in lower prices for essential drugs in the developed world? Pogge's claim about consumers in developed countries having to pay high prices for essential drugs is too sweeping. The claim is only true if no distinction is made between the United States and high-income countries with a public health care system (e.g., the Scandinavian countries). Consumers in the latter kind of countries have access to relatively cheap essential drugs. They do not pay for their essential drugs themselves, and they do not normally pay into personal health care insurance plans. It is therefore not obvious how the reform plan will be an economic benefit for the citizens of these countries. In response to this, it might be replied that these citizens actually do pay a high price for essential drugs. This is through their relatively high tax contributions (compared to the United States). A

substantial part of tax contributions that go toward paying for a public health care system is, after all, allocated to the acquisition of drugs.

However, if Pogge's plan is implemented, citizens of developed countries face a new tax bill of $70 billion a year that goes toward paying for essential drugs. It is therefore misleading to say that the reform plan will lead to significantly cheaper essential drugs. The reform plan does not make essential drug significantly cheaper. However, it re-allocates the burden of paying for these drugs from patients to taxpayers. Such a re-allocation of the burden of paying for essential drugs might be a good thing, but it requires argument to show that it is, and Pogge does not provide such argument over and above saying that such a re-allocation is justified because it evens out the effects of luck (Pogge, 2005: 184). It is, however, not true that everyone who is in the unfortunate situation of being in need of essential drugs is in this situation due to the effects of bad luck. There are countless examples of people in developed countries who have contracted malaria, hepatitis or HIV/AIDS (and therefore are in need of essential drugs) due to a decision to refrain from taking any of the existing, effective precautions against the relevant disease.

Let me end this point of criticism by commenting on Pogge's suggestion that citizens of the developed world have prudential reason for accepting the reform plan due to the fact that by giving the citizens of developing countries a free ride on pharmaceutical research conducted for the benefit of citizens in the affluent countries, the latter citizens are building goodwill toward themselves in the developing world. It is undoubtedly true that by offering such a free ride, the citizens of the developed world are building goodwill. However, it must here be remembered that the annual price tag on this goodwill is $70 billion. Given that it is unclear how much goodwill the developed world will receive by spending this amount of money on Pogge's plan and given that goodwill can also be secured by spending money in alternative ways, it is not at all obvious that a cost–benefit analysis will dictate that the money should be spent on Pogge's plan.

Perhaps Pogge wants to reply to this by suggesting that the strongest reason the developed world has for giving developing countries a free ride on pharmaceutical research is a moral one. This suggestion might be right, but it is morally compelling for the developed world to give the developing world a free ride *only* on the assumption that the developed world is significantly causally responsible for the public health problems in the developing world. This assumption is very controversial. Pogge has argued for its truth in (Pogge, 2002, 2002b), but it is beyond the scope of this paper to evaluate his argument.[19]

Practicality Matters

Let me now move on to a point of critique that focuses on practical obstacles to the implementation of Pogge's plan. In a recent paper (Rosenberg, 2004), Alex Rosenberg discusses a proposal to the effect that a system of government rewards for innovations should replace the current practice of granting patent rights to innovators. The government reward scheme that Rosenberg discusses has many similarities to Pogge's reward plan, and some of the practical difficulties that Rosenberg raises for a government reward scheme can, I think, be shown to apply in equal measure to the reform plan put forward by Pogge.

First, the second component of Pogge's plan requires the involvement of an international agency whose job would be to keep track of various drugs' impact on the global disease and pay rewards to pharmaceutical companies. The involvement of such an agency in the macroeconomic setup raises transaction costs and provides ample opportunity for corrupt behavior of employees of the agency and those who can influence them.[20] Pogge has acknowledged that around 10 per cent of the monetary resources going into the reform plan will have to be spent on administration and assessment (Hollis and Pogge, 2008: 31). In relation to the issue of corruption, it is worth stressing the unfortunate empirical fact that corrupt behavior is a rather widespread phenomenon amongst (government) officials in many of those developing countries in which data collection needs to be undertaken.[21] Pogge has argued that data about the global burden of disease and the health impact of various medicines collected under the reform plan would be useful beyond the strict purposes of this plan (Hollis and Pogge, 2008: 31). The data would, for example, enable better prescribing as the relative therapeutic benefits of different products are better understood. The vulnerability of the assessment procedure for corruption would, however, reduce the usefulness of the gathered data in comparison with data produced by standard academic and governmental research programs.

Second, it will be difficult for the agency in question to secure accurate information about the impact that various drugs have on the global disease burden. The problem is not only one of coming up with a plausible metric that can be used to determine a drug's impact on the global disease burden.[22] Assuming that this can be done, there is a further and more practical problem of applying the metric and doing the actual field work of visiting huge,

poor and often geographically isolated populations and getting an accurate overview of what the disease burden is in the area and how various drugs are contributing to its reduction. Visits of this kind must be made all over the world and on a continuous basis. Even with the best of wills of those who partake in this gigantic exercise, the chances of misrepresenting causal efficacy, failing to report data, making wrong estimates and miscalculating data input are huge, and any error with respect to the reporting, filing and computation of empirical data results in an unjust distribution of rewards. In relation to this, it is worthwhile to draw attention to a recent estimate of the reliability of data pertaining to the global disease burden and projections about what the global disease burden will be at some future point.

> The best data comes from countries with the strongest vital registration systems—i.e., for the reporting and recording of each death and its cause, among other things. Unsurprisingly, however, such systems are usually weakest and often absent in developing world countries. There is less confidence in current disease burden estimates in poor countries, and the authors of the GBD [Global Burden of Disease] studies urge 'great caution' in the use of their projections of future disease burden in places like sub-Saharan Africa in particular (Murray and Lopez, 1996: 331). For the purpose of a full-pull program, then, that data is weakest in the very places where it is wanted most. (Selgelid, 2008: 138).

I bring these issues of practicality to the fore because Pogge himself underlines that in order for his reform plan to be more than just a philosopher's pipe dream, it must take into account, and deal with, practical obstacles to its implementation (Pogge, 2005: 185).

Orphan Diseases

This point of critique relates to Pogge's (2005) suggestion that the second component of his reform plan will have an alleviating effect on the current problem with respect to lack of drugs for orphan diseases. It is not obvious that the component will have such an effect. By definition, orphan diseases affect only a very limited number of people. An effective drug for any such disease will therefore not be likely to have a significant impact on the global disease burden, and the corresponding reward will be relatively small. A relatively small reward will, in turn, not be enough to attract the needed research and development. It should be noted that Pogge in a subsequent writing acknowledges that his reform plan does nothing to alleviate the problem that few drugs are developed for orphan diseases (Hollis and Pogge, 2008: 107).

Drug Cocktails and Rules for the Phase-in Period for New Drugs

As mentioned in the section 'Pogge's Reform Plan', Pogge acknowledges that the question of reward distribution is somewhat complicated when it is producers of ingredients in 'drug cocktails' that need to be rewarded. In Pogge's view, this complication is, however, not insurmountable. A resolution to it is suggested in the following passage:

> Here the reform plan must formulate clear and transparent rules for distributing the overall reward, based on the impact of the drug cocktail, among the inventors of the drugs it contains. And it must also include specific rules for the phase-in period so as not to discourage ongoing research efforts motivated by the existing patent rules. (Pogge, 2005: 192)

The idea expressed in the first sentence of this passage is that we begin by determining what overall impact a given drug cocktail has on the global disease burden. Then we allocate a reward to the drug cocktail and split that reward between all the producers that have contributed with an ingredient to the cocktail. Such an approach is, however, under-specified in the sense that it leaves it open whether the reward should be split evenly between all the producers that have contributed to the cocktail or it should be split according to some formula that, for example, takes into account the costs of the individual ingredients. An 'even split' solution is theoretically the simplest one, and given that simplicity in the design of the details of Pogge's plan is something that the plan's proponents aim at (Hollis, 2008: 130), this is perhaps the solution that should be implemented. It is, however, easy to construct examples in which this solution leads to an intuitively unfair distribution of rewards. Two such examples are presented below.

Example (a): One of the ingredients in a drug cocktail is a certain protein that has to be harvested from blood plasma. Such a process is much more expensive than producing, say, aspirin which, we may assume, is one of the other ingredients in the cocktail. In this case, one of the manufacturers has much higher production costs than that of another, and it is intuitively unfair if this is not reflected in the reward that these producers respectively receive.

Example (b): X is a relatively new, life-threatening disease for which there currently is no treatment or cure. For people with a normal immune defense system, there is a 70 per cent chance of dying of X within six months of contracting the disease. For people with a weakened

immune defense system, the survival chance is even slimmer. D is a new drug that is introduced in the market, and it is a 100 per cent effective treatment for X. The treatment with D lasts six months, and it is a side effect of D that it reduces the immune defense system to a level such that if no additional treatment is given, there is a 70 per cent chance of dying from an infection during the six-month treatment period. P is an off-patent, first-line-of-defense antibiotic that is open to generic production. P even outs the detrimental effects of D on the immune defense system. This means that if people who take D also take P during their six-month treatment for X, they are at no higher risk of dying from an infection than people who have a normal functioning immune defense system. As a result of this, it becomes a standard medical practice shortly after D has come on the market to treat victims of X with a drug cocktail that consists of both D and P. The producers of P now apply for and obtain a 'new use' patent on the drug: the drug is now patented as a treatment for X. The producers of P also register the product (as a treatment for X) with the agency that reimburses pharmaceutical companies.

How should the respective producers of D and P be rewarded? In light of the fact that D is a new medicine and that the producers of D most likely have incurred significant research and development costs and that the producers of P have had no similar costs, it is intuitively unfair if the producers of D do not receive a significantly higher proportion of the overall reward than the producers of P.

If an 'even split' principle should not guide the distribution of rewards to producers of ingredients in a drug cocktail, which principle should? No obvious answer presents itself. In my view, one of the key theoretical problems of Pogge's reform plan, therefore, consists in finding a fair principle that can guide the distribution of rewards to producers of ingredients in drug cocktails.[23]

Leaving this issue to one side, there is the question of what rules should be in place during the phase-in period for drug cocktails and indeed all other essential drugs. Pogge does not provide an answer to this question but stipulates that the reform plan must provide it and that 'it is of crucial importance that all these rules be clear and transparent, lest they add to the inevitable risks and uncertainties that complicate the work of inventor firms and sometimes discourage them from important research efforts' (Pogge, 2005: 192). Stressing the need for clarity with respect to the formulation of these rules is not misguided, but it would be more interesting to hear something detailed about what rules/principles should guide the reward process.

Conclusion

This paper is a critical examination of Thomas Pogge's reform plan for how to incentivize research and development of essential drugs. The main conclusions of the paper are that: (i) there is reason to be skeptical that the HIV/AIDS pandemic in Africa can be used to support the idea that the current reward scheme for essential drugs is problematic because it creates an exclusion problem; (ii) the plan has little prudential appeal to those who are supposed to bear the vast majority of the economic burden associated with its implementation; (iii) the implementation of the plan faces serious practical obstacles; (iv) the plan contains no fair principle for the distribution of rewards to producers of ingredients in drug cocktails.

Nothing in this critique implies a stance of indifference toward the suffering experienced by people in the developing world due to lack of good health. This suffering is both in its scope and severity truly horrendous, but there are good reasons for believing that Pogge's reform plan does not constitute an attractive way of alleviating it.

Notes

1. (Pogge, 2005, 2006).
2. Essential drugs are drugs for diseases that ruin human lives (malaria, tuberculosis, pneumonia and HIV/AIDS are paradigm examples of such diseases).
3. In economic theory, 'deadweight losses' designate the type of losses that occur when someone is able and willing to pay more than the marginal cost of production for a product but is not willing or able pay the patent price for it (Hollis, 2008: 125; Pogge, 2008: 77; Ravvin, 2008: 112).
4. Another label is the 'access problem' (Ravvin, 2008: 116; Selgelid, 2008: 134).
5. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiated in the 1986 Uruguay Round bestows such a right to governments. See (WTO, 1986).
6. Pogge presents his reasons in (Pogge, 2005: 187, 2006: 145). In addition to differential pricing and compulsory licensing, a number of other solutions to the exclusion problem have been proposed. These solutions include bulk buying, priority review vouchers (PRVs) and advanced market commitments (AMCs). For a discussion of these solutions, see (Hollis and Pogge, 2008: Chapter 9). For the record, I should mention that I agree with Pogge that the current incentivizing scheme could be improved upon. With respect to this, I find the PRV proposal by (Ridley *et al.*, 2006) promising.

7. According to one study, less than 1 per cent of the 1223 new medicines launched on the international market between 1975 and 1997 were destined specifically for tropical communicable diseases (Trouiller *et al.*, 2001).
8. It is worth stressing how ambitious Pogge's reform plan is. Consider, for example, the following passages: 'My aim is to develop a concrete, feasible, and politically realistic plan for reforming current national and global rules for incentivizing the search for new essential drugs' (Pogge, 2005: 184) and 'I will sketch a concrete, feasible, and politically realistic reform plan that would give medical innovators stable and reliable financial incentives to address the medical conditions of the poor' (Pogge, 2006: 142).
9. In a recent publication, it is emphasized that pharmaceutical companies that wish to be rewarded under the new scheme are required to sell their products worldwide within a price window ranging between the average and marginal cost of production as determined by the fund in charge of reimbursement (Hollis and Pogge, 2008:74).
10. It is unclear how the reform plan will alleviate this problem. The following passage is, however, textual evidence for the suggestion that Pogge thinks it will: 'This second component of a plausible public-good strategy realizes yet one further tremendous advantage over the status quo: Under the current regime, inventor firms have incentives to try to develop a new medical treatment only if the expected value of the temporary monopoly pricing power they might gain, discounted by the probability of failure, is greater than the full development and patenting costs. They have no incentives, then, to try to develop treatments that few people have a need for and treatments needed by people who are unable to afford them at a price far above the marginal cost of production. The former category contains treatments for many so-called orphan diseases that affect only small numbers of patients' (Pogge, 2005: 189).
11. Pogge acknowledges that the feasibility of rewarding pharmaceutical companies in proportion to their products' effect on the global disease burden requires that there are rules/principals in place that allow us to measure the global disease burden and assess the contributions that various new essential drugs are making to its reduction (Pogge, 2005: 191).
12. Pogge's assessment is that the second component will cost $45–90 billion annually on a global scale (Pogge, 2005:191). It should be mentioned that Pogge has recently suggested that a reasonable minimum funding level for the reform plan is $6 billion (Hollis and Pogge, 2008: 44).
13. Pogge also thinks that his plan can be supported by moral considerations. Two of these have already been mentioned, and it is appropriate to mention a third one. In Pogge's own words, 'This argument has a moral twin: In light of the extent of avoidable mortality and morbidity in the developing world, the case for giving the poor a free ride [on the pharmaceutical research conducted for the benefit of citizens in the affluent countries] is morally compelling' (Pogge, 2005: 193).
14. See (WHO, 2005).
15. See (WHO, 2008) for an outline of WHO's recommendations.
16. Statistical data from the South African Health Review (Ntuli, 2000) lend credibility to the claim that clean drinking water, infrastructure and educated health personal are often lacking in developing countries. Eight per cent of all fixed public clinics in South Africa have no electricity, water is supplied by tanker to 12.5 per cent of the country's satellite clinics and an equal percentage of fixed clinics rely entirely on rainwater. Only two-thirds of the clinics nationally receive nurse supervisor visits as often as once per month. This is data from South Africa, which is a country that in comparison to other developing countries (countries characterized as either low- or middle-low income countries by the World Bank) is rather well developed. For the developing world as a whole, there is therefore no good reason to think that the relevant statistical data are more uplifting. The statistical data cited here are also cited in (Barnard, 2002: 169).
17. The reward given to the producers of (b) is small relatively to the size of the reward given to the producers of (a).
18. What is meant here by a 'high-tech drug' is a drug that requires clean drinking water, electricity or educated health personal in order to be effective. Conversely, a low-tech drug is a drug that requires neither of these things in order to be effective.
19. For a critical assessment of Pogge's view about the extent to which the developed world is causally responsible for public health problems in the developing world, see Patten (2005).
20. It is true that there are transaction costs involved in the current system for incentivizing research and development of essential drugs. Most importantly, this system requires both patent offices and patent courts, but, as Rosenberg notes, 'a patent system's greater reliance on individuals to pursue their own interests directly, instead of through an intervening government, is generally more effective than any alternative' (2004: 84).

21. See Lambsdorff (2008).
22. There is general agreement among the proponents of Pogge's plan that the most promising metric candidate is the Quality-Adjusted-Life Year (QALY) system, which currently is being used by national health systems in Australia, Canada, the UK and USA to measure the health impact of pharmaceuticals (Hollis, 2008: 127–128; Ravvin, 2008: 120; Selgelid 2008). Selgelid, (2008: 140–143) shows that the viability of health impact measurement by either QALYs or DALYs (Disability-Adjusted-Life Years) is severely threatened by the problem of causal attribution. This is the problem of determining the extent to which any reduction in the global disease burden is caused by one drug/intervention as opposed to another drug/intervention. Assume, for example, that drugs A and B together prevent 100 deaths and that A alone would have prevented 40 deaths and that B alone would have prevented 20 deaths. In such a scenario, there is no theoretically correct way of determining how many of the 100 prevented deaths should be attributed to A and how many to B. As a result of this, there are huge problems in finding a just way to split the reward for 100 prevented deaths to the producers of A and B.
23. This is so even if you ignore the problems of causal attribution identified in Selgelid (2008).

Acknowledgements

I wish to thank Judith Lichtenberg for helpful comments on an earlier version of this paper. I would also like to thank two anonymous referees from *Public Health Ethics* for very helpful comments on an earlier version of this paper.

References

Attaran, A. and Gillespie-White, L. (2001). Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? *Journal of the American Medical Association*, **286**, 1886–1892.

Barnard, D. (2002). In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries. *Kennedy Institute of Ethics Journal*, **12**, 159–174.

Friedman, T. (2001). It Takes a Village. *New York Times*, 27 April.

Hollis, A. (2008). The Health Impact Fund: A Useful Supplement to the Patent System? *Public Health Ethics*, **1**, 124–133.

Hollis, A. and Pogge, T. (2008). The Health Impact Fund: Making New Medicines Accessible to All: Incentives for Global Health. Available from: http://www.yale.edu/macmillan/igh/

Lambsdorff, J. G. (2008). *Corruption Perceptions Index (CPI)*. Berlin: Transparency International, available from: http://transparency.org/news_room/latest_news/press_releases/2008/2008_09_23_cpi_2008_en [cited 13 December 2008].

Ntuli, A. (ed.) (2000). *South African Health Review 2000*. Durban: Health Systems Trust.

Patten, A. (2005). Should We Stop Thinking about Poverty in Terms of Helping the Poor? *Ethics & International Affairs*, **19**, 19–27.

Pogge, T. (2002). *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms*. Cambridge: Polity Press.

Pogge, T. (2002b). Responsibilities for Poverty-Related Ill Health. *Ethics & International Affairs*, **16**, 71–79.

Pogge, T. (2005). Human Rights and Global Health: A Research Program. *Metaphilosophy*, **36**, 182–209.

Pogge, T. (2006). Harnessing the Power of Pharmaceutical Innovation. In *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing*. London: Pluto Press.

Pogge, T. (2008). Access to Medicines. *Public Health Ethics*, **1**, 73–82.

Ravvin, M. (2008). Incentivizing Access and Innovation for Essential Medicines: A Survey of the Problem and Proposed Solutions. *Public Health Ethics*, **1**, 110–123.

Ridley, D. B., Grabowski, H. G. and Moe, J. L. (2006). Developing Drugs for Developing Countries. *Health Affairs*, **25**, 313–324.

Rosenberg, A. (2004). On the Priority of Intellectual Property Rights, Especially in Biotechnology. *Politics, Philosophy & Economics*, **3**, 77.

Selgelid, M. J. (2008). A Full-Pull Program for the Provision of Pharmaceuticals: Practical Issues. *Public Health Ethics*, **1**, 134–145.

Trouiller, P., Torreele, E., Olliaro, P., White, N., Foster, S. and Wirth, D. (2001). Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure? *Tropical Medicine and International Health*, **6**, 945–951.

WHO. (2005). *Progress on Global Access to HIV Antiretroviral Therapy*. Available from: http://www.who.int/3by5/fullreportJune2005.pdf.

WHO. (2008). *Antiretroviral Therapy*. Available from: http://www.who.int/hiv/topics/treatment/en/index.html [cited 28 November 2008].

WTO. (1986). *The Agreement on Trade-Related Aspects of Intellectual Property Rights*. Available from: http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm [cited 13 December 2008].