

STATEMENT OF PRINCIPLES AND RECOMMENDED CORPORATE PRACTICES TO PROMOTE GLOBAL HEALTH



INTERFAITH
CENTER ON
CORPORATE
RESPONSIBILITY

About these Principles

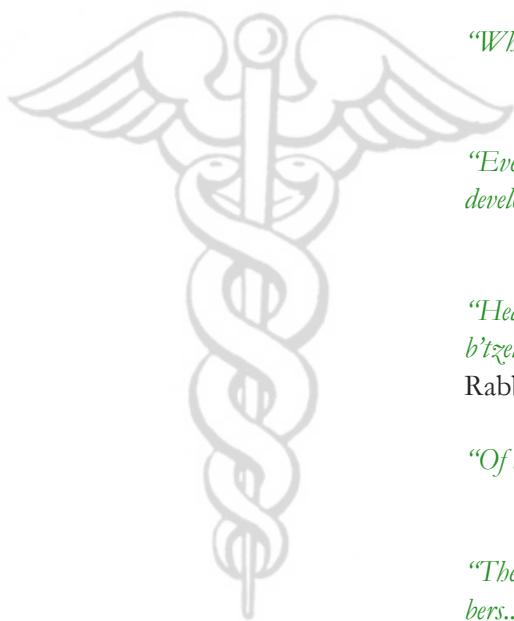
These Principles are an articulation of our positions on corporate responsibility regarding global health, along with our recommended best practices. We welcome affirmation of these principles and practices by all stakeholders.

Interfaith Center on Corporate Responsibility
Working Group on Global Health
March, 2014



ABOUT ICCR: www.iccr.org

Currently celebrating its 43rd year, ICCR is the pioneer coalition of active shareholders who view the management of their investments as a catalyst for change. Its 300 member organizations with over \$100 billion in assets have an enduring record of corporate engagement that has demonstrated influence on policies promoting justice and sustainability in the world.



"When it comes to global health, there is no 'them'... only 'us'."

Global Health Council

"Every human being has the right to life, to bodily integrity, and to the means suitable for the proper development of life; these (include) food, clothing, shelter, rest, (and) medical care."

Pacem in Terris, Pope John XXIII

"Health is not a luxury, nor should it be the sole possession of a privileged few. We are all created b'tzelem elohim -- in the image of God -- and this makes each human life as precious as the next."

Rabbi Alexander Schindler, Past President, Union of American Hebrew Congregations

"Of all the forms of inequality, injustice in health care is the most shocking and inhumane."

Martin Luther King, Jr.

"The health of a society is truly measured by the quality of its concern and care for the health of its members...We believe that health is a fundamental human right which has as its prerequisites social justice and equality and that it should be equally available and accessible to all."

Imam Sa'dullah Khan, The Islamic Center of Southern California

We try to remember that
medicine is for the patient...
It is not for the profits. The
profits follow, and if we have
remembered that, they have
never failed to appear. The
better we have remembered
it, the larger they have been.

— George W. Merck,
December 1, 1950

The Human Right to Health

Over 65 years ago, the United Nations Declaration of Human Rights was approved by the UN's member states. The Declaration states in Article 25: Everyone has the right to a standard of living adequate for the health and well-being of himself *[herself]* and of his *[her]* family, including food, clothing, housing and medical care and necessary social services.

The human right to health is recognized in other international documents. The 160 nations that have signed the International Covenant on Economic, Social and Cultural Rights recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. To achieve the full realization of this right, the Covenant lists steps to be taken, including those necessary for the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

The UN Guiding Principles on Business and Human Rights make clear companies' responsibility to respect, protect and remedy human rights within their global supply chains. The pharmaceutical industry has a pivotal role to play in protecting the human right to health by promoting the access, availability, affordability, and infrastructure required to deliver life-saving medicines where they are most needed.

Many members of the Interfaith Center on Corporate Responsibility (ICCR) have global ministries and witness the undue disease burden borne by the poorest and most vulnerable communities. Our members work to redress global health inequities as a question of social justice and human rights advocacy. Moreover, many ICCR members also represent health care institutions and, as such, they are uniquely positioned to offer solutions to some of the most intractable global health challenges. We commend health care companies that have formally adopted human rights policies addressing global health and encourage those that have not to do so.

The Social Contract

Responsible investors recognize that how companies manage environmental, social and governance (ESG) risks can be an important bellwether of long-term business success. Companies that behave ethically understand the importance of delivering goods and services that will benefit the common good, and their business decisions reflect the social contract between governments, society and the pharmaceutical industry. Promoting ethical business practices protects a company's reputation, maintains a social license to operate in current and future growth markets, and improves stakeholder relations.

The Business Case for Change: Risk and Opportunity

At a 2008 multi-stakeholder roundtable on increasing access to medicines, co-convened by ICCR, faith-based and socially responsible investors and public health organizations pointed out that in order to arrive at a sustainable business model in developing and emerging markets, the pharmaceutical industry must develop new ways to approach the three core elements of its traditional business model: pricing; research and development; and intellectual property. A number of pharmaceutical companies at the roundtable agreed that new approaches were needed.

The accepted pharmaceutical model of high drug prices in developed countries as a way to offset research and development (R&D) costs and to keep drug prices low in low- and middle-income countries (LMICs) is being increasingly challenged as a strategy to promote access and affordability. Pharmaceutical companies are facing mounting pressure to demonstrate a drug's value and cost-effectiveness, and many companies are conceding that the "blockbuster" drug model is a relic of the past. Competition from generic and biotech companies in Europe, Japan and the U.S. and, increasingly, India and China, further threaten the big pharma model.

This traditional relationship between drug prices and R&D costs has led to a gap in research into medicines for illnesses that overwhelmingly affect people who are poor, such as neglected tropical diseases and tuberculosis. To address this gap, the 2013 World Health Assembly approved a new initiative of demonstration projects to find alternative means of financing the development of drugs and other health technologies for diseases that disproportionately affect developing countries. There are opportunities for pharmaceutical companies to find new ways to finance R&D.

Business has a key role to play and must be more responsive, flexible and open. We need to take risks, and be committed to not just meeting society's expectations, but to exceeding them. It's not just doing what we must. It's about doing what we can to address the immense challenge which faces us.

—Sir Andrew Witty, CEO, GlaxoSmithKline, March 17, 2011

According to the 2013 UN Human Development Report, the combined output of the economies of Brazil, China and India is now nearly equal to the combined GDP of Canada, France, Germany, Italy, the United Kingdom and the United States, indicating that these developing and emerging markets present a major growth opportunity for pharmaceutical companies. R&D, including clinical development costs can be as much as 40-60% lower in these emerging markets. For companies and their investors, emerging markets are critical to industry growth.

Meanwhile, IMS Health predictions for drug spending in North America, Europe and Japan are modest at 1 to 4 % annually over the next few years. This rapidly changing landscape will require pharmaceutical companies to adopt a more sustainable business model with a region-by-region, product-by-product access strategy.

In the meantime, it is already clear that pharma will need the support of investors to navigate this complex and changing landscape.

—PharmaFutures, Pathways to Value: Pharma in a Changing World, 2013



We believe the following principles and recommended practices will assist pharmaceutical companies in promoting the human right to health, and to advance strategies that will enhance innovation and open access to new markets.

ICCR Global Health Principles

I. Access & Affordability: Global health business models must promote access to health for all, and be equitable and affordable, regardless of one's country or resources.

II. Innovative Research & Development Models: Companies must develop new models that address critical global health needs, including non-communicable diseases, HIV/TB/malaria and neglected tropical diseases that impact the most vulnerable.

III. Ethical Business Practices: Companies must develop, implement, and monitor a global code of conduct that incorporates responsible marketing practices; anti-bribery corruption measures; fair clinical trials; and robust oversight of supply chain management programs.

IV. Community Investment: Pharmaceutical companies working with communities, the private sector and other stakeholders must find solutions to overcome barriers to improving a country's health system infrastructure and supply chain distribution.

V. Partnerships & Collaboration: Companies must increase collaboration within the pharmaceutical industry and with other stakeholders to share knowledge and resources to develop and implement access to health initiatives.

VI. Transparency & Disclosure: Companies must increase transparency and disclosure on access strategies, health outcomes, public policy positions and lobbying activities in order to demonstrate responsible corporate citizenship and enable investors and other stakeholders to hold companies accountable.

The problem of progressively higher and higher prices is another universal concern that points to the need to change business models. It also raises some fundamental ethical issues.

—Margaret Chan, head of the World Health Organization (WHO), July 2013



RECOMMENDED PRACTICES

I. Access & Affordability

- Adopt a business model that sustains the company's profitability and promotes access to health.
- Develop sustainable access policies that are tailored to local health needs, socio-economic conditions and affordability.
- Integrate the access policy into the corporate strategy and make the board accountable for its implementation and results.
- Demonstrate accountability with a board committee responsible for oversight of the company's policies and programs related to the human right to health; recruit board members with human rights expertise; and educate board members on the issue.
- Establish key performance indicators to measure the impact and effectiveness of access to health policies.
- Manage access strategies in concert with local stakeholders and country priorities; measure outcomes; and update access strategies based on outcomes.
- Execute manufacturing and supply agreements with local manufacturers to broaden access to medicines and services in LMICs.
- Publicly advocate for and disclose public policy positions and outreach efforts to improve access.

II. Innovative Research & Development Models

- Demonstrate how the company is leveraging non-traditional R&D strategies, such as public-private partnerships, open innovation, open source and utilization of research prizes.
- Assist in strengthening the R&D capacity of institutions in developing countries, including technology transfer.
- Participate in demonstration projects, such as those approved by the 2013 World Health Assembly, that address R&D gaps related to discovery, development and/or delivery, including promising product pipelines for diseases that disproportionately affect developing countries and for which immediate action can be taken.
- Explore ways to de-link the cost of R&D from the price of medicine.
- Enter into licensing agreements for medicines, including participation in the Medicines Patent Pool, that address global health burdens that impact those who are poor.

Given the systemic nature of health challenges and the fact that only 15 percent of GHPs [Global Health Partnerships] today involve more than one multinational research-based pharmaceutical company, there is a need to capitalize on the collective expertise that a multi-company partnership can deliver and drive up this percentage.

—BSR, Working toward Transformational Health Partnerships in Low- and Middle-Income Countries, September 2012

III. Ethical Business Practices

- Adopt and implement a code of conduct for ethical marketing practices that applies to the company's sales force, third-party distributors and contractors.
- Publicly disclose information regarding marketing and promotional programs, including payments and promotional activities directed to physicians and other health care professionals and parties.
- Develop enhanced due diligence risk procedures that apply to third-party intermediaries in markets with less developed health care infrastructure and less robust legal regulatory enforcement.
- Establish anti-bribery corruption measures that demonstrate strong training and enforcement measures and train employees, business vendors and suppliers.
- Comply with internationally accepted standards for both in-house and outsourced clinical trials with an emphasis on quality assurance, control and patient rights, and commit to post-trial access to products for relevant patients.
- Create supply chain policies and procedures that reduce ESG risks including working with contractors and suppliers to enhance oversight, training and capacity-building programs at the company and industry level, and technology transfer.
- Adopt robust policies and procedures (including board oversight) governing a company's corporate political lobbying activities (direct and indirect), including the criteria used to evaluate membership in and contributions to third-party organizations; assessment of compatibility with the company's stated policies and Code of Conduct; and public disclosure of said policies and contributions.

IV. Community Investment

- Develop partnerships that address obstacles to improving healthcare infrastructure and delivery in LMICs.
- Align community investments with the national health system plan and priorities.
- Support local health care capacity-building, including training of healthcare workers, patient education, investing in health infrastructure and improving supply chain efficiency and integrity.
- Promote health literacy, including people's capabilities to make healthy choices, manage therapies and navigate health systems.
- Align philanthropic projects to long-term access; develop appropriate metrics to measure their impacts.

I have been struck again
and again at how important
measurement is to
improving the human
condition.

—2013 Annual Letter from
Bill Gates, The Bill and
Melinda Gates Foundation

V. Partnerships & Collaboration

- Participate in multi-stakeholder partnerships (governments, donors, patient organizations, and NGOs) that address unmet health needs and systemic issues, leverage core competencies, and involve appropriate stakeholders including: the World Intellectual Property Organization's (WIPO) Re:Search Program; Non Communicable Disease Alliance (NCD Alliance); and, London Declaration on Neglected Tropical Diseases.
- Engage in multi-company partnerships to address global health challenges by capitalizing on the collective expertise of the pharmaceutical industry, e.g. Drugs for Neglected Diseases Initiative (DNDI).
- Formulate goals and metrics for partnerships; track results; measure impacts; and report on outcomes.
- Disclose details of partnerships and collaborations and how they aim to impact access to health and local capacity.

VI. Transparency & Disclosure

- Disclose the company's emerging market strategies, including how access strategies are practiced in emerging markets.
- Report information on registration of medicines in LMICs to treat global diseases, i.e., HIV/AIDS, TB, malaria, non-communicable diseases and neglected tropical diseases.
- Publish the rationale behind any equitable pricing strategies, and the volume of sales of medicines to people who are poor.
- Provide details of licensing agreements related to research collaborations and the development of generic versions of branded medicines for LMICs.
- Report on the financial resources dedicated to R&D within the company, or in collaborative partnerships, for medicines to treat global diseases affecting the most vulnerable people on the planet.
- Communicate public policy positions and lobbying positions and expenses on issues that impact access to health, such as intellectual property.

We call upon companies, investors, faith-based communities and nongovernmental organizations to endorse these Global Health Principles. We will work with pharmaceutical companies to fully implement these recommended practices in order to ensure that global health needs are addressed in ways that are equitable, accessible, affordable and sustainable.

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