

Appendix A: Poverty, Global Health, and Essential Medicines

Due to the mutually reinforcing effects of poverty and ill-health, developing countries suffer from a disproportionate share of the global burden of disease. Around six million people die every year from AIDS, tuberculosis, and malaria alone, even though these diseases are treatable and preventable. The prevalence of these diseases illustrates the role that lack of access to medicines plays as both a cause and symptom of weak health systems. Pharmaceutical innovation driven by patents alone fails to incentivize the creation and distribution of treatments for diseases that are widespread in developing countries. The Health Impact Fund will disproportionately benefit these countries, contributing to an end to the cycle of poverty and disease.

INTRODUCTION

While the Health Impact Fund is a global mechanism that will require low pricing all over the world for registered medicines, it will have a particularly large impact on the poor, who do not have drug insurance. This appendix therefore examines in some detail the problem of access to medicines for poor people—its scope and its importance.

Some 18 million human beings die each year from diseases we can prevent, cure, or treat. This is equivalent to 50,000 avoidable deaths per day, or one-third of all human deaths.¹ Hundreds of millions more suffer grievously from these diseases, while the lives of additional hundreds of millions are shattered by severe illnesses or premature deaths in their families.² This huge incidence of avoidable mortality and morbidity occurs primarily in poor countries and especially among their poorest inhabitants, who continue to suffer from many of the communicable diseases that have been virtually eliminated in the rich world. This disease burden puts great strains on poor countries, communities, and families, helping to perpetuate their poverty, which in turn contributes to their members' ill health. As discussed in chapter 6, this situation is morally untenable.

INCOME POVERTY AND HEALTH

The Scale of Global Income Poverty

In 2004, some 970 million people, around 15 percent of the world's population, were living below the extreme poverty line of \$1 a day (more strictly defined, \$392.88 annually) in 1993 Purchasing Power Parity (PPP) terms (Chen and Ravallion 2007, 16579).³ Furthermore, those living below this very low poverty line fell on average around 28 percent below it. Their average annual purchasing power therefore corresponded to approximately \$420 in the US in 2008 dollars.⁴

These are the poorest of the poor. The World Bank also uses a somewhat less miserly poverty line, namely \$2 dollar a day, or an annual amount of \$785.76 PPP 1993. The Bank's data show that around 40 percent of the world's population, or over 2.5 billion people, lived in income poverty so defined in 2004,⁵ with this population falling on average 41 percent below this higher line.⁶ Individuals in this much larger group could buy, on average, about as much in 2004 as could be bought in the US in 2008 for \$690.

The Effects of Global Income Poverty on Health

The effects of such extreme income poverty are foreseeable and extensively documented. It is estimated that around 13 percent of all human beings (830 million) are chronically undernourished, 17 percent (1.1 billion) lack access to safe water, and 41 percent (2.6 billion) lack access to basic sanitation (UNDP 2006, 174, 33). About 31 percent (2 billion) lack access to crucial drugs and 25 percent (1.6 billion) lack electricity (Fogarty n.d., IEA 2002). Some 780 million adults are illiterate (UNESCO 2006), and 14 percent of children aged between five and 17 (218 million) are child laborers, more than half in hazardous work (ILO 2006, 6).

Worldwide, diseases related to poverty, including communicable, maternal, perinatal, and nutrition-related diseases, comprise over 50 percent of the burden of disease in low-income countries, nearly ten times their relative burden in developed countries (WHO 2006b, 3). If the developed world had its proportional share of poverty-related deaths (one-third of all deaths), severe poverty would kill some 16,000 Americans and 26,000 citizens of the European Union each week.

The cycle of mutually reinforcing poverty and disease besetting low income countries, and particularly the poorer communities in these countries, could be broken by significantly reducing severe poverty. But it is also possible to make substantial progress against the global burden of disease more directly by improving health care in developing countries.

Poverty does not merely render poor people more vulnerable to disease, but also makes it less likely that they can obtain medical treatment for the diseases they contract. This is because in poor countries medical care is rarely available for free, and poor people are typically unable to buy either the care needed by themselves or their families or the insurance policies that would guarantee them such care. The price of health care in poor countries therefore also plays a crucial role in explaining the catastrophic health situation among the global poor.

The Effects of Global Economic Inequality on Health

The following table presents the wealth and annual-income distributions of years 2000 and 2002, respectively, converted into US dollars at then current exchange rates. The figures give the per capita wealth and annual income for each decile. In 2000, owning property worth \$1,299 per person would have put a given household at the median of the global distribution: with half of humanity above and half below. In 2002, the median annual income per person was \$326.^{10,7}

Table 1: Global Wealth and Income Distributions

	Wealth per capita, 2000, US\$	Household income per capita, 2002, US\$
Percentiles 1-5		57
First decile	61	70
Second decile	183	109
Third decile	407	148
Fourth decile	611	199
Fifth decile	1018	274
Sixth decile	1,629	410
Seventh decile	2,851	669
Eighth decile	5,702	1,198
Ninth decile	17,920	5,005
Tenth decile	173,300	19,497
Top percentile	812,700	48,400
Top percentile US only	4,810,000	397,000
Global average	20,368	2,758
Global median	1,299	326

Source: Sales data: CIPIH 2006, p. 15.

Reading these figures, we should bear in mind that the goods needed to meet basic needs are cheaper in poor countries—usually by a factor of three to five. Even after accounting for this difference in purchasing power for a given amount of income, it is evident that large segments of humanity are extremely poor. Spending \$5 on a course of treatment involves a serious sacrifice of other urgently needed goods even for people at the median. And, by definition, half of humanity has an income below the median, many of them far below.

Severe and widespread poverty like this has always existed. But it has never been so easily avoidable. The poorest *half* receive 2.9 percent of all household income worldwide, and 1.1 percent of all household wealth. In 2000, the bottom half had a wealth shortfall from the median that amounted to only 2.4 percent of the wealth in the top decile alone. And in 2002, the bottom half had an income shortfall from the median that amounted to merely 4.3 percent of the income in the top decile alone.

Access to an available medical treatment is a function of two factors: the price of the treatment in question and the money a patient's household can devote to purchasing this treatment. The discussion above has already described how extremely limited the financial resources of many poor households are. The other factor, the price of medical treatments, is normally determined by the cost of providing such treatments. These costs are often much lower in poor countries because it costs less there to build and maintain medical facilities, to pay doctors and nurses, and so on. A very important exception to this rule are medicines, on which households in developing countries are estimated to expend between 60 and 90 percent of their total health expenditures (DFID 2006, 1). Especially advanced medicines still under patent protection can be extremely expensive relative to a poor household's financial resources.

High prices for advanced medicines are often presented as related to the very high cost of researching and developing new medicines. This high R&D cost provides a general explanation of why many diseases concentrated among the poor have been neglected in pharmaceutical research: commercial pharmaceutical enterprises will research and develop only those drugs whose global sales they foresee to be profitable enough to cover research and development expenses plus some reasonable rate of profit on the funds invested. Other research efforts will simply not be undertaken. We discuss this topic further in the section "The Disease Burden in Developing Countries" below.

Once a new medicine has in fact been patented and brought to market, the pricing strategy of the patent holder is unrelated to its costs for research and development. The latter are what economists call *sunk costs*, now in the past. The objective of the com-

pany now is quite simply to maximize its profits over the term of the patent. We can illustrate this with the example of Lipitor, a blockbuster drug sold by Pfizer. This drug cost perhaps a few hundred million dollars to bring to market, but it currently earns the company around \$13 billion each year. Pfizer could lower the price of the drug considerably and still make a handsome profit on it. But why would the company do this? Its objective is to make money for its shareholders, and it will seek to design its global pricing strategy for Lipitor so as to maximize its profits defined as sales revenues minus ongoing variable costs for manufacturing, marketing, distribution, and the like.

The problems inherent in using patents as the incentives of choice for eliciting pharmaceutical innovation are very substantially aggravated by an extremely unequal economic distribution.

When setting a global pricing strategy for a patented medicine, a firm would ideally like to differentiate among its potential customers, charging each customer the most she or he is willing and able to pay (so long as this price results in a profitable sale, in other words, exceeds the long-run marginal cost). Now the optimal price for a patented drug depends on the demand curve, and this demand curve, in turn, depends on the distribution of willingness to pay among potential customers worldwide. As it happens, this distribution is extremely unequal. And the optimal global pricing strategy for most patented medicines is then to choose the highest price acceptable to national health systems, insurance companies, and potential patients in the affluent countries. At this price, the medicine will be bought, as needed, by the one billion people in the affluent countries and another roughly 400 million people in the developing world – altogether about one quarter of the human population. Any substantial broadening of the potential customer base would require substantial price reductions that, by greatly reducing the profit margin, would lose more in potential profits than they would gain (through sales to additional patients).

The problems inherent in using patents as the incentives of choice for eliciting pharmaceutical inno-

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vation described in chapter 8 are very substantially aggravated by the fact that, in our world, this mechanism operates in the context of an extremely unequal economic distribution.

THE DISEASE BURDEN IN DEVELOPING COUNTRIES

Due to the mutually reinforcing effects of poverty and ill-health, developing countries suffer from a disproportionate share of the global burden of disease. This disease burden contributes to, and is exacerbated by, weak health infrastructure, including very low numbers of medical professionals in some areas, inadequate training, poor incentives and support systems for the medical professionals that are available, and inadequate health facilities, as well as limited transport, water, and sanitation infrastructure and weak educational systems. The lack of availability of medicines for diseases that predominantly afflict the developing world compounds these problems. Currently, developing countries account for more than 80 percent of the world's population but for only around 10 percent of global pharmaceutical sales (WHO 2006b, 15). The lack of market demand from developing countries leads inevitably to weak incentives for research and development into diseases which particularly afflict the poor. And to this is added the problem that even when medicines are developed, they are often priced out of the reach of most patients in developing countries. These are problems which the HIF can help to rectify.

Case Studies

Around six million people die every year from just three preventable and treatable infectious diseases—AIDS, tuberculosis, and malaria. A brief discussion of these conditions and of some other tropical diseases (malaria is classified as a tropical disease) illustrates the devastating impact of weak health systems in the developing world, of which the lack of urgently needed medicines—due to the medicines being either too expensive, not available in drug outlets serving the poor, or simply not having been invented—is both a cause and a symptom.

HIV/AIDS

According to the United Nations Programme on HIV/AIDS (UNAIDS), during 2007, 33.2 million people were estimated to be living with HIV worldwide, 2.5 million people were newly infected with HIV and 2.1 million people were killed by AIDS. “Every day, over 6800 persons become infected with HIV and over 5700 persons die from AIDS, mostly because of inadequate access to HIV prevention and treatment services” (UNAIDS 2007b, 1, 4). Around 95 percent of persons living with HIV/AIDS reside in low- and middle-income countries (UNAIDS 2007a, 1). Over two-thirds of those infected with HIV/AIDS live in sub-Saharan Africa, including 90 percent of infected children, while 76 percent of deaths from AIDS in 2007 occurred in sub-Saharan Africa. Adult HIV prevalence reaches, and sometimes exceeds, 30 percent in parts of southern Africa. AIDS remains a leading cause of mortality, and the leading infectious cause of mortality, worldwide and the primary cause of death in sub-Saharan Africa, which continues to bear a hugely disproportionate share of the HIV/AIDS disease burden (UNAIDS 2007b, 6–7).

A large proportion of those living with HIV/AIDS in developing countries do not have access to treatment due to the high cost of anti-retroviral medicines and poor health infrastructure. At the beginning of this decade, it was estimated that only five percent of those in need received AIDS medication. A number of governmental, intergovernmental and non-governmental efforts have been undertaken to improve the provision of retroviral medication to developing countries, including the WHO's 3 by 5 initiative, the US President's Emergency Plan for AIDS Relief (PEPFAR), and Global Fund and Clinton Foundation HIV/AIDS programs. Despite these efforts, most recent estimates are that nearly 70 percent of the approximately 9.7 million people in need of anti-retroviral therapy had not received it by the end of 2007 (WHO 2008a). In best-case scenarios, anti-retroviral medication costs around \$100–500 for a year of treatment, but it often costs much more (MSF 2007, 6). Drugs priced even at the lower end of this cost range are well beyond the reach of the poorer half of the human population. Many of the people cur-

rently being treated with antiretrovirals will benefit from being switched to second-line, patented drugs, which often cost in the thousands of dollars per year per patient. The high cost of these drugs may make such a switch to preferred medicines impossible not only for poor patients to pay for privately, but will also stretch the budgets of donation programs.

*Tuberculosis*⁸

It is estimated that tuberculosis (TB) killed one billion people during the past two centuries. Though TB cures have existed since the middle of the 20th century, and though TB medication is relatively inexpensive, TB remains the second leading infectious cause of mortality worldwide, killing 1.7 million people yearly. One-third of the world's population is infected with the latent form of the disease, and 5 to 10 percent of these are expected to develop active illness at some point in their lives. There are almost nine million new active cases each year and approximately 15 million persons are living with active TB at any one time.

The WHO declared TB a global health emergency in 1993. Though TB rates had been steadily declining in developed countries since the early 1800s, the disease started to make a come-back during the 1980s, largely as a result of HIV/AIDS (which promotes susceptibility to TB) and the growing problem of drug resistance. New York City spent over \$1 billion fighting an epidemic of multi-drug-resistant TB (MDR-TB) that plagued the city's prisons, hospitals, and homeless shelters during the 1980s and 1990s.

TB had all along remained a major problem in developing countries, which account for 95 percent of TB cases and 98 percent of TB deaths. This is largely due to lack of access to medication and the fact that the spread of TB is fostered by the poor nutrition, overcrowding and lack of sanitation and hygiene associated with poverty. The TB problem in poor countries has been exacerbated in recent decades by HIV/AIDS. The overall TB burden is highest in Asia, but the highest prevalence rates occur in sub-Saharan Africa.

In 1995 only 23 percent of those in need worldwide had access to WHO's recommended TB treat-

ment regimen. Treatment access increased to 56 percent by 1998 and 62 percent at the end of 2007. Although ordinary TB can be cured with a six-month course of medication costing only \$10–20, even this is commonly unaffordable for those who need treatment. Lack of affordability of TB medication is partly responsible for the problem of drug resistance, which is facilitated by people starting but not completing courses of treatment. This occurs in poor countries when patients cannot afford to continue medication, or cannot afford time off work or travel costs to clinics.

TB drug resistance levels are now higher than ever. MDR-TB is defined as TB resistant to at least two "first-line" TB medications. MDR-TB is usually curable, but treatment takes two years and is 100 times more expensive than standard treatment. The "second-line" medications used to treat MDR-TB are also both more toxic and less effective than first-line medications. In 2006 the WHO and the US Centers for Disease Control and Prevention announced the emergence and spread of "extreme" or "extensively" drug-resistant TB—XDR-TB. XDR-TB is defined as TB resistant to two first-line medications and two or three second-line medications. It has been found in every region and in a total of 45 countries, with only 30 percent to 40 percent of patients surviving. Though new drugs are needed to treat it, no new TB drugs have been developed since the 1960s and none can realistically be expected to become available before 2015.

A 2007 case of suspected XDR-TB led to the first imposition of federal isolation/quarantine restrictions in the US since 1963, and XDR-TB patients sometimes face prison-like conditions in South Africa. Despite the Millennium Development Goal of reducing the incidence of major diseases including TB, the disease continues to kill 1.7 million people annually (WHO 2006b, 8).

Malaria

Malaria kills over one million people, mostly children, every year, despite the fact that the current recommended and highly effective treatment for falciparum malaria, the most deadly variety, costs only

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\$1–2 per course. Like AIDS and TB, the heaviest burden of malaria is felt in developing countries, with 80 to 90 percent of malaria deaths occurring in sub-Saharan Africa (Selgelid 2007b, 73). Those who survive may suffer brain damage, learning disorders, and incapacitating weakness and lethargy later in life. The WHO observed in 2006 that “today, 58% of malaria cases occur in the poorest 20% of the world’s population, a greater proportion than that of any other disease of major public health importance in developing countries – and among poor people, the hardest hit by far are sick children and pregnant women” (WHO 2006b, 4). In addition to those one million deaths per year, there are between 350 and 500 million clinical episodes of malaria annually, again suffered mainly by poor people without health insurance (WHO 2005,intro.).

While many existing malaria drugs are effective and relatively inexpensive, the scale of malaria morbidity and mortality indicates that they are failing to reach those who need them, due to a combination of cost and poor health infrastructure. Until relatively recently, while it was widely acknowledged that new malaria drugs and diagnostics, including a vaccine, were needed, little R&D was devoted to this goal, undoubtedly because the extremely poor victims of malaria have little economic power and do not represent an appealing target for most drug companies. Grants from the Bill and Melinda Gates Foundation—one to establish the PATH Malaria Vaccine Initiative in 1999, another in 2004 to support research into the development of a semi-synthetic form of artemisinin, a key ingredient in first-line malaria treatments, to supplement the current botanical source—are partially redressing this situation, although it remains to be seen what impact these initiatives will have (PATH n.d.; Connor 2008).

Tropical and Parasitic Diseases

Tropical diseases, most of which are parasitic infections, are almost exclusively confined to the poor. As a result, little has been done to develop appropriate drugs. Of the 1,556 new drugs approved for commercial sale from 1975–2004, only 18—just over one percent—were for neglected tropical diseases (Chirac

and Torreele 2006, 1560; Trouiller et al. 2002, 2189). In addition to malaria, these diseases include Chagas’ disease, Helminthic infections, human African trypanosomiasis, leishmaniasis, and schistosomiasis.

Spread by a sand fly, leishmaniasis is common in India and Sudan. Each year 1.5 million people develop cutaneous leishmaniasis and 500,000 the more serious visceral variant (CDC). Chagas’ disease, another potentially lethal infection, is common in South America, where in 2000 it was estimated that 16 to 18 million people were infected (WHO 2000, 10). In Sub-Saharan Africa, about 60 million people are estimated to be at risk of human African trypanosomiasis, better known as sleeping sickness, of whom “only 3 to 4 million . . . are under surveillance, with regular examination and access to a health center” (WHO 2001). Other common parasitic afflictions that continue to plague the poor are schistosomiasis, lymphatic filariasis and onchocerciasis (river blindness). Pharmaceutical research into these conditions, to the limited extent that it exists, is undertaken primarily by product-development partnerships largely dependent on philanthropic funds. While welcome, these partnerships will only go a small way towards redressing the longstanding neglect of R&D for diseases primarily affecting the developing world (Chirac and Torreele 2006, 1561).

CONCLUSION

A vicious circle of poverty and ill-health afflicts many parts of the developing world. Measures directed at both the poverty and the health dimensions of the problem are needed. Major elements of the health problem are the high price of existing medicines and the lack of medicines that tackle some of the biggest sources of mortality and morbidity afflicting poor countries. As argued elsewhere in this book, the HIF could make a major contribution to solving (especially the second of) these problems by incentivizing new research on diseases which exact a large human health toll and encouraging innovators to distribute the fruits of their research at low prices.

However, high prices and lack of relevant essential-medicine R&D are by no means the only problems besetting the health sectors of poor countries.

Many developing countries are confronting major systemic problems in their healthcare sectors, with weak budgetary and administrative processes resulting in underfunding and/or poorly prioritized spending, leading in turn to shortfalls of trained and motivated health professionals, run-down facilities, poor administrative support and oversight and weak outreach, particularly in less accessible areas. These failings can constitute the “last mile problem,” which if not overcome means that medicines fail to meet patient needs even where they are available to Ministries of Health or other suppliers within a country. The HIF’s unique potential to address this problem is described in chapter 7.⁹

NOTES

1. In 2002, there were just over 57 million human deaths. The main causes that are highly correlated with poverty were (with death tolls in thousands): diarrhea (1,798) and malnutrition (485), perinatal (2,462) and maternal conditions (510), childhood diseases (1,124—mainly measles), tuberculosis (1,566), malaria (1,272), meningitis (173), hepatitis (157), tropical diseases (129), respiratory infections (3,963—mainly pneumonia), HIV/AIDS (2,777) and sexually transmitted diseases (180). See WHO (2004, 120–5).
2. Such morbidity is due to the conditions listed in note 1 as well as other communicable diseases, including dengue fever, leprosy, trypanosomiasis (sleeping sickness and Chagas’ disease), onchocerciasis (river blindness), leishmaniasis, Buruli ulcer, lymphatic filariasis, and schistosomiasis (bilharzia). See Gwatkin and Guillot (2000).
3. \$1 PPP 1993 is the equivalent of the purchasing power that US\$1 had in the United States in 1993.
4. The World Bank’s poverty database PovcalNet (www.iresearch.worldbank.org/PovcalNet/jsp/index.jsp, accessed June 4, 2008) enables the user to duplicate the Bank’s poverty estimates as well as to produce estimates based on different assumptions. Aggregating over the set of all low- and middle-income countries gives a ‘dollar a day’ poverty headcount for 2004 of 17.75% and a poverty gap (the mean distance below the poverty line as a proportion of the poverty line) of 5.02%. These figures mean that, if the burden of extreme poverty had been spread over all people in the developing world, it would have amounted to a 5% average shortfall from the dollar-a-day line in 2004. But since this burden was in fact concentrated on the 17.75% of the total developing country population living in extreme poverty (the non-poor are counted as having a zero poverty gap), it amounted to a 28% average shortfall for the members of this group. The inflation calculator available at the US Bureau of Labor Statistics website (www.bls.gov/cpi/home.htm, accessed June 4, 2008) shows \$392.88 in 1993 dollars to be equivalent to \$584 in 2008 dollars. 72% (100% – 28%) of \$584 is \$420.
5. PovcalNet, <http://iresearch.worldbank.org/PovcalNet/jsp/index.jsp>, (accessed June 4, 2008) gives a 2004 poverty headcount using this poverty line of 46.75% of the population of developing countries and a poverty gap of 19.3%.
6. This is arrived at by dividing the 19.3% poverty gap by the 46.75% headcount (see note 4 above).
7. Global wealth data from Davies et al. (2006). Global income data were kindly supplied by Branko Milanovic of the World Bank. The wealth figure for the top percent of US households is calculated from Kennickell (2003, tab. 10 [year 2001]). The income figure for the top percent of US households is from Saez and Piketty (2003), as updated in “Tables and Figures Updated to 2006 in Excel Format,” March 2008, <http://elsa.berkeley.edu/~saez/>, tab. A6, cell D95 (accessed August 1, 2008), and dividing by average size of tax unit.

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8. This section draws on Selgelid (2008), primarily 10–13.
9. Mercurio (2006, 3) argues that the problems of inadequate health systems are so acute and pose such pressing problems in many parts of the world that in these regions “the impact of patents on public health is moot.” As chapter 7 shows, the HIF, while designed primarily to respond to weaknesses in the existing patent system, has the potential to help address the broader problems in developing country health systems to which Mercurio refers. See also the section “Appeal to the Poor Being Doomed Anyway” in chapter 6 for a discussion of the no-impact argument.