

philosophers.html); on general philosophical resources (http://reference.allrefer.com/encyclopedia/Philosophy_and_Religion/Philosophy.html), guides to philosophy (<http://www.ditext.com/encyc/frame.html>), guides to philosophy on the Internet (<http://www.earlham.edu/~peters/philinks.htm>), and guides to political philosophy (<http://www.library.ubc.ca/poli/theory.html>).

abc NEWS CD-ROM

CASES

GlaxoSmithKline, Bristol-Myers Squibb, and AIDS in Africa¹

In 2004, the United Nations estimated that the previous year 5 million more people around the world had contracted the AIDS virus, 3 million had died, and a total of 40 million people were living with the infection. Seventy percent, or about 28 million of these, lived in sub-Saharan Africa, where the epidemic was at its worst. Sub-Saharan Africa consists of the 48 countries and 643 million people who reside south of the Saharan desert. In 16 of these countries, 10 percent are infected with the virus. In 6 other nations, 20 percent are infected. The UN predicted that in these 6 nations two-thirds of all 15-year-olds would eventually die of AIDS and in those where 10 percent were infected, half of all 15-year-olds would die of AIDS.

For the entire sub-Saharan region, the average level of infection among adults was 8.8 percent. Forty percent of Botswana's population was infected, 34 percent of Zimbabwe's, 31 percent of Lesotho's, and 33 percent of Swaziland's. Family life had been destroyed by the deaths of hundreds of thousands of married couples, who left more than 11 million orphans to fend for themselves. Gangs and rebel armies forced thousands of orphans to join them. While crime and violence were rising, agriculture was in decline as orphaned farm children tried desperately to remember how their dead parents cultivated the farms they now had to manage on their own. Labor productivity had been cut by 50 percent in the hardest-hit nations, school and hospital systems were decimated, and entire national economies were on the verge of collapse.

With its huge burden of AIDS illnesses, African nations desperately needed medicines, both antibiotics to treat the many opportunistic diseases that strike AIDS victims and HIV antiretrovirals that can indefinitely prolong the lives of people with AIDS. Unfortunately, the people of sub-Saharan Africa could not afford the prices that the major pharmaceutical drug companies charged for their drugs. The major drug companies, for example, charged \$10,000 to \$15,000 for a year's supply of the antiretrovirals

they marketed in the United States. Yet the average per-person annual income in sub-Saharan Africa was \$500. The AIDS crisis in sub-Saharan Africa posed a major moral problem for the drug companies of the developed world: How should they respond to the growing needs of this terribly destitute region of the world? These problems were especially urgent for the companies that held patents on several AIDS antiretrovirals, such as GlaxoSmithKline and Bristol-Myers Squibb.

GlaxoSmithKline, a British pharmaceutical company founded in 1873, with 2003 revenues of \$38.2 billion and profits of \$8 billion, held the patents to five antiretrovirals it had created. Formed from the merger of three large drug companies (Glaxo, Burroughs Wellcome, and SmithKline Beecham), it was one of the world's largest and most profitable companies. Bristol-Myers Squibb, an American pharmaceutical company founded in 1858, was also the result of mergers (between Squibb and Bristol-Myers). It had 2003 profits of \$3.1 billion on revenues of \$20.8 billion and had created and now held the patents to two antiretrovirals.

Although AIDS was first noticed in the United States in 1981 when the CDC noted an alarming increase of a rare cancer among gay men, it is now known to have afflicted a Bantu male in 1959, and possibly jumped from monkeys to humans centuries earlier. In 1982, with 1,614 diagnosed cases in the United States, the disease was termed AIDS (for "acquired immune deficiency syndrome"), and the following year French scientists identified HIV (Human Immunodeficiency Virus) as its cause.

HIV is a virus that destroys the immune system that the body uses to fight off infections and diseases. If the immune system breaks down, the body is unable to fight off illnesses and becomes afflicted with various "opportunistic diseases"—deadly infections and cancers. The virus, which can take up to 10 years to break down a person's immune system, is transmitted through the exchange of body fluids including blood, semen, vaginal fluids, and breast milk.

The main modes of infection are through unprotected sex, intravenous drug use, and child birth. In 1987, Burroughs Wellcome (now part of GlaxoSmithKline) developed AZT, the first FDA-approved antiretroviral, that is, a drug that attacks the HIV virus itself. When Wellcome priced AZT at \$10,000 for a year's supply, it was accused of price-gouging, forcing a price reduction of 20 percent the following year. In 1991, Bristol-Myers Squibb developed didanosine, a new class of antiretroviral drug called *nucleoside reverse transcriptase inhibitors*. In 1995, Roche developed saquinavir, a third new class of antiretroviral drug called a *protease inhibitor*, and the following year Roxane Laboratories announced nevirapine, another new class of antiretrovirals called *nonnucleoside reverse transcriptase inhibitors*. By the middle 1990s, drug companies had developed four distinct classes of antiretrovirals, as well as several drugs that attacked the opportunistic diseases that afflict AIDS patients.

In 1996, Dr. David Ho was honored for his discovery that by taking a combination—a “cocktail”—of three of the four classes of antiretroviral drugs, it is possible to kill off virtually all of the HIV virus in a patient's body, allowing the immune system to recover, and thereby effectively bringing the disease into remission. Costing upwards of \$20,000 a year (the medicines had to be taken for the rest of the patient's life), the new drug treatment enabled AIDS patients to once again live normal, healthy lives. By 1998, the large drug companies would have developed 12 different antiretroviral drugs that could be used in various combinations to form the “cocktails” that could bring the disease into remission. The combination drug regimes, however, were complicated and had to be exactly adhered to. Several dozen pills had to be taken at various specific times during the day and night, every day, or the treatment would fail to work and the patient's HIV virus could become resistant to the drugs. If the patient then spread the disease to others, it would give rise to a drug-resistant version of the disease. To ensure patients were carefully following the regimes, doctors or nurses carefully monitored their patients and made sure patients took the drugs on schedule. In 1998, as more U.S. AIDS patients began the new combination drug treatment, the number of annual AIDS deaths dropped for the first time in the United States.

Globally, however, the situation was not improving. By 2000, according to the United Nations, there were approximately 5 million people who were being newly infected with AIDS each year, bringing the worldwide total to about 34,300,000, more than the entire population of Australia. Approximately 3,000,000 adults and children died of AIDS each year.

The price of the new combination antiretroviral treatments limited the use of these drugs to the United States and other wealthy nations. Personal incomes in sub-Saharan

Africa were too low to afford what the combination treatments cost at that point. Yet the countries of sub-Saharan Africa were emerging as the ones most desperately in need of the new treatments. Of the 5 million annual new cases of AIDS, 4 million—70 percent—were located in sub-Saharan countries.

Numerous global health and human rights groups—such as Oxfam—urged the large drug companies to lower the prices of their drugs to levels that patients in poor developing nations could afford. By 2001, a combination regime of three antiretroviral AIDS drugs still cost about \$10,000 a year. Although the formulas for making the antiretroviral drugs were often easy to obtain, few poor countries had the ability to manufacture the drugs, and in most nations that had the capacity to manufacture drugs the large drug companies of the developed world had obtained “patents” that gave them the exclusive right to manufacture those drugs, in effect making the drug formulas the private property of the large drug companies.

GlaxoSmithKline, Bristol-Myers Squibb, and the other big drug companies did not at this time want to lower their prices. First, they argued that it was better for poor countries to spend their limited resources on educational programs that might prevent new cases of AIDS than on expensive drugs that would merely extend life for the small number of patients that might receive the drugs. Second, they argued that the combination drug “cocktails” had to be administered by hospitals, clinics, doctors, or nurses who could monitor patients to make sure they were taking the drugs according to the prescribed regimes and to ensure that drug-resistant versions of the virus did not develop. But most AIDS patients in developing nations such as those in sub-Saharan Africa, the big drug companies argued, had limited access to medical personnel. Third, they argued, the development of new drugs was extremely expensive. The cost of the research, development, and testing required to bring a new drug to market, they claimed, was between \$100 million and \$500 million. Besides the research involved, new drugs had to be tested in three phases: Phase I trials to test for initial safety; Phase II trials to test to make sure the drugs work; and Phase III trials that were wide-scale tests on hundreds of people to determine safety, efficacy, and dosage. If the big drug companies were to recover what they had invested in developing the drugs they marketed, and were to retain the capacity to fund new drug development in the future, they argued, they had to maintain their high prices. If they started giving away their drugs, they would stop making new drugs. Finally, the drug companies of the developed nations feared that any drugs they discounted or gave away in the developing world would be smuggled back and sold in the United States and other developed nations.

Critics of the drug companies were not convinced by these arguments. Doctors Without Borders—a group of

thousands of doctors who contributed their services to poor patients in developing nations around the world—said that although prevention programs were important, nevertheless hundreds of thousands of lives—even millions—could be saved if drug companies lowered their antiretroviral and opportunistic disease drug prices to levels poor nations could afford. Moreover, a September 2003 report by the International AIDS Society stated that studies in Brazil, Haiti, Thailand, and South Africa showed that patients in remote rural areas adhered exactly to their drug regimes with the help of low-skilled paramedics and that the development of resistance was not a major problem. In fact, in the United States 50 percent of AIDS patients had developed drug resistance but only 6.6 percent of AIDS patients studied in developing nations had developed resistance. By now, some of the antiretroviral combination treatments were being combined into blister packs that were easier to administer and monitor.

Other critics challenged the financial arguments of the drug companies. The cost estimates of new drug development used by the drug companies, they claimed, were inflated. For example, the figure of \$500 million that drug companies often cited as the cost of developing a new drug was based on a study that inflated its cost estimates by doubling the actual out-of-pocket costs companies invested in a drug to account for so-called “opportunity” costs (what the money would have earned if it had been invested in some other way). Moreover, these cost estimates assumed that the drug was being developed from scratch, when in fact most of the new drugs marketed by companies were based on research conducted for other drugs already on the market or on research conducted by universities, government, and other publicly funded laboratories. Critics also questioned whether companies would be driven to stop investing in new drugs if they lowered the price of their AIDS drugs. Since 1988 the average return on equity of drug companies averaged an unusually high 30 percent a year. Public Citizen, in a report entitled “2002 Drug Industry Profits,” noted that the ten biggest drug companies had total profits in 2002 of \$35.9 billion, equal to more than half of the \$69.6 billion in profits netted by all other companies in the Fortune 500 list of companies (the 500 largest U.S. companies). The ten big drug companies made 17 cents for every dollar of revenue, while the median earnings for other Fortune 500 companies was 3.1 cents per dollar of revenue; the return on assets of the big drug companies was 14.1 percent while the median for other companies was 2.3 percent. During the 1990s, the big drug companies in the Fortune 500 had a return on revenues that was 4 times the median of all other industries, and in 2002 it was at almost 6 times the median. Finally, the report noted, while the big drug companies spent only 14 percent of their revenues on drug research, they plowed 17 percent of their revenues into profits and 31

percent into marketing and administration. GlaxoSmithKline itself had a 2003 profit margin of 21 percent, a return on equity of 122 percent, and a return on assets of 26 percent; Bristol-Myers Squibb had a profit margin of 19 percent, return on equity of 36 percent, and return on assets of 14 percent. These figures, critics argued, showed that it was well within the capacity of the big drug companies to lower prices for AIDS drugs to the developing nations, even if a small portion of these drugs ended up being smuggled back into the United States.

GlaxoSmithKline, Bristol-Myers Squibb, and the other big drug companies, however, held their ground. Throughout the 1990s, they had lobbied hard to ensure that governments around the world passed legislation that protected their property rights in the medicines they had created. Before 1997, countries had different protections on so-called “intellectual property” (intellectual property consists of intangible property such as drug formulas, designs, plans, software, new inventions, etc.). Some countries, like the United States, gave drug companies the exclusive right to keep anyone else from making their newly invented drugs for a period of 15–20 years (this right was called a “patent”); other countries allowed companies fewer years of protection for their patents, and many developing countries (where little research was done and where few things were invented) offered no protection at all, considering intellectual property as something that belonged to everyone and so something that should not be patented. Some countries, like India, offered patents that protected the *process* by which a drug was made but allowed others to make the same drug *formula* if they could figure out another process by which to make it.

Arguing that research and development would stop if new inventions such as drugs were not protected by strong laws enforcing their patents, GlaxoSmithKline, Bristol-Myers Squibb, and the other major drug companies intensely lobbied the World Trade Organization (WTO) to require all WTO members to provide uniform patent protections on all intellectual property. Pressured by the governments of the large drug companies (especially the United States), the WTO in 1997 adopted an agreement known as TRIPS, shorthand for Trade-Related aspects of Intellectual Property rights. Under the TRIPS agreement, all countries that were members of the WTO were required to give patent holders (such as drug companies) exclusive rights to make and market their inventions for a period of 20 years in their countries. Developing countries—like India, Brazil, Thailand, Singapore, China, and the sub-Saharan nations—were given until 2006 before they had to implement the TRIPS agreement. Also, in a “national emergency” WTO developing countries could use “compulsory licensing” to force a company that owned a patent on a drug to license another company in the same developing country to make a copy of that drug. And in a

national emergency WTO developing countries could also import drugs from foreign companies even if the patent holder had not licensed those foreign companies to make the drugs. The new TRIPS agreement was a victory for companies in developed nations, which held patents for most of the world's new inventions, while it restricted developing nations whose own laws had earlier allowed them to copy these inventions freely. The big drug companies were not willing in 2000 to surrender their hard-won 1997 victory at the WTO.

Because the AIDS crisis was now a major global problem, the United Nations in 2000 launched the "Accelerated Access Program," a program under which drug companies were encouraged to offer poor countries price discounts on their AIDS drugs. GlaxoSmithKline and then Bristol-Myers Squibb joined the program, but the price discounts they were willing to make were insufficient to make their drugs affordable to sub-Saharan nations, and only a few people in a few countries received AIDS drugs under the program.

Everything changed in February 2001 when Cipla, an Indian drug company, made a surprise announcement: It had copied three of the patented drugs of three major pharmaceutical companies (Bristol-Myers Squibb, GlaxoSmithKline, and Boehringer Ingelheim) and put them together into a combination antiretroviral course of therapy. Cipla said it would manufacture and sell a year's supply of its copy of this antiretroviral "cocktail" for \$350 to Doctors Without Borders. This was about 3 percent of the price the big drug companies who held the patents on the drugs were charging for the same drugs.

GlaxoSmithKline and Bristol-Myers Squibb objected that Cipla was stealing their property since it was copying the drugs that they had spent millions to create and on which they still held the patents. Cipla responded that its activities were legal since the TRIPS agreement did not take effect in India until 2006, and Indian patent law allowed it to make the drugs so long as it used a new "process." Moreover, Cipla claimed, since AIDS was a national emergency in many developing countries, particularly the sub-Saharan nations, the TRIPS agreement allowed sub-Saharan nations to import Cipla's AIDS drugs. In August 2001, Ranbaxy, another Indian drug company, announced that it, too, would start selling a copy of the same antiretroviral combination drug Cipla was selling but would price it at \$295 for a year's supply. In April 2002, Aurobindo, also an Indian company, announced it would sell a combination drug for \$209. Hetero, likewise an Indian company, announced in March 2003 that it would sell a combination drug at \$201. By 2004, the Indian companies were producing versions of the four main drug combinations recommended by the World Health Organization for the treatment of AIDS. All four combinations contained copies of one or two of GlaxoSmithKline's patented

antiretroviral drugs and two of the combinations contained copies of Bristol-Meyer Squibb's patented drugs.

The CEO of GlaxoSmithKline branded the Indian companies as "pirates" and asserted that what they were doing was theft even if they broke no laws. Pressured by the discounted prices of the Indian companies and by world opinion, however, GlaxoSmithKline and Bristol-Myers Squibb now decided to further discount the AIDS drugs they owned. They did not, however, lower their prices down to the levels of the Indian companies; their lowest discounted prices in 2001 yielded a price of \$931 for 1-year supply of the combination of AIDS drugs Cipla was selling for \$350. In 2002 and 2003, new discounts brought the combination price of the big companies down to \$727, still too high for most sub-Saharan AIDS victims and their governments.

With little to impede its progress, the AIDS epidemic continued in 2004. Swaziland announced in 2003 that 38.6 percent of its adult population was now infected with AIDS. The United Nations estimated that every day 14,000 people were newly infected with AIDS. The World Health Organization announced that only 300,000 people in developing countries were receiving antiretroviral drugs, and of the 4.1 million people who were infected in sub-Saharan Africa only about 50,000 had access to the drugs. The World Health Organization announced in 2003 that it would try to collect from governments the funds needed to bring antiretrovirals to at least 3 million people by the end of 2005.

Questions

1. Explain, in light of their theories, what Locke, Smith, Ricardo, and Marx would probably say about the events in this case.
2. Explain which view of property—Locke's or Marx's—lies behind the positions of the drug companies GlaxoSmithKline and Bristol-Myers Squibb and of the Indian companies such as Cipla. Which of the two groups—GlaxoSmithKline and Bristol-Myers Squibb on the one hand, and the Indian companies on the other—do you think holds the correct view of property in this case? Explain your answer.
3. Evaluate the position of Cipla and of GlaxoSmithKline in terms of utilitarianism, rights, justice, and caring. Which of these two positions do you think is correct from an ethical point of view?

Notes

1. Sources: Compiled from information publicly available at the following websites: www.infoplease.com; www.avert.org; www.unaids.org; www.boovers.com; www.doctorswithoutborders.org; www.citizen.org/money.cnn.com; www.who.int; www.oxfam.org.