

Corporate Responsibilities for Access to Medicines

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Make everything as simple as possible – but not simpler.

Albert Einstein

Executive Summary

There is today a growing wave of demands being placed upon the pharmaceutical industry to contribute to improved access to medicines for poor patients in the developing countries.¹ This paper aims to contribute to the development of a systematic approach and broad consensus about shared benchmarks for good corporate practices in this area. A consensus corridor on what constitutes an appropriate portfolio of corporate responsibilities for access to medicines – especially under conditions of ‘failing states’ and ‘market failure’² – is not only in the interest of the world’s poor, but also of corporations that want to contribute to the solution of one of the most significant social problems of our time.

1. Introduction

1.1. Background and Purpose

World population has more than doubled from 3 billion in 1960 to about 6.7 billion today.³ The number of people living in Africa quadrupled in the same period to about 944 million, while Asia’s population grew to over 4 billion people. And, significantly, population growth was highest where poverty was most pronounced. Yet in spite of this, substantial progress has been achieved in human development, measured in higher per capita incomes, improved life expectancy at birth, lower infant and child mortality, higher literacy rates, and increased school enrolment.⁴

Progress has been striking but it has not ‘lifted all boats’ – that is, not all people in all countries have benefited alike. Today, about 20 percent of people in the developing regions – over a billion human beings – still subsist in absolute poverty.⁵ A further 1.5 billion are estimated to live on US\$ 2 or less a day. This brings the number of those struggling to meet their basic needs to about 2.5 billion.⁶ These women, men, and children also suffer from a lack

1 See e.g. Oxfam: *Investing for Life. Meeting Poor People’s Needs for Access to Medicines through Responsible Business Practices*. Oxfam Briefing Paper No.109, London, November 27, 2007; or Médecins Sans Frontières at www.msf.org/search/index.cfm?searchCriteria=access+to+medicine.

2 ‘Failing states’ are defined here as states characterized by deficits in the quality of governance and the concurrent lack of political will, authority, or capacity to deliver public goods; ‘market failure’ is defined as situations where markets fail to efficiently provide or allocate goods and services, for instance where those who need them cannot acquire them due to lack of purchasing power and, hence, market demand. Market failure occurs also in the context of public goods.

3 For more details see Population Reference Bureau: *2007 World Population Data Sheet*, at www.prb.org/Publications/Datasheets/2007/2007WorldPopulationDataSheet.aspx.

4 For country details see <http://hdr.undp.org/en/statistics/>; to track progress on achieving the Millennium Development Goals, see <http://www.un.org/millenniumgoals/pdf/mdg2007.pdf>.

5 Commonly defined as a severe deprivation of basic human needs depending not only on income (of \$1 or less per day, purchasing power parity adjusted) but also access to food, safe water, and sanitation facilities and to health and education services, roughly calculated on the base of the percentage given by the Millennium Development Goals Report 2007 (19.2 percent on p. 6) and the 2007 World Population Data Sheet (less developed regions: 5.404 billion people in mid-2007).

6 See Chen S. and M. Ravallion: “Absolute Poverty Measures for the Developing World 1981–2004.” In: *Proceedings of the National Academy of Science*, Vol. 104 (2007) No. 43, pp. 16757 ff. (Online available at

of democratic means to make their ‘voice’ heard, along with the many other deprivations and constraints that result from unfavorable social arrangements and lack of good governance.⁷ Almost by definition, this ‘system of poverty’ also prevents patients from accessing the medical care and medicines they need.⁸

There is today a growing wave of demands being placed upon the pharmaceutical industry to contribute to improved access to medicines for poor patients in the developing countries.⁹ This paper aims to contribute to the development of a systematic approach and broad consensus about shared benchmarks for good corporate practices in this area. A consensus corridor on what constitutes an appropriate portfolio of corporate responsibilities for access to medicines – especially under conditions of ‘failing states’ and ‘market failure’ – is not only in the interest of the world’s poor, but also of corporations that want to contribute to the solution to one of the most significant social issues of our time.

1.2. Value Premises and Axiomatic Assumptions

Human beings tend to perceive the world around them through a filter made up of personal preferences, judgments, worldviews and ‘lessons learned’ from past experience. Together, these determine the way we construct ‘reality’. This is not an objective representation of external facts and issues, but the subjective result of the assimilation, accommodation and adaptation processes we go through in life.¹⁰ Once we are convinced we have defined a problem accurately and found the “appropriate” solution we tend to focus on this at the expense of other approaches that might be more effective. Once we have made up our mind on a certain subject consistent with our worldview, that mindset is applied to all other issues as well.¹¹

Complex issues deserve more than self-referential simplification, however, and in this regard it is useful to recall Heinz von Foerster’s elevation of the pluralism of perspectives to the status of an “ethical imperative”.¹² This essay is not attempting to present *the one and only* correct solution to the exceedingly complex problem of access to medicines. As Alexander Riegler rightly emphasizes, “unambiguous solutions work for simple systems and simple problems only.” Systems of “organized complexity”, however, “evade our attempts to generate simple and clear-cut answers. These systems call for interdisciplinary approaches, for open inquiries that enable investigators to escape the confinements of a specific discipline and to become aware of aspects that are necessary to *satisfyingly* solve the problem.”¹³

What does this have to do with corporate responsibility for access to medicines? Much of the controversy around this subject can only be explained with the help of constructivist

www.pnas.org/cgi/reprint/0702930104v1.pdf). The authors also explain the methodological background to such calculations.

7 See Sen A.: *Development as Freedom*. Oxford University Press, Oxford 1999.

8 UK Department for International Development: *Fact sheet: Access to Medicines*. London, January 2006.

9 See e.g. Oxfam: *Investing for Life. Meeting Poor People’s Needs for Access to Medicines through Responsible Business Practices*. Oxfam Briefing Paper No.109, London, November 27, 2007; or Médecins Sans Frontières at www.msf.org/search/index.cfm?searchCriteria=access+to+medicine.

10 This, in a nutshell, is the crux of the plurality of constructivist philosophies and sciences. For a survey see Riegler A.: “Editorial. The Constructivist Challenge.” In: *Constructivist Foundation*, Vol. 1, No. 1, Brussels 2005, pp. 1-8; for details see Watzlawick P. (Ed.): *The Invented Reality: How do we know what we believe we know?* W.W. Norton, New York 1984; von Glasersfeld E.: *Radical Constructivism. A Way of Knowing and Learning*. Falmer Press, London 1995; Maturana H. and F. Vaerla: *Autopoiesis and Cognition*. Reidel, Boston 1979; von Foerster H.: *Understanding understanding*. Springer, New York 2003.

11 Riegler A.: “Editorial. The Constructivist Challenge.” In: *Constructivist Foundation*, Vol. 1, No. 1, Brussels 2005, pp. 1-8.

12 “Act always so as to increase the number of choices”. In: von Foerster H.: *Understanding understanding*. Springer. New York 2003, p. 227.

13 Riegler A.: “Editorial. The Constructivist Challenge.” In: *Constructivist Foundation*, Vol. 1, No. 1, Brussels 2005, p. 1.

philosophy: on the one hand, there is (almost) general agreement that good health – in the sense of escapable illness, avoidable afflictions and premature mortality¹⁴ – is among the most important quality of life elements. Indeed, the highest attainable standard of physical and mental health is a right for all human beings, wherever they may live. On the other hand, there is pluralism of opinion with regard to what exactly ought to be done and by whom to safeguard or restore poor people's health. Some of the divergence is grounded in different analyses of the underlying problems, or it may arise from the diverse personal values and axiomatic assumptions of different health stakeholders in modern societies. Last, but not least, differences can be traced back to conflicting, but legitimate, interests that arise in a society based on the division of labor.

While any social science must be driven by the search for truth and be as free as possible from the pressures exerted by various constituencies, it is practically impossible to rule out the influence of personal values and the vested interests of the researcher. Unlike natural science studies, where a result is determined to be 'right' or 'wrong' by mathematical deduction or experimental verification, conclusions derived from social science and political analysis depend to a large extent on *personal values* (concerning justice, equity or property rights, for instance), *worldviews* (for example, about the 'right' thing to do), and *axiomatic assumptions* (e.g. on the legitimacy of market mechanisms in healthcare versus a 'rights-based' approach). Such judgments are not only a theoretical matter – they influence an individual's viewpoint about whose interests should be pursued with what priority.

Paul Streeten once pointed out that no-one can be objective, pragmatic and idealistic all the same time.¹⁵ 'Disinterested' social and political science do not exist: a view presupposes a viewpoint.¹⁶ The valuations and axiomatic assumptions underlying a specific perspective predetermine what the analyst looks for and sees, how they define the problem and therefore, implicitly, what change or solution they come up with. The saying that 'things look different, depending upon where you stand' is simple but true: If 'globalization', 'capitalism', or 'multinational pharmaceutical companies' are seen as the root cause of lack of access to medicines for the poor, solutions will automatically focus on these perceived "culprits". You come to a different conclusion if you consider lack of good governance and hence misdirected governmental resources and poor health infrastructure as the basic problem of access to health.

Consequently, when it comes to determining a pharmaceutical company's responsibility with regard to improvements in access to medicines for the poor, there are huge differences of opinion. While Oxfam, for example, criticizes today's pharmaceutical business model for ensuring "maximum margins" by charging what the market can bear and by "defending patents unreservedly,"¹⁷ the financial analysts who assess pharmaceutical companies expect nothing less.¹⁸ The old "shareholder value" versus "stakeholder interest" Manichaeism is another bone of contention. Whereas, for example, Oxfam argues that the current patent laws are overly generous to patent owners,¹⁹ managers of pharmaceutical companies argue the opposite, pointing to the ever rising safety related requirements leading to a much longer time

14 See Sen A.: "Why Health Equity?" In: Anand S., F. Peter and A. Sen (Eds.): *Public Health, Ethics and Equity*. Oxford University Press, Oxford 2006, p. 23.

15 Streeten P.: "Vorwort." In: Myrdal G.: *Das Wertproblem in der Sozialwissenschaft*. 2nd edition, Neue Gesellschaft, Bonn 1975, p. 13.

16 This is especially so in the discourse on ways and means to achieve sustainable human development; Gunnar Myrdal showed this convincingly many years ago, see Myrdal, G.: *Asian Drama. An Inquiry into the Poverty of Nations*. Pelican, Harmondsworth 1968, Vol. I, p. 32 ff., see also pp. 1843 f.

17 Oxfam: *Investing for Life. Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices*. Oxfam Briefing Paper No. 109, London, November 27, 2007, p. 24.

18 See, e.g. Beynon K. and A. Porter: *Valuing Pharmaceutical Companies: A Guide to the Assessment and Evaluation of Assets, Performance and Prospects*. Woodhead, Cambridge 2000.

19 Oxfam: *Investing for Life. Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices*. Oxfam Briefing Paper No. 109, London, November 27, 2007.

before a patent gets granted, so that once the product is on the market already about half the patent life has already elapsed.

If we want a meaningful debate and a serious attempt at a consensus, then hardliner positions must be given up in all “camps”. When it comes to the protection of intellectual property, for example, neither the financial community nor the requests of nongovernmental agencies can be a yardstick for a reasonable contribution to solving the access problem for the poor. Determining what is in the public interest (as opposed to what is assumed to be) will vary significantly, depending on whether the *short-term* (availability of patented products as less expensive generics today) is given precedence over the *long-term* interest (research funds available to find innovative drugs to cure hitherto incurable diseases).

Differences in judgment due to divergent value premises certainly add fervor to a debate but this is a hallmark of pluralistic societies and should not be confused with differences in morality of the actors involved. As no single actor can solve by unilateral action problems of the magnitude of those discussed here, national, as well as international political institutions, NGOs and churches, business corporations and others must find a way to agree on a common ‘corridor of legitimate action’. The common good is best served when all actors in all social subsystems do their best in the area of their particular responsibility, without losing sight of the ties that bind them.²⁰

In my search for solutions that enjoy a broad societal support, I am not so naïve as to assume that my own points of view are unclouded by my construction of reality, my values and professional culture.²¹ I therefore make the *value premises* and *axiomatic assumptions* behind this essay on ‘corporate responsibilities for access to medicines’ explicit.

My value premises.

Firstly, I work on the assumption that the *business of business* is *business* and “*to use its resources and engage in activities designed to increase its profits*”.²² Profits, however, are not of intrinsic value; they are instrumental for the welfare of wider society. Their legitimacy stems from a community’s understanding of the rights and obligations that make up the fabric of the social contract. In mature societies, the “*rules of the game*” that Milton Friedman referred to 45 years ago have evolved with growing economic welfare. Today, most citizens of modern societies (who make up the employees, customers and shareholders of companies) continue to expect good financial business results – but *not* in isolation from good social and environmental performance, however this may be defined.

Based on the conviction that corporate citizens have moral obligations beyond the ‘must’-dimension of corporate responsibilities (see point 4.1. later in this paper), I perceive it to be in the enlightened self-interest of a pharmaceutical company to be part of the solution to the access-to-medicines problem, by committing to a human-rights-aware, innovative, and creative portfolio of assistance to the poorest 2.5 billion people in the world. I consider this first of all to be the ‘right’ thing to do. To contribute to the solution of a problem that claims millions of lives every year will (probably)²³ also contribute to a corporation’s social acceptance and hence to its long-term license to operate.

20 Donaldson T. and T.E. Dunfee: *Ties that Bind: A Social Contracts Approach to Business Ethics*. Harvard Business School Press, Boston 1999.

21 I work for human development through a corporate foundation financed by the pharmaceutical company Novartis, for details see www.novartisfoundation.org.

22 This is the much contested dictum of Milton Friedman in his 1962 book *Capitalism and Freedom* (Fortieth Anniversary Edition, The University of Chicago Press, Chicago 2002, p. 133.)

23 As the costs are generally easily measurable while the benefits remain vague, the validity and legitimacy of a ‘business case’ argument in the context of the corporate responsibility debate requires the development of relevant and verifiable indicators. See Leisinger K.M.: *The Business Case for Corporate Responsibility* (forthcoming).

Secondly, while there is no excuse for any corporate actor to violate human rights (in the present context of the ‘right to health’), the *primary duty bearers* cannot be discharged from their responsibilities. Synergies are needed – not a redistribution of responsibility. States and their authorities are the primary duty-bearers to implement policies that lead to the respect, protection and fulfillment of Human Rights. In accordance with Articles 55 and 56 of the Charter of the United Nations, “State’s resources” are meant to comprehend resources of *all* states, i.e. including the international community. International assistance and cooperation for health development must therefore be part of the necessary effort to realize the right to health – including improvement of the poor’s access to essential medicines. Where the states are not living up to their responsibilities the private sector should not be expected to step into the breach.

Since higher standards of living and education are pre-conditions of a better nutritional, sanitary and health status of society, an overall development path that results in broad-based improvement in living standards, especially for the lower social strata, is indispensable. Such human development is likely to lead to changed social attitudes, more responsible institutions and thus better governance. Such positive developments will also result in more productive, more peaceful and hence more sustainable societies, attracting more investments and thus more income. As economic growth is a necessary, but not sufficient, precondition for sustainable human development, those in power must ensure that policy reforms, good governance and institution-building efforts dissolve the systemic deficits and political inadequacies that are so often at the root of health problems. This would further strengthen the ability of domestic constituencies to hold their governments accountable.

As good health – in addition to its intrinsic value – is of high instrumental value, enabling human beings to increase their ‘human capital’ and hence their income opportunities, *direct* efforts to improve the state of health, especially of the lower social strata, must be given a much higher priority. Deprivations and structural inequities in access to basic healthcare perpetuate inequality of opportunities. To counter this, the allocation pattern of public health resources must be biased in favor of the poorest: Not only should those who need it most have first priority for reasons of fairness, also the cost-effectiveness of health interventions demands a focus on those who bear the highest burden of premature mortality and preventable or curable morbidity. The underlying value judgment is that when allocating resources under conditions of scarcity, the focus of public health expenditure should be to provide primary healthcare for the many rather than tertiary healthcare for the few.

Assistance from external sources – be it from development agencies, NGOs or corporations – will only be as effective as the domestic political and social constraints on health systems will allow.²⁴ No external resource can replace necessary internal reforms or additional allocation to satisfy the basic health needs of the 2.5 billion people living in dire poverty. Even the most generous corporate act will only be as strong as the weakest link in the long chain of factors that determines access to medicines.

My axiomatic assumptions.

There are problems the market can solve – and problems it cannot. In the same way that, in a functioning community, not everything can be reduced to market processes, likewise, the market alone is unable to create sustainable human development. Development is interplay between market forces and public policies. The efficiency of the market in allocating scarce resources must be combined with the principles of social equity and ecological sustainability. It is the primary duty bearer’s – i.e. the state’s – responsibility to care for those who are unable to participate in and benefit from markets. Corporations should not be expected to hold responsibility for distributional justice. Assisting the poor to meet their basic needs as well as

24 For an overview of the most essential building blocks see WHO: *Everybody’s Business. Strengthening Health Systems to Improve Health Outcomes*. WHO’s Framework for Action, Geneva 2007.

providing key infrastructure and other public goods such as infectious disease control belong to the public interventions of greatest importance.²⁵

There will always be competition for resources, not only within the health sector (e.g. hospital versus primary healthcare, prevention versus treatment or serving politically powerful urban constituencies versus ‘silent’ remote rural communities living in absolute poverty), but also between the health sector and other sectors (e.g. military). Calling for ‘hard choices’ might seem idealistic, but a muddling-through strategy is unlikely to result in the achievement of the health-specific Millennium Development Goals. Politically convenient compromises will directly impact the chances of survival of those who bear the highest disease burden. ‘Good health governance’ in the sense of creating and financing a health system that delivers appropriate, reliable, accessible and affordable health services for those who need them, is the overriding precondition for progress in the health condition of the poor.

The role of a pharmaceutical company in a global economy is to research, develop and produce innovative medicines that make a difference to sick people’s quality of life, and it is their duty to do so in a profitable way. No other societal actor assumes this responsibility. Many pharmaceutical corporations, however, perceive a *moral* obligation to do more, whenever possible, to help alleviate health problems of poor people all over the globe. Such corporate actions are, however, of a voluntary nature and should remain so.

I perceive the protection of property rights to be of utmost and general importance for human development – the “tragedy of the commons” remains an undervalued issue in the development discourse.²⁶ Convinced about the desirable effects that incentives bring to bear, I also see intellectual property protection to be a precondition for the successful research for and development (R&D) of innovative drugs and vaccines. Patents as such are therefore not up for negotiation in the access to medicines debate. Not only do they contribute to meet the needs of future patients and help to find solutions for hitherto unmet health needs, they are also crucial to securing future corporate existence of research oriented companies. Pharmaceutical innovations for poor patients require an intelligent mix of public and private research. The corporate responsibility challenge is therefore to find innovative and creative channels for the responsible use of patents under conditions of market failure and failing states. In this respect, a hierarchical differentiation of corporate responsibilities, involving different degrees of obligation and leaving room for voluntary leadership initiatives beyond legal requirements, is useful – particularly for companies with the resources to do more than the legal minimum demands.

Last, but not least, I am convinced that benchmarking corporate responsibility performance will help to create new layers of competition, especially where “reputation capital” is granted to those who deserve it. Competition for this kind of public recognition is likely to lead to more voluntary resources being made available for the fight against ill-health and needless mortality of the world’s poorest.

2. The Context

2.1. The Vicious Circle of Poverty and Health

The interrelationship between the ‘state of poverty’ and the ‘state of health’ of a nation and its citizens is well known: “Men and women were sick because they were poor, they became poorer because they were sick, and sicker because they were poorer.”²⁷ Not everybody is exposed to the same risks of premature death and high morbidity; within poor and rich

25 See also Sachs J.D.: *Common Wealth. Economics for a Crowded Planet*. The Penguin Press, New York 2008, p. 220 f.

26 See as an introduction the classic article of Garrett Hardin in *Science*, 13. December 1968, Vol. 168.

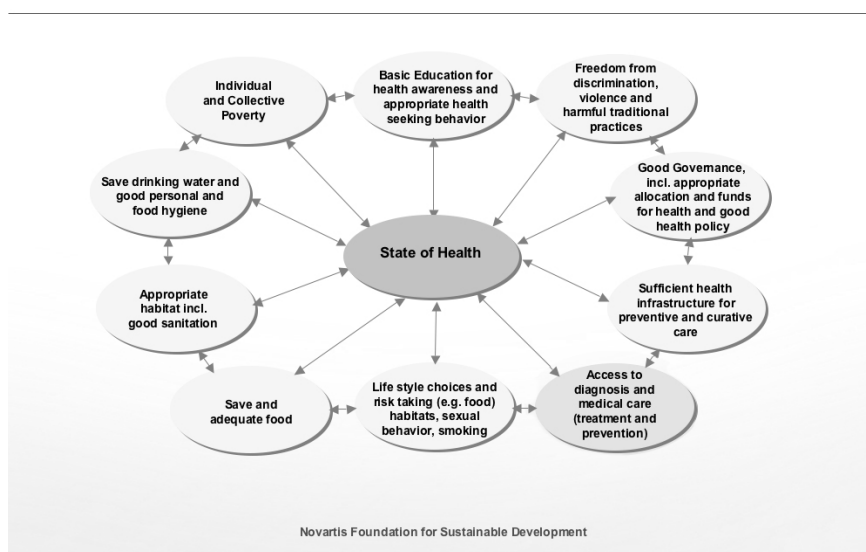
27 See Winslow C.-E.A.: *The Cost of Sickness and the Price of Health*. WHO, Geneva 1951, p. 9.

societies alike it is the jobless, the unschooled, the unskilled, and those living in remote and marginal areas who shoulder the highest mortality and morbidity burden. The reasons are obvious: deficits in nutrition, education, housing, sanitation, hygiene or primary healthcare services, or indirect causation due to unemployment, geographical isolation, political and social exclusion and even social exploitation. In contrast, there is empirical evidence that the more affluent and educated people are, the longer and healthier their lives become.²⁸ Poorer health and less healthy behaviors are also associated with lower socioeconomic status all over the world.²⁹

The mere perception of disease – its acceptance or non-acceptance – and the eventual demand for traditional or modern health services place the world’s poor at a further disadvantage. In a disease-ridden social environment, poverty-related illness becomes a ‘normal’ part of everyday reality and rarely results in demand for appropriate health services – even where available. Last but not least gender discrimination can pose life-threatening obstacles for seeking appropriate healthcare.³⁰

And yet, as poor health is not only a consequence of poverty but also a cause, the poorest would benefit most from health improvements: an individual’s state of health determines their ability to work, his or her labor productivity, and therefore earnings. And income level determines almost all other elements of living standard.³¹ For poor people, the health of their bodies and minds is a critically important asset – often their only asset. And vice versa: People’s abilities to manage their own lives, to develop their assets, and to learn and make use of their skills and knowledge all depend heavily on their state of health.

Poverty and Health: A Vicious Circle



- 28 See Daniels N, et alia: “Health and Inequality, or, Why Justice is Good for Our Health.” In: Anand S., F. Peter F. and A. Sen (Eds.): *Public Health, Ethics and Equity*. Oxford University Press, Oxford 2006, pp. 63 ff.
- 29 See also Nuffield Council on Bioethics: *Public Health: Ethical Issues*. London 2007.
- 30 See e.g. Nikièma B., S. Haddad and L. Potvin: “Women Bargaining to Seek Healthcare: Norms, Domestic Practices, and Implications in Rural Burkina Faso.” In: *World Development*, Vol. 36 (2008), No. 4, pp. 608-624.
- 31 Leisinger K.M.: *Health Policy for Least Developed Countries*. Basel 1985 (available through the Novartis Foundation for Sustainable Development). See also in this context Michael Marmot who drew attention to significant health inequalities even in the absence of absolute material deprivation and in countries that have general access to healthcare: Marmot M.: “Social Causes of Social Inequalities in Health.” In: Anand S., F. Peter and A. Sen A. (Eds.): *Public Health, Ethics and Equity*. Oxford University Press, Oxford 2006, pp. 37-61.

The top factors leading to disease, disability, or death clearly reflect the interrelationship of poverty and health:

Top Risk Factors Leading to Diseases, Disability, or Death

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

Source: World Health Organization, in: The Lancet Vol. 360 (2002), No. 9343, pp.1347 - 60

The human cost of 2.5 billion people facing a daily struggle for survival can be demonstrated by two of the most sensitive health indicators: infant and maternal mortality. Every year nearly 10 million children die before they reach their fifth birthday and 500,000 women succumb to preventable illnesses during pregnancy or due to birth complications. Health realities in the developing world remain hampered by lack of financial and technical means as well as a dearth of trained personnel, especially in rural areas and where the disease burden is highest. More deplorable still, there is not only scarcity but misallocation involved: state resources are fungible and significant amounts continue to be spent for military purposes even by the poorest countries.³²

This is a tragedy, even more so, according to WHO’s Director General, Dr. Margaret Chan, because “much of the ill health, disease, premature death and suffering we see on such a large scale is needless, as effective and affordable interventions are available for prevention and treatment.”³³ The good news is, that “a proven set of investments can slash the deaths and dramatically raise the well-being, energy levels, and productivity of the community.”³⁴ The work of the Millennium Village Project gives evidence for this already after a short period of time of its intervention.

2.2. Linkages between Health and Human Rights

The World Health Organization (WHO) benchmark publication on health and human rights draws attention to the remarkably complex linkages between the two:³⁵

- Violations of, or lack of attention to, human rights (such as torture, violence against children, harmful traditional practices, discrimination) can result in serious health consequences.

32 For details on Sub-Saharan Africa see www.sipri.org/contents/milap/milex/mex_graph_africa.htm.

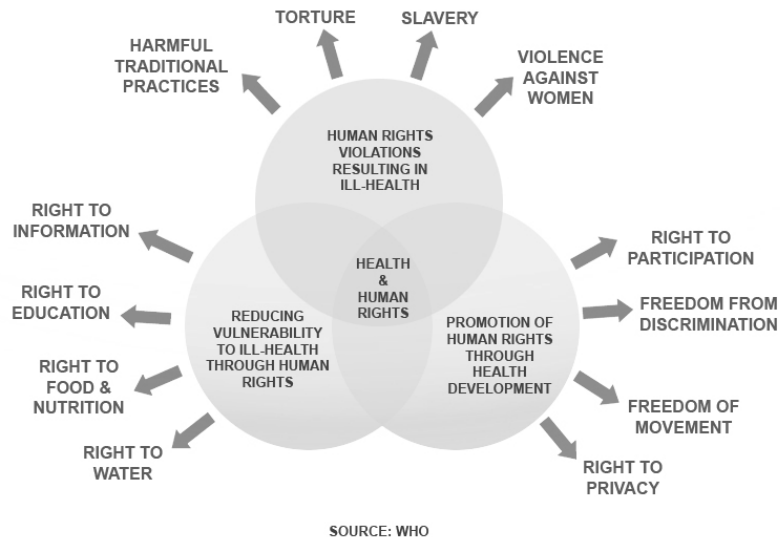
33 WHO: *Everybody’s Business. Strengthening Health Systems to Improve Health Outcomes. WHO’s Framework for Action*. Geneva 2007, p. iii (Foreword of WHI Director-General Margaret Chan).

34 Sachs J.D.: *Common Wealth. Economics for a Crowded Planet*. The Penguin Press, New York 2008, p. 232.

35 World Health Organization: “25 Questions and Answers on Health & Human Rights.” *Health & Human Rights Publication Series*, Issue No. 1, Geneva, July 2002.

- Health policies and programs can promote or violate human rights as a consequence of their design or implementation (discrimination against certain parts of the population, disregard of certain diseases).
- Vulnerability to morbidity and mortality can be reduced by ‘good governance,’ including spending resources according to actual needs and progressively with rising means.

Examples of the linkages between health and human rights:



Discussion of right-to-health issues and sub-issues, such as access to medicines, cannot be held in isolation from the factors that affect health, nor can sustainable solutions be achieved without reducing overall deficits in international and national development policies.

Past health improvements in poor and rich countries alike have, to a significant extent, been the result of improvements in income and education, with accompanying improvements in nutrition, hygiene, housing, water supply and sanitation. The historic successes achieved were, however, *also* the result of new knowledge about the causes, prevention, and treatment of illnesses – and of effective pharmaceutical products. In view of the extent of poverty-related health consequences, it is fair to argue that not only do the state and the international community have a *legal duty* to do all in their power to promote health, but all other members of civil society – including the private sector – have a *moral obligation* to support such endeavors.³⁶

It is here that the ‘Business and Human Rights’ debate and the right-to-health discourse overlap. The international community has long since established that there is a ‘right to health’ and has placed the nation state (and the international community) in charge of respecting, protecting, and fulfilling it.³⁷ Rights-based approaches to social and political deficits are based

36 U.N. Development Program, *Human Development Report 2005: International Cooperation at a Crossroads*. Oxford University Press, New York 2005, p. 24; see also Leisinger K.M.: “Capitalism with a Human Face.” In: *Journal of Corporate Citizenship*, Vol. 28, Winter 2007, pp. 113-132.

37 Article 25 of the Universal Declaration of Human Rights (1948) states that there is a “right to medical care,” confirming the reference in the World Health Organization’s constitution to the “right to the highest attainable standard of health.” This right was reiterated in the 1978 Declaration of Alma Ata as well as in the World Health Declaration adopted by the World Health Assembly in 1998. The most authoritative interpretation of the right to health is outlined in article 12 of the International Covenant on Economic, Social and Cultural Rights, which has been ratified by more than 145 countries so far. The United States has

on the premise that human rights are an entitlement simply by virtue of being human. They rest on internationally recognized human rights standards and principles to which governments all over the world are obliged to adhere. The functioning of markets and corporate willingness to become engaged in non-market activities such as donations or negotiated prices were heretofore not important elements in this argument.³⁸

But this has changed: Rights-based agendas are increasingly used to request action and provisions from business enterprises. The draft ‘Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines,’ published for public consultation in September 2007 by the Special Rapporteur are a good example of endeavors to shift important human rights obligations onto pharmaceutical companies.³⁹ The draft guidelines include a comprehensive list of demands similar to those voiced by NGOs working in this field of interest.⁴⁰ Most government and private sector stakeholder comments on the paper to date have not been favorable.⁴¹

The most obvious and fundamental obstacles to improvement in access to medicines for the world’s poor –absolute poverty and powerlessness, lack of good governance leading to deficits in health infrastructure, lack of well trained doctors, nurses, and pharmacists – have taken a back seat. Demands and pressures addressing the pharmaceutical industry to waive intellectual property rights, to make the latest patented medicines available at negotiated prices, or free of charge, and criticism of purchasing-power-biased research priorities have instead come to the fore. This approach could result in rapid, isolated interventions at a high cost to corporations, without broaching the enormous challenge of overcoming the systemic deficits and political inadequacies that lie at the root of the access-to-medicines issue.

A long-term, solution-oriented discourse on better access to medicines for the poor should not simply consist of demands on corporate property and arguments on the distributional issues of healthcare. In the words of Nobel Laureate Amartya Sen: “The factors that can contribute to health achievements and failures go well beyond healthcare, and include many influences of very different kinds, varying from genetic propensities, individual incomes, food habits, and lifestyles, on the one hand, to the epidemiological environment and work conditions, on the other [...] we have to go well beyond the delivery and distribution of healthcare to get an adequate understanding of health achievement and capability.”⁴²

Sustainable improvements in access to medicines for the poor necessitate complex systemic changes and political reforms. Demands for unilateral action focusing on selected elements of the complex problem will achieve little more than short-term symptomatic

not ratified this covenant. “25 Questions and Answers on Health & Human Rights.” *Health & Human Rights Publication Series*, Issue No. 1, Geneva, July 2002, note 19, p. 9ff.

38 See in this context Nelson P.J.: “Human Rights, the Millennium Development Goals, and the Future of Development Cooperation.” In: *World Development*, Vol. 35. No. 12, pp. 2041-2055.

39 U.N. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health: *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines* (draft for consultation, Geneva, 19 September 2007).

http://www2.essex.ac.uk/human_rights_centre/rth/docs/PH%20draft%20guidelines%2019%20sept%202007.doc.

40 See, Oxfam: *Investing for Life. Meeting Poor People’s Needs for Access to Medicines through Responsible Business Practices*. Oxfam Briefing Paper No.109, London, November 27, 2007, also Médecins sans Frontière’s views, e.g., http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122212.pdf.

41 United States Government Response to Requests from the United Nations (UN) Office of the High Commissioner for Human Rights for Contributions to a Report on Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, see also the reaction of IFPMA http://www.ifpma.org/Issues/GlobalHealth/fileadmin/templates/ifpmaissues/pdfs/2008_02_27_Contrib_2_Global_Health_Final_Industry_Focus_and_Actions_EN.pdf

42 Sen A.: Why Health Equity? In: Anand S., F. Peter and A. Sen A. (Eds.): *Public Health, Ethics and Equity*. Oxford University Press, Oxford 2006, p. 23-24.

alleviation on the micro-level that will be quickly absorbed by extant systemic limitations.⁴³ The strength of the ‘solution chain’ is determined by the weakest link. This is – as said before – often the willingness or ability of the primary duty bearer to live up to its responsibilities. Nevertheless the private sector *has* an important role to play.

2.3. The Role of Business in Society

No single actor is entitled to all rights, just as none is bound by every obligation – but all are better off if they cooperate. People living in a village expect different goods and services from the shopkeeper, the mayor, the doctor, the police officer and the teacher. Village people are accustomed to a certain division of labor, with concomitant responsibilities. Modern societies are more complex systems within which the rights and responsibilities of specific actors may blur. Yet in modern societies assigning and delimiting responsibility should be far more straightforward than in informal systems where neighborly assistance and reciprocal loyalties are common features. ‘Society’ as a social system can be thought of as a composite of relatively independent subsystems encompassing various players and sets of rules. All subsystems or societal groups are expected to perform certain functions and contribute toward society’s general welfare.⁴⁴

Following their needs, each subsystem develops its own ‘best practices,’ including laws, principles of action and rules of behavior. Public welfare as a whole is best served when the interests of all society’s subsystems dovetail – in other words, where there is an appropriate division of labor, and hence responsibilities, in society. To ensure the most efficient social organization and the greatest benefit for the common good, the subsystems of religion or the state, for example, have functions and responsibilities complementary to those of the economic or cultural subsystems. Moral norms emanating from the religious subsystem, such as sharing with the needy out of a sense of solidarity, or unconditional charity, are indispensable for the functioning of the system as a whole, but they are neither essential nor desirable for the functioning and effectiveness of the economic subsystem. Synergies occur, turning the systemic whole into more than just the sum of its parts, when ‘win-win’ situations are created between the different subsystems and friction is minimized.

With rising prosperity, the expectations placed on societal subsystems have changed. A rethinking of the role of the state and deeper awareness of the magnitude of social, health, and environmental problems facing global society are resulting in new responsibilities being assigned to the economic subsystem – and thus to corporations. Discrepancies between evolving public expectations and the mainly financial markets-driven objectives of business enterprises have resulted in a ‘legitimacy gap’ and unease about ‘multinationals’ in particular.⁴⁵ Both the current ‘Human Rights and Business’ debate over the meaning of ‘sphere of influence’ and ‘complicity,’ and the material content of corporate obligations towards economic, social and cultural rights are good examples of this dislocation.⁴⁶ While there has to be a fair balance of duties and rights for all subsystems, it is less clear what this means when any shift in the allocation of duties to one subsystem has direct implications for the vested interests of others. Problems arise when actors place heavy demands on one subsystem that bear no relation to a fair division of duties.

43 All preventative interventions such as vaccination campaigns, treated bed-nets, vector-control, or use of condoms are dealing with causes and therefore ought to be seen as systemic and not symptomatic interventions.

44 For details see Luhmann N.: *Social Systems*. (Writing Science) with Bednarz J. and D. Baecker. Stanford University Press, Stanford 1996.

45 See Lodge G. and C. Wilson: *A Corporate Solution to Global Poverty. How Multinationals can help the Poor and Invigorate their own Legitimacy*. Princeton University Press, Princeton and Oxford 2006.

46 For an overview see the excellent website of the Business and Human Rights Resource Center www.business-humanrights.org/Home.

There are advocates of the ‘capability not causality’ principle⁴⁷ according to which ‘Big Pharma’ should provide products at cost or significantly reduced prices commensurate with the purchasing power of the world’s poor. Most companies will argue that it is not their role to step in when those first in the line of responsibility fail to perform their duty. In order to form at least the basic architecture of a ‘consensus corridor’ for joint action, we will analyze the theoretical division of responsibility in the light of today’s dire facts on access to medicines.

3. The Access to Medicines Framework

There is consent among experts on the appalling facts regarding access to medicines:⁴⁸

- Used properly, essential medicines and vaccines could save up to 10.5 million lives each year and reduce unnecessary suffering – but 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 essential medicines surveys in 39 mainly low- and low-middle income countries found that, despite wide variation, average availability was 20% in the public sector and 56% in the private sector.⁴⁹
- Almost half of all medicines are inappropriately prescribed, dispensed, or sold, leading to wasted resources and potentially resulting in harm to patients.
- Patients do often 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.
- 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 drugs.

Resolving these failings will result in millions of lives and DALYs saved.⁵⁰ In view of the complexity of the challenge, nation states, the international community and other stakeholders must seek sustainable solutions in partnership.

3.1. The Primary Duty Bearers

The Nation State, supported by the international community, bears the primary responsibility for ensuring that the right to health is respected, protected, and fulfilled. These duties cannot (and should not) be delegated to any other organ of society. Yet, today, health outcomes under the leadership of those bearing the primary duty are “unacceptably low across much of the developing world.”⁵¹ The recent WHO Report on Health Systems sees the “failure of health systems” at the center of the resulting human crisis.

47 For an interesting discussion of this approach see Wettstein F.: “From Causality to Capability. Towards a New Understanding of the Multinational Corporation’s Enlarged Global Responsibilities.” In: *Journal of Corporate Citizenship*, Vol. 19 (2005), Autumn, pp. 105-117.

48 Department for International Development: *Fact Sheet: Access to Medicines*. London, January 2006.

49 WHO: *Everybody’s Business. Strengthening Health Systems to Improve Health Outcomes. WHO’s Framework for Action*. Geneva 2007, p. 9.

50 DALY stands for “disability adjusted life year” and 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 C.J.L.: “Quantifying the burden of disease: The Technical Base for Disability-Adjusted Life Years”. In: WHO: *Bulletin of the World Health Organization*, Vol. 72 (1994), pp. 429-445. For criticism of this measurement see Anand S. and K. Hanson K.: “Disability-Adjusted Life Years: A Critical Review.” In: Anand S., F. Peter and A. Sen (Eds.): *Public Health, Ethics and Equity*. Oxford University Press, Oxford 2006, pp. 183-199.

51 WHO: *Everybody’s Business. Strengthening Health Systems to Improve Health Outcomes. WHO’s Framework for Action*. Geneva 2007, p. 1.

To improve this state of affairs WHO defined “Six Building Blocks” of health systems based on the following aims and attributes:⁵²

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

To fulfill their duty, governments of poor countries are expected to be deliberate, concrete, and focused upon meeting their right-to-health (and hence access-to-medicines) obligations. As with the other economic, social, and cultural rights, governments with limited resources for ensuring the right to health should obey the principle of *progressive realization* and move incrementally, but expeditiously, toward the set goals. Reforms of current (public) health systems are unavoidable – and they must be carefully designed around the needs of the poor, or run the risk of failing to benefit those who need improvements most.

Significant progress is feasible even under current budget constraints: If low-income countries were to devote about 15 percent of their national budgets to health – as recommended by Jeffrey Sachs – and if this were topped up with appropriate development assistance, it would be enough to provide adequate primary healthcare to poor people.⁵³ A reality check shows that the governments of many developing countries continue to spend more of their scarce resources on issues other than health and education.⁵⁴ Moreover, the ‘rich’ regularly fail to deliver on the promises so nobly made at G8 summits and regional conferences.

To make matters worse, instead of applying the best practices in healthcare propagated by WHO, many governments seem instead to be driven by political vanity or corruption to adopt poorer practices where scarce resources are wasted and funds are misallocated.⁵⁵ Improvements in the quality of governance will, almost by definition, lead to improvements in access to medicines for the poor. This renders political reform and the progressive development

52 WHO: *Everybody's Business. Strengthening Health Systems to Improve Health Outcomes. WHO's Framework for Action*. Geneva 2007, p. 3.

53 See Sachs J.: “Primary Health for All.” In: *Scientific American*, January 2008.

54 Abbasi K.: “Healthcare Strategy.” In: *British Medical Journal*, 3 April 1999, pp. 933-1006; Gwatkin D.: *The Burden of Disease among Global Poor*. Lancet, 23 October 1999, pp. 586 ff.

55 WHO: *The World Health Report 2000. Health Systems: Improving Performance*, Geneva 2000.

of democratic institutions and practices essential – empowering organized citizens will help to hold such governments accountable.⁵⁶

Just as the longest journey begins with a single step, even small changes are welcome. Although governments seeking to step up healthcare for their poor will not be able to increase resources independently from overall economic growth, they could easily abolish price increases of medicines due to import tariffs, duties, and sales taxes. Such markups often increase the end-user price of medicine unnecessarily, sometimes by more than 80 percent.⁵⁷ Many of the countries that apply the highest tariff rates – sometimes even on donated drugs – have poor access to medicines.⁵⁸

There is substantial room for improvement by the primary duty bearers. However, where capacity and efficacy in the public sector are low, adopting strategies that place still greater workload on public institutions may prove detrimental.⁵⁹ Other actors must therefore assist to facilitate improvements.

3.2. Other Duty Bearers

3.2.1. The International Community

Next in the line of responsibility is the international community. WHO's right to health publication contains for instance this paragraph on the issue:

Although the human rights paradigm concerns obligations of States with respect to individuals and groups within their own jurisdiction, references to 'State's resources' within human rights instruments include international assistance and cooperation. In accordance with Articles 55 and 56 of the Charter of the United Nations, international cooperation for development and the realization of human rights is an obligation of *all* [emphasis added] states. Similarly, the Declaration on the Right to Development emphasizes an active program of international assistance and cooperation based on sovereign equality, interdependence and mutual interest.⁶⁰

In addition, there are a number of relevant binding treaties, such as the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child. In the Millennium Declaration, 147 Heads of State and Government “recognize that, in addition to our separate responsibilities to our individual societies, we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level.” Unfortunately for the world's poor, political rhetoric – not only at election time but also at G8 Summits – is not matched by concrete action.

The issue goes beyond simply transferring more development assistance from rich to poor countries: unfair trade practices, such as huge subsidies for agriculture in industrial countries, deprive the developing world of hundreds of billions of dollars of income every

56 Drèze J. and A. Sen: *Hunger and Public Action*. Clarendon Press, Oxford 1989.

57 See Bates R.: “Taxed to Death.” In: *Foreign Policy*, July/August 2006.

58 American Enterprise Institute for Public Policy Research: *Tariffs, Corruption and Other Impediments to Medicinal Access in Developing Countries: Field Evidence*. Washington, D.C. 2006 (AEI Working Paper #130), available at www.aei.org/publications/pubID.24749/pub_detail.asp.

59 See Filmer D., J. Hammer J. and L. Pritchett: *Health Policy in Poor Countries: Weak Links in the Chain*. 11/1999, World Bank Policy Research Working Paper No. 1874., Washington 1999.

60 See World Health Organization: “25 Questions and Answers on Health & Human Rights.” *Health & Human Rights Publication Series*, Issue No. 1, Geneva, July 2002. note 19, p. 15 ff.

year.⁶¹ Instead of preaching liberalization when it suits the North, practicing it where it helps the South could result in a dramatic increase of gross income for the developing world.

3.2.2. Nongovernmental Organizations

Many NGOs play a vital role in development and, notably, in almost all aspects of health-related work for the poor. Consultations with poor people reveal that they often consider the role of governments to be important but ineffective and even harmful.⁶² Corruption emerges as a key issue in poor people's daily struggles – whether in securing an education for their children, enjoying access to justice and police protection, or benefiting from basic healthcare. NGOs in contrast – in particular emergency NGOs and religious organizations – score highly for responsiveness and trust. They have a role in ensuring the poor are heard and they are instrumental in supporting the formulation and implementation of policies that directly benefit the poor. NGOs such as Oxfam were among the first to make human rights an integral dimension in the design, implementation, monitoring and evaluation of health-related programs.

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

3.2.3. The Pharmaceutical Industry

The point of reference for corporate right-to-health obligations is laid out in a half-sentence in the preamble to the Universal Declaration of Human Rights, namely that “every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance” [emphasis added]. For the former president of the American Society of International Law, Louis Henkin, and for a number of right-to-health activists, the case is clear: “Every individual includes juridical persons ... and every organ of society excludes no-one, no company, no market, no cyberspace. The Universal Declaration applies to all of them.”⁶³

There is extensive debate on what this should mean for pharmaceutical corporations – as organs of society – with regard to their contribution toward the respect, protection, and fulfillment of the right to health within their sphere of influence. Far less plurality of interpretation seems to apply to another article of the Universal Declaration of Human Rights, namely Article 17 UDHR i.e. (1), in which it is stated that “Everyone has the right to own property alone as well as in association with others,” and (2) that “No-one shall be arbitrarily deprived of his property.” Yet these are equally significant in the human rights and business discourse.

Successful pharmaceutical companies contribute to the respect, protection and fulfillment of the right to health, first and foremost, *in the context of normal core competence business*

61 Agricultural subsidies in the North still amount to over USD 300 billion a year, depriving the developing world of export opportunities (www.globalpolicy.org/globaliz/econ/2003/0709africa.htm); another absurd fact is that labor-intensive products – a competitive advantage niche of many developing countries – are often subject to higher tariffs than other goods from the developing world.

See <http://www.globalissues.org/TradeRelated/FreeTrade/ProtectOrDeregulate.asp>.

62 Narayan D. et al.: *Voices of the Poor. Can Anyone Hear Us?* Oxford University Press/World Bank, Washington, D.C. 2000.

63 Henkin L.: “The Universal Declaration at 50 and the Challenges of Global Markets.” In: *Brooklyn Journal of International Law*, Vol. XXV (1999), No. 1 (April), p. 25.

activities. There is convincing empirical evidence that the return on this investment for society is substantial. But beyond this core contribution, pharmaceutical companies are also perceived to have a moral responsibility to do more – and many do so.

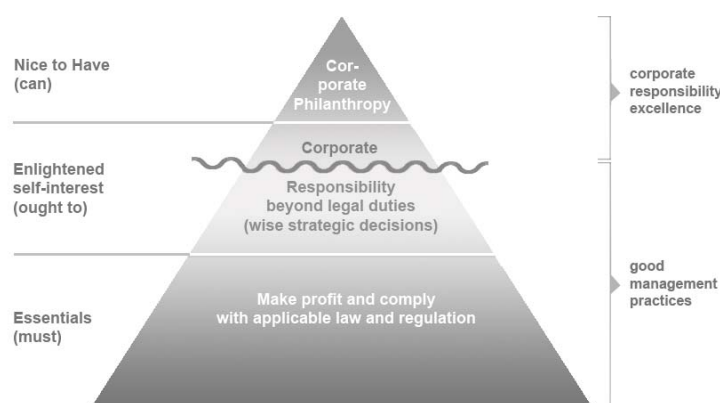
4. The Corporate Responsibility Hierarchy for Access to Medicines

To help establish priorities on potential obligations with regard to human rights and corporate responsibilities in general, a differentiating hierarchy of responsibilities is needed.⁶⁴ The following model is intended to facilitate systematic analysis of corporate access-to-medicine obligations. It distinguishes three degrees of corporate obligation, the boundaries of which are, of course, fluid:

- the ‘must’ dimension – non-negotiable essentials incumbent on the respective industry by social consensus;
- the ‘ought to’ dimension – good corporate responsibility standards particularly relevant in sensitive business areas, or countries where the quality of the law is insufficient or inadequately enforced;
- the ‘can’ dimension – voluntary assumption of additional responsibility according to capacity.

Opinion will vary as to what responsibilities should be in which dimension. My experience in this regard has been that managers of pharmaceutical companies would often like to see deliverables that are in the ‘ought to’ dimension shifted to the ‘can’ dimension, while NGO representatives would like some ‘ought to’ responsibilities shifted onto the ‘must’ level. As no categorization will adequately satisfy all stakeholders, corporations must learn to assess and articulate what demands they consider reasonable and why – as well as what is unreasonable and why.

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64 This follows Ralf Dahrendorf’s approach in distinguishing social norms according to different degrees of obligation, see Dahrendorf R: *Homo Sociologicus*. Opladen, Cologne 1959, p. 24 et seq; for a similar differentiation of corporate responsibilities see Carroll A.B.: *Business & Society. Ethics and Stakeholder Management*. South-Western Publishing Co., Cincinnati, 2nd edition 1993, p. 35.

4.1. The ‘Must’ Dimension

The primary responsibility of a pharmaceutical company arises in the context of its normal business activity. This is to say, by conducting research and development, bringing innovative and effective products to the market, and by providing goods and services that meet customers’ needs at competitive prices.

Successful pharmaceutical corporations make their most substantial contributions to the right to health through cutting-edge research, and the development and manufacture of high-quality drugs.⁶⁵ These are essential tools for the reduction of premature mortality as well as the prevention and cure of diseases that respond to drug therapy. Pharmaceutical products raise the quality of life of sick people, avoid costly hospitalization, and allow people to go back to normal working lives instead of being bedridden.⁶⁶ No other actor in society is engaged in such efforts and successfully delivers such results.

The fulfillment of these core responsibilities must be done in a legitimate way, that is, in compliance with all laws and regulations concerning healthy workplaces, environmental protection, and the safety and efficacy of products and services. Also part of the “must”-dimension is the obligation to adhere to ethical principles and transparency concerning clinical trials, as laid down in the Declaration of Helsinki⁶⁷ and in the WHO Guidelines for good clinical practice for trials on pharmaceutical products.⁶⁸

Successful business conduct ensures, apart from creating and preserving well-paid jobs, general social benefits such as contributions toward pension and insurance systems. Moreover, the resources provided by direct corporate taxes as well as taxes on profits and employment income make an important contribution to state finances – and hence enable the primary duty bearer to fulfill the right to health.

The ecological deliverables resulting from this dimension of corporate conduct include healthy workplaces, the prevention of occupational accidents and diseases, and reduced exposure to and release of harmful substances. In addition, companies must strive to ensure that their activities do not contribute directly or indirectly to the neglect of respect, protection, and fulfillment of the right to health.⁶⁹

Given the large unmet medical needs associated with acute and chronic diseases (such as cancer), as well as emerging new infectious diseases and drug resistance, success in fulfilling this unique role is of vital importance for the better health of present and future patients. It is without doubt the industry’s most important contribution to the respect, protection, and fulfillment of the right to health.

65 See the definition given by the EU High Level Committee on Health: “Innovation encompasses many different options going from the development of a completely new medicine for the treatment of a disease otherwise incurable to modifications of known pharmaceutical formulations to improve benefits for the patients, such as a less invasive administration route or a simpler administrative schedule.” See http://ec.europa.eu/health/ph_overview/Documents/ke02_en.pdf, p. 5.

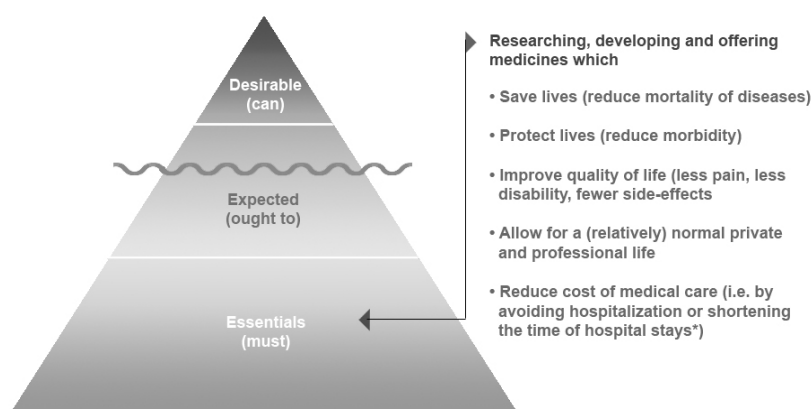
66 See OECD: *Health Data 2004*, Paris 2005; Journal of the American Medical Association: *Health, United States, 2004* with Chartbook on Trends in the Health of Americans (available at <http://www.cdc.gov/nchs/hus.htm>); Manton K.G. and X. Gu, *Proceedings of the National Academy of Sciences*, Vol. 98, No. 11 (May 22, 2001), pp. 6354-59; see also Milken Institute: *An Unhealthy America: The Economic Burden of Chronic Disease – Charting a New Course to Save Lives and Increase Productivity and Economic Growth*. Santa Monica 2007.

67 See www.wma.net/e/policy/b3.htm, see also <http://www.arvo.org/eweb/dynamicpage.aspx?site=arvo2&webcode=Helsinki> as well as http://www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf.

68 Available at <http://homepage.vghtpe.gov.tw/~mre/goodexp/Fercap-Survey/WHO-GCP-1995.pdf>.

69 See in this context the Guidelines for Compliance with the Right to Health of the Human Rights Compliance Assessment Tool of the Danish Institute for Human Rights (www.humanrights.dk).

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* Source: A US study concludes that USD 1.00 expenditure in innovative drugs is associated with USD 3.65 reduction in healthcare expenditures, see Lichtenberg F.R. / Brown C.C. *The Economic Benefits of New Drugs*, Boston 2001

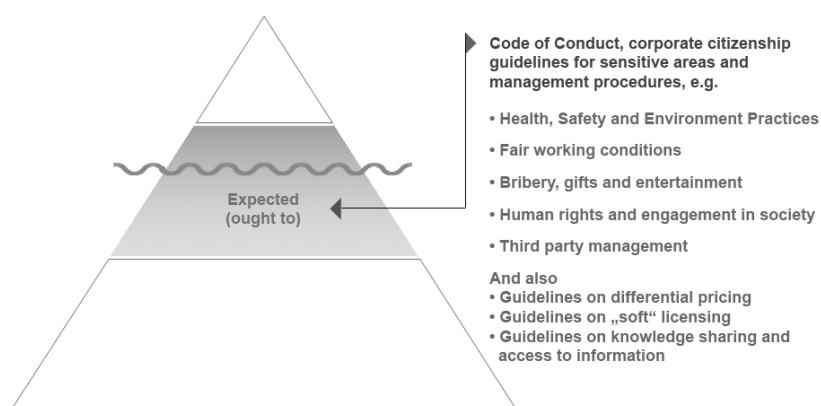
4.2. The 'Ought to' Dimension

A company's license to operate depends first and foremost on complying with law and regulation, but its social acceptance is increasingly contingent on the degree to which it responds to broader public expectations that go beyond legal minima. Where the quality of local legal norms is insufficient, companies ought to apply higher standards, such as fair labor conditions and wages that allow employees to lead a decent life and cover their basic needs. This is particularly important for internationally active corporations who work in countries where regulatory standards are low or not enforced. No responsible company can hide behind inadequate laws they are expected to adhere to higher, self-imposed corporate responsibility norms. Good companies will also strive to avoid benefiting from the unhealthy or unsafe working conditions of third parties and seek to provide assurance on the business practices of customers and suppliers.

For employees in the developing world, leading pharmaceutical companies have established a comprehensive program of medical services that includes free or heavily subsidized facilities for diagnosis, treatment, and psychosocial care of workers with HIV/AIDS or other poverty-related diseases such as tuberculosis (TB) or malaria. Other relevant corporate actions for workers in subsidiaries in the developing world include free or heavily subsidized meals, nursery schools for single mothers, free training opportunities using company infrastructure, and scholarship programs for the children of low-income employees.

As far as prices for life-saving drugs and vaccines are concerned, responsible companies are willing to adjust the price, on a case-by-case basis, for patients living in individual or collective poverty.

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Finally, most pharmaceutical companies have a track record of providing donations in cases of acute emergency (the 2004 tsunami, for example). This brings us to the ‘can’ dimension of corporate endeavors to respect, protect, and fulfill the right to health.

4.3. The ‘Can’ Dimension

Corporate services of the ‘can’ dimension predominantly comprise corporate philanthropy – defined as those expenditures beyond a company’s business activities which have no specific association with direct corporate advantage or financially measurable reward. Such deliverables are in addition to responsibility endeavors in the daily corporate working processes. Nevertheless, they can have a significant impact on the well-being of poor people and hence on the fulfillment of their right to health.⁷⁰ Corporate philanthropy constitutes an important aspect of good corporate citizenship – but as it is necessarily performance-dependent, it does not satisfy many NGO representatives.

Corporate philanthropy is part of the ‘discretionary’ business responsibilities, “purely voluntary, guided only by business’ desire to engage in social activities that are not mandated, not required by law, and not generally expected of business in an ethical sense”.⁷¹ Corporate managers who are willing to use their “moral free-space”⁷² in support of solutions to the most difficult and complex problems posed by extreme poverty, do so primarily as a consequence of their personal value premises.⁷³

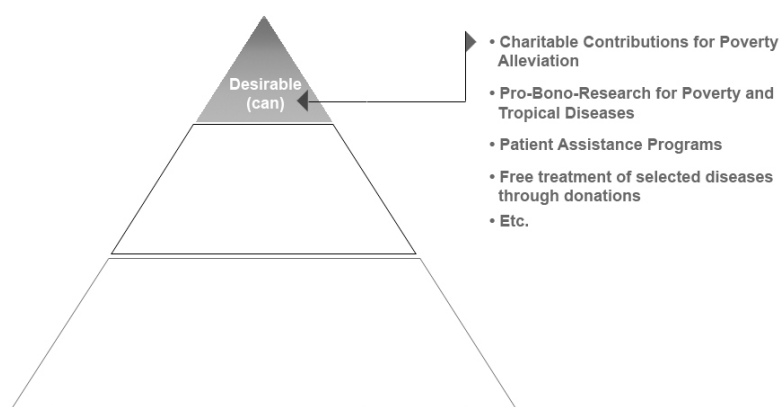
70 See Leisinger K.M.: “Corporate Philanthropy: The ‘Top of the Pyramid.” In: *Business and Society Review* Vol. 112, No. 3 (Fall 2007), pp. 315-42.

71 Carroll A.B.: *Business & Society. Ethics and Stakeholder Management*. South Western Publishing, Cincinnati, 2nd edition 1993, p. 32. See also Buchholtz A.K., A.C. Amason and M.A. Rutherford M.A.” “Beyond Resources. The Mediating Effect of Top Management Discretion and Value on Corporate Philanthropy.” In: *Business & Society*, Vol. 38 (1999) No. 2, pp. 167-187.

72 Donaldson Th. and Th. W. Dunfee.: *Ties that Bind. A Social Contracts Approach to Business Ethics*. Harvard Business School Press, Boston 1999, pp. 38-41 and 254 ff.

73 Hambrick D.C. and P.A. Mason: “Upper Echelons: The organization as a reflection of its top managers.” In: *Academy of Management Review*, Vol. 9 (1984) No. 2, p. 193-206; also Lerner L.D. and G.E. Fryxell: “CEO stakeholder attitudes and corporate social activity in the Fortune 500.” In: *Business & Society*, Vol. 33 (1994), No. 1, pp. 58-81; also Jones G.R.: “Personal Values and Corporate Philanthropy – a theoretical model for the role senior executives’ personal values play in decisions regarding corporate philanthropy.” In: Flinders University of South Australia: *School of Commerce Research Paper Series: 0023*, December 2000;

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4.4. Portfolio of Good Practices

Millennium Development Goal 8 sets out the target for the international community “in co-operation with pharmaceutical companies, [to] provide access to affordable, essential drugs in developing countries.” Voluntary corporate services to improve poor people’s access to medicines can be classified in either the ‘ought to’ or the ‘can’ dimension. Both stakeholder and corporate views differ on this. There is, however, a body of good practices in which most large pharmaceutical companies are already engaged.⁷⁴ This list reflects many of the services itemized in the ‘ought to’ and ‘can’ dimensions, but there is as yet no consensus among pharmaceutical companies:

- *Differential pricing* – i.e. reduced tenders for selected drugs against poverty-related and tropical diseases for use in least-developed countries, particularly for single-source pharmaceuticals (those with patent protection or marketing exclusivity).
- *Donations* for disease eradication programs or emergencies, adhering to WHO Guidelines for Drug Donations.
- *Research and development investments* for diseases affecting predominantly poor people in the developing world (so-called ‘neglected’ diseases).
- *Support for broader health and development goals* in developing countries.
- *Work with stakeholders* in countries of operation to ensure access-to-medicines initiatives are integrated into national systems and priorities and to avoid ‘vertical’ and ‘parallel’ systems.

also Buchholtz A.K. et alia: “Beyond Resources: The Mediating Effect of Top Management Discretion on Values of Corporate Philanthropy.” In: *Business and Society Review* Vol. 38 (2), 1999, pp. 168-187, and Solomon R.: “Corporate Roles, Personal Values: An Aristotelian Approach to Business Ethics.” In: *Business Ethics Quarterly*, Vol. 2 (1992) pp. 317-40. This seemingly also applies to disaster relief, see Cagir D.: “Agency Costs or Advertising? Corporate Donations for Tsunami Relief.” In: Claremont McKenna College, *Leadership Review*, Vol. 5 (Fall, 2005);

74 Department for International Development, Department of Health, Department of Trade and Industry: *Increasing People’s Access to Essential Medicines in Developing Countries: A Framework for Good Practices in the Pharmaceutical Industry*. A UK Government Policy Paper, London, March 2005.

- *Exploring opportunities for production in developing countries* including through wholly-owned subsidiaries and the use of voluntary licenses, where these measures would increase sustainable access to essential medicines.

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) supports its members using these means to increase access to medicines.⁷⁵

Yet pharmaceutical companies that are genuinely committed in such ways unfortunately get little praise from those who advocate access to medicines. Rarely do free corporate contributions result in ‘reputation capital’, despite the benefits that millions of poor patients have gained from such acts. Donations that have without any doubt proved their value⁷⁶ and which cost donors millions of dollars annually that could be invested in alternative activities – are sometimes denounced as mere public relations exercises. This is regrettable. There are leaders and laggards; there are short-term ‘PR-driven’ actors and those who have been contributing to healthcare solutions for decades – but rarely is any differentiation made between these.

Differential pricing is a telling example: several companies have applied differential pricing to medicines for poverty-related illnesses and products that the World Health Organization regards as essential. This is rarely acknowledged by activists, however, who instead raise the ‘demand bar’ to include *all* medicines sold by a company. Unreasonable claims of this nature are likely to result in ‘responsibility fatigue,’ with the perverse side-effect of strengthening the resolve of more conservative corporate managers who eschew philanthropy in favor of narrow market interests.

In the attempt to achieve a common understanding of what constitutes good practice it is important to note that essential medicines are of overriding importance for the poor segments of the population in developing countries. *Essential medicines* are defined by WHO as “a list of minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.”⁷⁷ It is these medicines which satisfy the priority healthcare needs of the majority of the population in poor countries – a focus on essential medicines is also in line with the value premise that those most in need should be first in line to benefit from corporate non-market actions.

In contrast to what is commonly argued by critics of the pharmaceutical industry, patents do not form a significant obstacle to access to essential medicines. A study by Amir Attaran found that in 65 low- and middle-income countries, where 4 billion people live, patenting is rare for 319 products on WHO’s Model List of Essential Medicines. Only 17 essential medicines are patentable, although they are in practice rarely patented, so that overall patent incidence is low (1.4 percent) and concentrated in larger markets.⁷⁸ Indeed, low-cost interventions that could prevent at least two-thirds of today’s infant and maternal mortality are known and available at affordable prices.⁷⁹

75 IFPMA: *Principal Focus and Action of the Research-Based Pharmaceutical Industry in Contributing to Global Health*. (mimeo) Geneva, February 2008.

76 See e.g. www.novartisfoundation.org/page/content/index.asp?Menu=3&MenuID=324&ID=741&Item=73.1.2&ConID=1180&nYear=

77 For details, see www.who.int/medicines/publications/EML15.pdf.

78 Attaran A.: “How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?” In: *Health Affairs*, Vol. 23 (2004) No. 3, pp. 155–66.

79 Department of International Development, Department of Health et al.: *Increasing Access to Essential Medicines in the Developing World. UK Government Policy and Plans*. London 2004. ‘Affordable’ not necessarily by the rural poor living from subsistence agriculture, but affordable with the national and international means that could be made available if the necessary political will were mobilized. See

A number of programs initiated and run by the Novartis Foundation for Sustainable Development in collaboration with NGOs and government institutions show that even when drugs are given away for free – as in the case of the multi-drug-therapy for leprosy and TB and malaria drugs in selected countries – it is not assured that they reach the patients who need them.⁸⁰ Lack of health infrastructure, including professional diagnosis and therapeutic advice, logistical hindrances, particularly in remote rural areas during rainy season, wrong disease perceptions or stigma, lack of health education and, last but not least, difficulties in patient compliance, necessitate extensive additional investments well over and above the value of the free medicine – a point acknowledged by NGOs such as Oxfam.

5. A Call for Joint Action

The scale and complexity of today's global health problems and the human tragedy associated with premature death and preventable disease elevates the access-to-medicines debate to one of the central corporate responsibility priorities for pharmaceutical companies. While governments continue to hold the primary responsibility for ensuring access to healthcare and thus to essential medicines for all their citizens, pharmaceutical companies are expected to assume their share of responsibility.

Corporate initiatives, however, cannot have their optimal impact if governments are not also doing their part to reduce excess mortality and morbidity within the prevailing resource limits, to counter potential threats to health (be it through health education or preventive measures), and to develop more effective health systems.⁸¹ The most sophisticated breakthroughs in research and the most generous offers of low-priced medicines will make little difference for the poorest people if there is no basic health infrastructure to reach them. Likewise, voluntary contributions by pharmaceutical companies cannot reach their full potential if the international community is not living up to its commitments. Today, we are still far from achieving the health-related Millennium Development Goals. Midway through the period 1990–2015, the general child and maternal mortality goals are projected to remain unmet almost universally, with sub-Saharan Africa lagging behind most significantly.⁸²

The causal complexity of poverty and its interdependence with health deficits makes 'simple' solutions impossible. One-dimensional answers and unilateral endeavors are inappropriate for problems that have their origin in systemic failures. Without a multi-stakeholder approach that includes national governments, the international community, NGOs and the private sector, even the well-intended efforts of single actors will have little sustainable impact. The pooling of resources, skills, experience and goodwill, on the other hand, can generate valuable synergies.

I share the vision of Jeffrey Sachs, that “Modern businesses, especially the vast multinational companies, are the repositories of the most advanced technologies on the planet and the most sophisticated management methods for large-scale delivery of goods and services. There is no solution to the problems of poverty, population, and environment without the active engagement of the private sector, and especially the multinational companies. Yet the main objective of such companies is to earn profits rather than to meet social needs. The two

Commission on Macroeconomics and Health: *Increasing Investments in Health Outcomes for the Poor*. 2nd consultation, Geneva 2003 (www.who.int/macrohealth/events/health_for_poor/en/E_REPORT.pdf).

80 See www.novartisfoundation.org/platform/apps/project/view.asp?MenuID=245&ID=539&Menu=3&Item=44.12

81 Spinaci S. and D. Heymann: Communicable Disease and Disability of the Poor. In: *Development*, Vol. 44 (2001), No. 1, pp. 66 ff.

82 see Baird M. and S. Shetty: “Getting There. How to accelerate progress toward the Millennium Development Goals.” In: *Finance & Development*, December 2003, pp. 14 -19.

are definitely not incompatible, but they are not the same.”⁸³ It should not be impossible to eventually build up the robust and sophisticated networks that are needed to achieve those initial common successes that help to build up the trust that enables sustainable collaboration also in difficult areas. Sachs reminds us that there is nothing inherent in global politics, technology or sheer availability of resources on the planet to prevent us from doing the right thing. “The barriers are in our limited capacity to cooperate, not in our stars.”⁸⁴

Pharmaceutical companies’ legitimacy will increasingly depend on being perceived as a force for good in the fight against poverty-related illnesses and premature mortality – indeed, successful endeavors in this respect will be among the determining factors in evolving new business models. Hence, at least with corporate responsibility leaders, common learning curves for tangible benefits for the poor should be feasible. No partner in enlightened coalitions for better access to medicines should act as if the readiness to constructive dialogue is appeasement. None of the real big issues – and the lack of access to medicines of 2.5 billion people is a ‘real big issue’ – of the past 50 years has been brought closer to a solution without the readiness to meet, to take each other serious and to talk also about the legitimate differences in the mutual positions. There is no other way to develop the reciprocal trust necessary to give something in exchange for something else.

Partnerships where participants have the ability to continuously revise their knowledge, together with process-oriented approaches where participants allow the dynamics of interaction to inform and influence their perception of what matters, stand the best chance of success. Under such conditions it matters less who has the *a priori* ‘higher moral standing,’ than who is able to substantiate which demands can be met and which are unreasonable. Given stakeholder consensus on, and common understanding of, the basic supporting pillars for solutions, reaching agreement on the details can be facilitated on a case-by-case basis as the “us versus them” attitude softens up.

Fortunately there is growing consensus among mainstream stakeholders on a variety of important issues:

- All serious stakeholders in the access-to-medicines debate agree on the huge complexity of the factors determining health.
- While there are controversial viewpoints on the obligations of particular actors, there is general agreement on the necessity of a multi-stakeholder approach involving all actors – the international community, the nation state, NGOs, health professionals, patients, and the private sector.
- While there are significant differences in opinion over the extent, depth, and breadth of pharmaceutical corporations’ commitments as well as whether they should be allocated to the ‘must’-, ‘ought to’- or ‘can’- dimension, there is basic agreement that differential pricing, donations, licenses, and *pro bono* research services are important elements.

There is also significant consensus that all “organs of society” (to use the expression of the preamble of the Universal Declaration of Human Rights) should contribute to solutions according to their sphere of influence, abilities, and enlightened self-interest – and in the context of a fair distribution of societal responsibility. With growing recognition in the pharmaceutical sector of the moral imperative for corporate engagement in the ‘ought to’ and ‘can’ dimensions of corporate citizenship, underpinned by respect for universal norms, there is good reason for optimism.

83 Sachs J.D.: *Common Wealth. Economics for a Crowded Planet*. The Penguin Press, New York 2008, p. 52.

84 Ibid, p. 7.