



Human Rights Challenges Facing Abbott Laboratories: Risks and recommendations

By

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For over 100 years, Abbott Laboratories, a global broad-based healthcare company incorporated in Illinois, has been driven by their mission: “to use our expertise and resources to improve people's lives around the globe.”¹ Motivated by this goal, Abbott has grown into a top-20 pharmaceutical company, with 65,000 employees, more than 100 facilities worldwide, and a broad range of pharmaceutical, medical and nutritional products that generated \$22.5 billion in sales in 2006.²

Over the past few decades, the pharmaceutical industry has enjoyed growth and profitability, with global sales topping \$600 billion by the end of 2005,³ making the industry highly attractive among investors.⁴ For the top pharmaceutical companies, much of the profit comes from the sale of patent-protected “blockbuster” drugs in developed markets.⁵ In 2005, North America, Europe and Japan accounted for 87% of global pharmaceutical sales.⁶ Although the vast majority of sales occur in these markets, the global patent protection for these blockbuster drugs was strengthened by the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁷

However, investors and analysts are starting to question whether the pharmaceutical companies will be able to maintain the high growth rates and profit levels. The industry has been facing mounting financial pressures in various sectors. First, pharmaceutical companies increasingly have to compete with generic versions of popular drugs whose patents have expired.⁸ Furthermore, investors have become wary of the substantial investments companies are making in new drug research and development (R&D). There is an estimated 99.9% risk of failure for the R&D of new products, while the average cost of introducing a new product to the market surged from \$300 million in 1992 to \$800 million in 2003.⁹ Companies are subsequently spending more on marketing successful products to try to recoup the additional costs.¹⁰

Yet, as one investor group noted, it is not the financial pressures but rather the “rising expectations of the sector's wider responsibilities to society that has proved especially disorienting.”¹¹ The public is increasingly calling pharmaceuticals out for failing to meet certain standards of ‘corporate responsibility.’ For instance, the public has been criticizing pharmaceutical companies for heavily marketing drugs that only slightly improve on older products and for bribing generic-drug makers to delay bringing the

cheaper versions to the market.¹² Other public concerns about the ‘corporate responsibility’ of the industry include numerous violations of competition and marketing laws, the “role of ‘big pharma’ in medical research,” and unsound executive pay policies.¹³

The most widespread and persistent public campaign against the practices of pharmaceuticals has been the charge that they are violating the human right to health: by failing to address the global health crises predominantly affecting the developing world, by inhibiting universal access to essential medicines, and by prioritizing intellectual property concerns and profit over saving the lives of millions who die from preventable and treatable diseases. As a leading pharmaceutical company with a large R&D budget and a product line that includes essential medicines, Abbott has been criticized by consumers, investors, medical professionals, human rights activists, and governments for failing to ensure universal access to essential medicines, thereby violating the universal right to health. This memo focuses on Abbott’s responsibility with respect to the universal right to health and how Abbott *has* addressed, *is* addressing and *should* address this universal human right.

Among other concerns about Abbott’s business practices and product pipeline, human rights activists are most concerned about Abbott’s failure to make available two of its life-saving antiretroviral drugs. Norvir (ritonavir), approved by the FDA in 1996, is a protease inhibitor, which impedes the human immunodeficiency virus’s (HIV) ability to reproduce itself.¹⁴ Norvir is widely used in drug combinations, as small doses of Norvir boost the effectiveness of other protease inhibitors.¹⁵ In 2000, Abbott introduced Kaletra (lopinavir+ritonavir), a single-pill combination of Norvir and a new Abbott-made protease inhibitor. The lopinavir/ritonavir combination pill has been deemed an essential medicine by the World Health Organization (WHO)¹⁶ and is included in its antiretroviral treatment guidelines. According these WHO guidelines, boosted protease inhibitors—such as Kaletra—represent the cornerstone of second-line therapy.¹⁷ In October 2005, Abbott received FDA approval for a new tablet version of Kaletra that does not require refrigeration, does not have to be taken with food, and requires fewer pills per day than the original capsule version. These three improvements make the newer tablet form of Kaletra ideal for resource-poor settings, including most developing countries.

Human rights at issue:

Although patients, doctors and activists agree that governments have the primary responsibility for ‘progressively realizing the right to health’ in their own countries—by, for instance, ensuring universal access to the health care systems and to essential medicines—they also acknowledge that governments cannot fulfill the right to health on their own. Many of the critical life-saving medicines are made and marketed by large Western pharmaceutical companies and are priced out of reach of millions of poor patients and of the impoverished governments trying to purchase the medicines to provide to their citizens. Therefore, governments and the public continue to emphasize “the crucial role and responsibilities” of the pharmaceutical industry “in the promotion and protection of the right to health.”¹⁸ Abbott has come under fire several times for failing to recognize its responsibility to promote and protect the right to health and for its business practices that directly contradict this responsibility. This section highlights only a handful of specific violations of the right to health for which Abbott has been criticized.

The 10/90 Gap: Failure to respond to global health needs

Only 10% of the approximately \$80 billion spent on health research annually by the public and private sectors is spent on the needs of 90% of the world’s population that live in the developing world.¹⁹ While the amount of Abbott’s health research budget spent on the health needs of the poor is not publicly known, it is clear that Abbott is not heavily invested in researching and developing affordable life-saving drugs for the so-called ‘neglected diseases’ that account for millions of deaths per year in the developing world. The lack of essential medicines for these diseases—including tuberculosis, malaria, respiratory infections, and diarrhea—results partly from drug companies’ unwillingness to conduct research into their cures and partly because when a cure *has* been developed, it is priced far out of reach of the patients who need it most.²⁰ In order to fulfill its responsibility to promote and protect the right to health, therefore, the concerned public has called on Abbott to invest more heavily in the needs of the 90% of

the population in developing countries and to “work in partnership with governments and others to close health disparities.”²¹

Pricing: Favoring patent protection and profit over saving lives

Along with all of the other top-20 R&D pharmaceutical companies, Abbott continues to advocate strongly for the protection of patent rights, even where protecting these rights will conflict with governmental health initiatives to protect the right to health of its citizens. One legal scholar has said that by withholding affordable life-saving medicines in order to preserve intellectual property rights, Abbott is “playing a deadly game of Pharmaceutical Apartheid.”²² Abbott is currently embroiled in a legal battle in India, where NGOs and generic drug companies are opposing Abbott’s application for patent protection for its three antiretrovirals. The NGOs claim that these drugs are “not true innovations” but are rather “old molecules, which have been slightly modified or patented for a new use,” which is not in compliance with Indian patent law.²³ Generic versions of these drugs, already available in India, would need to be withdrawn if the new patents are granted, threatening the lives of HIV patients who rely on affordable generic drugs in India and other developing countries.²⁴ Abbott was also criticized in the United States for a 400% price increase in patent-protected Norvir in 2003, which made it significantly more difficult for patients relying on drug combinations with Norvir to get their medicine.²⁵

Availability - Not just talking the talk

Abbott states on its website that it registers its drugs all over the world and offers price discounts through its access programs in developing countries. However, Abbott has been widely criticized for not following through with its commitment, as its drugs are often “more difficult or expensive to obtain than claimed.”²⁶ For instance, Médecins Sans Frontières (MSF), and international NGO that helps provide treatment in developing countries, has been complaining that Abbott has not made Norvir or Kaletra available in China despite their registrations in 2002 and 2003 respectively. MSF has been contacting

Abbott about “the growing and urgent” need in China for second-line therapies such as Kaletra since 2004, but neither the old nor the new version has yet been made available.²⁷

Thailand: A threat of withdrawal

Abbott has most recently been in the news for its dispute with the Thai government, during which Abbott threatened to pull several life-saving medicines from Thailand, threatening the lives of Thais who need access to these drugs for survival.²⁸ Since 2001, every Thai citizen (including the 580,000 people living with HIV/AIDS) has been covered under one of three national health insurance plans.²⁹ Currently, the government is treating more than 82,000 HIV-positive people, however with increasing drug prices for second-line HIV drugs and a limited health budget, the government has been unable to fulfill its commitment to universal access to essential medicines, including antiretrovirals.³⁰ Thus, in January 2007, in compliance with TRIPS article 31(b)³¹ and section 51 of the Thai Patent Act, the Thai government issued a compulsory license allowing it to produce a lower-cost version of Kaletra.³² The legality under domestic and international law of the compulsory license was confirmed by Susan Schwarb, the United States Trade Representative³³ and by Dr. Margaret Chan, the Director General of the WHO.³⁴

Abbott responded by withdrawing registration applications for its new heat-stabilized Kaletra tablet, which is especially important for countries like Thailand with warm climates and poor patients who are not likely to have access to refrigerators.³⁵ In addition, Abbott threatened to withdraw other life-saving medicines from the Thai market.³⁶ When there are no generic versions or therapeutic equivalents available, withdrawing these drugs “is equivalent to taking patients off medical life support.”³⁷ Abbott’s response been publicly criticized as “profoundly cynical and immoral,”³⁸ and its withdrawal of life-saving treatments has been condemned as a violation of the universal right to health.

Past Human Rights Issues

As the human rights at issue are at the core of Abbott's business—the development and marketing of life-saving medicines—Abbott has been dealing with similar human rights issues for many years. In a very public dispute in February 1998, Abbott, along with 38 other multinational pharmaceutical manufacturers and the South African Pharmaceutical Manufacturers Association brought a lawsuit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act No. 90 of 1997 violated TRIPS and the South African Constitution.³⁹ The Amendment Act, which introduced a legal framework to increase the availability of affordable medicines in South Africa, included provisions for the generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines.⁴⁰ The legal action “turned into a public relations disaster for the drug companies,” as public demonstrators, several governments around the world, and medical professionals demanded that the pharmaceutical companies drop the lawsuit.⁴¹ Eventually, in April 2001, the “strong international public outrage” and the “companies’ weak legal position” led the companies to drop the case.⁴²

In another high-profile dispute in 2005, Brazil and Abbott fought over the price of Kaletra in the Brazilian market. Since the mid-1990s, Brazil has offered comprehensive AIDS care, including universal access to ARVs. Kaletra is one of 17 medications that doctors had been using to treat 170,000 Brazilians covered by the AIDS program in 2005, yet Kaletra alone accounted for nearly a third of the program's costs.⁴³ Following months of negotiations and threats from Brazil that it would issue a compulsory license if Abbott didn't lower the drug's price to an affordable price, Abbott finally agreed to lower the price of Kaletra significantly. In the final agreement, Abbott lowered the drug's price to 63 cents per pill from \$1.17 cents per pill and donated \$3 million worth of other pharmaceutical products, saving the government an estimated \$339.5 million from 2006 to 2011.⁴⁴ In return, Brazil committed to purchasing Kaletra from Abbott only through 2011.⁴⁵

International Human Rights Standards

Access to essential medicines implicates several international human rights standards: the right to life, the right to health, the right to the benefits of scientific progress, and the rights to education, to work, and to an adequate standard of living.

The Right to Life

The right to life is the most basic of all rights and underlies all human rights treaties and declarations.⁴⁶ The right to life is clearly stated in Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR): “[The right to life] shall be protected by law. No one shall be arbitrarily deprived of his life.”⁴⁷ As one scholar explained, “medications can be indispensable for life,” so policies that diminish accessibility or affordability of certain medications “will, in effect, deprive people of life.”⁴⁸ The Human Rights Committee of the United Nations which monitors implementation of the ICCPR has stated that the right to life not only prohibits the State from directly causing death but also imposes positive obligations on the State to *protect* life, including obligations to reduce infant mortality, increase life expectancy, and eradicate epidemics.⁴⁹ Legally, many international and domestic courts have held or implied that the right to life includes the right to live with human dignity, and that the right to live with dignity includes the right to health.

The Right to Health

The core provision on the international right to health is article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. [Steps required] include those necessary for...[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases” and “[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness.”⁵⁰ Through a series of UN documents, the formal

content and scope of the right to health has been further clarified and has become increasingly specific with respect to access to essential medicines.⁵¹

In May 2000, the Committee on Economic, Social and Cultural Rights, which at times issues authoritative interpretations of specific treaty provisions, adopted General Comment No. 14 on the “Right to the Highest Attainable Standard of Health.” The Comment explained that the right to health includes “the provision of equal and timely access to basic ... curative ... health services ... ; appropriate treatment of prevalent diseases ... ; and the provision of essential drugs ...”⁵² Furthermore, the Comment recognized that universal access to essential medicines is a core, non-derogable duty of all member States as is preventing, treating, and controlling epidemic and endemic diseases.⁵³ Although the comment primarily addresses the obligations of States, it also emphasizes that the private business sector has responsibilities regarding the realization of the right to health.⁵⁴

The following year, the Commission on Human Rights in 2001 adopted a resolution on access to medicines in the context of pandemics such as HIV/AIDS; the resolution reaffirms that access to essential medicines in this context is a fundamental element of the right to health.⁵⁵ Finally, the right to health is also included in several other international treaties, including the Convention on the Rights of the Child, the International Convention on the Elimination of All Forms of Racial Discrimination, and the Convention on the Elimination of All Forms of Discrimination against Women, and in several regional human rights instruments.

The Rights to the Benefits of Scientific Progress

Several scholars and activists have noted that the immense disparities in access to essential medicines across the globe are “starkly inconsistent with the notion of a universal right to benefit from scientific progress.”⁵⁶ Article 15 of the ICESCR states that parties “recognize the right of everyone...[t]o enjoy the benefits of scientific progress and its applications.”⁵⁷ In 2001, the ESCR Committee adopted a General Statement on “Human Rights and Intellectual Property” which makes clear that the right to enjoy the benefits of scientific progress- which include medication- must be respected in the realm

of international trade any intellectual property regime must include provisions for protecting the public health.⁵⁸

The Rights to an Adequate Standard of Living, Social Security, Education, and Work

The Universal Declaration on Human Rights states that “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including ...medical care and necessary social services, and the right to security in the event of ...sickness...or other lack of livelihood in circumstances beyond his control.”⁵⁹ Access to essential medicines “both reflects and has a direct bearing on” the right to an adequate standard of living and to social security; furthermore, access to essential medicines is necessary for millions of sick people to be able to attend school and to work.⁶⁰ As a legal scholar has said, “[a]ny remaining possibility for individuals stricken with drug-resistant tuberculosis or malaria, HIV/AIDS...to have choices and agency in their lives—which is both the underlying premise and promise of human rights—evaporates when access to medications is denied.”⁶¹

Acceptance and Enforceability of the Human Rights Standards

Each of the aforementioned rights implicated by access to essential medicines has achieved different degrees of acceptance and justiciability internationally and in domestic courts, particularly with respect to their application to access to medicine concerns. For instance, the right to life is generally universally accepted; however only a limited number of international and domestic courts have considered the ‘right to essential medicines’ to be included in the ‘right to life,’ and certainly *any* claim that there is a human rights-based right to essential medicines has been strongly opposed by developed countries and their research-based pharmaceutical industries.⁶² The other economic and social rights outlined above have undergone normative development, international clarification and legal interpretation in recent years, but there remain significant barriers to state accountability and legal enforcement: the language remains vague enough that the specific obligations of states are often unclear; the relevant treaties call for the

‘progressive realization’ of these rights yet there are no benchmarks for monitoring progress; and often the fulfillment of these rights relies on a partnership between states (which are obligated to respect the rights) and the private sector (whose legal obligation to protect these rights are unclear at best or strongly refuted.)

Although the ‘right to essential medicines’ may be difficult to enforce under the aforementioned international legal treaties, there are many binding international agreements and national laws that legally protect the same rights without relying on the language of human rights. For instance, the WTO agreement on TRIPS, which provides a legally enforceable framework for enforcing Intellectual Property Rights globally, allows flexibilities for developing countries to ensure access to affordable high-quality drugs. One such flexibility is the right to issue a compulsory license, by which the government allows another party to produce the patented product without the consent of the patent owner.⁶³ In 2001, WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health, which clarifies some of the flexibility contained in the TRIPS Agreement and emphasizes that it should be interpreted “in a manner supportive of WTO members’ right to protect the public health and, in particular, to promote *access to medicines for all*.”^{64,65}

In several countries, national courts have found that the State has an obligation to protect the right to health, which includes an obligation to provide essential medications. A recent study looked at 71 court cases from 12 low-income and middle-income countries in which “access to essential medicines was claimed with reference to the right to health.”⁶⁶ The study found that in “59 cases, access to essential medicines as part of the fulfillment of the right to health could indeed be enforced through the courts, with most coming from Central and Latin America.”⁶⁷ The study determined that the success was primarily linked to constitutional protections of the right to health, supported by the human rights treaties. The study found that claiming “a link between the right to health and the right to life” the support of “public-interest non-government organizations” were also factors of success.^{68,69}

Finally, most countries have comprehensive marketing, patent and competition laws that reserve some control for the government over the marketing and patenting of products, including medicines. Several countries have their own compulsory license

provisions in their patent laws; for instance, a U.S. law permits no-prior-negotiation government use by the federal government and its contractors under certain conditions.⁷⁰ Further examples of domestic laws that can legally protect access to medicines will be discussed later in the memo in the case of Thailand.

Corporate human rights initiatives

Although many of Abbott's stakeholders (patients, prescribing physicians, purchasing governments) and critics (student groups, consumer groups, NGOs, the media) frequently use human rights language when discussing access to essential medicines, Abbott has never mentioned the right to health or any other human right in its business description, access programs, or public statements. Abbott maintains that the existing access-to-medicines issues in developing countries are due to poor health infrastructure and inadequate government programs; Abbott has ignored the response of humanitarian organizations such as MSF and Partners in Health who have been able to demonstrate that it is possible to deliver high quality ARVs even in the most resource poor settings when the pharmaceutical companies ensure that the drugs are affordable, registered and available in the developing countries. The organizations argue that the access issues are largely due to the patent protections and the monopoly pricing schemes which, even when discounted, still leave the prices of life-saving drugs far out of reach. Abbott consistently maintains, however, that "Abbott's HIV patents are not preventing access to HIV treatment in developing countries."⁷¹

Abbott states on its website that it "has made its HIV medicines and a rapid HIV test broadly available at significantly reduced prices to people with HIV in 69 developing countries."⁷² However, Abbott does not address the NGO complaints that even in countries where Abbott has registered its drugs and has discounted the prices, the drugs are not *physically* available, seriously discrediting Abbott's access programs. Abbott also does not list its pricing schemes for low-middle and middle income countries, including Thailand and Brazil, where the life-saving drugs are up to ten-times more expensive than in the least-developed countries and remain unaffordable for the patients and governments alike. Nowhere in its literature or on its website does Abbott report on the

status of the registration and availability of its drugs in developing countries; for instance, although Abbott says it will price the new version of Kaletra at the same price as the capsule version and register it widely, it is still unavailable outside of developed markets. Abbott’s literature on ‘expanding access to treatment and testing’ focuses largely on its philanthropic initiatives; for example, Abbott notes on its website that it has “donated more than four million rapid HIV tests to prevention programs throughout the developing world.”⁷³ Abbott fails to mention human rights, the right to health, or any voluntary access-to-medicine responsibilities in its code of conduct.⁷⁴

Multi-stakeholder initiatives

Although Abbott collaborates with “hundreds of organizations globally,”⁷⁵ only a few of the organizations focus on issues related to human rights or access to treatment. Abbott was one of the founding partners of the Accelerating Access Initiative (AAI), a cooperative endeavor of UNAIDS, WHO, UNICEF, the UN Population Fund, the World Bank, and seven research-based pharmaceutical companies to provide better access to ARVs.⁷⁶ However, NGOs have often criticized AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.⁷⁷ Abbott also initiated the Abbott Global AIDS Care program, a “unique public-private partnership comprising Abbott, the Abbott Fund and the government of Tanzania” to strengthen Tanzania’s health care system “to meet the needs of people with HIV and other lifelong diseases.”⁷⁸ Although these initiatives address issues of health and access to treatment, none of them addresses the ‘right to health’ or any other human rights.

Legal and business risks

Sphere of Influence

Abbott’s sphere of influence over the ‘right to health’ and access to medicines is extensive. Unlike in other businesses for which issues of human rights often occur as a byproduct of the business’ operation—such as labor conditions in a workplace or security concerns at a company’s plantation or extraction site—access to medicines is at the *core*

of Abbott's business. Furthermore, Abbott markets in 130 countries and has 100 facilities worldwide; its geographic presence increases its sphere of influence beyond the developed world into all countries in which Abbott markets its products and benefits from sales. Abbott's size augments its influence in each of the locations its business touches, as it has the financial capacity as well as political influence to monitor and shape its business practices in each country in which it markets. The concept of a 'sphere of influence' suggests that the more control a company has over a situation with human rights impacts—or the potential to bolster the respect for human rights—the more responsibility the company has to address and improve the human rights. Using this concept, Abbott not only has extensive control over its product line (and new product development) and ensuring that the product is physically accessible and affordable worldwide, but also has the unique means to improve respect for the right to health, and in the case of AIDS and other treatable diseases, the right to life. Although Abbott has business relationships with governments worldwide and therefore a certain degree of influence, the largest limitation to Abbott's influence over the right to health in certain countries is the government's infrastructural limitations to making medicines available to its citizens; however, to an extent, Abbott could financially support a country's healthcare infrastructure, as it has in Tanzania.

Critical Actors

Second to Abbott, the most critical actors affecting the right to health and access to medicines are governments who monitor the registration of drugs, structure the country's healthcare systems, budget for drug procurement, and institute insurance schemes. Other major actors include international NGOs, including MSF and Partners in Health, who assist with the procurement of affordable drugs and the distribution of essential medicines to poor patients around the globe. Finally, international organizations including the WHO and WTO, who respectively regulate international health programs and international trade, affect the realization of the right to health by compiling the list of essential medicines, pre-qualifying certain essential drugs for registration, creating the legal framework for intellectual property rights and exceptions to patent protections, etc.

Legal Risks

Under current international law, Abbott has no *legal* obligations under international human rights treaties. Although Abbott's prohibitively high prices for its essential drugs have made it more difficult for governments to ensure the health of its citizens, it is unlikely that Abbott would be found complicit in a human rights violation under the Alien Tort Statute or other international or domestic laws. First, countries have typically been brought into court over 'right to health' issues under their respective domestic laws, as it is difficult to prove a violation of the obligation under international law to *progressively realize* the right to health of a country's citizens. Second, there are safeguards in place for a country to provide for the health of its citizens without the assistance of pharmaceutical companies—such as compulsory licenses—so that excessive drug pricing and other pharmaceutical business practices can not be the direct cause of lack of access to treatment or health care.

Pharmaceuticals may not be legally responsible under international law for the right to health. However, there are increasingly examples of domestic legal systems where legislation has been used to challenge pharmaceutical companies' restrictive policies. These lawsuits are most often based on competition, marketing or patent laws. For instance, in 2001, the South Africa Treatment Action Campaign filed a complaint with the South Africa Competition Commission against GlaxoSmithKline and Boehringer Ingelheim for excessive pricing of first-line AIDS drugs. In 2003, the South African Competition Commission found the companies were dominant in their respective markets⁷⁹ and that the companies had abused their dominance by excessive pricing and refusing to license generics. South Africa now produces and imports low-cost versions of both drugs and exports them to countries in sub-Saharan Africa.⁸⁰

Thailand has similar competition laws to those in South Africa and several other countries that prohibit dominant companies from abusing their market power. Section 25(1) of Thailand's Competition Act prohibits "unreasonably fixing or maintaining purchasing or selling prices of goods or fees for services," and section 25(3) prohibits a

dominant firm from “suspending, reducing or restricting services, production, purchase, distribution, deliveries, or importation without justifiable reasons.”⁸¹ Abbott’s withholding or withdrawing drugs from the Thai market would likely violate these provisions, and penalties could include financial penalties against Abbott, “reductions, including to zero, of royalty payments [of compulsory licensed products] and authorizations of exports of compulsory licensed products outside of Thailand.”⁸² There have been previous cases in which the Thai Competition Commission has found anti-competitive market segmentation strategies to be anti-competitive under the ‘refusal to supply’ doctrine, which may suggest that the Commission would be receptive to a similar challenge against Abbott.⁸³

In addition to the potential legal challenges in national courts in countries in which Abbott markets, there may be long-term legal risks to ignoring the societal demand for pharmaceutical companies to address access-to-medicine concerns. Daniel Vasella, Chairman and CEO of Novartis, noted in November, 2000, that increased societal demands for corporate responsibility and ethical conduct have been driving change, and “unless the pharmaceuticals industry achieves its objective of being an accepted and valued player in society, we will be at a disadvantage in every new law and regulation that comes up.”⁸⁴ David Kessler, the former administrator of the FDA, agreed, adding that “at stake is the very patent protection system that allows them to control drug prices. If they want to keep the power of pricing their products, they must bend for a true international crisis...saving lives in South Africa and around the globe may be the best way for the pharmaceutical industry to save itself.”⁸⁵

Business Risks

Abbott’s disputes with less-developed countries including Thailand, Brazil and South Africa have been made very public by the media and interested stakeholders, and in each case, Abbott’s unwillingness to respond to the urgent needs of millions of patients who would die without life-saving treatment was met by public criticism, boycotts, and protests which received media coverage of their own. Given the severity of the public health crisis and the immorality of valuing profits over saving lives (as many

stakeholders view the tradeoff), these public campaigns have been damaging to Abbott's reputation, which could be a serious business risk in the long run. As one scholar noted, "It is now often argued that a company's corporate social responsibility record has an impact on the bottom line through its effect on the company's "reputational capital," and that there is an empirical connection between reputation-goodwill and firm market value."⁸⁶

In March 2007, 16 faith-based institutional investors with approximately \$35 million in Abbott Laboratories holdings issued a public statement calling on Abbott to reverse its decision to withdraw new drug applications from Thailand. The statement said, "Several well known and highly regarded public health organizations have condemned this action and influential media organizations have taken a negative view of Abbott's actions. We believe the company is overlooking risks that can have a serious effect on brand, its relationships with patients, and ultimately, shareholder value."⁸⁷

In addition to the risk to Abbott's reputation in the long-run, Abbott's actions led to boycotts of its products by medical professionals—the group of stakeholders that Abbott relies on for prescribing and selling their products in their major markets. On March 26, 2007, the American Medical Student Association, representing over 68,000 physicians-in-training, issued a statement that AMSA "stands in solidarity with Thai colleagues in their national day of action protesting Abbott's alarming decision" and encouraging "future and current US healthcare professionals to boycott visits and telephone calls from representatives of Abbott until the company supplies all withdrawn medicines to Thai markets. AMSA calls on its physician colleagues to shut the door on Abbott as Abbott has shut the door on patients in Thailand."⁸⁸

The potential financial loss of a boycott of Abbott's products by consumers and medical professionals in its major markets would be more damaging than Abbott's imagined business risk of lowering its prices in developing markets or issuing licenses. Although Abbott and other drug companies state in public that compulsory licenses interfere with their R&D incentives, developing countries' compulsory licenses have never affected their monopoly profits in rich country markets.⁸⁹ This is particularly true as countries often have strict criteria that they apply before deciding to issue compulsory licenses; for instance, Thailand estimates that with its criteria for compulsory licenses,

they will only consider licenses for fewer than 15% of medicines.⁹⁰ Furthermore, compulsory licenses do “not touch on the out of pocket payment market, the current market of patented drugs. [Compulsory licenses] only open new markets for those who never had access to these drugs before.”⁹¹

Influential Stakeholders and Tactics

Several groups of Abbott’s stakeholders could play an important role in addressing Abbott’s response to the right to health. First, as mentioned above, physicians in major markets could severely impact Abbott’s marketing and sales by boycotting Abbott products. Abbott’s primary marketing efforts are directed toward encouraging physicians to prescribe Abbott’s products. When massive groups of doctors or doctors-in-training band together to boycott Abbott products and to bar company sales representatives from entering their offices, Abbott is very likely to respond. A local or global boycott of Abbott’s products would likely be an effective tactic to influence the company’s practices. A critical mass of consumers boycotting Abbott’s products would also likely be influential, but the number of consumers boycotting would have to far exceed the number of physicians boycotting Abbott’s products to have the same impact on Abbott.

Abbott consumers and activists could also launch complaints with Competition Commissions in their respective countries, as competition complaints escalate the pressure on Abbott “by triggering a legal proceeding to which it must respond and spend resources defending.”⁹² Furthermore, competition complaints provide “an opportunity for media events, drawing local and international attention to Abbott’s behavior...[and records produced during the investigation] may become public through freedom of information laws or other means.”⁹³ Finally, under TRIPS, compulsory licenses that are issued on the grounds of unfair competition can authorize “unlimited exports and lower royalty payments (including to zero) as a penalty, thus decreasing local prices and providing opportunities for local developmental benefits through exports.”⁹⁴ Most competition laws allow any interested party to file a complaint; it is not usually required that the filer be a competitor or even a consumer of the company’s product.”⁹⁵

Governments can also be influential stakeholders by threatening to issue compulsory licenses when Abbott refuses to offer affordable prices for its products. In Brazil, for instance, once the government threatened to issue a compulsory license, Abbott was more inclined to negotiate a more favorable package for its life-saving drugs in Brazil. Finally, activist groups can be influential when they draw public attention to Abbott's monopolistic business practices, as negative press coverage can trigger other stakeholders to join the campaign and can damage Abbott's reputation and potentially lower its stock value. On April 26, 2007, activists have planned a 'Global Day of Action,' including demonstrations at an Abbott facility in Massachusetts, and other activists have planned large demonstrations at Abbott's annual shareholder meeting in Chicago on April 27, 2007. The *Financial Times* noted last year that "there is little doubt that activist pressure...[has] helped push the pharmaceutical companies to offer more generous terms in their access programs."⁹⁶

Recommendations

Achieving widespread access to medicines will require a broader response to the public health crisis, including responsible actions by developing country governments, donor governments, the private sector and other members of society. Pharmaceutical companies play an important role in the broad response to the health crisis. Today's social contract, on which pharmaceutical companies depend to finance R&D and protect intellectual property, demands companies to take creative, wide-ranging steps to increase access to medicines and help protect the universal right to health.⁹⁷ Abbott's present response to access to medicine issues is inadequate; Abbott engages in one dispute after another with developing countries: shirking its responsibility to address the right to health within its sphere of influence, engaging in expensive and time-consuming negotiations and litigation over patent rights in markets that account for less than 1% of global pharmaceutical sales, and drawing negative publicity and damage to its reputation in the process.

It is also important that Abbott address the right to health through responsible company behavior, and not through philanthropy alone."⁹⁸ While Abbott's philanthropic

programs and donations of HIV tests and treatments are laudable, “the existence of such handouts does not address the question of affordability in the long term...In addition, it is possible that these ad hoc responses and the infrequency with which AIDS drugs are consumed in Africa may contribute to the creation of drug-resistant strains of the virus.”⁹⁹ Abbott should integrate its ‘access to treatment and prevention’ programs into its business model to ensure sustainability and effectiveness. Abbott should regularly monitor the success and impact of its access programs and report regularly to its shareholders about the programs. Integrating access programs into the business model would also improve Abbott’s image, as it would be clear to shareholders and investors that Abbott was committed to access-to-medicine issues and recognized its global responsibility as a large drug company.

Best Practices

Several investor groups, concerned about the inadequate responses of pharmaceutical companies to the public health crisis, have outlined best practices for the companies going forward. For example, in March 2003, the Pharmaceutical Shareowner Group, along with 12 investor signatories, published the *Investor Statement on Pharmaceutical Companies and the Public Health Crisis in Emerging Markets*,¹⁰⁰ which stressed that as well as the ethical imperative, an inadequate response to the issue could impact upon long-term shareholder value.¹⁰⁰ The statement sets out a framework of good practices for companies to consider in their management decisions and disclosures; it is also intended as a tool for investors and analysts to assess the long-term investment value of pharmaceutical companies.¹⁰¹

Abbott should revise its differential pricing scheme so that drugs are not only affordable in low-income countries but in low-middle and middle income countries as well. Abbott should ensure the availability and affordability of its drugs in markets where it claims to be registered; this may involve working with other stakeholders including NGOs who are on the ground in the developing countries and are effectively monitoring whether drugs are *actually* available at the listed prices. Abbott should issue voluntary licenses to a range of generic suppliers with technology transfers; this would not only

lower the opportunity cost of producing drugs which sell at non-profit prices, but would also give Abbott the ability to control the risk of diversion by setting clear, consistent guidelines and standards for licensees which would not be possible under compulsory licenses.

Abbott should continue to engage with stakeholders as it claims to do, but Abbott could also benefit from additional partnerships. For instance, Novartis has used its support for the UN Global Compact as a lever for modernizing its approach to corporate responsibility, which investors responded to favorably.¹⁰² Pharmaceutical companies Aventis, Pfizer and Novo Nordisk are also signatories to the Global Compact. Abbott should also look into joining the Global Business Coalition on HIV/AIDS, which assists over 170 member companies address HIV/AIDS in their businesses.

Reporting on Human Rights Initiatives

Abbott should not only indicate to its shareholders and the public that it recognizes its responsibilities to protect the right to health as a global pharmaceutical company, but it should also articulate the business case for its public health response. Reporting on the business case will be valuable for current and potential investors and will help the company manage future risk. Furthermore, Abbott should include an objective assessment of the options available for expanding access to medicines, and report systematically on its goals and activities so that performance can be evaluated transparently.¹⁰³ The Global Reporting Initiative (GRI) is considered a useful model for corporate disclosure on social, environmental and ethical issues.¹⁰⁴ One strength of GRI is its multi-stakeholder approach, which has ensured that the framework is respected by governments, business, investors and non-governmental organizations. Pharmaceutical companies Aventis, Bristol-Myers Squibb, Johnson & Johnson, Novartis and Novo Nordisk have already incorporated the GRI model in their reporting.¹⁰⁵

Conclusion

Pharmaceutical companies are uniquely positioned to address the rights to health and to essential medicines that are widely recognized by civil society and increasingly enforced by national and international courts. Although pharmaceutical companies cannot be solely responsible for universal access to medicines, they must do more than they are currently doing to not risk losing the social contract on which they rely. For Abbott, the benefits of taking these steps—some of which are substantial—not only outweigh the potential costs incurred but also outweigh the almost definite costs to Abbott of inaction and lagging behind competitors’ response to the crisis. There is still room for a leader in the pharmaceutical industry’s response to the public health crisis, and if Abbott accepts the challenge, Abbott in particular—and the rest of the world in general—stands to gain.

¹ Abbott Laboratories website, http://www.abbott.com/global/url/content/en_US/40:40/general_content/General_Content_00035.htm.

² Abbott Laboratories Fast Facts, http://www.abbott.com/global/url/content/en_US/10.17:17/general_content/General_Content_00054.htm.

³ IMS Health, http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_77491316,00.html.

⁴ Henderson Global Investors, *Fulfilling its Potential: Sustainability, Responsibility and Ethics in the Pharmaceutical Industry, An Agenda for Change 2* (2003).

⁵ A “blockbuster” drug is a drug that exceeds \$1 billion in sales in a given year.

⁶ IMS Health, *supra* note 3.

⁷ Henderson Global Investors, *supra* note 4, at 2. The TRIPS agreement will be discussed more extensively in a later section of this memo.

⁸ *Id.* at 1.

⁹ *Id.* at 3.

¹⁰ *Id.*

¹¹ *Id.* at 1.

¹² John Carreyrou, *Inside Abbott’s tactics to protect AIDS drug*, Wall Street Journal, Jan. 3, 2007, at A1.

¹³ Henderson Global Investors, *supra* note 4, at 1.

¹⁴ John Carreyrou, *supra* note 12.

¹⁵ John Carreyrou, *supra* note 12.

¹⁶ For thirty years, the World Health Organization’s “Essential Drugs List” has identified medicines that are most important to meet the health care needs of the majority of the population and should therefore be available and affordable. The Essential Drugs List is updated every two years. The current version (March 2007) includes 19 antiretrovirals and nearly 100 other medicines for HIV-related care, including drugs for treating and preventing opportunistic infections. <http://www.who.int/medicines/publications/EML15.pdf>

¹⁷ Second-line treatments are becoming increasingly necessary as patients build resistance to first-line medicines. Currently, even at their discounted prices, second-line drugs cost four to ten times more than the first-line treatments.

¹⁸ Media Release from the South African Competition Commission, Oct. 16, 2003. (following a ruling against GlaxoSmithKline for excessive pricing of its drugs in South Africa)

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- ¹⁹ See e.g., Global Forum for Health Research, 10/90 Report on Health Research 2003-2004 (2004).
- ²⁰ Brook Baker, *The Power of Pills: Placing Access to Essential Medicines on the Human Rights Agenda*, (June 23, 2005) (unpublished manuscript)
- ²¹ Henderson Global Investors, *supra* note 4, at 11.
- ²² Brook Baker, Health GAP, *Standing Up To Abbott's Decision to Withhold Registration and Marketing of Life-Saving Medicines*, Mar. 13, 2007.
- ²³ Noemie Bisserbe, *It's patent vs patient in AIDS fight*, Economic Times News Network, Feb. 15, 2007.
- ²⁴ Generic competition has allowed reducing the cost of treatment of HIV from \$10,430 per year in 2001 to \$132 per year today. NGOs purchase more than 80% of their drugs from India for treatment programs in other developing countries. *Id.*
- ²⁵ John Carreyrou, *supra* note 12
- ²⁶ Andrew Jack, *The Drug Companies: A new mood of cooperation*, Financial Times, Dec. 1, 2006.
- ²⁷ K. Hartsough et al., Interfaith Center on Corporate Responsibility, *Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets* (2006)
- ²⁸ Press Release, Christian Brothers Investment Services, CBIS and ICCR Urge Abbott Labs to Keep HIV/AIDS Drug on the Shelf in Thailand (Mar. 22, 2007)
- ²⁹ Ministry of Public Health and National Health Security Office of Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand 1* (2007)
- ³⁰ Abbott Offers to Lower Price of Antiretroviral Kaletra for Thai Government Health Programs, Feb. 9, 2007, http://www.kaisernet.org/daily_reports/rep_index.cfm?DR_ID=42829
- ³¹ TRIPS will be discussed more extensively in the next section.
- ³² Brook Baker, Health GAP, *Pharma's Seven Deadly Lies about Thai Compulsory Licenses*, Apr. 5, 2007.
- ³³ Ministry of Public Health and National Health Security Office of Thailand, *supra* note 29, at 53.
- ³⁴ *Id.* at 58.
- ³⁵ Brook Baker, *supra* note 22.
- ³⁶ The six other drugs are the painkiller Brufen; an antibiotic, Abbotix; a blood clot drug, Clivarine; the arthritis drug Humira; the high-blood pressure drug, Tarka; and the Kidney disease drug, Zemplar. Brook Baker, Health GAP, *A New Low in the Pharma Drug Wars*, Mar. 14, 2007.
- ³⁷ *Id.*
- ³⁸ Brook Baker, *supra* note 22.
- ³⁹ Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa. Case No 4183/98, filed Feb 18, 1998.
- ⁴⁰ Health Care and Intellectual Property: Parallel Imports, www.cptech.org/ip/fsd/health-pi.html.
- ⁴¹ Cooper H. et al., *Patents Pending: AIDS Epidemic Traps Drug Firms In a Vise: Treatments vs. Profits*, Wall Street Journal, Mar. 2, 2001, at A1.
- ⁴² Ellen F. M. 'T Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond* 43-44, July 24, 2003.
- ⁴³ Paulo Prada, *Brazil Near Deal with Abbott for Price Cut on AIDS Drug*, New York Times, Oct. 5, 2005.
- ⁴⁴ *Id.*
- ⁴⁵ Brook K. Baker, *supra* note 32.
- ⁴⁶ Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right under International Law*, 21 B.U. Int'l L. J. 325, 330 (2003)
- ⁴⁷ International Covenant on Civil and Political Rights, G.A. Res. 2200, U.N. GAOR, Supp. No. 16, at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, 174 (entered into force Mar. 23, 1976) [hereinafter ICCPR]
- ⁴⁸ Alicia Ely Yamin, *supra* note 46.
- ⁴⁹ *The Right to Life*, U.N. GAOR Human rights Comm., 37th Sess., Supp. No. 40, at Gen. Comment No. 6, para. 5, U.N. Doc. A/37/40 (1982).
- ⁵⁰ International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), UN Doc. A/6316 (1966), art. 12, 993 U.N.T.S. 3 (entered into force Jan. 3, 1976) [hereinafter ICESCR]
- ⁵¹ Brook Baker, *supra* note 22.
- ⁵² United Nations Committee on Economic, Social, and Cultural Rights (CESCR), General Comment 14: The right to the highest attainable standard of health (Art. 12), U.N. Doc. E/C.12/2000/4 (2000), para. 17.
- ⁵³ *Id.* at para. 43(d) and 44(c).
- ⁵⁴ *Id.* at para. 42.

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- ⁵⁵ Commission on Human Rights resolution 2001/33: Access to medication in the context of pandemics such as HIV/AIDS, E/CN.4.RES.2001.33 (adopted Apr. 20, 2001).
- ⁵⁶ Alicia Ely Yamin, *supra* note 46, at 343.
- ⁵⁷ ICESCR, *supra* note 50, art. 15.
- ⁵⁸ *Human Rights and Intellectual Property*, U.N. Comm. On Econ., Soc. & Cultural Rts., 27th Sess., para. 2, U.N. Doc. E/C.12/2001/15 (2001)
- ⁵⁹ *Universal Declaration on Human Rights*, G.A.Res. 217A, U.N. GAOR, 3d Sess., art. 25(1), U.N. Doc A/810 (1948) [hereinafter UDHR]
- ⁶⁰ Alicia Ely Yamin, *supra* note 46, at 341.
- ⁶¹ *Id.* at 342.
- ⁶² Brook Baker, *supra* note 22.
- ⁶³ “TRIPS and Health: FAQs on Compulsory licensing of pharmaceuticals and TRIPS,” World Trade Organization. Available at: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
- ⁶⁴ World Trade Organization, *Declaration on the TRIPS Agreement and Public Health (Doha Declaration)*, WT/MIN(01)/DEC/2 (Nov, 2001), para. 4 (emphasis added).
- ⁶⁵ Several countries have incorporated provisions in their domestic trade laws that mandate that their trade policies respect other nations’ public health initiatives under Doha. *See e.g.*, U.S. Trade Promotion Authority Act (P.L. 107-210), August 6, 2002 §2102(b)(4)(c)
- ⁶⁶ Hans V Hogerzeil et al., *Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?*, *Lancet* 368: 305–11 (2006)
- ⁶⁷ *Id.*
- ⁶⁸ *Id.*
- ⁶⁹ Costa Rica, India, Venezuela, Colombia, Argentina, and South Africa are among the countries in which national courts have found a State obligation to provide medications in HIV/AIDS cases and for other diseases. Alicia Ely Yamin, *supra* note 46, at 340.
- ⁷⁰ 28 U.S.C. § 1498(a) and U.S. Executive Order 12899 § 6.
- ⁷¹ K. Hartsough et al., *supra* note 27.
- ⁷² <http://www.abbottglobalcare.org/sections/TestingAndTreatment/default.html>
- ⁷³ <http://www.abbottglobalcare.org/sections/Preventing/default.html>
- ⁷⁴ http://www.abbott.com/static/content/document/COBC_English.pdf
- ⁷⁵ www.abbott.com/global/url/content/en_US/40.10.30:30/general_content/General_Content_00040.htm
- ⁷⁶ http://www.ifpma.org/health/hiv/health_aai_hiv.aspx
- ⁷⁷ K. Hartsough et al., *supra* note 27.
- ⁷⁸ www.abbottglobalcare.org
- ⁷⁹ Courts in several countries have found that a single drug can be viewed as a ‘market’ for purposes of competition law. This logic “is particularly compelling with AIDS drugs where for at least some patients only one drug can be used in their cocktail most efficaciously.” Sean Flynn, *Considering Competition Complaints Against Abbott*, Mar. 23, 2007. Available at: <http://www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm>
- ⁸⁰ For more information on this case, *see* www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm.
- ⁸¹ Sean Flynn, *supra* note 79.
- ⁸² *Id.*
- ⁸³ For a description of previous cases before the Thai Commission, *see* Sean Flynn, *supra* note 79.
- ⁸⁴ David Pilling, *Pharmaceuticals Industry Fears Loss of Support from Public*, *Financial Times*, Nov. 24, 2000.
- ⁸⁵ David Kessler, *Getting medicines to South Africa for HIV and AIDS patients*, US National Public Radio, Feb. 19, 2003.
- ⁸⁶ Aaron A. Dhir, *Realigning the Corporate Building Blocks: Shareholder proposals as a vehicle for achieving corporate social and human rights accountability*, 43 *Am. Bus. L.J.* 365, 372
- ⁸⁷ Christian Brothers Investment Services, *supra* note 28.
- ⁸⁸ American Medical Student Association, Press Release, “US Medical Students Stand in Solidarity with Thais in Response to Abbott Laboratories’ withholding Essential Medications,” March 26, 2007.
- ⁸⁹ Brook K. Baker, *supra* note 32.
- ⁹⁰ Brook Baker, *supra* note 36.
- ⁹¹ Ministry of Public Health and National Health Security Office of Thailand, *supra* note 29, at 17.

⁹² Sean Flynn, *supra* note 79.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Andrew Jack, *supra* note 26.

⁹⁷ K. Hartsough et al., *supra* note 27.

⁹⁸ Consumers International, *Branding the Cure* 5. Promotion and the Pharmaceutical Industry in Europe,” Consumers International. P. 5 (2006)

Available at: http://www.consumersinternational.org/Shared_ASP_Files/UploadedFiles/ECD91B6F-FE37-45C0-AE34-898BFB39C700_BrandingtheCure-fullreport.pdf

⁹⁹ James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 Fla. J. Int’l L. 261, 271 (2002).

¹⁰⁰ Pharmaceutical Shareowner Group, *Investor Statement on Pharmaceutical Companies and the Public Health Crisis in Emerging Markets* (2003). Available at: www.pharmaproject.org.

¹⁰¹ *See also*, K. Hartsough et al., *supra* note 27.

¹⁰² Henderson Global Investors, *supra* note 4, at 7.

¹⁰³ K. Hartsough et al., *supra* note 27.

¹⁰⁴ www.globalreporting.org

¹⁰⁵ Henderson Global Investors, *supra* note 4, at 14.