Symposium on Global Bioethics

"Lifting All Boats": Access to Medicines and the Pharmaceutical Sector

KLAUS M. LEISINGER

Despite the substantial progress that has been achieved in human development over the past three decades, measured in higher per capita incomes, improved life expectancy at birth, lower infant and child mortality, higher literacy rates, and increased school enrolment,[1] there is no reason for complacency: progress made has not "lifted all boats"—that is, not all people in all countries have benefited alike. Behind the aggregated social and economic success indicators there is an inconvenient truth, that is, the existence of an enduring poverty crisis that results in devastating human misery, as outlined in the introduction to this symposium.

In this article, I first describe the vicious circle of health and poverty. Not only does poverty lead to death, disability, and disease, but ill health can also lead to poverty, in particular when it comes to the "working poor" and where cash payments for health services are the norm. In the second part, I describe some of the health realities in the developing world, which need to be recognized and understood in any effort to break the vicious circle. In the final part, I address the question of how pharmaceutical companies can contribute to the "lifting of more boats" through a variety of approaches, from differential pricing to philanthropic endeavors.

Health and Poverty

The interdependence of poverty and human health is well known: "Men and women were sick because they were poor, they became poorer because they were sick, and sicker because they were poorer."[2] The main risk factors for disease, disability, or death clearly reflect this interdependence of poverty and health, as Table 1 shows. In developed countries, the majority of risk factors are amenable to lifestyle changes (tobacco, alcohol, obesity, physical inactivity, etc.). By contrast, the top risk factors in underdeveloped countries are not; they are imposed by poverty (underweight, unsafe water, nutritional deficiencies, etc.).

The reasons for poverty-related health deficits are obvious: inadequate nutrition, insufficient education, poor housing and sanitation, poor hygiene, and lacking primary healthcare services or indirect causation because of unemployment, geographical isolation, political and social exclusion or exploitation (e.g., child labor), and discrimination (e.g., gender). By contrast, the more affluent and educated people are, the longer and healthier their lives become.[3]

The world's poor are put at a further disadvantage by the mere perception of disease. In a disease-ridden social environment, poverty-related illness becomes

This paper was written for a conference funded by the Commonwealth of Australia under the International Science Linkages program under grant agreement EF080010, in association with Innova-P2, funded by the European Community's Seventh Framework Programme Grant 217665.

Cambridge Quarterly of Healthcare Ethics (2010), **20**, 1–9.

doi:10.1017/S0963180110000964

Table 1. Main Risk Factors for Disease, Disability, or Death

Poorest Countries	Developed Countries
1. Underweight	1. Tobacco
2. Unsafe sex	2. High blood pressure
3. Unsafe water, sanitation, and hygiene	3. Alcohol
4. Indoor smoke from solid fuel	4. High cholesterol
5. Zinc deficiency	5. Obesity
6. Iron deficiency	6. Low fruit and vegetable intake
7. Vitamin A deficiency	7. Physical inactivity
8. High blood pressure	8. Illicit drugs
9. Tobacco	9. Unsafe sex
10. High cholesterol	10. Iron deficiency

AU1 Source: World Health Organization. *The Lancet* 2002;360:1347?60.

a ''normal'' part of everyday reality and rarely results in demands for appropriate health services. For instance, it has been shown that poor people who live in regions that are prone to natural disasters will adopt an attitude of fatalism (''what will be, will be'') rather than demand or seek preventative measures.[4]

In addition, gender discrimination makes things worse on all development fronts: women have historically been at a disadvantage in the labor market; concomitantly, poverty and deteriorating health conditions intensify the caregiving activities that women undertake in the home to alleviate the consequences of poverty. Gender-based discrimination can also deter women from seeking healthcare where necessary, therefore increasing the risk of death, disease, or disability.[5]

Figure 1 summarizes the main factors that contribute to good health. Although the figure details the obvious, namely, that the poor are more vulnerable to ill health than the rich, poor health is also a cause of poverty. In developing countries, many patients have to resort to out-of-pocket payments for medical care. Even those who may initially be able to sustain a significant household expenditure on health-related costs are unlikely to be able to do so over longer periods of time. Out-of-pocket payments often lead to both declining incomes and worsening health outcomes or even ''financial catastrophe,'' as the World Health Organization (WHO) has called it:[6]

> When people have to pay fees or co-payments for health care, the amount can be so high in relation to income that it results in ''financial catastrophe'' for the individual or the household. Such high expenditure can mean that people have to cut down on necessities such as food and clothing, or are unable to pay for their children's education. Every year, approximately 44 million households, or more than 150 million individuals, throughout the world face catastrophic expenditure, and about 25 million households or more than 100 million individuals are pushed into poverty by the need to pay for services.

For poor people, the health of their bodies and minds is a critically important asset—often their only asset—and vice versa: people's abilities to manage their own lives, to develop their assets, and to learn and make use of their skills and knowledge all depend heavily on their state of health. Yet, the healthcare

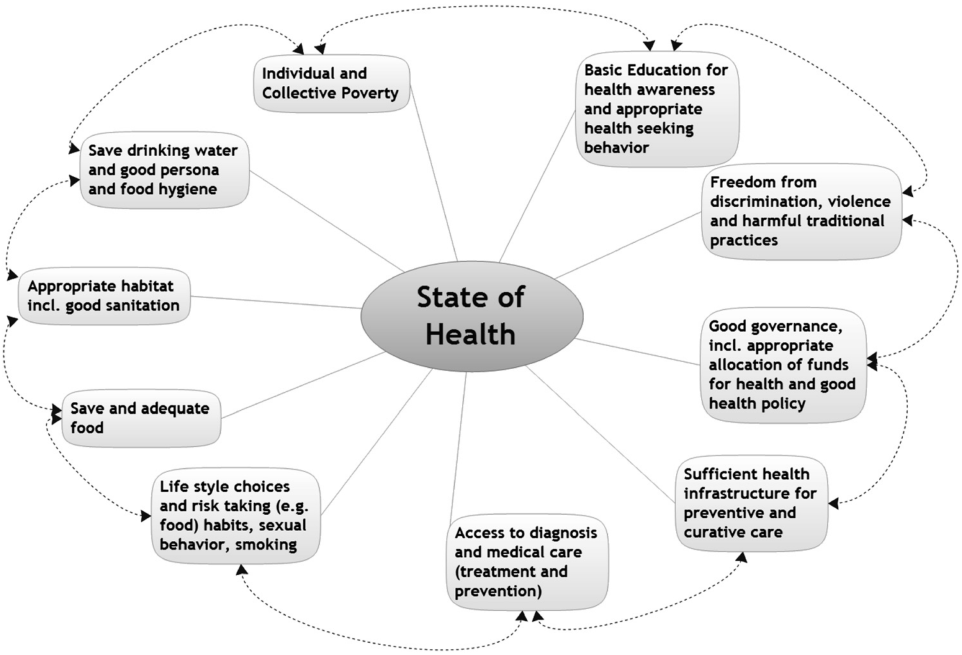

Figure 1. Factors contributing to good health. Novartis Foundation for Sustainable Development.

conditions in developing countries often militate against a good state of health, as the next section summarizes.

Health Realities in Developing Countries

Health systems in the developing world remain hampered by a serious lack of financial resources. Between 2003 and 2007,[7] the average public expenditure on health as a percentage of gross domestic product (GDP) varied between 0.26% in Myanmar (Burma) and 8.72% in France. Hence, 33 times as much was invested by the government of France in citizen health compared to the equivalent in Myanmar. All low- and middle-income economies combined (144 out of 210[8]) spent, on average, 2.58% of GDP on health. High income countries (66 out of 210) spent on average 6.79% of GDP on health during the same period.

More deplorable still, there is not only resource scarcity but misallocation: state resources are fungible, and significant amounts continue to be spent for military or prestige purposes even by the poorest countries. The world average of military spending as a percentage of GDP between 2003 and 2007 was roughly the same as low- and middle-income spending on health, namely, 2.45%.[9] More than 4% was spent on military purposes by countries struggling with adequate health services in the Middle East, Angola (4.31%), and Eritrea (23.55%[10]).

Prioritizing military or prestige spending over health expenditure is a tragedy, even more so, according to WHO's Director General, Dr. Margaret Chan, because "much of the ill health, disease, premature death and suffering we see on such a large scale is needless, as effective and affordable interventions are available for prevention and treatment."[11] For instance, low-cost pharmaceutical interventions that could prevent at least two thirds of today's infant and maternal mortality are known and available at affordable prices.[12]

At the same time, appropriate allocation of funds for health is only one factor in determining health outcomes, as was illustrated in Figure 1. An adequate health infrastructure, which includes technical equipment, facilities, and trained personnel, is another important factor. In the worst case, even well-targeted investments made by low income countries into their health infrastructure might be wasted. The most worrying example of this is the healthcare personnel brain drain from developing countries:

> International medical graduates constitute between 23 and 28 percent of physicians in the United States, the United Kingdom, Canada, and Australia, and lower-income countries supply between 40 and 75 percent of these international medical graduates. India, the Philippines, and Pakistan are the leading sources of international medical graduates. The United Kingdom, Canada, and Australia draw a substantial number of physicians from South Africa, and the United States draws very heavily from the Philippines. Nine of the 20 countries with the highest emigration factors are in sub-Saharan Africa or the Caribbean.[13]

As a result, countries that can ill afford to lose physicians are subsidizing healthcare systems in affluent countries by providing fully trained nurses and medical doctors:

> Ghana, with a population of 20 million, has only 1500 doctors, and more than two thirds of young Ghanaian doctors leave the country within three years of graduation.[14]

Lack of trained healthcare staff can lead to complications even where access to medicines is provided. A study undertaken by the UK Department for International Development (DFID) found that almost half of all medicines are inappropriately prescribed, dispensed, or sold in developing countries, leading to wasted resources and potential harm to patients.[15]

The combination of the poverty crisis and the vicious circle of poverty with current health realities in developing countries could hardly be any more bleak for the 2.7 billion people who live on less than two dollars a day and the approximately 10 million who die each year due to lack of access to essential medicines.[16] What can be done to improve this dire situation?

Duty Bearers and Their Duties Toward the Global Poor

Complex issues do not have simple solutions, and no actor can solve a problem of such a magnitude and complexity on their own, and yet, if all duty bearers lived up to their responsibilities, the quality of life of the world's poor would change dramatically for the better.

Who then are the duty bearers? In the following, I argue from a human rights perspective. The human right of everyone to the enjoyment of the highest attainable standard of physical and mental health (hereafter, the human right to health) has been enshrined in a variety of national and international legal documents.[17] It is clear that the primary responsibility for ensuring that the right to health is respected, protected, and fulfilled—and this includes access to essential medicines—lies with state institutions. First and foremost, the nation state must provide access to health services to its citizens. These state duties cannot (and should not) be delegated to any other organ of society. Yet, today, health outcomes under the leadership of those bearing the primary duty are "unacceptably low across much of the developing world."[18]

A recent WHO report sees the "failure of health systems" as being at the center of the resulting health crisis. To improve this sad state of affairs the WHO has defined "Six Building Blocks" of health systems, based on the following aims and attributes:[19]

- Good *health services*, which deliver effective, safe, quality personal and nonpersonal health interventions to those who need them, when and where needed, with minimum waste of resources
- A well-performing *health workforce*, which works in ways that are responsive, fair, and efficient to achieve the best health outcomes possible, given available resources and circumstances, that is, there are sufficient numbers and mix of staff, fairly distributed, competent, responsive and productive
- A well-functioning *health information system* that ensures the production, analysis, dissemination, and use of reliable and timely information on health determinants, health system performance, and health status.
- A well-functioning health system that ensures equitable access to *essential medical products, vaccines, and technologies* of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use
- A good *health financing system* that raises adequate funds for health in ways that ensure people can use needed services and are protected from financial catastrophe or impoverishment associated with having to pay for them
- *Leadership and governance* that involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition building, the provision of appropriate regulations and incentives, attention to system-design, and accountability.

To fulfill their duties, governments of poor countries are expected to be deliberate, concrete, and focused upon meeting their right-to-health (and hence access-to-medicine) obligations.[20] As with other economic, social, and cultural rights, governments with limited resources for ensuring the right to health should obey the principle of *progressive realization* and move incrementally, but expeditiously, toward the set goals.

Significant progress is feasible even under current budget constraints: if low-income countries were to devote about 15% of their national budgets to health—as recommended by Jeffrey Sachs many years ago—and if this were topped up with appropriate development assistance from rich countries, it would be enough to provide adequate primary healthcare to poor people.[21] However, the governments of many developing countries continue to spend more of their scarce resources on areas other than health and education.[22]

Next in the line of duty is the *international community*. "State's resources"—also with regard to granting access to medicines—are seen today to include international assistance and cooperation. In accordance with Articles 55 and 56 of the Charter of the United Nations, international cooperation for development and the realization of human rights is an obligation of all states.[23] Similarly, the Declaration on the Right to Development emphasizes an active program of international assistance and cooperation based on sovereign equality, interdependence, and mutual interest.[24] In addition, there are a number of relevant binding treaties, such as the *International Covenant on Economic, Social and Cultural Rights* and the *Convention on the Rights of the Child*.[25] In the *Millennium Declaration*, 147 heads of state and government "recognize that, in addition to our separate responsibilities to our individual societies, we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level."[26] Unfortunately for the world's poor, political rhetoric is not matched by concrete action.

Moving beyond state institutions, other important actors are nongovernmental organizations (NGOs). Many NGOs, such as Oxfam or *Médecins sans Frontières*, play a vital role in almost all aspects of health-related work for the poor. Wherever poor people are interviewed NGOs score highly for responsiveness and therefore often have the trust of those they help.[27] Effective NGOs ensure that the poor are heard, and they are instrumental in supporting the formulation and implementation of policies that directly benefit the poor. NGOs such as Oxfam were among the first to make human rights an integral dimension of the design, implementation, monitoring, and evaluation of health-related programs.

NGOs are at the forefront of campaigns for increased and better coordinated resources for healthcare and more comprehensive corporate awareness of access-to-medicines issues. Although NGO demands upon companies may at times be perceived to be unreasonable (e.g., with regard to patents), it is important to recognize that their contribution to raising knowledge and public awareness of the tragic extent and deadly consequences of mass poverty is invaluable. NGOs have a critical role to play in awareness raising and collaboration in the field.

Last, but not least, the pharmaceutical industry is also a duty bearer. The primary responsibility of a pharmaceutical company arises in the context of its normal business activity, this is to say, by conducting research and development, by bringing innovative and effective products to the market, and by providing goods and services that meet customers' needs at competitive prices.

Successful pharmaceutical corporations make their most substantial contributions to the health of patients through cutting-edge research and the development and manufacture of high-quality drugs.[28] These are essential tools for the reduction of premature mortality as well as the prevention and cure of diseases that respond to drug therapy. Pharmaceutical products raise the quality of life of sick people, avoid costly hospitalization, and allow people to go back to normal working lives instead of being bedridden.[29] No other actor in society is comprehensively engaged in such efforts and successfully delivers such results.

Because pharmaceutical companies are profit oriented, they sell in markets that are beyond the purchasing power of the 2.7 billion people who live on less than two dollars a day. There is no doubt that companies do have a moral duty to facilitate access to live-saving medicines through voluntary but sustainable and reliable commitments.

There is a body of good practices in which most large pharmaceutical companies are already engaged,[30] of which the following are examples.

There is differential pricing, that is, reduced tenders for selected drugs against poverty-related and tropical diseases for use with poor patients in low-income countries, particularly for single-source pharmaceuticals (those with patent protection or marketing exclusivity). Differential pricing is one of the most effective and simplest ways to facilitate access to essential medicines.[31] A comprehensive approach to differential pricing would see states and others provide better incentives for preferential prices for life-saving medicines, be it by public acknowledgement, tax incentives, or more innovative means such as prolonging the patent duration of drugs that are sold with differential pricing to the world's poor.

Differential pricing will only be effective to reduce the price of already existing drugs. To provide drugs to the poor, when there is no market for the rich, requires additional *research and development investments* for neglected and tropical diseases affecting predominantly poor people in the developing world. As quoted in Tikki Pang's contribution to this symposium, of the 1,556 new drugs developed between 1975 and 2004, only 21 (1.3%) targeted tropical diseases of the developing world.[32] This imbalance must be overcome with concerted research programs focusing on the diseases of the poor, a task that pharmaceutical companies must share with publicly funded efforts.[33]

Donations for disease eradication programs (such as leprosy) or emergencies (such as the Haiti Earthquake) are part of the corporate philanthropy approach to discharging duties. For instance, since the program to cure leprosy patients by donating the multi-drug-therapy globally free of charge was started in the year 2000 by Novartis, more than five million patients have been cured.[34] Within this approach, it is important to adhere to the WHO *Guidelines for Drug Donations*.[35]

The best aid provides opportunities and empowerment rather than charity: serious efforts in development-cooperation work with performance-based funding and set exit targets, that is, mutually agree on a time line, after which the respective problem is solved to free the funds for the investment into other issues. Wherever possible, in terms of economies of scale, pharmaceutical companies ought to *explore opportunities for production in developing countries*, including through wholly-owned subsidiaries. At the same time, they should consider the use of voluntary licenses, where these would increase sustainable access to essential medicines.

Last but not least, pharmaceutical companies ought to become part of public education programs, not only for the prevention of communicable diseases such as malaria, tuberculosis, or HIV, but also for lifestyle-related sicknesses.

Conclusion

Poverty and lack of access to healthcare and medicines is one of the biggest issues of our times. None of the big issues of the 21st century can be resolved without the sustained, collaborative effort of all duty bearers. Collective action requires the readiness to have dialogues, to take each other seriously, and to overcome understandable differences. Collective action also means to focus on what can be done together today where the problems are—and leave ideological peculiarities aside. One does not have to solve all differences in prevailing value premises, axiomatic assumptions, and political perspectives before joining forces in the fight against a disease that can be managed if and when all relevant stakeholders are cooperating in good faith. As Nelson Mandela has said, "Like slavery and apartheid, poverty is not natural. It is man-made and it can be overcome and eradicated by the actions of human beings."[36] State institutions, acting on behalf of their citizens and providing international assistance where required, must work closely with NGOs and the pharmaceutical industry to realize the human right to health, enshrined in the UN *Declaration of Human Rights* more than six decades ago.

Notes

1. World Bank. *The Complete World Development Report, 1978–2009 (*Single User DVD): 30th Anniversary Edition. Washington, DC: World Bank; 2008; available at http://publications.worldbank.org/ecommerce/catalog/product-detail?product_id=7208402&; (last accessed 5 Jul 2010).
2. Winslow CEA. *The Cost of Sickness and the Price of Health*. Geneva: World Health Organization; 1951:9.
3. Daniels N, Kennedy BP, Kawachi I. Health and Inequality, or, Why Justice Is Good for Our Health. In: Anand S, Peter F, Sen A, eds. *Public Health, Ethics and Equity*. Oxford: Oxford University Press; 2006:63.
4. Pan-American Health Organization. *The Strategic Plan 2003-2007 for the Pan American Sanitary Bureau*, SPP36/4. Washington, DC: World Health Organization; 2002:16; available at http://www.paho.org/English/GOV/CE/SPP/spp36-04-e.pdf (last accessed 5 Jul 2010).
5. Nikièma B, Haddad S, Potvin L. Women bargaining to seek healthcare: Norms, domestic practices, and implications in rural Burkina Faso. *World Development* 2008;36(4):608–24.
6. Xu K, Evans DB, Carrin G, Aguilar-Rivera AM. *Designing Health Financing Systems to Reduce Catastrophic Health Expenditure*. WHO Technical Briefs for Policy Makers. Geneva: World Health Organization; 2005:2; available at http://www.who.int/entity/health_financing/documents/pb_e_05_2-cata_sys.pdf (last accessed 8 Jul 2010).
7. AU2 World Bank. Available at http://databank.worldbank.org, individual report run in June 2010.
8. World Bank. Available at http://data.worldbank.org/about/country-classifications/country-and-lending-groups, individual report run in June 2010.
9. World Bank. Available at http://search.worldbank.org/data?qterm=military+spending, individual report run June 2010.
10. Figure only available for 2003.
11. WHO. *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action*. Geneva, World Health Organization; 2007:iii; available at http://www.who.int/healthsystems/strategy/everybodys_business.pdf (last accessed 8 Jul 2010).
12. Department of International Development. *Increasing Access to Essential Medicines in the Developing World*. London: Department for International Development; 2004; available at http://webarchive.nationalarchives.gov.uk/+/http://www.dfid.gov.uk/Documents/publications/accessmedicines.pdf (last accessed 8 Jul 2010).
13. Mullan F. The metrics of the physician brain drain. *New England Journal of Medicine* 2005; 353(17)1810–8. Available at http://content.nejm.org/cgi/content/full/353/17/1810 (last accessed
AU3 8 Jul 2010).
14. Coombes R. Developed world is robbing African countries of health staff. *British Medical Journal* 2005;330:923.
15. Department for International Development. Fact Sheet: Access to Medicines. London: Department for International Development; January 2006. Available at http://webarchive.nationalarchives.gov.uk/+/http://www.dfid.gov.uk/Documents/publications/atm-factsheet0106.pdf (last accessed 8 Jul 2010).
16. See note 15, Department for International Development 2006.
17. Schroeder D. Does the Pharmaceutical Sector Have a Coresponsibility to Secure the Human Right to Health? *Cambridge Quarterly of Healthcare Ethics*, this issue, xx–xx.
18. See note 11, WHO 2007:1.
19. See note 11, WHO 2007:3.
20. WHO Office of the United Nations High Commissioner for Human Rights. Factsheet 31: The Right to Health. Undated:24; available at http://www.ohchr.org/Documents/Publications/Factsheet31.pdf (last accessed 12 Jul 2010).
21. See Sachs JD. Primary Health for All. *Scientific American* 2008;298:34–6; available at http://www.scientificamerican.com/article.cfm?id=primary-health-for-all-extended (last accessed 12 Jul 2010).
22. Abbasi K. The World Bank and world health: Healthcare strategy. *British Medical Journal* 1999;318:933–6; available at http://www.bmj.com/cgi/content/full/318/7188/933 (last accessed

12 Jul 2010); Gwatkin D. The burden of disease among global poor. *The Lancet* 1999;354(9178): 586–9.
23. Charter of the United Nations 1945; Chapter IX: International Economic and Social Co-operation: Articles 55 and 56; available at http://www.un.org/en/documents/charter/chapter9.shtml (last accessed 12 Jul 2010).
24. WHO Health & Human Rights Publication Series. 25 Questions and Answers on Health & Human Rights 2002;1:16; available at http://www.who.int/hhr/information/25%20Questions%20and%20Answers%20on%20Health%20and%20Human%20Rights.pdf (last accessed 12 Jul 2010).
25. United Nations. International Covenant on Economic, Social and Cultural Rights 1976; available at http://www2.ohchr.org/english/law/cescr.htm (last accessed 12 Jul 2010); United Nations. Convention on the Rights of the Child 1990; available at http://www2.ohchr.org/english/law/crc.htm (last accessed 12 Jul 2010).
26. United Nations. Millennium Declaration 2000. Article 2; available at http://www.un.org/millennium/declaration/ares552e.htm (last accessed 12 Jul 2010).
27. Narayan D. *Can Anyone Hear Us? Voices of the Poor*. Washington, DC: Oxford University Press/World Bank; 2000.
28. See the definition given by the EU High Level Committee on Health: "Innovation encompasses many different options going from the development of a completely new medicine for the treatment of a disease otherwise incurable to modifications of known pharmaceutical formulations to improve benefits for the patients, such as a less invasive administration route or a simpler administrative schedule." See http://ec.europa.eu/health/ph_overview/Documents/ke02_en.pdf, page 5. (last accessed 15 Jul 2010).
29. See OECD. *OECD Health Data 2004*, Paris: OECD; 2005; Centers for Disease Control and Prevention. *Health, United States, 2004 with Chartbook on Trends in the Health of Americans*; available at http://www.cdc.gov/nchs/hus.htm (last accessed 22 Jul 2010); Manton KG, Gu X. Changes in the prevalence of chronic disability in the United States black and non-black populations above age 65 from 1982 to 1999. *Proceedings of the National Academy of Sciences* 2003;98:6354–9; see also Milken Institute. *An Unhealthy America: The Economic Burden of Chronic Disease—Charting a New Course to Save Lives and Increase Productivity and Economic Growth*. Presentation for Stakeholder Forum, Santa Monica 2007; available at http://www.milkeninstitute.org/pdf/econ_burden_rdv.pdf (last accessed 22 Jul 2010).
30. Department for International Development, Department of Health, Department of Trade and Industry. *Increasing People's Access to Essential Medicines in Developing Countries: A Framework for Good Practices in the Pharmaceutical Industry*. A UK Government Policy Paper. London, Department for International Development; March 2005; available at http://www.psp-one.com/files/3138_file_pharm_framework.pdf (last accessed 22 Jul 2010).
31. Essential medicines are defined by WHO as a list of minimum medicine needs for a basic healthcare system, listing the most efficacious, safe, and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. Details available at http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf (last accessed 15 Jul 2010).
32. Chirac P, Torreele E. Global framework on essential health R&D. *Lancet* 2006;367:1560–1.
33. See, e.g., the Novartis Institute for Tropical Diseases. Details available at http://www.novartis.com/research/nitd/index.shtml (last accessed 15 Jul 2010).
34. More information available at Novartis. Fighting leprosy; available at www.corporatecitizenship.novartis.com/patients/access-medicines/access-in-practice/leprosy-publications.shtml (last accessed 15 Jul 2010).
35. WHO. Guidelines for Drug Donations Revised 1999; available at http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf (last accessed 22 Jul 2010).
36. Mandela launches anti-poverty campaign. *Developments* 2005;29; available at http://webarchive.nationalarchives.gov.uk/20100823124637/http://www.developments.org.uk/articles/mandela-launches-anti-poverty-campaign/ (last accessed 22 Jul 2010).