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ABSTRACT: HIV/AIDS is a public health issue that poses both economic and humanitarian problems for all nations. Though millions are infected worldwide, less-developed regions are disproportionately affected due to lack of resources, both in health care infrastructure and in the provision of affordable treatment. The 2005 Economic Report to the President recommends that pharmaceutical companies practice differential pricing of HIV/AIDS drugs and enforcement of patent/intellectual property rights as policy solutions to the AIDS crisis. These measures, while important, are but two components in the battle against HIV/AIDS. It is not enough to simply lower the price of drugs; effective policy must also address the socioeconomic and political issues that exacerbate the AIDS crisis in the developing world.

The 2005 Economic Report to the President (ERP) describes the global epidemic of acquired immunodeficiency syndrome (AIDS) as a humanitarian problem as well as an economic problem. Worldwide, over 40 million people are infected with HIV, the virus that causes AIDS, and over 25 million have died of the disease since the 1980s. HIV/AIDS is a public health issue that faces all countries; however, a lack of resources in health care infrastructure and in the provision of affordable treatment means that less-developed regions of the world are disproportionately affected by the disease. Ninety-five percent of those living with HIV/AIDS are residents of the developing world (Sherman & Oakley, 2004). Over two-thirds of the afflicted live in Sub-Saharan Africa and of these, only 50,000 are currently receiving the care that they need.

In order to stop the spread of HIV/AIDS, the ERP suggests that “compassionate pricing policies” are needed. The ERP recommends that pharmaceutical companies practice differential pricing of HIV/AIDS drugs and enforcement of patent/intellectual property rights as policy solutions to the global AIDS epidemic. While important components in the battle against HIV/AIDS, these measures are not enough. To effectively fight the disease, the socioeconomic and political issues that exacerbate the AIDS crisis in the developing world must also be addressed in order to ensure that all have access to the necessary resources to prevent and treat HIV/AIDS.

In the past decade, advances in drug treatments known as anti-retroviral medicines, or ARVs, have increased both life expectancy and quality of life for those afflicted with HIV/AIDS. In the United States, deaths from AIDS decreased by 30% in the three years following the introduction of ARVs (Sherman & Oakley, 2004). ARV therapies involve a complicated and regimented “cocktail” mixture of various drugs that cost about $10,000 to $15,000 per year/per person; an expensive treatment option for most consumers, even those who are residents of industrialized countries (Sherman & Oakley, 2004).

Due to the lack of resources and healthcare infrastructure in the developing world, the ERP recommends that differential pricing be encouraged and expanded. The ERP defines differential pricing as “charging different prices to different buyers of the same product” (p.164). Differential pricing is possible because pharmaceutical companies possess intellectual property rights and patents. Research and development lead to high fixed costs, but low marginal costs can lead to high profits. In addition, patents (which legally allow companies to be the only seller of a product for 20 years from the time a patent is filed) allow companies to enjoy high profits from successful drugs for many years after a patented drug goes on the market. The ERP gives the example of an AIDS drug called PLC that sells for twice as much in the U.S. as it does in Uganda; PLC’s manufacturer can still make a profit as long as the lower price is only offered in limited markets.

However, many consumers view differential pricing as unfair. Why should one group pay one price and another group pay a lower
price? The ERP argues that if cost was uniformly low across the board, companies would not make enough profit to justify the high fixed costs that go along with research and development. Cann (2004) states that pharmaceutical companies invested an estimated $33 billion in research and development in 2003, representing 15.6% of total sales. The average cost of developing a new drug is $800 million. Low costs for all consumers would eventually lead to decreased innovation, increased pricing for all, less access to drugs for low-income consumers.

The ERP asserts that the key to increased access to ARVs in the developing world lies in differential pricing on the part of drug companies. However, according to the ERP, “despite price reductions by manufacturers and large-scale international assistance, the price of these treatments has so far exceeded what most residents of the developing world can afford” (p. 159). Though some pharmaceutical manufacturers have cut prices and allowed increased availability of generic substitutes, it is estimated that only two to four percent of Africans with HIV/AIDS have access to ARVs, in large part due to the prohibitive cost of these drugs (Cann, 2004; Forman, 2004). This is because the per capita income of the average African is less than $50 per month, and the healthcare expenditure by most African governments is less than $10 per person per year (Halbert, 2002; Sherman & Oakley, 2004).

Differential pricing thus creates a dilemma—pharmaceutical companies are not charitable organizations; they exist to make a profit (Cann, 2004). If they can’t recoup the high fixed costs associated with research and development, they have no incentive to work toward innovation of newer and more effective treatments. However, if pharmaceutical companies do not offer ARVs and other HIV/AIDS drugs at steeply discounted prices to consumers in developing countries, those afflicted with the virus have little chance of survival and the pandemic will worsen, creating significant economic and humanitarian effects that will negatively affect millions of people. Though sales to developing countries account for only about two percent of drug sales worldwide, pharmaceutical companies maintain that lowering prices will negatively affect their ability to control prices in the long term (Halbert, 2002). Because most profit is made in industrialized countries, Halbert (2002) suggests that pharmaceutical companies are concerned about losing their ability to “monopolize price controls” (p. 266). The ERP’s solution to this dilemma lies in strong intellectual property protection for patents, including drug patents.

One solution that provides legal precedent is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international treaty that sets minimum standards for intellectual property regulation for all member countries of the World Trade Organization (WTO). TRIPS became effective on January 1, 1995. Because TRIPS sets minimum, not maximum, standards of protection, countries are free to even more strongly enforce patent law, which has created controversy between developing and industrialized countries around the subject of AIDS drugs in the developing world (Sherman & Oakley, 2004). Industrialized countries and special-interest groups such as pharmaceutical companies fought for more stringent intellectual property laws, while developing countries and special-interest groups such as AIDS activists objected to TRIPS (Sherman & Oakley, 2004).

TRIPS’ self-stated objective is that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations” (Sherman & Oakley, 2004). TRIPS strictly regulates both compulsory licensing and parallel importing, two methods often used to obtain cheaper drugs. In compulsory licensing, a government can force patent holders to allow another manufacturer to produce their product with a special license before the patent expires, usually at a cheaper price (Halbert, 2002). Parallel importing involves purchasing a drug at a lower price in another country importing the drug, and then selling it at a lower price in direct competition with the patent owner (Sherman & Oakley, 2004). Ironically, the U.S. has practiced parallel importing on a large scale; despite the fact the U.S. government officially opposes such practices.

Perhaps the best example is that of the Anthrax drug Cipro. After the attacks on the World Trade Center on September 11, 2001, there was widely perceived heightened threat of Anthrax attacks in the U.S. According to Halbert (2002), Cipro is a patented drug owned by the German pharmaceutical company Bayer. Neither American nor Canadian supplies of Cipro were sufficient to meet demand in the event of an anthrax epidemic. In response to the heightened sense of risk, the Canadian
government ordered a million doses of Cipro from a generic drug manufacturer, violating Bayer’s patent. After threatening to follow the lead of the Canadians, the United States government negotiated a reduced price in order to stockpile enough Cipro for a large attack. In this case, the U.S. used the threat of compulsory licensing to lower the price of a medicine needed by U.S. consumers. The U.S. has ignored this double standard as it works to protect the interests of U.S. pharmaceutical companies abroad (p. 267).

In light of actions such as the U.S. in the Cipro case, many developing countries have sought to modify TRIPS to allow the production of cheap, generic versions of patented drugs. This has been a major point of contention between industrialized and developing nations; industrialized countries insist that TRIPS can only be modified to include patent- lessening on AIDS drugs, but not other drugs that also treat pandemics, such as malaria or tuberculosis (Sherman & Oakley, 2004). This is in direct opposition to the demands of developing countries, who insist that public health needs should trump patent rights. Halbert (2004) describes the TRIPS agreement as the result of a strategy on the part of pharmaceutical companies in which they “defined themselves as the ‘victims’ of immoral and malicious ‘pirates’ and ‘thieves.’ Developing countries that violated intellectual property rights were not only engaged in unfair trade, they were morally bankrupt” (p. 261).

The fight came to a head in 1997, when the South African government passed a law known as the South African Medicines and Related Substances Control Act Amendments Act, which challenged the stringent regulations set forth in TRIPS and allowed for generic drugs to be manufactured in South Africa, despite patent status (Cann, 2004). Halbert (2002) asserts that the South African government believed the Medicines Act to actually be in line with TRIPS, in that compulsory licensing and parallel importing were allowed under TRIPS in certain circumstances.

The pharmaceutical industry was quick to fight back. Along with PhRMA, the largest lobbying organization for the pharmaceutical industry, thirty-nine pharmaceutical companies filed a lawsuit in 1998 to stop the Medicines Act (Sherman & Oakley, 2004). The U.S. government attempted to challenge the Act through the WTO, and then negotiated directly with the South African government (Sherman & Oakley, 2004). The U.S. put strong pressure on South Africa to comply with TRIPS, but was unsuccessful in getting South Africa’s legislature to conform to their demands. The case created a backlash around the world, with public figures such as Nelson Mandela and Kofi Annan, as well as the European Union and thousands of AIDS activists, all siding with the South Africa against the U.S., PhRMA and the drug companies. In 2001, the lawsuit was dropped due to the negative publicity (Sherman & Oakley 2004).

In the same year, thousands of AIDS activists, the United Nations, the World Health Organization, and many developing nations increased the pressure on the pharmaceutical industry to lower prices in the developing world in order to increase access to ARVs (Sherman & Oakley, 2004). This resulted in the passage of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights, which in turn led to several large drug companies (including Merck, Bristol-Meyers Squibb, Glaxo-SmithKline, and Pfizer) significantly reducing prices on ARVs and other AIDS drugs in Africa (Sherman & Oakley, 2004). In his April 7, 2004 testimony about AIDS in Africa to the Senate Foreign Relations Committee, Dr. Jonathon Mermin, a Country Director for the Centers for Disease Control, gave the example of the effectiveness of an ARV drug that decreased in price from $15 to $3, allowing many more patients access to the drug (U.S. Senate, 2004). Examples like this one emphasize the need for differential pricing.

There are objections to patent/intellectual property law on other grounds, as well. Cann (2004) critiques the notion of property rights, and property in general, as being ideologically Western in nature; the concept of property rights assumes the existence of a cultural norm of individual ownership that is not present in many developing societies, which tend to favor the collective as opposed to the individualistic. This has led to ideological resistance to the concept of intellectual property rights, as well as legal conflict. Another challenge to intellectual property regulations, such as TRIPS, is that indigenous/traditional knowledge and medicine lie at the core of “modern,” patented pharmaceutical products, a source of conflict and claims of “bio-piracy” (Cann, 2004).

Opponents of stringent patent law contend that it can actually constrict both innovation and competition. In the past ten years, the number of biotechnology patents has increased by 400%, which means that more and more knowledge and ideas are off-limits, which has the
potential to stifle research, innovation, and competition (Cann, 2004). Cann (2004) suggests that the amount of research and development expense and income are not correlated; he provides the example of an AIDS drug that cost $3.2 million to develop yet made over $40 million in profits in only six months. Both Cann (2004) and Halbert (2002) assert that innovation is also due in large part to government subsidies of pharmaceutical companies.

In conclusion, while differential pricing and intellectual property rights are important, they are but two components in the battle against the spread of HIV/AIDS. Simply reducing the price of drugs is not enough. Sherman and Oakley (2004) give the example of malaria and tuberculosis; treatments are available at the cost of “only pennies a day” in the developing world, but these diseases are still among the leading causes of death. According to Cann (2004), even if ARV prices decrease significantly, the economic, social, political, and infrastructural problems surrounding the HIV/AIDS crisis will remain. Even if patented or generic drugs were to be made consistently available at slightly over cost (and then added to the costs of medical personnel, distribution, monitoring, testing, and education), effective prevention and treatment would still be beyond reach in many nations (p. 803).

Solutions that are humanitarian as well as economic in nature are needed in order to effectively fight the HIV/AIDS pandemic.

References


