

# Poverty, Disease, and Medicines in Low- and Middle-Income Countries: The Roles and Responsibilities of Pharmaceutical Corporations

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**Abstract:** Providing access to medicines and health care is one of the most challenging issues facing society today. In this paper the author highlights some of the complexities of the health value chain as well as the problems that the world's poor have in terms of access to medical care and medicines. He then attempts to delineate the roles and responsibilities of all stakeholders in order to define the specific corporate responsibilities of pharmaceutical companies in the context of the entire responsibility system—the strength of which is determined by its weakest link. Finally, he looks forward to a transformational change being wrought for pro-poor health development by forging new coalitions that cut across both the health and traditional development stakeholders.

Our problems are man-made.  
Therefore they can be solved by man.  
—John F. Kennedy, June 1963

## Introduction

Today, health features higher on the international development agenda than ever before, and improving the health of poor people has become a key issue for all relevant stakeholders.<sup>1</sup> Three of the eight Millennium Development Goals (MDGs) call for specific health improvements by 2015: reducing child deaths, maternal mortality (MDG 4 and 5), and slowing the spread of HIV/AIDS, malaria, and tuberculosis (MDG 6). Moreover, health is increasingly viewed as fundamental to

the achievement of other MDGs: eradicating extreme poverty and hunger (MDG 1), achieving universal primary education (MDG 2), promoting gender equality and empowerment (MDG 3), and ensuring environmental sustainability (MDG 7).

But evidence is mounting of a radical shift in mindset and momentum by multiple stakeholders to finally take on this grand global challenge. At one level, the complexity of the health care system has begun to be addressed as part of a web of social determinants based on economic, cultural, political, and technological considerations. At another level, the success of the global response to HIV/AIDS and other infectious diseases, kick started in 2000 by the launch of the Millennium Development Goals (MDGs), is now being matched by global strategies to address women's and children's health and neglected tropical and chronic non-communicable diseases. This progress is combining with a growing consensus on the central role of adopting a truly multi-stakeholder approach to addressing extreme poverty in all its forms.<sup>2</sup> As one part of the solution, target 17 of MDG 8 calls for action to:

Develop a global partnership for development. . . . In cooperation with pharmaceutical companies, provide access to affordable essential medicines in developing countries.<sup>3</sup>

While the merits of this target have attained significant attention as a unifying model for multi-stakeholder engagement, its practical implementation has yet to materialize. In both the public and private sectors, the reasons for the failure to significantly improve the health status of the poor are undoubtedly diverse and multi-dimensional. This paper endeavors to show the complexity of the health value chain as well as the problems that the world's poor have in terms of access to medical care and medicines; it then attempts to delineate the roles and responsibilities of all stakeholders in order to define the specific responsibilities of pharmaceutical corporations in the context of the entire "responsibility chain"—the strength of which is determined by its weakest link. Finally, it looks forward to a transformational change being wrought for pro-poor health development by forging new coalitions that cut across both the health and traditional development stakeholders.

## **Health and its Determinants**

### *The Importance of Health*

Health is a crucially important economic and social asset, particularly for poor people, who suffer from far higher levels of illness and die much earlier than do

the better-off. Disease is one of the factors making or keeping them poor, for it decreases people's ability to work and depletes their productivity. If poor people fall ill, their entire household can become trapped in a downward spiral of lost income and high out-of-pocket health care expenditures.<sup>4</sup> There continue to be dramatic inequities in life expectancy between countries—without there being any underlying biological reason. This is indicative of social and political problems—these are man-made and thus can be solved by man.

The health of the poor must thus be a matter of major concern for everyone committed to sustainable development, from patients, health care providers, national and international policy makers to the providers of goods and services.

### *Poverty and Health*

Disease and poverty are interdependent. People are sick because they are poor. They become poorer because they are sick and sicker because they are poorer.<sup>5</sup>

Advances in human development over the past four decades have been impressive: Poverty continues to decline in many countries and regions; the level of under-five deaths dropped to its lowest level in more than six decades; fewer children are underweight; more women get skilled help during childbirth; more people have access to safe drinking water and sanitation; deaths from malaria have been reduced by 20 percent worldwide (the largest absolute drops in malaria deaths were in Sub-Saharan Africa, where eleven countries have reduced malaria cases and deaths by over 50 percent); and new HIV infections have declined globally from 2001 to 2008.<sup>6</sup>

Income per capita has been rising in most low-income countries, and this is good news as rising incomes are “highly correlated with many development indicators, such as secondary school enrollment, access to water and sanitation, births attended by skilled staff, total fertility rate, children immunized against measles, malnutrition prevalence, and infant mortality.”<sup>7</sup> The rising gross domestic product (GDP) in most low- and middle-income countries led also to a decline in the share of people who suffered from deficits in health care because they could not afford it.<sup>8</sup>

But there is no reason for complacency; continued economic growth—and a minimum of fairness in its distribution—are absolutely necessary for achieving all MDGs, especially those related to health. The global community has made insufficient progress to date towards achieving the health-related MDGs. For example, every year, over 8 million children die from preventable causes, and more than 350,000 women die from preventable complications related to pregnancy and

childbirth. Progress among the lowest-income countries and LDCs has generally been poor, and many countries—particularly fragile states and countries emerging from conflict—are off track. There are huge social and economic issues waiting to be solved:<sup>9</sup> About 1.4 billion of the world's 7 billion people continue to live in extreme poverty (measured at US\$ 1.24 a day), and 2.5 billion live in absolute poverty (measured at US\$ 2 a day) in 2011.<sup>10</sup> They have to eke out an existence with an extremely low income and, consequently, must cope with malnourishment and nutritional deficiencies, a lack of access to safe drinking water and sanitary facilities, squalid living conditions, inadequate access to basic preventive and curative health care services—including pharmaceuticals as well as insufficient knowledge about health issues.

### *Social Determinants of Health*

The conditions into which people are born, in which they grow, live, work, and age determine their state of health much more than any other factor.<sup>11</sup> These conditions are shaped by the distribution of money, power and resources at global, national, and local levels. These in turn are influenced by policy choices. Political governance is therefore a major factor determining the differences in the health status within and between countries. Poor living conditions are the breeding grounds for illness; misery makes people more vulnerable to diseases. The patients affected are not only “income-poor”; they are “largely hidden, concentrated in remote rural areas or urban slums and shanty towns. They also are largely silent, as the people affected or at risk have little political voice.”<sup>12</sup> At the same time as chronic non-communicable diseases (NCDs) are becoming more important in low- and middle-income countries, partly as the outcrop of globalization, neglected tropical diseases such as schistosomiasis, onchocerciasis, leishmaniasis, lymphatic filariasis, trachoma, Chagas disease, Dengue fever, and others are still taking their toll.<sup>13</sup> They are prevalent in settings of absolute poverty and therefore have a low visibility in the rest of the world. In addition, HIV/AIDS, malaria, and tuberculosis cost millions of lives and continue to affect the existence of hundreds of millions of people.

Intervention priorities were previously, and still are in many cases today, mainly set on solving specific health problems, such as certain infectious diseases, non-communicable diseases, nutrition-related health, maternal health, or access to health care services. The influential WHO Commission on Social Determinants of Health<sup>14</sup> stresses the importance of also addressing the core societal factors

that account for health inequities across populations—a strategic aspect of special importance for mothers and children.

### *Medicines and Health*

Pharmaceutical products play an important role in health care. Along with well-trained and motivated health professionals, pharmaceutical products are the most effective way to prevent, alleviate, and cure illnesses. Many, if not most, of the illnesses plaguing people living in poverty can be prevented, alleviated, or cured with the relatively small number of medicines listed on the World Health Organization (WHO) Essential Medicines List,<sup>15</sup> many of which are available at relatively low prices.

Used properly, medicines can significantly lessen the disease burden and its detrimental impact on development. Like education and employment, people all over the world comprehend access to basic health care as a fundamental human right.<sup>16</sup> But around 2 billion people worldwide have inadequate or no access to essential medicines and vaccines; more than 80 percent of these people live in low-income countries.<sup>17</sup> The death toll of deficits in access to medicines is estimated to be about 10 million people a year.<sup>18</sup>

## **Ensuring and Improving Health**

### *Good Governance*

Today, most of the countries showing high morbidity and mortality rates spend vastly insufficient resources on preventive and curative health. The World Health Report 2010 estimates that 20–40 percent of all health spending is wasted through inefficiency,<sup>19</sup> pointing among other factors to *medicines* (“underuse of generics and higher than necessary prices for medicines,” “use of substandard and counterfeit medicines,” and “inappropriate and ineffective use of medicines”), *health workers* (“inappropriate or costly staff mix”), *health-care services* (“inappropriate hospital admission and length of stay”), but also health system leakages (“waste, corruption and fraud”). These inefficiencies have fatal consequences for those who need health care most: the rural and urban poor. The “poverty-and-governance system”—far more complex than can be expressed in mere financial terms—is to blame for the immense health deficiencies of hundreds of millions of people and for tens of millions of preventable deaths, year after year.<sup>20</sup> However, waiting for long-term changes on the systems’ front would cost countless human lives and hurt the prospects of survival for hundreds of millions of people. They need

immediate preventive and curative action with international assistance that works despite adverse circumstances.

In order to make sustainable progress in the state of health of the world's poor, the social causes underlying disease and premature death must be given "serious attention"<sup>21</sup>—that is, debates around health and the provision of health care must reflect the influence of societal, economic, environmental, and cultural factors on a person's lifestyle, as well as their interactions with familial, social, and community networks. Otherwise they deal with the symptoms only, and not with the causes.

Against this background, the influence of the quality of governance is clearly measurable: Developing countries (e.g., Sri Lanka, Costa Rica, Mali) as well as states within countries (e.g., Kerala state in India) with a comparable resource base (land, water, soil quality, climate, etc.) and similar social structures, have made widely differing economic and social advances over the past fifty years. This suggests that, although historical legacies (e.g., a colonial past), unfavorable world economic conditions, or other external factors are important, they do not play the decisive part in the quality of life of people in the countries concerned.

Good governance matters, not only for sustained economic growth, but also for its "social performance," as can become manifest in the state of health of a country.<sup>22</sup> Political participation, stability and the absence of violence, government effectiveness, regulatory quality, the rule of law, freedom of press, and the control of corruption—all have a very high dividend for poverty reduction and the improvement of health. In other words, the realization of basic health rights of the world's poor people encompasses addressing underlying health determinants, such as adequate nutrition, sanitation, safe water, adequate housing and working conditions, a healthy environment, good emergency services and an appropriate referral system, but also good governance.<sup>23</sup> Accountability that commitments are honored, efforts harmonized and progress (or lack of it) tracked helps to fairly allocate public resources on health and to avoid or correct irrational spending patterns.<sup>24</sup> The focus must be on national leadership and ownership of results—no external intervention can substitute for good governance.

With good governance, a significant part of the heavy burden of disease and preventable mortality can be eliminated or at least substantially reduced with a small number of well-known interventions. The conclusions of the WHO's Commission on Macroeconomics and Health,<sup>25</sup> drawn in 2001 by its chairman, Prof. Jeffrey D. Sachs, are basically still valid today, although things are changing with the increases of hypertension and diabetes:

“The main causes of avoidable deaths in the low-income countries are HIV/AIDS, malaria, tuberculosis (TB), childhood infectious diseases, maternal and perinatal conditions, micronutrient deficiencies, and tobacco-related illnesses. If these conditions were controlled in conjunction with enhanced programs of family planning, impoverished families could not only enjoy lives that are longer, healthier, and more productive, but they would also choose to have fewer children, secure in the knowledge that their children would survive, and could thereby invest more in the education and health of each child.”<sup>26</sup>

Many of the primary health care interventions known to reduce mortality (above all, infant and maternal mortality) and lower the burden of disease are not costly.<sup>27</sup> A package of six vaccines assembled by the WHO, for example, costs less than 1 US\$, and de-worming (which can increase school attendance) costs just 50 cents a year.<sup>28</sup> Today’s price of a state of the art malaria treatment is under 1 US\$ and is even available in a dispersible form for pediatric use.<sup>29</sup> Education on the benefits of impregnated bed nets and reliable logistics for the distribution of these are interventions that result in a noticeably lower mortality due to malaria—and this even at a low level of socio-economic development. The availability and effective distribution of essential medicines such as antibiotics, medicines against parasitic illnesses, medicines to treat HIV/AIDS as well as malaria and TB, and vaccines against meningitis, measles, tetanus, and polio—as well as other medicines listed on the WHO List of Essential Medicines<sup>30</sup>—can save millions of lives, even if there is little economic progress on the aggregate level of the country. If the interventions are strategically well planned and targeted on diseases that impose the heaviest burden on society, the inputs efficacious and the services reliable and dedicated, the benefits for society will exceed the economic, social, and human costs of disease and death by far.<sup>31</sup>

### *Health Systems*

Everyone who should have access to treatment does not actually do so. There are huge deficits in basic health infrastructure and significant shortages of skilled and motivated health personnel. Where basic health services are available in appropriate quality, awareness, knowledge and education about health matter for individuals with early symptoms to make use of what is available.

The weakest link in a long chain of responsibility is most often staff. Where workplace relations and decision-making processes are not fair and where patients are not treated respectfully and empathetically, the whole health system loses the trust of its “customers.”<sup>32</sup> Poor patients in poor countries are not only getting fewer

services by skilled health workers, and when they receive care it is likely to be of a lower quality than that provided to richer people.<sup>33</sup>

The WHO has called the current health outcomes “unacceptably low across much of the developing world” and diagnosed the “failure of health systems” as being at the center of the resulting human crisis.<sup>34</sup> In many countries with a high burden of disease, according to the UN Development Program (UNDP), health systems are not equipped to provide health care for all, reflecting the inability of governments and societies to mobilize the requisite resources and institutions. In particular, countries need to improve three areas of service delivery that focus on people’s needs: infrastructure, available staff to deliver services, and adequate and effective funding.<sup>35</sup>

Over-specialization in private curative services co-exists with deficits in public primary health care services; the availability, quality, and motivation of staff show immense disparities. Poor countries often have fewer than 1.1 doctors and 0.9 nurses per 10,000 people, with access unevenly distributed across income groups. “Wealthy people are better able to get to well staffed facilities and can afford to be seen by doctors.”<sup>36</sup> The lowest quintile has less access to even basic services such as antenatal care, professional birth attendance, and immunization services. The resulting consequences in health status delivery are glaring.

Risk protection through health insurance schemes remains highly unequal, despite the clear evidence of their beneficial impact and the fact that out of pocket payments can have a disastrous impact on a household’s financial situation.<sup>37</sup>

The global health agenda is shifting from an emphasis on disease-specific, “vertical” approaches to a focus on health systems strengthening, or “horizontal” approach, for a number of reasons.

1. The first factor contributing to the focus on health systems is the effort by the World Health Organization (WHO) to restore policies for primary health care (PHC). The PHC approach was officially launched on the global stage through the Alma Ata Declaration of 1978.<sup>38</sup> Implementation of PHC at the country level, however, confronted many challenges in poor countries. The WHO was seeking to resurrect the PHC approach with the World Health Report 2008, issued in October on the 30th anniversary of the Alma Ata Conference, with a renewed emphasis on the principles of universal coverage, people-centered approaches, and effective delivery of primary care.<sup>39</sup>



2. Second, medicines and vaccines on the WHO Essential Medicines List are available at low prices from generic producers. Used properly, they can save up to 10.5 million lives each year and reduce unnecessary suffering.<sup>40</sup>
3. Third, disease-specific approaches over the past decade have created unintended side-effects:
  - a. They have contributed greatly to health improvement, particularly since existing multilateral and national health agencies could not deal with the devastating effects of diseases like HIV/AIDS in many developing countries. But now, recipient countries are confronted with a fragmented array of uncoordinated disease control programs promoted by multiple donors.
  - b. Disease-specific programs reduce the effectiveness of health ministries. They have attracted financial and human resources away from government agencies and may be contributing to a weakness of health systems.
  - c. Two of the major disease-specific programs—the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Global Alliance for Vaccines and Immunization, a consortium of organizations to promote immunization and vaccination—have launched significant efforts to strengthen health systems in recipient countries. While those programs have encountered problems in implementation, they nonetheless reflect recognition of the need to develop both disease-specific and health-system-strengthening approaches.
4. A fourth factor is the growing recognition about the difficulties that health systems weaknesses present in achieving the Millennium Development Goals (MDGs). Problems in health systems performance are major causes for the delays in achieving key targets of the health-related MDGs—those related to child mortality (MDG 4), maternal mortality (MDG 5), and the prevention of HIV/AIDS, malaria, and other diseases (MDG 6). These delays are particularly pronounced in countries in sub-Saharan Africa.
5. Fifth, the growing demand for aid effectiveness and donor harmonization at the country level, based on the principles of the Paris Declaration,<sup>41</sup> reflects concerns about system-wide impacts of global health initiatives. The increase in resources devoted to health worldwide, however, has focused more on inputs (especially human and financial resources) rather than on outputs or health impacts (such as effective coverage and improved health).

Yet, there is limited evidence that previous attempts to achieve strong donor coordination (through poverty reduction strategies and sector-wide approaches) have helped improve health systems performance.

Ideally, efforts at fighting specific diseases *and* strengthening health systems would support each other. But “balance” is difficult to define, especially when the knowledge base is thin and contested about how vertical programs affect horizontal efforts. There is not enough evidence whether and how improving the one necessarily promotes or injures the other. Yet, clearly, the disease-focused programs are nervous about shifts in global resources to health systems. Advocates of single-disease control programs are concerned that the renewed emphasis on health systems could move resources away from their programs and undermine progress achieved to date. The risk of allowing infectious diseases to increase should be carefully monitored as efforts develop to strengthen health systems. A community-based approach, with attention to collective quality of life, could help avoid undesired consequences of a unilateral focus.

#### *Access to Medicines*

About 2 billion people have inadequate or no access to life-saving essential medicines.<sup>42</sup> Poor patients in Africa and Southeast Asia are most affected. Ten million people die due to the lack of access to essential medicines:

1. A third of the world’s population lacks access to the medicines they need, rising to 50 percent in parts of Asia and Africa. Recent access surveys in thirty-nine mainly low- and low-middle-income countries found that, despite wide variation, average medicines availability was 20 percent in the public sector and 56 percent in the private sector.
2. The geographic aspect of access—“having medicines continuously available and affordable at public or private health facilities or medicines outlets that are within one hour’s walk from the homes of the population<sup>43</sup>—is often not given.
3. Almost half of all medicines are inappropriately prescribed, dispensed, or sold, leading to wasted resources and potentially resulting in harm to patients.
4. Patients often do not follow the prescribed regimen; they only take up to 50 percent of the medicine given to them, resulting in reduced treatment efficacy and potentially leading to resistance.

5. In developing countries, medicines account for 60–90 percent of household expenditures on health. Yet, inappropriate prescriptions, high prices, low quality, and improper usage mean that the poor often receive little health benefit from what they spend on medicines.<sup>44</sup>

Appropriate use of quality medicines (instead of substandard or counterfeit products), including correct use of antibiotics (in adequate supply and doses), proper use of injections, adherence to treatment of chronic diseases, and use of the most cost-effective therapies, depends on many social, political, and other factors. Actors bearing responsibility for the appropriate use of medicines include research-based companies, generics producers, procurement agents, importers, wholesalers, central medical stores, retail pharmacists, prescribers, patients, and many more.<sup>45</sup>

While most health care actors recognize the complexity of the access puzzle and its variability from one setting to another, they assign different degrees of importance to individual factors: governmental allocations for health, household income, geography, cultural acceptability, skilled health staff and technical infrastructure, education, gender relations—just to list a few. In many settings, cultural and language barriers, lack of community participation, mistrust, and conflicting interests of actors constitute substantial barriers to access. Migrants, ethnic minorities, and indigenous people may have additional obstacles to overcome; they use services less than other populations, even though their needs may be greater.<sup>46</sup> Last but not least, unpleasant side effects or complicated dosage patterns can make patients' compliance with the appropriate regimen difficult.

All this is preventable. However, if we look at the proposals for solving these problems, we find a significant pluralism. Many suggestions take a simplistic approach, focusing only on drug patents or prices. This may be politically attractive, but it is not likely to achieve scalable or sustainable results. In fact, sustainable, equitable access to appropriately used medicines for poor people in low-income countries is a highly complicated issue. In this context, Laura Frost's and Michael Reich's definition is most telling:

[A]ccess refers to people's ability to obtain and appropriately use good quality health technologies when they are needed. Access is not only a technical issue involving the logistics of transporting a technology from the manufacturer to the end-user. Access also involves social values, economic interests, and political processes. Access requires a product as well as services and is linked to how health systems perform in practice.<sup>47</sup>

Access to medicines is more than a “single event,” it is rather a process involving many actors and activities over time. It is not a yes-or-no dichotomy, but rather a continuous condition of different degrees; “more like a rheostat than an on-off switch.”<sup>48</sup> If access to medicines is generally accepted to be a complex problem, effective efforts must address the respective and particular reasons for the barriers in a given place, at a given time, and for a given population.

The following sections of the paper outline roles and responsibilities for improving access to medicines of different actors.

### **Roles and Responsibilities of Different Stakeholders in Ensuring and Improving Health**

#### *The Human Rights Framework to Define Roles and Responsibilities*

The global health architecture is undergoing fundamental structural changes. UN Secretary General Ban Ki-moon suggests in his Joint Action Plan for Women’s and Children’s Health<sup>49</sup> to call many different stakeholders to action, at least governments and policymakers, civil society, regional bodies, donors, the private sector, UN and multilateral agencies, health-care professionals, academics and research institutions. In an increasingly complex world with diminishing public funding, progress depends on placing a priority on working together, whether through public-private partnerships, community groups and health authorities, or in any combination to share skills and assets, risks and rewards.

The WHO presents its updated approach in *Everybody’s Business*.<sup>50</sup> In its 2007 strategy document, the World Bank emphasizes the need for a “collaborative division of labor with global partners,”<sup>51</sup> including the WHO, UNICEF, and the United Nations Population Fund (UNFPA), which are viewed as providing technical expertise in disease control, human resource training, and service delivery. The Bank considers its comparative advantages in broader systemic issues, especially health financing and health economics, as well as public-private partnerships, public sector reform and governance, inter-sector collaboration for health, and macroeconomics and health. A major challenge for the Bank is implementing its strategy at a time when the Bank receives a smaller proportion of global health funds, and the substantive problems encompass more than the bank’s areas of comparative advantage.

As noted in the World Bank’s strategy document, the once-dominant players are increasingly marginal and less influential. This is true for both the World Bank’s prior financial dominance and the WHO’s prior normative dominance.

Global health policymaking has become a multi-stakeholder process—but without an explicit institutional process and with competition and confusion at global and national levels. There is the normative and distributional dimension, and there are social values and conflicting interests involved which make the problem of access to medicines a highly political issue.

The “role and responsibility question” can in good faith be approached from very different ethical, social, or political angles, using the wisdom of many different schools of thought. As the Universal Declaration of Human Rights (UDHR) is globally the most commonly accepted normative standard, and in light of the development of the “right to health” debate,<sup>52</sup> it is perhaps most useful to approach the role and responsibility question from a human rights perspective. The benefit of using a human rights approach lies in the fact that different parties are requested to live up to their diverging legal duties and moral responsibilities in different ways. *All* of them are called upon to contribute.

Article 25<sup>53</sup> of the UDHR can be taken as a good starting point for the access to medicines debate, as it puts health into the appropriate context:

- a. (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”
- b. (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.”

Article 22<sup>54</sup> of the UDHR is of interest too, as it clearly recognizes “social security” as one important standard of living component:

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

The Preamble of the UDHR,<sup>55</sup> however, enlarges the circle of responsible actors by determining that securing “effective recognition and observance” of the rights

and freedoms proclaimed is the responsibility of *every individual and every organ of society*, nationally and internationally, by progressive measures. The debate on health-related human rights has much to gain from the work of John Ruggie, the Special Rapporteur of the Secretary General. His framework lays the foundations of a system for better managing business and human rights challenges based on distinct yet complementary responsibilities for states and corporations, and effective remedy in case of abuse.<sup>56</sup>

#### *Individual Duties*

The state of health of a person and the risks of falling ill are to a great extent determined by individual habits and lifestyles. While governments should play a stronger role in risk prevention policies, education, and social marketing, individuals must accept their part of responsibility for their own health. Individual commitment and corresponding actions cannot be replaced by communities or governments and even less by the international community. Duties in the context of the right to health begin at home.

#### *Community Obligations*

Local communities can do much improve their members' perception of health risks and to reduce them. Functioning communities regard it as their essential obligation to analyze health-related problems and determine their needs and to initiate community efforts and mobilize community resources that will improve health-related infrastructure such as supplies of safe water, will eliminate habitats for vectors that spread diseases and thus interrupt the transmission of the disease, will provide community support and care for the needy, and will train community workers for health, education, and other items. Significant health results can be achieved without much financial means; even poor communities can achieve a great deal, such as encouraging health-promoting behaviors (breast-feeding, use of mosquito nets, boiling of unsafe water) and developing peer pressure against health risks (unsafe sex, excessive alcohol consumption, violation of women's reproductive rights).

#### *National Governments and Their Institutions*

There is consensus among all health development stakeholders: local governments and their national institutions bear the main responsibility for ensuring public health.<sup>57</sup> Economic and social policy priorities determine the scope of resources allocated to health, education, sanitary and general infrastructure. This determines the state of health of lower income classes. Governments have the duty to respect,

protect, and fulfill the right to health progressively to the extent allowed by their resources. As poor countries suffer from scarcity of resources for a critical minimum of public infrastructure, tough choices have to be made.<sup>58</sup> The International Covenant on Economic, Social and Cultural Rights expects governments to do their best with regard to ensuring availability, accessibility, acceptability, and quality of health services:<sup>59</sup>

- a. **Availability**, including, among other things, hospitals, clinics, trained medical personnel, and the availability of essential medicines according to the WHO Essential Medicines list;
- b. **Accessibility**, not only in the sense of physical reach for all sections of the population without discrimination of, for example, ethnic minorities, indigenous people, or women and children in rural areas, but also in terms of economic accessibility (affordability) in the sense that poorer households should not be overburdened with user fees, transport costs, and costs for medicines;
- c. **Acceptability**, in the sense that health facilities must be respectful of medical ethics, culturally appropriate, and gender-sensitive;
- d. **Quality of Health Facilities**, that is, scientifically and medically appropriate, transparent, “customer-oriented” care, and effective referrals. The motivation and the professional competence of locally available human resources are of preeminent importance.

The *Human Development Report 2010* analyzed the experiences of the past twenty years and pointed to the following pillars to build upon for lasting improvements in the health situation of a given country:<sup>60</sup>

- Appropriate **national health policy** (also the appropriate allocation and equitable distribution of resources) plays an important part in determining the scope of improvements in mortality rates and disease burdens.
- The better use of **proven methods in maternal and neonatal health care** results in lower maternal, neonatal and infant mortality rates.
- The most **cost-effective interventions reduce mortality and improve health**. As the majority of the most important interventions are not costly, the lack of resources is not always the main obstacle to providing essential health care services.

- **Good governance** correlates measurably with longer life expectancy and a lower probability of maternal mortality. Contrary to common expectations, countries rich in natural resources fare worse than average. This finding underscores the importance of good governance and the relativity of resource availability.

An integrated and holistic approach is necessary, with a focus on strengthening health care systems. Successful interventions, as Mary Robinson and Andrew Clapham note,

require not only that quality health systems are available, accessible and acceptable to all but that positive action is taken to address the economic, social and political inequalities behind mortality and ill-health. . . . Understanding and addressing influences such as gender, poverty, culture and age is a crucial part of the process. These powerful determinants of health shape the distribution of diseases, access to and use of health services, and the course of health outcomes. Attention to the human rights principles of non-discrimination and equality can highlight differential treatment of distinct population groups moving beyond averages to focus attention on the health needs of vulnerable or marginalized groups, and thus help to ensure that health systems meet the health needs of all segments of a population. In the end, nothing could be more important to promoting greater enjoyment of the right to health than strengthening health systems around the world.<sup>61</sup>

There are a number of valuable hints for sustainable solutions. To improve the health of all citizens, the WHO defined “six building blocks” of effective health:<sup>62</sup>

- **Delivery of effective, safe, quality-assured personal and non-personal health interventions** to the individuals and communities who need them, when and where needed, with the minimum waste of resources;
- **A health workforce able to perform responsively, fairly, and effectively** to achieve the best health outcomes possible, given available resources and circumstances—i.e., there should be enough trained and competent staff evenly distributed to meet the needs;
- **A health information system** that ensures the production, analysis, dissemination, and use of reliable and timely information on health determinants, health systems performance, and health status;



- ***Equitable access to essential medicines, vaccines, and technologies*** of assured quality, safety, efficacy, and cost-effectiveness, and their scientifically sound and cost-effective use;
- A ***health financing system*** that raises adequate funds for health in ways that ensure people have access to needed services and are protected from financial catastrophe or impoverishment associated with health care costs; and
- ***Leadership and governance*** that involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition building, appropriate regulations and incentives, attention to system design, and accountability.

Governments all over the world are expected to be deliberate, concrete, and focused on meeting their health-related obligations. In order to make at least feasible progress under given constraints, governments should obey the principle of *progressive realization* and move incrementally, but expeditiously, towards the set goals. To have a substantial impact on the health situation of the poorest people, reforms of current health care systems are unavoidable.<sup>63</sup> As previously discussed, the vicious circle of disease-poverty-disease is similarly complex as is access to affordable health care and essential medicines, available and accessible at a health facility or medical outlet within one hour's walk from a patient's home. The Working Group on Access to Essential Medicines pointed to the following issues—all of them political in nature:<sup>64</sup>

- a. There is ***inadequate national commitment*** to making health care a priority from the national to the local levels. Key among the problems are the lack of political will by policymakers to make the needs of the poor a priority; donor programs that can skew or limit national governments' abilities to set health policy; debt servicing and conditionality for loans from international financial institutions that can further limit government responsiveness to basic social service needs of citizens; and, unfortunately, the threat of corruption that continues in the health care sector at all levels.
- b. There are ***inadequate human resources*** for health, a problem that threatens to undermine all efforts to strengthen health systems and improve health care in much of the developing world. Education, information, and in-service training remain potent tools to change that situation; but so are

retention plans and attractive compensation schemes for health professionals working in rural areas or those getting offers to emigrate.<sup>65</sup>

- c. The *international community has not provided adequate finance or consistently fulfilled its existing promises to developing countries.*
- d. A persistent *lack of coordination of international donors* also reduces access to medicines.

The price of pharmaceuticals can be an issue for poor patients. This is especially so where poor patients are forced to purchase medicines through out-of-pocket payments.<sup>66</sup> *Money always matters* for poor people, but the significance of non-financial obstacles is underestimated when discussing deficits in the health care sector of low-income countries. The right mix of resources and conditions needs to be put in place. This includes political will, finances and ideas, innovative technologies, and experience from local partners. Of special importance is cost-effectiveness so that available resources are used for the biggest impact. One “low-hanging fruit” is the removal of unnecessary price markups due to import tariffs, duties, and sales taxes for medicines. This would result in more medicines being available for a given financial endowment.<sup>67</sup> Many countries with significant deficits in access to medicines for the poor still apply high tariff rates on pharmaceuticals—sometimes to protect unproductive local manufacturers.<sup>68</sup> This continues despite the fact that more than ten years ago forty African heads of state agreed to reduce or eliminate taxes and tariffs on, for example, malaria medicines, bed-nets, and rapid diagnostic tests.<sup>69</sup>

Tariffs, duties, and taxes on pharmaceutical products in general and certainly on donated or preferentially priced essential medicines need to be abolished, as they unnecessarily increase the manufacturers’ selling price. For patients who have to pay out of pocket, such markups in addition to inefficient procurement practices and other deficits can double the manufacturer’s price for a medicine. Tariffs on medicines are essentially a regressive form of taxation, since a smaller proportion of the payers’ income is affected by the tariff as incomes rise. This regressive “tax” negatively affects the poor and the sick.<sup>70</sup> Tariffs, duties, and taxes can be abolished without major revenue losses for the government, as they make up for an “insignificant” amount of revenue when compared with the national GDP—there are absolutely no reasons why poor countries should retain these markups.<sup>71</sup>

But even the best political system and the most appropriate leadership in low-income countries does not substitute for a minimum of financial resources.

Latest figures on total health expenditure per capita show amounts of US\$ 54 in least developed countries and US\$ 66 in low human development countries.<sup>72</sup> This amount of money must cover the salaries of doctors, nurses and health auxiliaries, the hospital and laboratory infrastructure, all medical interventions and all medicines—be it for prevention, communicable diseases, chronic diseases, or emergency services. For comparison, the expenditures for health in countries like Switzerland, Germany, and the United States are between 70 and at least 100 times higher. In addition, in most low and middle income countries, the largest proportion of health care expenditures is paid out of pocket, making country efforts toward universal health coverage<sup>73</sup> particularly crucial. Ten years ago, the WHO Commission on Macroeconomics and Health<sup>74</sup> concluded that a set of *essential interventions* costs around US\$ 34 per person per year. In today's prices, this is about US\$ 54—still a very modest sum indeed, especially compared with average per capita health spending in the high-income countries of more than US\$ 2,000 per year (US\$ 4,000–7,000 in current US\$). According to the 2010 WHO World Health Report, thirty-one of the WHO's member states spend less than US\$ 35 per person per year (and four countries spend less than US\$ 10), even when contributions of external partners are included.<sup>75</sup> This still leaves a gap of US\$ 19 per capita to cover the most basic needs for the poor. To reach US\$ 54 needed per person for approximately 900 million people living in least developed countries in 2011, countries and the international community would have to come up with about US\$ 17 billion—a little more than 1 percent of the US\$ 1,531 billion spent on defense by the top fifteen countries with expenditures in that category in 2009, according to the Stockholm International Peace Research Institute Yearbook 2010.<sup>76</sup>

### *The International Community*

In June 1945, with the horrors of war and the resulting misery still freshly in people's minds, the international community pledged in Articles 55 and 56 of the Charter of the United Nations to take “joint and separate action” to achieve “higher standards of living, full employment, and conditions of economic and social progress and development” and to arrive at “solutions of international economic, social, health, and related problems.”<sup>77</sup> These ideas still serve international development assistance and have been reaffirmed as a “collective responsibility” in many later UN conventions as well as in the Millennium Declaration signed by 147 Heads of State in 2000. The object is not only to transfer financial and technical resources into poor countries, but also to see to it that relationships between industrialized and developing countries enable the achievement of the MDGs.

This includes the removal of issues of trade, agricultural subsidies, climate protection, and other matters that result in hundreds of billions a year of lost income for many developing countries that could otherwise be invested, for instance, in the health sector.<sup>78</sup> E.g., agricultural subsidies in OECD countries alone amount to an estimated US\$ 1 billion a day. The export of surpluses on political motivations costs many developing countries more every year in terms of lost income than is ever reimbursed in the form of development assistance.

WHO, UNICEF, UNFPA, UNDP, the World Bank, and other institutions such as The Global Fund to Fight AIDS, Tuberculosis and Malaria, and the GAVI Alliance require a minimum of financial and human resources from the international community to professionally carry out their mandates. Direct budget support to governmental health institutions in poor countries can also be of vital significance where and when good governance prevails. Despite all the recent criticism it is undisputed that Foreign Aid has played and continues to play an important role in reducing poverty, in accelerating human development and in the achievement of the Millennium Development Goals.

In most cases, greater and faster progress could be made in all aspects of poverty alleviation if the international community lived up to its promises and made the appropriate financial resources available.<sup>79</sup> Historic successes in fighting certain diseases such as eradicating smallpox, containing poliomyelitis, and progress in family planning, would not have come about without the assistance of the international community. The fact that not all assistance endeavors are equally effective is not surprising but does not negate the overall positive impact.<sup>80</sup> The same is true for improving aids effectiveness and impact.<sup>81</sup> Fortunately, the resources for development cooperation have increased over the past two years after a long decline. They still lag, however, behind pledges made at international conferences. The 2010 World Health Report indicates that the combined external financial assistance for health (official development assistance plus contributions from non-OECD countries and key private players) was about US\$ 21.8 billion in 2007—roughly 5.5 US\$ per capita. Despite this assistance, total health expenditures for low-income countries remained low, insufficient to ensure universal access to even a basic set of health services in many countries.<sup>82</sup> If there are no increases in domestic finance and external support, the MDGs fighting infant and child mortality, maternal mortality, or HIV/AIDS, malaria, and TB will not be achieved. This means the waste of millions of lives.

The international community has to provide resources for the use of already existing knowledge and available technologies, and for research and development

of medicines to treat neglected (leishmaniasis, filariasis, Chagas disease, Dengue fever, and schistosomiasis) and other diseases. Neglected diseases cause substantial disease burdens and preventable deaths. Comparable observations are valid for tuberculosis. The WHO estimates that one-third of the people in the world are infected with TB. Each year, 10 million people get the active disease, and nearly 2 million people die as a result.<sup>83</sup> And, there is a growing threat of multi-resistance against the available medicines. While today the cure of sick patients with existing medicines must have priority, there is an urgent need for R&D to treat poverty-related and chronic diseases that rapidly become a high burden in low-income countries.

### *Non-governmental Organizations*

Many NGOs have played a significant and positive role in international development and health issues. Their efforts to alert society of poverty in developing countries and its deadly consequences have raised the level of awareness and improved the availability of resources. Relief agencies on site usually benefit the poorest of the poor and supplement, or indeed often substitute for, the inadequate efforts of government institutions. Oxfam, Médecins sans Frontières, Save the Children, Medicines for Malaria Venture and others, have set high standards for good practices in the health sector and rightly earned great respect.

In a situation where most members of the OECD should consolidate their budgets and reduce their debt burden, it would be naïve to assume that development cooperation will be spared from government austerity programs. Many aid programs will probably be taken over by NGOs and financed by private donors. The importance of NGOs is likely to increase, and so are their members in public-private-civil society partnerships.<sup>84</sup> NGOs will have to become more selective, make better use of available knowledge, and systematically apply all accessible experiences and all available expertise—including that of the private sector. Even the best organized and most professional NGOs cannot solve the poor world's health problems alone. They can increase the impact of their work by cooperating with suitable partners—and the criteria for cooperation should be strictly objective in terms of the problem-solving contribution that a specific actor is able to bring to the table.

The atmosphere between most NGOs and the private sector has improved markedly in recent years, and their interactions are today much more at ease and much more professionally conducted than 20 years ago. As a consequence, there has been a rise in the number of successful partnerships for solving a wide array of

development problems. If partners can contribute different resources to solving a problem, outcomes are better, and, above all, quicker. Some civil society organizations and corporate managers may still be waging the ideological battles of the Cold War and cling to old negative stereotype judgments, but they are declining in number and influence.

### *Pharmaceutical Corporations*

Pharmaceutical companies are “organs of society,” and as such they have rights and obligations like all other “organs.”<sup>85</sup> However, by far not all demands placed on pharmaceutical companies by civil society constitute legitimate obligations.<sup>86</sup> Pharmaceutical corporations serve the primary function of creating value by producing meaningful and valuable medicines and services that make a difference to the patient’s well-being—and can be sold in markets at a profit. The duty to observe the prevailing laws and regulations is undisputed—so is the fact that the welfare of society is enhanced by a thriving economic sector. Corporations are specialized organs of society performing specialized functions.<sup>87</sup> They have responsibilities that are different from the binding obligations of states who signed human rights treaties.

The main responsibility of the research-based<sup>88</sup> pharmaceutical industry lies in R&D of medicines, their production and profitable sale. No other “organ of society” accomplishes this. There are problems the market can solve and ones it cannot. Generally, markets are a highly effective means for allocating scarce resources and improving efficiency. Wherever market mechanisms can be used, they ought to be used consistently and creatively—for example, to provide access to medicines for poor patients through innovative business models, such as C. K. Prahalad’s bottom-of-the-pyramid,<sup>89</sup> Michael Porter’s and Mark Kramer’s “shared value” approach,<sup>90</sup> or others. Wherever possible, preference should be given to market-based over transfer efforts by governments, NGOs, or the private sector.

However, markets are not good at ensuring the provision of public goods, such as health, education, or security, where network externalities come into play.<sup>91</sup> Where individual patients have no purchasing power, collective actors such as governments must become active. Most medicines researched, developed, and marketed by an OECD-based pharmaceutical company are likely to be out of reach for a family living in absolute poverty. The well-substantiated<sup>92</sup> health benefits achieved by successful corporate R&D, cost-effective production, and market distribution of medicines, however, are of no help to poor patients if we rely on

markets only. Therefore, a growing number of stakeholders expect a pharmaceutical company to do more.

### **Debate and Realities in Stakeholder Collaboration toward Better Health**

There is almost no more contended concept as “corporate responsibility,” or, as some name it, “corporate social responsibility (CSR).”<sup>93</sup> Some understand by the term that a manager’s responsibility is to maximize profits as long as laws and basic moral rules of society are not violated. Others maintain that a company is a corporative citizen that has to satisfy a variety of additional societal expectations.<sup>94</sup> As there are differences of values, outlooks, and interests, different actors propose different concepts and have different judgments on what is appropriate. Beyond “doing no harm” there are few fundamental “rights” or “wrongs.” Individuals who participate in the social, political, or ethical debates bring in their personal values and axiomatic assumptions—and these are diverse.<sup>95</sup> A broad-based understanding of “Corporate Responsibility” in modern societies comprises the following duties:<sup>96</sup>

- a. ***First, do no harm.*** The pivotal corporate responsibility is to act with integrity when performing all value-creating tasks in the core area of their competence. Acting with integrity comprises non-negotiable duties such as complying with national laws and regulations, respecting human rights, applying fair labor norms, protecting the environment, and working against corruption to prevent harm being inflicted on people, communities, and future generations. Striving for comparable standards in the company’s supply chain is part of good practices. “Doing no harm,” however, describes only the minimum of corporate responsibility. Enlightened corporate leaders do more. They not only avoid harm, but also to “do Good.”
- b. ***Do good, and be part of the solution.*** In modern societies, civil society organizations want companies to accept a large number of additional obligations, such as supporting social, ecological, cultural, or other projects and programs. Complying with such expectations can be in the company’s enlightened self-interest—although not necessarily and not in all cases. Additional corporate deliverables are always voluntary in nature. As available corporate financial, managerial, and other resources can at any time be invested for different purposes benefiting the long-term profitability of the company, the acceptance of responsibilities that extend the limits of

the conventional business model deserves, just like any other decision of strategic importance, careful evaluation.

Additional commitments are best taken in areas that are connected to the company's business expertise. Thus a company has a better understanding of problems and a greater motivation to act. The proximity to a company's core expertise also results in better-informed decisions and contributions of a higher quality, and is likely to result in greater sustainable success. The entirety of corporate responsibility dimensions—the “must,” “ought to,” and “can” dimensions<sup>97</sup>—are an integral part of a company's strategy and culture. All corporate responsibility activities have to be professionally managed, including the “doing good” part—that is, with clearly defined objectives and the highest possible cost-effectiveness, subject to performance monitoring and accountability as well as transparent communication.

While “doing good” is morally right, a definable “business case” makes actions more attractive to decision makers. A “return on investment” for additional responsibilities beyond the conventional business model is, however, very difficult to measure—at least in the short term. Decisions to engage in additional corporate responsibility deliverables, therefore, depend largely on normative convictions of the top management and on its awareness about societal needs. Taking a longer-term view, however, plausible arguments can be found to substantiate that the acceptance of additional responsibilities is in a company's enlightened self-interest. Companies which take a more holistic view of their role in society and communicate with diverse stakeholders are likely to better understand the changing values and expectations in society and develop an antenna for their possible impact. This results in less friction with civil society and may trigger new business models. Another benefit of transcending conventional business models is a greater attractiveness for socially sensitized employees and ethically minded investors. Yet, the possibility of being rewarded with “reputation capital” is a bit underwhelming in most Western societies.

The primary responsibility of a research-based pharmaceutical company is to be successful with integrity in its R&D, and in its production and profitable sale of medicines and vaccines. This not only increases shareholder value, it also contributes significantly to the quality and protection of life. The progress made in curing or managing the many expressions of cancer comes from the pharmaceutical industry—as does the most powerful weapon in the fight against one of the deadliest plagues of modern history in the developing world. Contrary to popular belief, it was neither government nor academia that discovered the principal



medicines necessary to treat and prevent AIDS, transforming it from an inevitably fatal illness to a chronic, manageable disease. Despite this being one of the great success stories in modern medical history, it remains largely untold.<sup>98</sup> Effective medicines also help reduce the length of hospital stays and absences from work due to illness. Corporate success is highly desirable from the perspective of social policy and social ethics; it has helped to make the world a better place:

- a. The past sixty years have shown that innovation and technology are among the main forces driving improvements in the state of health in the developing world. Developing countries, according to the Human Development Report 2010,<sup>99</sup> have increased life expectancy in as much as half a century as the now-developed countries did in 300 years. Sick people in developing countries were able to benefit from innovations that were not available in the seventeenth, eighteenth, and nineteenth centuries. Innovations in medicine and other interventions in public health (e.g., better sanitation, education, and nutrition) became quickly available in many developing countries, benefitting hundreds of millions of people.
- b. Effective prevention—vaccines for TB, diphtheria, neonatal tetanus, whooping cough, poliomyelitis, and measles—became available too. Poor countries benefitted from the rapid spread of these improvements when the costs fell dramatically. The Human Development Report 2010 cites a study showing that 85 percent of mortality reductions in sixty-eight countries since 1950 can be explained by innovations made globally.<sup>100</sup> This progress for was achievable through biomedical research over the past many years. Similar progress for future generations of patients depends on today's research efforts, including that of pharmaceutical companies.

Positive average trends like these, however, are not applicable for all countries. Nor are they relevant for all strata of society, as noted earlier. The blessings of modern medicine do not reach all patients. Places where human misery is greatest and life-threatening diseases are most pervasive often lack even rudimentary health services, including effective and affordable medicines. This has deadly consequences for about millions of people every year.<sup>101</sup>

The debate on how to improve poor and uninsured patients' access to effective and affordable medicines is part of the *political* debate around the world. Methods and techniques of political communication are routinely applied, as is agitation. The relative weighting of the significance of individual obstacles to access is subject to

a great variety of opinions and influenced by diverging interests. It is therefore also to be expected that quite different conclusions and recommendations for action will be drawn from a largely undisputed factual situation.

*Civil Society Criticism Focuses On Patents and Prices.*

Various NGO representatives, academics, and officials in the UN system voice the opinion that the pharmaceutical industry is responsible for a significant part of the public health tragedy in developing countries.<sup>102</sup> They assign pharmaceutical companies a moral responsibility for providing patients' access to life-saving and life-sustaining medicines (e.g., patient assistance programs).<sup>103</sup> They articulate criticism not only on their pricing policy, but also on their research priorities focusing on "lucrative markets," while there are poverty-related diseases. Many NGOs and civil society representatives' criticism often focuses on patents as *the* main obstacle for access.<sup>104</sup> While such a simplification might help to be heard and to collect funds, it is not helpful to solve the real problems. The answer is not of an either-or-nature and even less one about patents only. More research for neglected diseases is necessary—and so is ongoing research for diseases that are still prevalent in industrialized societies. From an ethical point of view, it is important to remember that the life of a cancer patient in a rich country has the same intrinsic value than the life of a Dengue fever patient in a poor country.

From a moral and an "emotional truth" point of view, it is obvious that no person ought to die because someone holds a patent for the medicine that could save her life. Every decent human being perceives that something is badly wrong, if a person suffers from a life-threatening disease for which there is a cure but which is out of financial reach. And yet, this is the situation for millions of people all over the world. The debate on the upsides and downsides of patents is old, and different viewpoints persist:<sup>105</sup> On the one hand, intellectual property protection incentivizes research and development. This is especially so for the pharmaceutical sector, where it is estimated that R&D outlays would be reduced by 64 percent without patents.<sup>106</sup> The costs to discover and develop a new drug, conduct clinical trials, and obtain regulatory approval, are usually in the range of about US\$ 1 billion. One of the reasons for this is the fact that less than 1 percent of the compounds examined in pre-clinical stages are cleared for testing in human beings, and only 22 percent of the compounds entering clinical trials successfully reach development stage and achieve regulatory approval.

In the absence of patent protection, generic companies—having to demonstrate bio-equivalence to the innovative branded drug only—can enter a market

in a short time and take away up to 80 percent of the sales of the innovator. On the other hand, generic competition tends to reduce prices substantially—and this again, if all local health systems and other problems were solved, can improve access to medicines and their appropriate use. This, however, does not necessarily mean that intellectual property should be abandoned to create wider access. The relevant question is not “patents or not?” but “What is a responsible use of patents?” The application of differential prices for life-saving medicines is *one* answer to that question. Other answers include patient assistance programs, such as the one Novartis has developed for its leukemia medicine Gleevec, or donation programs, such as the one Novartis has designed for the global fight against leprosy, or, in selected countries, against tuberculosis. All these approaches are compatible with the protection of intellectual property, and yet they allow for price concessions or even free access. The debate about additional innovative ways to facilitate access without jeopardizing intellectual property must go on and involve stakeholders with different valuations and varying interests.

Attempts to weaken intellectual property open a dilemma between the well-being of future and today’s patients. On the one hand, unpatented medicines and lower prices would benefit today’s poor patients. On the other hand, protection of intellectual property and higher prices are necessary to finance R&D for innovative medicines. The health and life of future patients and those suffering from diseases that cannot be managed with existing medicines (many cancers, Alzheimer’s disease, but also HIV/AIDS) depend on the success of today’s research. Cutting off incentives to invest large amounts of money into R&D of new medicines to cure diseases currently not curable or fatal would be highly unethical—and still does not improve the access of poor patients to essential medicines, let alone their appropriate use.

Access to medicines for poor patients in low-income countries would already be much better if all essential medicines—most of them being available as generics at low commodity prices—were sustainably available to the patients who need them.<sup>107</sup> Most of the medicines on the WHO Essential Medicines List can in most of the cases cure disease or sustain life. The demand on “Big Pharma” to lower prices rationally applies only to the newer medicines on the WHO Essential Medicines List—those that are still patented. But these are only about 5 percent of the medicines on the list. It is true that some may have complicated regimens, severe side-effects, or other serious disadvantages influencing patients’ compliance in comparison to newer medicines—but most of them could make a huge difference to sick patients if they were available within walking distance.

The practical application of normative notions such as “responsibility,” “duty,” or “obligation” always needs contextualization. Complex problems never have simple solutions—and there is no “one size fits all” solution at hand. Even two countries with similar objectives may need different sets of measures, depending on their starting position, pre-existing laws and regulations, perceptions among the different stakeholders and patients, and absorptive capacity.<sup>108</sup> The obstacles to be overcome in order to improve access to basic medical services and essential medicines for patients with no purchasing power are so formidable that substantial problems are to be expected even if all stakeholders mean well and constructively cooperate.

Corporate responsibility for access to medicines cannot be isolated from all other actors responsible for health. Even medicines provided for free do not necessarily reach patients who need them most. The entirety of responsibilities forms the “access to medical care chain”—and this chain is only as strong as the weakest link, such as the shortage of health workers or low morale and inappropriate behavior of staff due to misaligned incentives, and weak management practices.<sup>109</sup> Cooperation under such difficult conditions requires robust partnerships and trust in each other’s integrity. It is necessary to acknowledge the complexity and multi-causality of the problems to be solved and to break them down so that different competent members forming a team can apply their specific knowledge and bring their own experiences and resources to bear. In the remainder of the paper, we outline existing and propose new strategies to do so.

### **Existing Pharmaceutical Industry Activities**

Many pharmaceutical companies have for many years gone far beyond of what is legally required and what represents the conservative business model.<sup>110</sup> There is an array of access to medicines initiatives as part of a portfolio of good corporate citizenship today:<sup>111</sup>

- ***Differential pricing***—i.e., prices adapted by the manufacturer to the purchasing power of governments and households in low-income countries, particularly for single-source pharmaceuticals (those with patent protection or marketing exclusivity);<sup>112</sup>
- ***Patient assistance programs and donations*** for disease eradication programs or emergencies, adhering to WHO Guidelines for Drug Donations;<sup>113</sup>
- ***R&D investments*** for diseases affecting predominantly poor people in the developing world where the means of treatment are not available

today (such as for Dengue fever); where a risk of resistances to available therapies are growing (TB, but also malaria), or where available medicines have serious side effects or entail complicated and arduous treatments that make adherence to the therapy difficult;<sup>114</sup>

- Testing chemical compounds with anti-infective properties from the *corporate compound library*;
- *Support of broader health and development goals* in developing countries such as health education, training of medical staff or others;<sup>115</sup> The private sector has much more to offer than just financial resources. The experience of the Novartis Foundation for Sustainable Development over the past 30 years shows that many procedures, management methods and accountability mechanisms common to the business world have substantial supportive effects.<sup>116</sup> And for health development, pragmatic and goal-oriented partnerships can make a huge difference.
- *Cooperation with government stakeholders* in countries of operation to ensure access-to-medicines initiatives are integrated into national systems, respect health priorities and avoid “vertical” and “parallel” systems; and
- *Exploration of opportunities for production in developing countries*, e.g., through wholly owned subsidiaries or the use of voluntary licenses, where these measures would increase sustainable access to essential medicines.

Considering the dimension of the health problem in low-income countries, any contribution to their solution is welcome. Given, however, the importance of market-driven approaches and assuming a proper institutional frame, “differential pricing” could be a cornerstone for improving access to existing patented medicines<sup>117</sup> at affordable prices while protecting intellectual property and providing incentives for R&D into new medicines, this concept deserves a deeper analysis.

### *Differential Pricing*

In April 2001, a high level meeting on “Differential Pricing and the Financing of Essential Medicines,” organized by the WHO and the World Trade Organization secretariats under the auspices of the Norwegian Foreign Affairs Ministry and the Global Health Council, went on record with “a large measure of common thinking among participants” on two central points:<sup>118</sup>

First, that differential pricing could, and should, play an important role in ensuring access to existing essential medicines at affordable prices, especially in poor countries, while allowing the patent system to continue to play its role of providing incentives for research and development into new medicines.

Second, that while affordable prices are important, actually getting medicines, whether patented or generic, to the people who need them in poor countries will require a major financial effort and that for these countries most of the additional financing will have to come from the international community.

Ten years later there is still a wide agreement on these central points, as well as on the following:

***The price of medicines is a necessary condition to improve access to essential medicines.***

High prices for medicines indisputably pose an obstacle to poor patients' access to medicines all over the world. Calls to lower prices are therefore perpetual. Patent-protected medicines from OECD based companies are almost certainly too costly for the majority of patients living in low-income countries. One of the many reasons for this is that research-based pharmaceutical companies usually add the total R&D costs to the prices of the (relatively few) medicines that make it to the market. Another reason is that attractive properties of new medicines (e.g., higher efficacy, fewer side effects) are used to justify higher prices. Last but not least, the prices of medicines also contain a certain risk premium.

Markets fail because the existing supply of innovative medicines is not met with sufficient demand due to poor patients' lack of purchasing power. When newly introduced medicines are patent-protected and companies are free to set prices—within the limits of the advantages the new product has over already introduced medicines and government regulation—poor patients are priced out of the market. This is particularly so in low-income countries, where governments do not have the means (or in some cases the political will) to allocate adequate funds and where poor people do not have access to health insurance schemes. Under conditions of collective poverty and lack of health insurance, poor patients have to spend a large part of their available financial means to buy health care and medicines privately and to pay out of pocket. With personal incomes of less than US\$ 2 per day—barely enough to meet basic needs—more than 2.5 billion people<sup>119</sup> have substantial difficulties paying for medical care. The 2010 World

Health Report of the WHO reports that “about 150 million people a year face catastrophic health-care costs because of direct payments such as user fees, while 100 million are driven below the poverty line”<sup>120</sup>. Other studies confirm the high risk of impoverishment due to out-of-pocket payments for medicines.<sup>121</sup> The figures would be even higher if transport and accommodation costs as well as lost incomes due to illness were added in.

*There ought to be a “business case” for differential pricing.*

The application of a complex differential pricing scheme may absorb considerable corporate resources that could otherwise be used to increase profits. It is wise to look for a “business case”—that is, to consider the benefits that can be derived and the possible incentives to apply differential pricing. More corporate leaders would engage in access to medicines schemes—not only because it is a noble thing to do, but because it is in their enlightened interest, due to the emerging middle class with increasing purchasing power and insurance coverage in low- and middle-income countries.

The literature on differential pricing creating a business case mentions above all the possibility of expanding total sales by allowing prices that are compatible with the purchasing power of customers who otherwise could not afford to buy the goods or services available (such as airline tickets for last-minute passengers, software for students, but also negotiated prices for pharmaceuticals or offers for public tenders).<sup>122</sup> As a result, new customers are attracted, new relationships are created, and the name of the company gets known to more potential customers who might, as their income increases, remain loyal to the company or brands they came to know. This is also of importance to pharmaceutical markets in developing countries, as emerging markets there grow to an extent that “the established pharmaceutical order” is expected to change.<sup>123</sup>

Within the pharmaceutical product portfolio, the medicines that are attractive candidates for differential pricing are those where there are substantial “sunk” R&D costs, high fixed costs, and relatively low variable costs of production. A business case of applying differential prices can, however, only be created if this translates into increasing quantities of tablets, capsules, or vials sold to patients who at conventional prices would not be able to afford them. Where there is a wide availability of generic medication at low commodity prices, there is merely a necessity to discuss differential pricing of “Big Pharma.” Differential pricing should not eat into the “normal” business, but create additional overall sales by opening up new markets. If this is not the case, the overall effect on the corporate

balance sheet is negative, and companies simply do not engage. Under conditions of absolute poverty and in the absence of additional finances from national and international sources sales can drop sharply when prices are substantially reduced, while demand increases only marginally due to the fact that individual poverty or lack of medicines coverage through health insurance prevents the majority of needy patients to purchase the medicines at the reduced prices.

A last aspect of the “business case” could be the prevention of compulsory licensing: Under certain conditions, governments are allowed by the trade-related aspects of intellectual property rights (TRIPS) to produce and sell a patented product locally without the intellectual property owner’s consent. The principal requirement for the issue of a compulsory license is that all attempts to obtain one under reasonable commercial terms by the government or a local manufacturer have failed over a period of time and therefore a significant health emergency or enduring public health crisis remains unsolved.<sup>124</sup> A number of countries have so far used compulsory licenses and achieved different results.<sup>125</sup>

As compulsory licensing is a tool to circumvent patent laws, companies usually try to find a way to prevent such a measure. Differential pricing could be used as a token in negotiations with authorities as an alternative to increase access without compulsory licensing—which will not result in a significant improvement of access for poor patients if not embedded in health systems reforms. It might be politically more attractive for governments to show “strength” by imposing compulsory licensing on multinational pharmaceutical companies than to invest in sustainable improvements. But, in the end, without such improvements there will be no lasting success in poor people’s access to medicines.

***Drug prices are not a sufficient condition to determine access.***

Differential pricing and even donations can only benefit patients in an institutional setting that provides professional medical care and a functioning, efficient health care and supply system. Even donations do not automatically guarantee that they reach needy patients. Laura Frost and Michael Reich quote the example of medicines where serious access problems continued to persist despite prices coming down considerably due to generic competition.<sup>126</sup> Additional and sometimes costly attendant measures such as social marketing, product advocacy, and securing patients’ acceptance and compliance are necessary. The Novartis Foundation for Sustainable Development experienced that even the free availability of the multi-drug therapy against leprosy does not ensure that all patients have access without the Foundation’s considerable additional efforts—and the important work



brought in by the NGOs engaged in the fight against leprosy. In places where insufficiently trained or unmotivated staff is in charge of distribution, or where corruption and mismanagement are widespread, problems with drug distribution can begin as early as the medicines arriving in the country. Medicines can “get lost,” stored in the wrong place, sold to third parties, or re-exported for the personal enrichment of corrupt individuals. And those arriving in peripheral areas, but handled by inadequate staff, can be wrongly stored and wasted, or dispensed upon incorrect diagnosis or in incorrect dosages.

### **Novel Approaches to Stakeholder Collaboration for Global Health**

Given the dimension and complexity of the health issues discussed here it is obvious that no single actor on its own is capable of achieving a sustainable impact. What is needed are coalitions of enlightened partners that

- exert visionary leadership and shared commitment,
- pledge to bring in their specific skills, resources and experiences,<sup>127</sup>
- possess the ability to cooperate in a trustful manner despite partners’ pluralism of interests,
- create proper governance processes and practice good management,
- strive for efficiency and create incentives (win-win-situations),
- feel accountable to the common objectives, the local partners and the donors,
- ensure that operations are aligned with the national health systems, and
- are willing to create transparency about resources invested, successes achieved and problems encountered.

There is a great wealth of knowledge about lessons learned from Global Public Private Partnerships—new ventures must not start from scratch and run the risk of making mistakes that have been made before.<sup>128</sup>

#### *Research and Development*

Medicines for diseases largely besetting patients living in poverty rarely have a prospect of being profitable. Therefore, pharmaceutical companies usually neglect them when it comes to allocating scarce R&D resources.<sup>129</sup> Although product approvals for neglected diseases have increased,<sup>130</sup> the international consensus is that more innovative financing mechanisms and cost-sharing models

are needed. They could involve national institutions (e.g., public research institutions in countries such as China and India), multilaterally financed institutions (e.g., the World Bank), internet-based donation schemes, and private foundations (e.g., the Bill and Melinda Gates Foundation). Better targeting of new research funds is necessary too to allocate the resources as cost-effectively as possible.<sup>131</sup> A promising approach to support product development are “new coalitions” between pharmaceutical companies and other health-stakeholders such as e.g., the Global Alliance Vaccine Initiative (GAVI) or the Medicines for Malaria Venture (MMV).<sup>132</sup>

Learning from the successes of CGIAR,<sup>133</sup> a “Consultative Group on International Health Research” (CGIHR) could be created where national and international funds are used to support disease-specific research and/or development centers. Pharmaceutical companies having anti-bacterial active ingredients in their patent library could contribute to the CGIHR by making them available for screening against specific neglected or poverty-related diseases. Companies could also make patented chemical compounds exclusively available for poverty-related and tropical diseases. Whatever institutional frame, new alliances—based on a shared sense of purpose, trust and commitment—are necessary for achieving progress with neglected diseases. Research-based companies will continue to play an important role as experience shows that when the discovery of medicines for poverty and neglected diseases is part of the core mission of a company’s mainstream discovery process, using resources and talent from other internal research groups the chances for success rise significantly.

### *Differential Pricing “Plus”*

Empirical evidence shows that differential pricing—even in a low-income country with a functioning and efficient health system—needs national and international political collateral measures.<sup>134</sup> If done in isolation, it will have only limited impact for poor patients while significantly affecting pharmaceutical companies in a negative way. This again would undermine the corporate motivation to become engaged on a larger scale. The most important preconditions for the successful differential pricing strategies include the possibility of market segmentation, the prevention of diversion to markets with high purchasing power, and the political safeguarding in industrial countries. There are different models for market segmentation. Two basic possibilities are by country (for instance, according to their rank on the UNDP Human Development Index)<sup>135</sup> or to do a social segmentation of patients within a country. The social segmentation approach (i.e., through public tenders or

special contractual arrangements with institutions serving the poor) has advantages over a country-wise approach:

- There is a high-income class in every low-income country; and there is no logical justification for them having access to medicines at prices targeted at the poorest.
- In middle-income countries, there are patients living in absolute poverty and suffering from access to medical care deficits. These patients ought to have access to affordable life-saving medicines. Where it is possible to effectively segment the patient population according to their purchasing power and serve them with adapted prices, it becomes necessary to prevent leakage of these products into the higher-income strata in developing countries, or even their re-export into the markets of OECD countries. National health authorities in low- and middle-income countries can play a critical role in creating access to medical care and to essential medicines. Assisted by international funds, they can bid for a special contract for essential medicines, allow different trademarks, packaging and labeling of the lower-priced medicines. This would significantly help to prevent diversion or the re-export of the differentially priced medicines.<sup>136</sup> If leakage cannot be prevented, companies will be reluctant to apply differential pricing in order to avoid a substantial negative impact on their business in the high-income markets.

The governments of industrial countries are asked as well to support differential pricing systems for poor patients in the developing world. They can do this by preventing parallel imports of medicines marketed elsewhere at differential prices and by refraining to use lower-priced medicines for the poor as benchmark for price regulation in industrial countries (“external reference pricing”).<sup>137</sup> The success of differential pricing to facilitate the access of poor patients in low-income countries depends on the political acceptance in industrialized countries that such lower prices are restricted to serve the poor population. There has to be a shared understanding that special circumstances (such as helping poor patients get access to life-saving medicines) also require special approaches (such as preferential prices) and that companies performing such solidarity services should not be punished in other markets for doing so. Likewise, governments should support “social marketing” for the acceptance of price differentials between low-income and high-income countries.

*“Granting of Reputation Capital”*

Public appreciation in the form of “reputation capital” awarded to those companies who invest intellectual and financial resources into new business models and innovative philanthropy strategies to serve poor patients is likely to make a difference when it comes to the willingness of the top management of pharmaceutical companies to become engaged. While mainstream NGOs and most media have little willingness to give credit to such companies, socially responsible investment initiatives such as the Access to Medicine Index (ATM) have started to differentiate the rating of pharmaceutical companies according to their practices regarding access to medicines.<sup>138</sup> The involvement of responsible investors, the increasing trend toward benchmarking, and greater transparency are positive developments for access to medicines efforts.<sup>139</sup> Differential pricing is viewed by such institutions as one of many ways to fulfill a company’s societal obligations.

Corporate managers who get their companies involved in solutions for improving access to medicines of the world’s poor in many cases do so because their values and social awareness call for it. They will not be conditioned by the absence of public appreciation from NGOs, media, or politics. But those enlightened personalities remain a minority. Mainstream management will continue to allocate resources strictly according to return on conventional financial investment criteria. From that perspective, there are few incentives to do more than what the law, the market, and basic decency demand. Assuming that the “value set” of mainstream managers is not something that can be changed near-term, the prospects for more companies becoming engaged are not bright.

The picture could change if there were more positive feedback from society for those managers and companies that are doing “the right thing” from the point of view of a poor patient’s health. If, in a first phase, those civil society organizations who publicly are the most visible and audible advocates for better access to medicines would differentiate their judgments on deserving corporations, the media would probably follow and make such corporate deeds an issue for public debate. If the many committed people in, for instance, NGOs, churches, and the political world who are advocating for better health with moral fervor and huge energy were to give credit to the corporate leaders who engage in the fight against misery, positive motivational effects are likely. Human nature responds to recognition and acknowledgement—managers, being humans, are likely to respond to positive public acknowledgement.<sup>140</sup> Senior managers always have a certain decision free-space and can exercise discretion—positive feedback from society

is likely to motivate them to support social purposes and makes this compatible with enlightened managerial egoism.<sup>141</sup> Within management circles, peer pressure will develop and thus create even more dynamism.<sup>142</sup> As reputation ranks high on the corporate agenda, public appreciation is likely to motivate even dry business managers to get involved.<sup>143</sup>

### *Global Financing*

The pooling of resources through prepaid funds, community health insurance, or micro-insurance schemes, but also through conditional cash transfers, would greatly help lessen the pressure on individuals' pocketbooks. New financial mechanisms must be developed and scaled up to avoid financial catastrophes for sick individuals. Also, the call for additional financing provided by the international community remains as valid and urgent as ever. Even if all pharmaceutical companies used differential pricing for their products, expanding access to essential medicines will only be substantial if sustainable and adequate domestic and international financing is ensured.

The public indebtedness following the financial crisis and the pressure to consolidate budgets in most OECD countries might be a game changer for foreign aid. Instead of a few donors paying large amounts, the future lies in innovative funding through a large number of individual donors paying small amounts for specific purposes, thus adding up to large amounts. A few examples of this have already been successfully tested. In the 2008 U.S. presidential campaign, two candidates successfully financed their campaigns through a system that allowed many donors to support them with small amounts of money via Websites. Likewise, a number of NGOs already collect significant amounts of money by enabling clients of different businesses to contribute small amounts to support charitable causes. The money, usually one US\$ or two, can be added to hotel bills and paid via credit cards. Other possible sources of funds include a levy on currency transactions, a financial transaction tax (Tobin tax), and voluntary contributions via mobile phone bills, Internet fees, lottery tickets, air tickets, and tobacco as well as alcohol taxes.<sup>144</sup> Once a critical minimum of funding is available, segmenting markets by adapting the prices of medicines to the purchasing power of poor patients can make a real difference for poor patients' access to medicines.

### **A Final Thought**

The search for better ways and means to improve access to medicines is not the search for a nostrum—there is no “silver bullet solution” that fits all circumstances.

As Amartya Sen advises us in the preface of *The Idea of Justice*, the goal is not to create a perfect world. Instead we should apply all our strength and resources today to eliminating the most glaring injustices and most obvious social wrongs.<sup>145</sup> If all responsible stakeholders are committed to this goal and—under changing conditions and in different contexts—consistently willing to look for optimal solutions, the collective learning curve can be shortened and leaps accomplished for the benefit of poor patients in low-income countries and beyond.

## Endnotes

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1. Chan and Lansley 2011.
2. United Nations 2004, 2005; UN Secretary-General Ban Ki-moon 2010.
3. [http://www.who.int/topics/millennium\\_development\\_goals/medicines/en/index.html](http://www.who.int/topics/millennium_development_goals/medicines/en/index.html).
4. Russel 2005; Xu Ke et al. 2007; Niëns et al. 2010.
5. Leisinger 1985.
6. UNDP 2010; WHO May 2010c; United Nations 2011.
7. World Bank 2010, 217.
8. Kaiser Family Foundation, Pew Global Attitudes Project 2007, 15–16.
9. World Bank 2010, chap. 1.
10. World Bank 2008, 10; Chen and Ravallion 2007, 9ff.
11. Commission on Social Determinants of Health, World Health Organization 2008; Blas et al. 2011, p. 200, supports this view.
12. WHO 2010a, iii.
13. WHO 2010a, 14.
14. Commission on Social Determinants of Health, World Health Organization 2008; Blas et al. 2011.
15. See WHO 2010d.
16. Kaiser Family Foundation, Pew Global Attitudes Project 2008, 2. Countries hardest hit by HIV, such as those in sub-Saharan Africa, consider this to be the top problem.
17. <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html>; see also WHO 2004a.
18. UNDP 2010, 50.
19. WHO 2010b, 79.
20. See [www.who.int/healthinfo/global\\_burden\\_disease/en/index.html](http://www.who.int/healthinfo/global_burden_disease/en/index.html).

21. Commission on Social Determinants of Health/World Health Organization (2008); Blas et al. 2011.
22. Kaufmann, Kraay, and Mastruzzi 2009. The comparison of the “bad governance” country list with that of the UNDP Human Development Report Country Index is revealing.
23. Riedel 2009, 24ff.
24. Commission on Information and Accountability for Women’s and Children’s Health 2011.
25. See the results of the Commission on Macroeconomics and Health, Sachs et al. 2001.
26. Ibid., 3.
27. Friberg et al. 2010. See also *The Lancet* series on child survival, vols. 361 and 362; as well as *The Lancet* separate print on Newborn Health, vol. 364.
28. UNDP 2010, 51.
29. The anti-malarial medicine Coartem (artemether and lumefantrine) provided by Novartis without profit for public-sector use in collaboration with international organizations in malaria-endemic developing countries. The medicine is well-tolerated and highly effective, providing cure rates of over 95 percent even in areas of multi-drug resistance.
30. For more on this subject, see [www.who.int/medicines/publications/essential\\_medicines/en/](http://www.who.int/medicines/publications/essential_medicines/en/).
31. Commission on Macroeconomics and Health, Sachs et al. 2001, 10.
32. Editorial, “Building Trust and Value in Health systems in Low- and Middle-income Countries.” *Social Science and Medicine* 61 (2005): 1381–1842.
33. WHO 2010b, 11.
34. WHO 2007, 1.
35. World Bank 2010, 55.
36. Ibid.
37. *Medicus Mundi Schweiz* 2011; Cameron et al. 2009; Cameron et al. 2009.
38. [http://www.who.int/hpr/NPH/docs/declaration\\_almaata.pdf](http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf).
39. United Nations 2010.
40. “Disability adjusted life year” is used to measure the burden of disease of a community in terms of “time lived with a disability and the time lost due to premature mortality.” For detailed technical explanation, see Murray 1994, 429–445. For criticism of this measurement, see Anand and Hanson 2006, 183–199.
41. [http://www.adb.org/media/articles/2005/7033\\_international\\_community\\_aid/paris\\_declaration.pdf](http://www.adb.org/media/articles/2005/7033_international_community_aid/paris_declaration.pdf).
42. <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html>; see also WHO 2004a.
43. Anand and Hanson 2006, 81.
44. Department for International Development 2006.

45. Seiter 2010 11, 38.
46. WHO 2010b 10ff.
47. Frost and Reich 2008, 8.
48. Ibid.
49. UN Secretary-General Ban Ki-moon (Draft for Consultation, June 1st, 2010, 13–15).
50. WHO 2007.
51. World Bank 2007, 18.
52. Clapham and Robinson 2009. See the Declaration at <http://www.un.org/en/documents/udhr/index.shtml>.
53. <http://www.un.org/en/documents/udhr/index.shtml>.
54. Ibid.
55. Ibid.
56. Ibid.
57. See, e.g., the September 2006 report of the former Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Paul Hunt, “The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health,” 13 ([http://www.ifhro.org/images/stories/ifhro/documents\\_UN\\_special\\_rapporteur/3\\_4\\_10.pdf](http://www.ifhro.org/images/stories/ifhro/documents_UN_special_rapporteur/3_4_10.pdf)).
58. WHO 2006.
59. Riedel 2009, 8ff.
60. UNDP 2010, 59ff.
61. Clapham and Robinson 2009, 18–19.
62. WHO 2007, 3.
63. What is possible with today’s knowledge at a low price is astonishing, see e.g., the work to reduce maternal mortality in *The Lancet* (October 13, 2007): 1283–1392.
64. Working Group on Access to Essential Medicines, Leach, Paluzzi, and Munderi 2005, 29ff.
65. For revealing examples see Kanchanachitra et al. 2011.
66. Cameron et al. 2009.
67. See Bates 2006.
68. American Enterprise Institute for Public Policy Research 2006.
69. Reuters Health E-Line 2011.
70. Olcay and Laing 2005, 10; WHO and HAI Global 2011; WHO, HAI Global, and Creese 2011.
71. Olcay and Laing 2005, 35–36.
72. UNDP 2010, 201.
73. For country examples, see Joint Learning Network for Universal Health Coverage, <http://www.jointlearningnetwork.org/>.



74. Commission on Macroeconomics and Health, Sachs, et al. 2001, 11–12 (in 2001 US\$ and prices).
75. WHO 2010b, 21.
76. <http://www.sipri.org/media/pressreleases/2010/100602yearbooklaunch>.
77. [www.admin.ch/ch/d/sr/i1/0.120.de.pdf](http://www.admin.ch/ch/d/sr/i1/0.120.de.pdf).
78. [www.gopetition.com/petitions/reduce-or-eliminate-harmful-agricultural-subsidies.html](http://www.gopetition.com/petitions/reduce-or-eliminate-harmful-agricultural-subsidies.html) and [www.independent.co.uk/news/world/politics/eu-subsidies-deny-africas-farmers-of-their-livelihood-478419.html](http://www.independent.co.uk/news/world/politics/eu-subsidies-deny-africas-farmers-of-their-livelihood-478419.html).
79. Sachs 2008, 227ff.
80. Nunnenkamp and Öhler 2011.
81. OECD 2011.
82. WHO 2010b, 31.
83. [www.who.int/tb/publications/2010/factsheet\\_tb\\_2010.pdf](http://www.who.int/tb/publications/2010/factsheet_tb_2010.pdf).
84. World Bank 1998.
85. As stipulated by the “Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines” drafted by the former Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standards of physical and mental health,” Hunt 2008, [http://www.essex.ac.uk/human\\_rights\\_centre/research/rth/docs/GA2008.pdf](http://www.essex.ac.uk/human_rights_centre/research/rth/docs/GA2008.pdf).
86. See Hunt and Khosla 2010; Gruskin and Raad 2010; Leisinger 2005.
87. See the draft of John Ruggie’s “Guiding Principles for the Implementation of the United Nations ‘Protect, Respect and Remedy’ Framework” ([www.reports-and-materials.org/Ruggie-UN-draft-Guiding-Principles-22-Nov-2010.pdf](http://www.reports-and-materials.org/Ruggie-UN-draft-Guiding-Principles-22-Nov-2010.pdf)), especially p. 6 (Guiding Principles).
88. Generics manufacturers must be seen differently as they do not conduct research and development for innovative medicines or vaccines.
89. Prahalad (2004). An excellent example of an innovative business model designed to address the neglected health needs of poor people in rural areas is “Arogya Parivar” (health family), launched in India by Sandoz and Novartis Over-the-Counter division in 2006. It combines healthcare education with access to affordable medicines through local pharmacies. The pilot phase started in Uttar Pradesh and Maharashtra focusing on products against tuberculosis, other respiratory infections, coughs, colds, allergies, skin and genital infections, malnutrition in mothers and children, diabetes, intestinal worms and digestive problems. Products are easy-to-use and packages are reduced in size so that weekly individual treatment costs are kept below USD 1.25. Because transport and communication in rural India are often difficult, a decentralized model was adopted, organizing the 500 health advisors and supervisors in autonomous ‘cells.’ By the end of 2010, Arogya Parivar partnered with 50,000 rural clinics and pharmacies in 28,000 villages across 11 states, representing a population of around 42

million people. The program will be piloted in at least two other countries including Vietnam and Kenya.

90. Porter and Kramer 2011, 63–77.

91. UNDP 2010, 5.

92. Lichtenberg and Brown 2001.

93. I prefer the term “corporate responsibility” to denominate all corporate responsibilities towards society, comprehending economical, social, ecological and political issues and deliverables of legal and voluntary nature. Corporate Social Responsibility (CSR) is often understood to comprise mainly deliverables transcending those being part of the normal business activities and the meaning of “social” tends to be biased towards “socially deprived” or “socially disadvantaged.”

94. From the myriad publications on this, two may be considered to constitute two political extremes. The first is Milton Friedman’s essay in the *New York Times Magazine* of September 13, 1970, where he says the focus of business action must be on striving to turn a profit within the scope of local laws. The second is Peter Ulrich 2008.

95. Leisinger 2009, 3ff.

96. For insights on the derivation and deepening of this understanding of corporate responsibility, refer to the following works: Leisinger 2004; Wieland 2009, vol. 7; Küng, Leisinger, and Wieland 2010. On the problems presented here, see Leisinger 2009, 3ff.

97. For an explanation of this differentiation in the context of corporate responsibilities of pharmaceutical companies, see Leisinger 2011, 104ff.

98. Bloom 2011.

99. UNDP 2007.

100. UNDP 2010, 50.

101. *Ibid.*

102. Médecins sans Frontières and Oxfam 2010; Oxfam, VSO, and Save the Children 2002; Vachani and Smith November 2001, 2004. Prod. #: CMR300-PDF-ENG.

103. Hemphill 2010, 225–242.

104. ‘t Hoen 2009; <http://www.plosmedicine.org/search/simpleSearch.action?startPage=0&volume=&eLocationId=&id=&filterArticleType=&filterKeyword=&filterJournals=PLoSMedicine&query=Drug+companies+should+be+held+more+accountable>; Oxfam 2011): <http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-summ-en.pdf>.

105. For a comprehensive discussion of the issue, see Hassan, Yaqub, and Diepeveen 2010.

106. *Ibid.*, 26.

107. WHO 2004a; also 2004b.

108. Seiter 2010.
109. Bryan et al. 2010.
110. See [ifpma.org/healthpartnerships](http://ifpma.org/healthpartnerships); see also Ritter 2010.
111. On this same subject, refer to the Department for International Development 2005.
112. See also Yadav 2010.
113. See the WHO Guidelines for Donations, [http://whqlibdoc.who.int/hq/1999/who\\_edm\\_par\\_99.4.pdf](http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf); as a specific example see the donation of the Multi-Drug-Therapy for Leprosy by Novartis at [www.novartisfoundation.org/page/content/index.asp?Menu=3&MenuID=324&ID=741&Item=73.1.2&ConID=2001&nYear=](http://www.novartisfoundation.org/page/content/index.asp?Menu=3&MenuID=324&ID=741&Item=73.1.2&ConID=2001&nYear=).
114. For more on this subject, refer to [www.novartis.com/research/nitd/index.shtml](http://www.novartis.com/research/nitd/index.shtml).
115. See [www.novartisfoundation.org/page/content/index.asp?MenuID=594&ID=1797&Menu=3&Item=44.17](http://www.novartisfoundation.org/page/content/index.asp?MenuID=594&ID=1797&Menu=3&Item=44.17).
116. [www.novartisfoundation.org](http://www.novartisfoundation.org).
117. The focus on “essential” versus “all” medicines is important when discussing access to medicines for poor patients. WHO has defined essential medicines to be those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy, safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. See [http://www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html). Effective treatment with essential medicines is available for most leading infectious diseases as well as for the most important non-communicable diseases.
118. WHO and WTO 2001, 2; background papers available from WHO ([www.who.int/medicines/docs/par/equitable\\_pricing.doc](http://www.who.int/medicines/docs/par/equitable_pricing.doc)) and WTO ([www.wto.org/english/tratop\\_e/trips\\_e/wto\\_background\\_e.doc](http://www.wto.org/english/tratop_e/trips_e/wto_background_e.doc)).
119. According to the World Bank’s supplement to World Development Indicators 2008: Poverty Data, p. 10.
120. WHO 2007, 972–983.
121. Niëns et al. 2010. [www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333](http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000333).
122. See the comprehensive analysis of Yadav 2010.
123. IMS Health: 2010.
124. For some HIV/AIDS-related experiences, see Steinbrook 2007, 1996ff.
125. Bird 2009.
126. Frost and Reich 2008, 40ff and 24–25.

127. For some unorthodox examples of cooperation between consumer goods companies and essential medicines actors, see Hayford et al. 2011.

128. Buse and Tanaka 2011.

129. Troullier et al. 2002, 2188ff.

130. Cohen, Dibner, Staroselsky, and Wilson 2010.

131. Ibid.

132. <http://www.mmv.org/partnering/pdp-model>. A concrete example is the development of a dispersible pediatric form of anti-malarials <http://www.mmv.org/achievements-challenges/achievements/coartem-d>.

133. Consultative Group on International Agricultural Research, [www.cgiar.org](http://www.cgiar.org)

134. Yadav 2010; and Reich 2008; WHO and WTO 2001.

135. UNDP Human Development Index, latest rankings 2010): <http://hdr.undp.org/en/statistics/>

136. During the time I served as CEO for the pharmaceutical division of a predecessor company of Novartis in East Africa, some of the products awarded by public tenders were stamped “GK” (Government of Kenya) or manufactured with a color different from the same product sold in the private market. As a consequence, it was very difficult to divert the medicines from their use in public health centers.

137. For details see WHO and HAI Global 2011.

138. The ATM Index rates, among others, the commitment to and performance of “General Access to Medicines Management,” “equitable pricing,” and “donations and philanthropic activities.” See <http://www.accessmedicineindex.org/publication/access-medicine-index-2010-full-report>.

139. Lee and Kohler 2010, 641–658.

141. This argument is not meant to insinuate that people act morally only if there are strong incentives to do so. The argument is based on Amitai Etzioni’s approach that people’s behavior is influenced by two factors: by what they perceive to be their moral obligation and by what they perceive to be in their interest. Etzioni acknowledges significant differences with regard to the extent to which each of these factors work with different personalities. See Etzioni 1988.

141. Brennan and Baines 2006, 29–43.

142. Kolk and Van Tulder 2006, 789–801.

143. Leisinger 2007: 315–342.

144. WHO 2010b, 29.

145. Sen 2009, vii.

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