

# Biomedical Research, Neglected Diseases, and Well-Ordered Science

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ABSTRACT: In this paper we make a proposal for reforming biomedical research that is aimed to align research more closely with the so-called fair-share principle according to which the proportions of global resources assigned to different diseases should agree with the ratios of human suffering associated with those diseases.

Keywords: biomedical research, neglected diseases, well-ordered science.

## *1. Well-Ordered Science and the Fair-Share Principle*

The practice of the sciences is well-ordered (in the sense of Kitcher 2001) only if inquiries are directed in ways that promote the common good, conceived as aiming at the goals that would be endorsed in a democratic deliberation among well-informed participants committed to engagement with the needs and aspirations of others. Whether or not this particular elaboration of the idea of the common good is adopted, we maintain that a necessary condition for well-ordered science is that research addressed to alleviating the burden of suffering due to disease should accord with the 'fair-share' principle: at least insofar as disease problems are seen as comparably tractable, the proportions of global resources assigned to different diseases should agree with the ratios of human suffering associated with those diseases (Flory and Kitcher 2004). Thus if the disease burden associated with a form of respiratory infection is twice that of a specific type of cancer, and if there are approaches to both diseases that are roughly equally promising, then the funds assigned to the respiratory infection should be approximately twice those given to the cancer.

It would be difficult to maintain that contemporary biomedical research (BMR) is well-ordered in this sense. Of the 57.5 million people who died in 2002, a third succumbed to communicable diseases (infections or parasitic infestations), perinatal and maternal conditions, or nutritional deficiencies (World Health Organization 2004). Many of these deaths could have been prevented if those who suffered had had access to existing technology, available elsewhere but typically not readily exportable to the places and circumstances in which they lived and died. If the priorities of BMR in the affluent world were different, existing technology might have been adapted to the local needs, or, where that was not possible, alternative ways of responding to disease might have been sought. Many poor people die, or are disabled, by diseases that have vanished from the affluent parts of the world because of advances in environmental

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control (drained swamps, clean water sources) or because children are routinely vaccinated — but the poor continue to live in uncontrolled environments to which the vaccines cannot readily be delivered. In principle, the deaths and disabilities are preventable, since there is a known solution, but the solution is only available under special conditions.

These features of the disease burden are quite at odds with the distribution of effort in contemporary BMR. Of the \$125.8 billion spent on such research in 2003 globally (of which were about 45% public and 55% private; see Global Forum for Health Research 2006), only a negligible amount was assigned to ailments that primarily affect the poor. For instance, malaria, pneumonia, diarrhea and tuberculosis together account for 21 percent of the global disease burden, but receive only 0.31 percent of all public and private funds devoted to health research (Global Forum for Health Research 2004: 122).<sup>1</sup> An overview of research and development spending in relation to the global disease burden (GDB) is presented in Table 1. The imbalance is also reflected in the outcomes of biomedical investigations. To report one figure, between 1975 and 1997, 1393 new drugs that target tropical diseases were granted market authorization. Only 13 of these were for use in combating tropical infectious disease (Truiller *et al.* 2002). And the imbalance doesn't only concern money spent or newly developed compounds but also the day-to-day work of biomedical researchers. A recent study found that many tropical diseases are addressed in only about a fifth as many published research articles as other diseases with matched disease burden (Vanderelst and Speybroek 2010).

<i>Condition</i>	<i>GDB (in million DALYs)</i>	<i>R&amp;D funding (Mill. US\$)</i>	<i>% of total GDB</i>	<i>R&amp;D funding per DALY (US\$)</i>
All	1,470	105,900	100	72
HIV/AIDS + TB + Malaria	167	1,400	11.4	8.4
Malaria	46.49	288	3.1	6.2
TB	34.74	378	2.3	10.88
Cardiovascular Disease	148.19	9,402	9.9	63.45
Diabetes	16.19	1,653	1.1	102.07

Table 1: Relationship between research funding and global disease burden (GDB); data for 2001 (source: Global Forum for Health Research 2006: 90).

<sup>1</sup> In the calculation of the disease burden here, attention is paid to the number of years of healthy life lost rather than to the simpler measure of number of deaths. The two measures — deaths and 'DALYs' — yield roughly equivalent distributions of disease burdens (see Flory and Kitcher 2004).

## 2. *Neglected Diseases*

A large part of the research and development that a drug requires from initial basic research to clinical trial and registration typically occurs in large multi-national pharmaceutical companies. In their search for profits, those companies look for research and development projects that have a positive expected return, and, among those, for the ones with the largest such return. Drug development is very costly, and thus only chemicals for which there's a large potential market will be chosen for research and development. An often cited study estimates the average development costs for a single new drug to be around \$800 million (DiMasi *et al.* 2003). The potential markets for tropical diseases are too small to arouse the multinationals' interest, not because too few people are afflicted but because the average sufferer is far too poor to pay the appropriate fraction of the required threshold.

For our purposes, neglected diseases will be those that multinational pharmaceutical companies ignore on the grounds that, however many potential buyers there might be for a future drug, the overall revenue accruing would be too small to meet the constraints of profitability. As a crude measure, if  $\$x$  is the amount that an average sufferer from a disease could afford to pay each year, and there are expected to be  $N$  potential sufferers, then

$$Nx < 800,000,000.$$

To the extent that a disease is found only among the world's poor,  $x$  will be decreased, and for diseases virtually confined to the poor,  $x$  is likely to be less than 10 (and may well be less than 1). That means that diseases can afflict millions of people annually and still be neglected.

It is thus no surprise that major pharmaceutical companies pay little attention to the following conditions, each of which afflicts only the poor. We give the annual mortality rates, estimated for 2002 (World Health Report 2004):

Leishmaniasis	51,000
Schistosomiasis	15,000
Chagas Disease	14,000
Leprosy	6,000
Dengue fever	19,000
African trypanosomiasis	48,000

Even major killers like malaria (1,272,000 deaths annually) and tuberculosis (1,566,000 deaths annually) are neglected in our sense — as are diseases that do not kill but disable many thousands (onchocerciasis, lymphatic filariasis). For a disease afflicting 10 million people to pass the profitability threshold, the average sufferer would have to be able to pay \$800 for a single new drug, an astronomical figure from the perspective of the world's poor.

It is worth taking a closer look at some of the diseases we have listed, so that we can understand the causes of the neglect. Neglected diseases tend to be endemic in tropical countries with a low average income, and, frequently, to surface only in these countries. Furthermore, within these countries the primary sufferers are the poorest members of the population. Chagas disease, for example, is carried by a parasite that

lives in cracks and holes of substandard housing, usually in housing occupied by the rural poor; river blindness (onchocerciasis) is transmitted by the bite of blackflies, which breed in fast-flowing rivers and streams, and, in this case too, the victims are overwhelmingly likely to be the rural poor; African sleeping sickness results from bites by tsetse flies that live in vegetation by rivers and lakes, in forests and in wooded savannas. 88 percent of those who suffer from leishmaniasis have a daily income of less than \$2; even if all those killed by the disease in a year were to pay for a new drug, the average amount demanded of them would be over \$15,000 (800,000,000 divided by 51,000) roughly equivalent to twenty years' earnings.

There are, however, exceptional cases. The mosquito that transmits Dengue fever is found in urban and suburban areas, and thus afflicts both the relatively rich as well as the poor. But the threshold requirement would demand \$40,000 of each of the roughly 20,000 people afflicted, and that is an absurd expenditure, even if some of those infected are 'relatively well-to-do'.

### 3. *Contemporary Biomedical Research*

Let us digress from neglected diseases for a moment and look at the BMR that is in fact done. Especially in the United States there are now growing concerns that BMR is not effectively and efficiently serving its patients, even if focusing narrowly on the welfare of U.S. or Western patients (see for instance Angell 2004, Goozner 2004 and Kassirer 2005). We will here summarize the main observations about the U.S.<sup>2</sup>

*Profits.* Pharmaceutical companies make astronomical profits, which are on average higher than those of companies in any other industry. To mention but a few numbers (*cf.* Public Citizen 2003a):

- In the 1990s, the top-ten pharmaceutical companies had a profit margin of about 25% of sales, which was larger than that of any other U.S. industry.
- In 2002 (which, incidentally, was a recession year) the combined profits of the top-ten pharmaceutical companies in the Fortune 500 (\$35.9 billion) were greater than those of all other 490 businesses combined (\$33.7 billion)
- The median profits for other industries are about 3-5% of sales, for commercial banking, the second most profitable industry, 13% of sales.

*Innovation.* The usual justification for the existence of the high profits is that they are required in order to guarantee the innovativeness of the industry. But neither is it true that most of the profits is actually invested in research and development nor that the U.S. pharmaceutical industry is particularly innovative. For the top-ten companies, R&D spending is between 10.9% (1990) and 13.7% (2000) of sales, much less than the profit margin. Rather, according to Securities and Exchange Commission data, the biggest budget item is 'Marketing and Administration' (or similarly called, depending on the company), which covers everything from advertising, continuing education of

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<sup>2</sup> In general, the situation outside the U.S. is similar but usually less extreme. We focus here on the American market because of its global significance and because it is well documented. This section draws on Angell 2004.

medical doctors, expenditures for pharma representatives (including free samples for prescribing doctors), marketing proper, salaries and legal expenditures, and averaged 34.9% over the decade 1990-2000 (Kreling *et al.* 2001: 45). The salaries paid to top managers are as astronomical as the profits. For example, in 2001 Charles Heimbold, the CEO of Bristol-Myers-Squibb received \$74,890,918 plus roughly the same in stock options, John Stafford, the chairman of Wyeth \$40,521,011 plus roughly same in stock options and William Steere, former chairman of Pfizer, \$28,264,282 plus \$60,187,019 in stock options (Families USA 2002: 5-6).

And the money does not appear to be well spent, if developing drugs with genuine medical benefit is the stated aim. For instance, in 2002 78 new drugs were approved but only 17 were so called new medical entities or NMEs, *i.e.*, genuinely novel drugs, only a fraction of which were actually developed entirely by the big pharmaceutical companies. Most 'new' drugs that do arrive in the market are so-called 'me-too' drugs, slight variations of already existing products where modifications were introduced in order to be able to patent the entity. The bulk of NMEs is developed in universities, small biotechnology firms and outside the United States (Angell 2004: Ch. 4).

*Advertising and Marketing.* Among the industrialized countries, direct-to-customer (DTC) advertising is legal only in the United States and New Zealand. Spending on DTC advertising by the U.S. pharmaceutical industry soared from \$55 million in 1991 to \$2.5 billion in 2000 (Rosenthal *et al.* 2002; Wilkes *et al.* 2000). DTC advertising has at least two adverse effects. First, it makes consumers realize or believe that they suffer from a condition that can and should be treated by using a prescription drug that otherwise would have gone unnoticed and for which treatment would not have been required. There is a growing number of studies claiming that the pharmaceutical industry 'creates' many diseases (such as premenstrual dysphoric disorder, social anxiety disorder or female sexual dysfunction) in order to sell drugs for their treatment (for a book-length study of this phenomenon, see Moynihan and Cassels 2005). Second, for a given condition or disease patients often request a particular brand-name drug although a much cheaper and sometimes more effective and safer generic version is available.

But DTC advertising constitutes only a small share of the total amount of money spent on promoting drugs (about a sixth, see Rosenthal *et al.* 2002). Since doctors feel uncomfortable with prescribing drugs they haven't heard of or know little about, the bulk of marketing expenditure is directed towards influencing their behavior more directly. Marketing tools that target prescribing doctors include:

- Sales representatives. Drug companies employ about 90,000 sales reps to market their products to physicians at a cost of about \$12 billion (Hensley 2003). About the same amount is spent on the free samples given to doctors. Usually sales reps also have a budget to buy doctors lunch, dinner or other gifts. Some cases have been reported in which doctors listen to sales talks for a fee (Chin 2002). There is one sales rep for about five to six physicians, and physicians receive several calls from reps during the week, specialized doctors who prescribe a lot may receive several calls in one day.

- Medical journal advertising. Many medical journals depend in their existence on ads from the drug industry. It has been suggested that this introduces a bias in favor of industry, if only because drug companies may refuse to advertise in journals with critical articles (Lexchin and Light 2006; Smith 2003).
- Continuing medical education. U.S. pharmaceutical companies spend billions of dollars per year to support medical congresses, meetings and continuing education events. Though such events are supposed to be educational in character, they are often of a decidedly promotional character. Drug companies pursue at least two aims with these marketing tools. First, it is prohibited by law to advertise a drug for a use for which it has not been approved. However, doctors can prescribe drugs for any use they want. Hence, if doctors can be made to prescribe drugs for new uses, markets can be extended. Second, bribing doctors into prescribing one's own drugs is of course illegal too. Continuing medical education events present an opportunity to give presents, masked as educational tools, to doctors and thus to make them feel obliged and at least positively disposed towards the company (see Angell 2004, Ch. 8).

There are two further marketing tools that are not directly or not only targeted at doctors but rather form part of the research process for a drug:

- Visible aspects of the drug. Pharma companies spend millions on market research on the name, shape, color and other visible aspects of pills (Neukirchen 2006). Drug companies today typically hire branding consultants years before their drug enters the market to find a distinguishing name that is attractive to doctors and patients alike. Moreover, once a name is settled on, lawyers search registered brand names worldwide to check for potential trademark infringements, which again is a long and costly process (Kirkwood 2003).
- Increasing market size. Suppose a given drug has been approved for some particular use. Drug companies can then extend the market size in either of two ways. First, they can conduct so-called phase IV clinical trials (that is, trials testing for unknown effects of drugs that are already approved and marketed), which are up to FDA standards, and subsequently seek FDA approval for the new use or uses. An additional benefit of this process is that the company can get an additional three years exclusive marketing rights for the drug. But trials that satisfy FDA standards are lengthy and expensive. Hence companies often prefer to take an alternative route. They sponsor substandard phase IV trials and disseminate positive results at physicians' congresses and continuing education meetings. Though it is illegal to *market* drugs for unapproved uses, it is not illegal to present research results to prescribing doctors, even if these results are based on studies that do not live up to the usual standards, and, as we mentioned before, doctors are free to prescribe a drug for any use they see fit.

*Patent races.* One major reason for the abundant profits pharmaceutical companies make is the patenting law that allows inventor firms to take out 20-year monopoly rights on selling their drugs. The usual justification for patent protection of inventions is that the monopoly profits in which it results are a necessary condition for the continuing innovativeness of the industry. We have already seen that, whether or not patenting is a necessary condition for innovation, it is certainly not a sufficient condition as the U.S. pharmaceutical industry is hardly innovative. And it is likely that patenting has at least one serious adverse side effect, *viz.*, that it gives companies a strong incentive to engage in rent-seeking and other uncompetitive behavior. At any rate, it seems to be considerably more lucrative to extend existing monopoly rights than to invest in new research (Angell 2004: 174).

The mechanisms companies use in order to stretch out their patent rights include:

- Filing bogus patents and then lawsuits in order to get an extra 30 months of patent life. Brand-name drug producers sometimes list new frivolous patents with the FDA shortly before a monopoly is going to expire. Then once a generic competitor enters the market the brand-name producer can file a lawsuit against the generics firm no matter how far-fetched the infringement claim may seem and thus receive an automatic patent extension of 30 months.
- Pay the generics producer to refrain from competition. Since generic drugs usually sell at a fraction of the price of the branded equivalent, paying the generics firm to delay entering the market appears to be lucrative for both sides in many cases. The first generics producer is granted six months exclusivity, such payments guarantee an extended monopoly for the brand-name company.
- Filing bogus ‘citizen petitions’. Citizen petitions are a way for concerned consumer groups, corporations or individuals to urge the FDA not to approve a generic drug for health and safety concerns. Since brand-name drug companies can file a citizen petition and since cases usually take a long time to be decided, this way a patent can be extended even if the case against the generic is very weak.
- Best Pharmaceuticals for Children Act. If a drug is tested to work in children, a patent can be extended for six months. Pediatric tests can be conducted independently of whether the condition the tested drug targets is likely to be found in children. Thus, for example, drugs for high blood pressure or high cholesterol levels are regularly tested in children despite the dubious medical value of these tests.

*Corruption and undue financial and personal links.* 94% of U.S. physicians have been reported to benefit from the pharmaceutical industry in one way or another (Campbell *et al.* 2007). The most frequent form of benefit was receiving food in the workplace (83%) or drug samples (78%), and over a third (35%) of doctors said that they received reimbursements for attending continuing medical education or other types of meetings. These benefits are often thought to influence prescribing behavior. But this is only one type of financial link the pharmaceutical industry has with other players in the field and that is of doubtful value for the patient. Others include:

- The FDA. The pharmaceutical industry pays so-called user fees to the FDA for expedited drug approval. Soon after the introduction of the Prescription Drug User Fee Act in 1992, user fees accounted for about half the budget of the FDA's drug evaluation center and, by now, more than half of the employees of the FDA are dependent on user fees (Angell 2004: 208-9). The agency is thus highly dependent on money from the industry. The pharmaceutical industry also provides 'experts' to serve in drug approval committees.
- Clinical research. In 1991, 80% of clinical trials was conducted by academic and other publicly funded medical centers such as the National Institutes of Health (NIH). Although the trials were financially supported by the industry, a certain degree of independence was guaranteed by the fact that the clinicians involved in the trials were usually employees of a university or the NIH and thus had independent sources of income. Moreover, the trials used to be designed by the researchers conducting the study. By 1998, that figure dropped to 40% of drug trials, and more and more CMOs and SMOs are playing an important part in this stage of drug development. But since these organizations are highly specialized they are dependent on industry money for their existence. And it is hardly surprising that there is considerable evidence to the effect that trial results are affected by this structure, for instance in the trial design, data analysis and publication of results (Bodenheimer 2000).
- Lobbying and campaign donations. In 2002, the pharmaceutical industry employed 675 lobbyists in Washington (more than one for each member of Congress and nearly seven for each U.S. senator) at a cost of \$91.4 million, which does not include at least another \$50 million spent in order to influence congress through advertising, direct marketing *etc.* (see Public Citizen 2003b). In the 1999-2000 election cycle, pharmaceutical companies gave \$20 million in direct campaign contributions plus \$65 million in soft money. Moreover, there are various personal links between the government and the industry. For instance, among the 675 lobbyists employed in 2002, 26 were former members of Congress and various politicians are former industry members (thus Donald Rumsfeld who used to be CEO, president and chairman of G. D. Searle and George Bush Sr. who was on the Eli Lilly board of directors, see Angell 2004: 202).

*Basic research.* The following observations belong, strictly speaking, to the previous category but since academic research plays an important role in our proposal for a solution to the neglected-disease problem, we discuss it separately here. Prior to 1980, many results of publicly funded BMR ended up as patents owned by the government. Since the government did not have a unified patent policy, application procedures for commercial use were long and tedious, the government never granted exclusive rights and since it did not have resources for commercial development itself, most fruits of the research never reached the market. Of the 30,000 patents the government had amassed by then, only 5% were ever commercially licensed. Two pieces of legislation, the Bayh-Dole and the Stevenson-Wydler Act, changed this situation dramatically, mainly by giving universities and small businesses (through the former act) and the



NIH itself (through the latter) patent-control over their inventions stemming from government-funded research and the ability to charge royalties to the pharmaceutical industry in exchange for licenses.

These acts were indeed followed by a formidable increase in the forming of marketable products from the results of basic research. The biotechnology boom that ensued was but part of that development. But there were side effects too. More and more academic researchers started seeing themselves not as purveyors of some independent good (the common good, no matter how construed, say, or intellectual curiosity) but rather as partners of industry. Along with the general pro-business shift during the Reagan years, the ethos at many medical schools shifted from academic to commercial, at least to some extent. Many of the new small biotechnology firms were founded by university researchers to exploit discoveries made earlier, and hundreds of doctors left academia in order to work for biotech firms or big pharmaceutical companies. Today, it is estimated that 23% to 28% of academic investigators in BMR receive research funding from industry (Bekelman *et al.* 2003). And the ties go both ways: two thirds of academic medical centers hold equity in start-ups that sponsor some of the research conducted in these centers (*ibid.*). We have already mentioned that there is some evidence to the effect that this pro-industry orientation influences the results of research. But there is also reason to believe that it contributes to a shift in research goals.

#### *4. Minimalist Proposals*

Returning to the theme of our paper, the closer aligning of investments into BMR with the fair-share principle, we now examine a number of solutions that have been proposed. The solutions we look at here are all minimalist in the sense that they propose to leave the current system, as characterized in Section 3, intact as much as possible and at the same time add financial incentives to develop treatments that target diseases of the poor. We shall show that these proposals all suffer from ignoring what seems to us to be the core of the problem: the flaws of the current system.

##### *4.1. Income Transfers*

Since the root of the problem of neglected diseases lies in the distribution of income, so that the sufferers of some diseases are people who lack sufficient funds to pay for research, it is natural to think that the problem would best be solved by adjusting the distribution of income and allowing the market to work its supposed magic. Some scholars take it to be axiomatic that the market organization of the biomedical industry ensures that existing funds are allocated most efficiently among research projects. If certain projects are not sufficiently funded (in the extreme case, not funded at all), this isn't primarily a problem for the pharmaceutical industry (an allocation problem) but rather a distributional problem. The most efficient solution would consist in an income redistribution from rich to poor, thereby creating a market for drugs and vaccines for neglected diseases.

This argument is deficient for several reasons. First, the organization of the pharmaceutical industry is far from being that of a perfectly competitive market. To begin with, much basic research is conducted or funded by state institutions, such as universities and the NIH. Further, because companies receive patents on newly developed drugs, patents that are typically valid for a period of 20 years, the market for many of the most effective drugs is effectively a temporary monopoly of the patent holder. As usually happens in the presence of monopolies, goods are offered at higher prices and lower volumes. The rationale for the monopolistic organization of industries in which research and development plays a prominent role is that, without monopoly rents, there would be insufficient stimulus for innovation. We'll scrutinize this rationale below.

So far, we've been concerned with the initial assumption that the pharmaceutical industry operates under the conditions of a perfectly competitive market. We are even more skeptical about the idea of adjusting the market through income transfers. One obvious question concerns the beneficiaries: which people are going to receive them? There seem to be three possible answers: individual poor people, the states that represent them, or organizations, centered in the affluent world, that would buy the drugs and distribute them. To transfer funds directly to individuals appears a bad idea, principally because health isn't the sort of good that one can buy more or less of, depending on one's economic preferences. In an obvious sense, health is a precondition for free economic decision-making; unhealthy people aren't in a good position to develop preferences that genuinely express their interests. Bad health and poverty influence one another, and, as many economists have noted, alleviating the unhealthy conditions in poor parts of the world would bring economic gains in its train (see for instance Sachs 2005).

For the most part, transferring money to states in which poverty and disease are endemic won't work well either. As is well known, there are problems of corruption, inefficiency, and lack of power in the regions of the world that are most affected by neglected diseases. Moreover, since the people who suffer from such diseases are typically the disadvantaged, even relative to their fellow citizens, both market considerations and political wisdom will tell against using the resources transferred in meeting their needs.

#### *4.2. Advance Purchase Commitments*

The second proposal we discuss is a mechanism favored by many well-intentioned affluent sponsors, as well as by many potential recipients. One attractive way of carrying out the redistribution of income is through instituting so-called Advanced Purchase Commitments (APCs). Since pharmaceutical companies would know in advance that states in which neglected diseases are prevalent had received designated public funds to support research into the principal neglected diseases that afflict them, there would be incentives for the companies to undertake the pertinent sorts of research. Although we recognize the force of this line of argument, we also think that its method of stimulating research into neglected diseases faces some important limitations (*cf.* Brown 2006).

For, in the first place, some multi-national companies currently collaborate with so-called public-private partnerships (PPPs), or conduct a limited amount of research into neglected diseases in order to improve their public image (and thus use a 'loss leader' to increase sales of more profitable ventures). Large-scale APCs would replace these positive behaviors (*cf.* Pharmaceutical R&D Policy Project 2005). It might be thought, however, that, on a sufficiently large scale, the trade would be well worth making — provided that the commitment to APCs were intensive and assured for the long-term, the benefits currently produced by PPPs would be offset by a more comprehensive strategy. But there precisely lies the trouble. If the market is to generate the anticipated benefits for neglected disease research, the pharmaceutical companies must have confidence that the political decision to make large transfers of income and to institute APCs will be sustained over a period long enough to cover the extensive research into the most effective strategies. We think it likely that in the current BMR system such confidence won't easily be fostered, and that, in consequence, the incentives will favor secretive and non-collaborative practices, frequently characteristic of commercial research (Pharmaceutical R&D Policy Project 2005: 7). Finally, this approach is likely to be less cost-effective than alternatives, in part because the funds transferred have to cover the industry's cost of capital during the period of research; according to some estimates, this doubles the cost of research and development (Pharmaceutical R&D Policy Project 2005: 77).

Our last concern focuses on the re-emergence of a problem of neglected diseases at a different level. Imagine that there are APCs for drugs and vaccines across a range of neglected diseases. From the pharmaceutical perspective there are surely going to be big prizes, so that the research effort will be driven by the attempt to respond to the most urgent of the neglected diseases. In consequence, it's likely that there will be duplication of research effort, and an inefficient outcome, in which several companies race against one another to be the first to develop an effective treatment and so garner the large returns. Effort that might have been spent on tackling different diseases will be wasted. As we'll suggest below, this seems to be one arena in which a certain amount of planning would foster division of labor and a useful collaboration.

#### *4.3. The Health Impact Fund*

One of the most forceful voices in the fight for more global justice today is Thomas Pogge's. Pogge has outlined a reform of BMR that specifically focuses on global health inequalities (Pogge 2005). Pogge has proposed the creation of a Health Impact Fund (HIF) with three components:

1. The results of successful efforts to develop new essential drugs are to be provided as public goods that all pharmaceutical companies anywhere may use free of charge.
2. Inventor firms are entitled to recompense, to be awarded out of public funds, in proportion to the impact of their invention on the global disease burden.
3. The public funds would be amassed as the outcome of a fair, feasible, and politically realistic scheme. Affluent countries would contribute a pool.

A great advantage of this proposal is that, if it could be implemented, it would provide a sustainable solution to the problem of neglected diseases. The linking of recompense directly to the global disease burden provides straightforward incentives to invest in strategies for addressing the conditions that cause most suffering (subject to considerations of research tractability, of course).

Although we are sympathetic to Pogge's line of solution we think that, as it stands, there are numerous issues that need to be addressed. In short, we see problems in the following areas:

- *Costs.* Pogge's idea is to create a dual system in which the HIF operates alongside the market system that characterizes the *status quo*. As we have seen, the current system of intellectual-property protection creates extensive ownership rights for new drugs, and this has led to inflated drug prices. Since in the dual system patents filed under the HIF regime compete with those of the market, to attract potential inventors, the new regime must offer comparable (or higher) profits. The costs for the government will therefore be high, unnecessarily high in our view.
- *Financing.* Pogge does not explain how to finance the proposal. He estimates the cost of the plan to be some US\$45-90 billion annually but does not indicate how this is to be financed except that Western governments should bear the costs. To be sure, Pogge provides a long and persuasive discussion about why governments *should* pay. But this is no argument to the effect that they will do so.
- *Efficiency.* A system in which innovators are rewarded with a monopoly on their inventions provides incentives to hide research results. No idea is ever entirely new and always builds upon earlier ideas (see below discussion on 'innovation chains'). Pharmaceutical companies almost always develop entities that originate elsewhere, mostly in basic research done at universities. Thus, BMR would profit much from sharing ideas and results but the system Pogge suggests creates adverse incentives.
- *Treatments.* The current system is skewed towards patentable solutions: drugs, gadgets, forms of administering treatments and so on. Many effective solutions, however, are not patentable. Brown (2008; 2006) mentions diet, exercise and environmental approaches. Here is an example. An effective strategy against the spread of Chagas, a tropic parasitic disease endemic in poor, rural areas of Central and South America, is to keep dogs and other animals out of the house, and, in general, to keep houses clean (see Cohen and Gürtler 2001). These kinds of solutions would still be neglected under the scheme proposed by Pogge and thus would fail to encourage research needed to develop useful new drugs.
- *Measurement.* In Pogge's scheme, an inventor firm is to be rewarded in proportion to the impact of their invention on the global disease burden. The global disease burden is usually quantified in terms of disability-adjusted life years or DALYs. DALYs for a disease are the sum of the years of life lost due to premature mortality in the population and the years lost due to disability for inci-

dent cases of the health condition. Mortality is relatively straightforwardly quantified as number of deaths times standard life expectancy at age of death in years. Morbidity or years lost due to disability are measured by multiplying the number of incident cases with the average duration of the case until either remission or death and the disability weight. The disability weight is the key instrument to make different forms of disease commensurable. Here 0 is defined as 'ideal health' and 1 as 'condition comparable to death'. Some examples for the weights different kinds of disability receive are given in Table 2 below.

<i>Disability class</i>	<i>Severity weight</i>	<i>Indicator conditions</i>
1	0.00-0.02	Vitiligo on face, weight-for-height less than 2 SDs
2	0.02-0.12	Watery diarrhea, severe sore throat, severe anemia
3	0.12-0.24	Radius fracture in a stiff cast, infertility, erectile dysfunction, rheumatoid arthritis, angina
4	0.24-0.36	Below-the-knee amputation, deafness
5	0.36-0.50	Rectovaginal fistula, mild mental retardation, Down-syndrome
6	0.50-0.70	Unipolar major depression, blindness, paraplegia
7	0.70-1.00	Active psychosis, dementia, severe migraine, quadriplegia

Table 2. Source: Murray and Acharya 1997: 716

Obviously, awkward choices have to be made: how does blindness compare to deafness, and how paralysis to a chronic heart condition? Is blindness worse for an Afro-American than for a European descendant? Does an inhabitant of Kerala suffer more from a lost leg than a Londoner? How do children compare to adolescents, adolescents to adults and adults to the aged? But it is nearly as obvious that with limited funds, awkward choices have to be faced at some point. The problem this aspect of Pogge's scheme is not only that every disease has an explicit cash value but also that by its nature it has to be inflexible. If companies are to be induced by monetary incentives to invest in tackling certain forms of disease, they must be enabled to plan ahead for the duration of the drug development, which means that the cash value each disease has must be fixed for a very long time. And any such fixed scheme is likely to be subject to much criticism,

both fundamentally and particularly when conditions and preferences change.

More specific to neglected *tropical* diseases is another problem, *viz.* that DALYs appear to dramatically understate actual disease burden for these diseases for at least two reasons (Engels and Savioli 2006). First, some diseases such as hydatid disease, fascioliasis, strongyloidiasis and rabies are simply absent from the WHO calculations. Second, some diseases cause much more organ pathology than estimated when their weights were calculated. Global quantifications of complications of some diseases nonexistent because of the lack of appropriate diagnostic tools in endemic areas. For these reasons we agree with Vanderelst and Speybroek who argue that such diseases should not be ‘neglected twice: once by being attributed an underestimated DALY and again by limited scientific attention’ (*op. cit.*, p. 1).

### 5. *A New Proposal for a Reform of (U.S.) Biomedical Research*

As mentioned, the three solutions discussed above share the goal to affect the current system minimally. We believe that many of the considerations given in Section 3 shed doubt on the desirability of this goal. To the contrary, there seems to be a *prima facie* case for reform, quite independently of issues regarding global health inequalities. The proposal we are making has two parts. It first envisages a reform of the organization of BMR that targets the various flaws and deficiencies of the current system. Second, in this reformed system, various incentive mechanisms are to be introduced that realign the research priorities of BMR more closely with the ideal of the fair-share principle. Let us discuss the two parts of the reform in turn.

#### 5.1. *Less Intellectual Property, More Regulation*

The three proposals that were discussed above have in common the presupposition that patenting treatments is necessary to secure innovation. Recent work in intellectual property (IP) economics suggests, however, this does not have to be so. In particular, it has been argued that in markets where production of copies of an initial idea is costly (such as, when it takes time), competitive markets without patents can produce innovation (Boldrin and Levine 2002). Depending on the exact parameter values, it is possible that the right to first sale — possibly over an extended period, during which competitors are struggling to reproduce the research breakthrough — can cover the costs of the initial investment.

We take this argument to show two things. First, it is possible that there is innovation without patent protection. Second, it is therefore an empirical question whether innovations in a given market require patenting and if so what form is optimal. It is certainly true that there are highly innovative industries that are not protected by strong IP rights. Open-source software development is but one example, and even in the case of pharmaceutical innovation, it has been shown that in some countries there existed a thriving drug industry before drug developments could be patented in these countries (Boldrin and Levine 2008). But it is also true that because of high evidential

standards for safety, drug development is very costly (though the commonly cited \$800 million may well be an exaggeration), and there is no guarantee that there will be investors willing to pay large amounts upfront without an assurance that imitators will be kept out of the market for at least some time.

The correct answer to the question ‘What is an optimal IP regime?’ depends on numerous factors such as the time it takes imitators to bring rival products to the market, the demand elasticity for that good and so on, and must be answered empirically. Unfortunately, few empirical studies have addressed the question. But there is some evidence that the current IP regime protects too much and too strongly. Allowing innovators to own their ideas and the financial rewards that come along with ownership creates monopoly profits because owners can set prices above the equilibrium level without fearing that rival firms compete for their market share. The existence of monopoly profits, in turn, induces so-called rent-seeking behavior on the part of the monopolists (Kahana and Katz 1990). Rent-seeking comes in numerous forms: excessive advertising and marketing, corruption, lobbying, legal action to protect ones IP and so on, all of which are common in current BMR as we have seen above. One might still regard these as adverse effects that have to be tolerated in order to guarantee innovation. But we have also seen above that the industry is far less innovative than it tries to make us think. Putting these two considerations together we have to conclude that the current IP system does not provide incentives to invent new treatments that have genuine medical benefit but rather to do whatever is necessary to create markets for existing products or slight modifications thereof and to sell these at inflated prices.

There is, therefore, a good case to be made to reduce patent life and, at least as importantly, the number and kinds of things that can be patented. Currently, the U.S. Patent and Trademark Office (USPTO) grants 20-year patents on new compounds. This 20-year period starts on the date of filing and is reduced by the time it takes the company to run clinical trials and get FDA approval such that effective patent life is about 14 years (Public Citizen 2001: 16). The USPTO by law requires inventions to be (a) genuinely novel, (b) useful and (c) non-obvious (Angell 2004: 240). In practice, these conditions are interpreted very laxly. For instance, not only the chemical formula of a new drug can be patented but also new uses, new dosage forms, combinations of old drugs as well as the coatings and colors of pills.

A central ingredient in the reform we propose is a gradual reduction of patent life and patentable aspects of inventions. As knowledge of how markets react to such a policy change is limited, its implementation should proceed ‘adaptively’ (*cf.* Mitchell 2009). That is, it should be implemented in small steps while monitoring the target variables (in this case, quality and quantity of innovation, industry profits, extent of rent-seeking) and later interventions should adapt to what has been learned about the effects of earlier interventions.

Some of the desired effects can be achieved by enforcing currently existing regulation. For example the USPTO requirements that inventions be genuinely novel and useful should be interpreted as ‘providing genuine medical benefit’ when the intervention is a new medical treatment. In other cases, new and tighter regulation must be in-

roduced. The pharmaceutical industry has financial links with all major stakeholders, which should be prohibited or to the extent that it is already prohibited, the regulation should be enforced. To give a few examples, a large part of FDA funding stems from user fees from the pharmaceutical industry, as was mentioned above. The FDA should, however, be an independent regulator rather than a service provider to the industry and therefore this practice should be outlawed. Direct-to-consumer advertising should be prohibited and so should all ways drug companies currently use to influence doctors' prescription behavior. Medicare and Medicaid should be required to pay only for generics in so far as this is medically justifiable.

One important aspect of drug research and development that has been unduly commercialized in recent years is that of drug testing. Like drug approval, drug testing should be independent of the pharmaceutical industry. To finance it, we envisage a 'club solution' for clinical research. That is, in order to be eligible to apply to the FDA for drug approvals, a company must be a member of a club that is regulated by the public and for which it pays a membership fee (proportional to the company's revenues, say). If a company seeks to test a drug, it has to apply to the club which reviews the proposal independently and on the basis of medical benefit alone. If a project is deemed beneficial, the club finances the clinical research without further financial flows from the applying company.

### *5.2. Providing Incentives for Research into Neglected Diseases*

In such a reformed industry it will be much cheaper and easier to provide incentives for researching drugs for neglected diseases. APCs do not seem to be such a bad idea once the system has been reformed and if carried out properly. In the current system, APCs are an imperfect tool among other things because projects have to compete with market projects, and that means that comparatively high rewards have to be offered to inventor firms. The reform decreases these rewards to the extent that it decreases monopoly profits for market projects. A coordinating agency can then overlook that money is spent wisely and in a way that accords with the fair-share principle.

We therefore propose that an institute for global health analogously to the National Health Institutes be created. Its objective would be to fund and coordinate research for diseases and conditions that primarily affect the global poor.<sup>3</sup> A reformed system that includes such an institute would be more flexible than the system Pogge envisages for at least three reasons. First, diseases wouldn't have to have exact cash values. An APC can be issued whether or not its size precisely reflects the impact on the global

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<sup>3</sup> The details of what exactly gets funded and how have to be worked out very carefully of course. For example, Mary Moran and colleagues argue that advance-purchase commitments have the adverse effect of replacing existing altruistic behaviors with for-profit motives and recommend instead the support of so-called public-private partnerships in which publicly-funded agencies co-operate primarily with small pharmaceutical companies in neglected-disease research projects (Pharmaceutical R&D Policy Project 2005). We agree in principle but point out that recommendations such as this are made on the basis of the current system of biomedical research and will have to be reviewed once this system has been reformed.



disease burden as measured in DALYs. Changes in perceived needs can therefore be implemented more flexibly. Second, there is no need to prioritize patentable solutions. Social or environmental approaches can be rewarded just as much as medicines or other patentable treatments. Third, as explained above, Pogge's system provides incentives to investigate those treatments that are the cheapest to develop per DALY. A coordinating agency can take heterogeneities in the difficulty of finding treatments into account and reward solutions accordingly—and thereby even go beyond the fair-share principle.

There are of course other mechanisms that can be used. The 1983 Orphan Drug Act for instance introduced tax incentives for companies that develop drugs for diseases with less than 200,000 sufferers in the U.S. Similar legislation can be enacted for neglected diseases. Further, the FDA could (and should), in addition to requiring genuine medical advance for drug approvals, give priority to drugs that have a high impact on the global disease burden. Companies should also be motivated to charge different prices in different markets (which in effect would mean that the patients in high-income countries substitute patients in low-income countries).

A major issue is how these pro-neglected disease research incentives are to be financed. If the implications of empirical studies we used here can be relied on, this is less of a problem than it may seem. Consider the following figures. In 2007, \$227.5 billion were spent on prescription drugs in the United States (Hartman *et al.* 2009). Branded drugs account for over 80% of the sales (in value; but less of a third in number of prescriptions).<sup>4</sup> Generic drugs cost 30 to 80 percent less than their branded counterparts (*ibid.*). Taking the relatively conservative estimate that generics cost half of branded drugs and assuming that the suggested reduction in the lifetime of patents results in an increase of market share for generics from 20% to, say, 80% U.S. patients can save nearly \$65 billion annually. But not all of this has to return to the pockets of U.S. patients. Splitting the pie equally between U.S. patients and neglected-disease projects would create over \$30 billion of additional funding for neglected-disease projects and still leave each U.S. resident \$110 annually better off due to reduced prices for prescription drugs.. And if we remind ourselves that in the period 2000-4 public to private partnerships, with a cumulative funding of only \$76 million, had neglected-disease projects under way that were expected to yield eight to nine new drugs within five years, we can imagine that an annual funding of over \$30 billion per year can make a great difference for realizing the ideal of the fair-share principle.

This in our view is one of the main attractive features of the proposal outlined here. It will be much harder to convince U.S. patients who already spend some \$750 per capita annually for prescription drugs that they ought to spend \$150-300 *more* in order to finance drugs for neglected diseases, as Pogge suggests. If however the two parts of the reform we propose are offered as a package, U.S. patients will see that they can end up with more money in their pockets and at the same time contribute to alleviating suffering elsewhere.

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<sup>4</sup> <http://www.gphaonline.org/about-gpha/about-generics/facts>. Accessed on August 1st, 2009.

There is one final challenge our proposal faces. James Robert Brown has argued in favor of socializing all BMR (Brown 2004; 2006; 2008). In particular, when discussing and criticizing the instrument of APCs, he asks (Brown 2006: 17): ‘Finally, why put up money for corporations to find a solution, anyway? Why not put the same money directly into medical research that we can do ourselves? Why reward private corporations, when normal university researchers would do better work, motivated by a combination of curiosity and humanitarian concern?’

Our response is one of cautious empiricism. While there is a lot of evidence that the *status quo* is suboptimal to say the least, we know very little about what system works better. This is the main reason for advocating a piecemeal approach, as we have done here, rather than a cold turkey. Moreover, it is not clear to us that a system of government-funded research with no IP protection whatsoever would solve any of the problems we address here. The Bayh-Dole Act was introduced in 1980 exactly because the results of basic (government-funded university) research weren’t transformed into useful products. Whatever the motivations of researchers were prior to 1980, they did not lead to consolidated efforts on their part to tackle global health issues. An approach in which different motivations — academic curiosity, concern for others, monetary reward — are allowed to coexist, and that has constant adaptation and revision built into it, seems to us more suited to the situation, epistemic and ethical, we are in.

### 6. Conclusions

In the short run, certainly, and probably in the long run as well, there are bound to be neglected diseases in the sense of conditions that receive little attention from scientific or pharmaceutical research. Chagas disease may be among them, partly because of its relative rarity, partly because of its biological difficulty. Yet, in the different sense we’ve introduced here, Chagas disease may not count as neglected, for, although it doesn’t receive its fair share, the deviation may be justified on grounds of intractability (supposing for the moment that public health measures by themselves are not capable of effecting a sustainable solution). Would those who suffer from it have a case for complaining that they had been slighted, when an adjustment of the research agenda in their favor would deprive many more people afflicted with equally grave conditions of respite?

Perhaps. There may be some diseases whose populations of sufferers are so small that the available scientific workforce can’t attend to them, but above some threshold — and, we should hope, a low one — each disease needs enough effort to provide it with the chance to become tractable. We see here a natural division of labor between the short-term efforts of the pharmaceutical industry and the less structured world of university medical research.

Well-ordered science is an ideal, and its critics have often fastened on that fact. In the case of neglected diseases, however, we can take some steps to realize the ideal. Wide-ranging discussion of the burdens of various diseases can set up the scale on which recompense can be provided, and thereby redirect the research of pharmaceuti-

cal companies. We don't imagine that the result of this will be perfect, but it would surely be an improvement on the way we do things now.

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