Big Pharma and Big Profits: Denying Access to AIDS Medication

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Almost 40 million people around the world are currently living with HIV/AIDS. The number of people affected by the AIDS pandemic has steadily climbed over the last decade, devastating entire populations and destroying communities, especially in Africa. While the international community has yet to find a solution to this grave threat to global health, innovations in drug development have allowed countless people to significantly prolong their lives through HIV/AIDS medication, specifically antiretroviral drugs (ARVs). This valuable medicine, however, is available only to a small portion of people living with HIV. Millions of people, the majority of which live in the Global South, are unable to receive drug treatment because they cannot afford the high costs of the medicine.

Evidence clearly demonstrates that the effects of the AIDS pandemic are most pronounced in Africa. Sub-Saharan Africa has the lowest treatment coverage for children of any region in the world, and over 85% of HIV-infected pregnant women live in sub-Saharan Africa. The region accounts for two-thirds of the total treatment need in low- and middle-income countries, but over 70% of its people in need of ARVs do not have access to treatment.[1] Desire for profits and unwillingness to lower drug prices are preventing access to life-saving medication in Africa.

Current Access

"Towards Universal Access," a report published in April 2007 by the World Health Organization (WHO), UNAIDS, and the United Nations Children's Fund (UNICEF), reveals that less than 30% of people living with HIV in low- and middle-income countries have access to the ARVs that can dramatically prolong their lives. In sub-Saharan Africa, 1.3 million people living with HIV are now receiving the drugs, which translates into a coverage rate of 28% in the region. While this is a substantial improvement from the 2% coverage rate in 2003, over two thirds of patients are still not receiving the drugs that could save them from an early death.[2]

A primary cause of low coverage rates is the high cost of ARV drugs. In 2006, the average price paid for first-line ARVs in low-income countries was between $123 and $493 per person per year.[3] In Africa, individual incomes are low and limited government budgets cannot pay high prices for drugs. As a result, life-saving medication remains out of reach for the world's poorest.

The global pharmaceutical market was worth approximately $643 billion in 2006. The U.S., Europe, and Japan accounted for over 72% of global pharmaceutical sales, while Asia, Africa, and Australia combined account for a mere 8.6% of the market.[4] To put those percentages in

perspective, although Africa is responsible for only a fraction of global pharmaceutical spending, it is home to more than 60% of people living with HIV.[5]

Access to ARVs can significantly prolong the life of a person with HIV. Under the WHO's "3 by 5" initiative, a global effort to extend antiretroviral therapy, the number of patients in low- and middle-income countries receiving treatment increased from 400,000 to 1.3 million between 2003 and 2005. WHO estimates that during these two years between 250,000 and 350,000 premature deaths were avoided due to the increased ART.[6]

Despite evidence that plans like the "3x5" initiative effectively increase access to ARVs and consequently save lives, treatment continues to be severely limited. Governments, NGOs, and multilateral institutions of both developed countries and the Global South still have not ensured drug treatment access for the world's 40 million people living with HIV. There are many complex factors that influence the availability of HIV/AIDS treatment, particularly intellectual property laws, patents, high drug prices, and the influence of the leading pharmaceutical companies (often collectively referred to as "Big Pharma"). These factors have combined to produce devastating consequences for people living with HIV in Africa.

Intellectual Property Rights and the World Trade Organization

Intellectual Property (IP) rights were created in order to reward innovation and allow inventors to recoup the research and development (R&D) costs incurred during product development. Companies assert that without this kind of protection, they would not be guaranteed to make profits off of a successful invention. It follows that there would consequently be no incentive for companies to invest in R&D, and many valuable discoveries would not occur.

In 1994, the World Trade Organization (WTO) completed the Trade-Related Aspects of International Property Rights agreement (TRIPS), which called for the standardization of IP law among all WTO members by January 1, 2005. While all countries signed the agreement during the Uruguay Round, the country with the most to gain from TRIPS was clearly the United States, which earns large amounts of money from American patents in foreign markets.[7]

Those involved in the talks indicated they would be mindful of the Global South's need for protection against potential abuses by patent-holders. They therefore included in the TRIPS agreement a key provision, known as compulsory licensing, in which a government can grant someone other than the patent owner the right to produce the patented product or process. This allows a government to prevent patent owners from abusing their patents by blocking trade or the international transfer of technology.

The drugs produced under compulsory licensing are generic drugs, or drugs that are identical to a brand-name drug in safety, strength, quality, and dosage form. Article 31 of TRIPS states that a generic firm can obtain a compulsory license as long as:

- it first tries to negotiate a commercial license from the patent owner
- it produces predominantly for the domestic market

- the remunerations paid to the patent owner are subject to judicial review.[8]

Despite such provisions, TRIPS still poses significant problems for the Global South and fails to adequately address limitations on treatment access. The second criteria of Article 31, for example, does not address how countries with insufficient or no manufacturing capacities in the pharmaceutical sector can find a way to access generic drugs, as it restricts countries who are capable of manufacturing generics from exporting their drugs to countries who are not.

Furthermore, countries risk significant international pressure if they choose to issue a compulsory license, as seen in the case of Brazil. Brazil began providing free ARV access to its citizens in 1997, a policy that eventually cut the country's HIV infection rate in half. The government, however, was spending the majority of the program's budget on only a few brand-name drugs. The country contacted drug manufacturer Abbott Laboratories to request a voluntary license so that Brazil could make generic copies of the drug Kaletra. Brazil chose to request a license for Kaletra because the drug is well suited for those living in low- and middle-income countries; it does not require refrigeration and can be taken without food.

When Abbott refused to grant the request, Brazil stated its intention to issue a compulsory license for its national laboratory for production of a generic form of Kaletra. The U.S. Congress then threatened to enact trade sanctions on Brazil.[9] The U.S. also issued a formal WTO complaint in January 2001, which it withdrew six months later, after receiving a large amount of negative publicity for its action.[10]

Thus far, the only low-income African countries that have chosen to issue compulsory licenses are Cameroon, Ghana, Guinea, Eritrea, Swaziland, Zambia, Zimbabwe, and Mozambique.[11] As of July 2006, only six countries (Canada, China, India, South Korea, the Netherlands, and Norway) had passed laws allowing their domestic firms to produce generic medicines for export to countries that do not possess the capacity to produce their own medicines.[12]

The Doha Declaration

In light of the controversy surrounding compulsory licensing, in November 2001 the WTO issued the Doha Declaration of TRIPS and Public Health, which reaffirmed the rights of WTO member countries to grant compulsory licenses. The Declaration states, "The TRIPS agreement does not and should not prevent members from taking measures to protect public health… and, in particular, to promote access to medicines for all."[13] Furthermore, Paragraph 6 of the Doha declaration demanded that the WTO take action to prevent future compulsory licensing problems. Paragraph 6 states,

> "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."[14]

A flurry of debate arose as the international community discussed such a solution, and developed countries were quick to advocate proposals from which they would benefit. The U.S. proposed that the solution to Paragraph 6 should be limited to include only a few selected diseases. Many countries rejected this stipulation, arguing that it would allow a country with manufacturing capacity to determine how to combat the diseases facing its citizens, while a smaller or weaker country that lacked manufacturing capabilities would be forced to accept external dictates concerning the diseases eligible for compulsory licensing.[15]

In addition, the U.S., Switzerland, the EU, and Japan attempted to limit Article 6 to treatments only, which would exempt patents on diagnostic tests from compulsory licensing.[16] These arguments undermined the ability of countries of the Global South to effectively address their serious health emergencies.

On August 30, 2003, the General Council announced its response to the issues surrounding Article 6 in the "Decisions on Implementation of Paragraph 6 of the Doha Declaration." The document states that countries without manufacturing capabilities can declare compulsory licenses and on that basis alone legally import generic medications. But the decision created new challenges for countries that lack manufacturing capabilities. It introduced restrictive regulations, such as the requirement of two separate compulsory licenses (one by the exporter and one by the importer) and WTO monitoring of the granting of the licenses.[17]

The stipulations of the decision have not yet been officially approved, as the declaration was deemed a "temporary waiver." WTO members agreed in December 2005 that the waiver would become permanent if at least 2/3 of the 148 WTO member countries ratified by amendment by December 1, 2007.[18]

A more recent development that threatens to undermine the effects of previous WTO decisions is the U.S.' use of "TRIPS-plus" measures in bilateral, regional, and multilateral trade agreements. Such measures, often slipped into large and complex agreements, typically include heavy protections for IP and pharmaceutical companies. TRIPS-plus stipulations include:

- extending the length of patents beyond the normal 20-year period
- data exclusivity (a regulation that slows the creation of generics by protecting drug companies' drug testing data for five years)
- permitting patents to be made on the same product for different uses
- restrictions on compulsory licensing

TRIPS-plus provisions appear in bilateral agreements that the US has signed with the Southern African Custom Union (comprised of Botswana, Lesotho, Namibia, South Africa, and Swaziland), Morocco, Jordan, Singapore, Chile, and Australia.[19]

Not only is this strategy contrary to the spirit of the WTO's decisions and declarations, but it may also be illegal. On September 30, 2004, 12 members of the U.S. House of Representatives submitted a letter to President Bush expressing opposition to IP provisions in free trade agreements, warning that those agreements could violate the TRIPS agreement and the Doha Declaration.[20]

For the Sake of Innovation?

When defending its tight grip on patents and high drug prices, the pharmaceutical industry's primary argument is that high prices are necessary if a drug company is to recover its research and development (R&D) costs. Pharmaceutical companies claim that without the profits brought in by high prices, drug companies could not afford to invent and produce the drugs for which there is so great a demand.

On average, a new drug costs $800 million in R&D costs and takes almost 12 years to pass through all of the stages of drug development.[21] Most drugs do not contribute to profits; the industry depends on a handful of "blockbuster" drugs. Thus, to compensate for all of the failed drugs that never make it to market, companies maximize profits on the few that do, through high prices and patents. Patent life has increased from about 8 years for drugs discovered in 1980 to as long as 20 years for current discoveries.[22] This time frame, however, only prevents other drug companies from creating a product identical to the new drug.

After the introduction of a breakthrough brand-name drug, other drug companies begin to compete with the drug's original manufacturer by developing slightly differentiated products. These products can be sold even during the patent period, so a drug company's pure monopoly on the drug is limited to the amount of time it takes a competitor to create a slightly modified version of the product (generally one to five years).[23]

While R&D may be expensive, the financial situation of drug companies is not as precarious as they often lead the public to believe. Drug companies are far from financial crisis, and R&D investments are generally well rewarded, as is evident in the doubling of the international pharmaceutical market from $300 billion dollars in 1999 to $600 billion dollars in 2005.[24] The pharmaceutical industry as a whole is still highly profitable. From 1970 to 2002, the average profit margin for the Fortune 500 drug firms consistently exceeded the margin for all Fortune 500 companies taken together.[25] From 1982 to 2001, *Fortune* magazine ranked the drug industry as the most profitable industry in the United States.[26] With such consistently high profits, it is clear that drug industry R&D is clearly not as risky as companies claim.

Pharmaceutical companies often attack such analyses of their accounts, maintaining that their sales of a drug appear to be more profitable in accounting terms than they really are because the money spent on R&D for the drug has already been expensed in the past. This line of thought, however, is misleading. The amount of money that leading drug companies are currently bringing in as profits is much higher than the amount they are currently spending on R&D.[27] Overall, US drug companies spend just 10% of their sales revenues on R&D.[28] This implies that no matter when the R&D of a drug occurs, the cost of development was likely more than covered by the company's profits at the time.

It is also not uncommon for drug companies to receive outside funding for their R&D. According to the National Institutes of Health (NIH), taxpayers funded 55% of the research that led to the discovery and development of the top five selling drugs in 1995.[29] A Global Economic

Justice Report calls attention to drug companies' attempts to hide this type of information from the public. The report notes that Miles White, CEO of Abbott's Laboratories, claimed that funding for R&D for new medications came only from private investors, when "in fact, some of the major drugs used for treating AIDS… were discovered by researchers funded by the U.S. government and only later turned over to private pharmaceutical companies for marketing."[30] In these cases, drug companies are entirely unjustified in maintaining that their financial stability rests primarily on their ability to earn back R&D costs.

PEPFAR: The Battle Over Generics

The Rise of Generics

One of the most effective ways of combating the high prices and patents that characterize brand-name medication is the development of generic drugs. Front-line drug prices in the world's less developed countries dropped by up to 20% in 2006, and many drugs are now less than half the price they were in 2003.[31] Competition from generic drug manufacturers is a leading cause of this sharp decrease in prices that has allowed a greater portion of the population to access ARVs.

The first key breakthrough for the generic market occurred in 2001, when generic drug manufacturer Cipla introduced the drug Triomune. Triomune is a combination ARV drug, meaning that Cipla successfully combined three drug components that brand name pharmaceutical companies had been selling separately. This development resulted in lower prices and fewer pills per day for consumers. Cipla made Triomune available in Africa for approximately $400 per person per year at a time when brand name ARVs cost roughly $12,000 a year per person. William F. Haddad, Chairman and CEO of generic biotechnology firm Biogenerics Inc., described the effects of this landmark development, saying, "All of Africa had 15,000 people covered by the multinational drug companies [before the generics entered the market]… Now Cipla alone covers 400,000 patients."[32]

Due to increased competition from generic drug manufacturers, prices for brand-name drugs dropped by thousands of dollars over the following years. By 2005, leading Western firms were charging approximately $500 per year for their brand name drugs. Indian generic makers were offering a year's supply of ARV generics for an even lower price of roughly $140.[33] Although the low price of $140 per year is still unaffordable for many people in Africa, this drop in price increases the number of people able to receive life-prolonging medication because of the massive price reductions prompted by the emergence of generic drug companies.

Drug companies, however, have balked at this rise in generics, as competition from generic manufacturing companies cuts directly into their profits. Big Pharma is not alone in its battle against generics; the pharmaceutical industry has received a great deal of support from the Bush Administration. From 1998-2005, the pharmaceutical and health products industry spent more than $800 million in federal lobbying and campaign donations.[34] Recent U.S. policies on funding for global AIDS treatment reflects this close relationship between Big Pharma and the Bush Administration, particularly in the case of the President's Plan for Emergency AIDS Relief (PEPFAR).

PEPFAR Drug Approval

PEPFAR is an initiative passed in 2001 calling for the allocation of $15 billion over the course of five years to combat the global HIV/AIDS pandemic, particularly in the Global South. In 2006, almost 20% of PEPFAR's overall budget went to the purchase of ARV drugs.[35] Since its inception, PEPFAR has repeatedly bought the bulk of its ARVs from Big Pharma, rather than purchasing from generic drug manufacturers at a much lower cost. In 2006, 73% of the ARVs purchased with PEPFAR funds were made by brand-name manufacturers.[36] As a result, fewer people receive life-prolonging ARVs so that the drug companies that manufacture brand-name drugs at high prices and spend millions of dollars on lobbying the government can maintain their lucrative profit margins.

While PEPFAR does not explicitly forbid money from being spent on generics, there are many legal and procedural stipulations that prevent a large proportion of the funds from being spent on the cheaper ARVs made by generic drug manufacturers.

According to regulations issued in December 2003, PEPFAR can only spend money on drugs that are "approved by a stringent regulatory authority or otherwise demonstrate quality, safety and efficacy at the lowest possible cost."[37] The Bush Administration has established that this "stringent regulatory authority" is the U.S. Food and Drug Administration (FDA). While this may initially seem like a logical standard, many argue that the requirement is excessive.

Several years ago, the WHO created a "prequalification" system, designed to assist member countries in selecting the drugs they purchased to fight AIDS, tuberculosis and malaria. Under the system, manufacturers of both brand name and generic drugs submit their products for WHO evaluation, after they have been tested and licensed elsewhere. WHO examines them for purity, safety and efficacy. Once approved, the drug is published on a list and periodically retested to ensure that it meets WHO standards.

While the WHO is a well-respected international institution, U.S. policies do not fully acknowledge its standards for drug approval. Furthermore, FDA regulations appear to be significantly stricter, delaying the availability of generic drugs. By the end of 2005, the WHO prequalification project had approved a total of 38 generic ARV drugs, while the FDA had approved a mere 15 generic formulations.[38]

The Bush Administration insists that FDA oversight is essential in ensuring the safety of PEPFAR drugs. U.S. Global AIDS Coordinator Mark Dybul has acknowledged that the data collected by the WHO during the prequalification process may contain all the information PEPFAR needs to reassure itself that generics are good enough. But the data collected by the WHO is confidential, and the U.S. therefore claims it will not accept the WHO process.

"We need to see the data ourselves," Dybul said, explaining that if substandard drugs were approved by the WHO and used by PEPFAR, "you would crucify us for not having the due diligence of looking at the data ourselves -- and rightly so."[39] Tom Flaven, spokesman for the Office of the U.S. Global Aids Coordinator, echoes the same sentiment, "The WHO runs a

wonderful system for pre-qualification, but it's voluntary. They can't share the company data. We are not going to buy pills unless we see the data about the safety and efficacy of those pills because we feel responsible for the people who are taking them."[40]

But many generic manufactures do not want to turn over their data to the U.S. government or the FDA. Generic manufacturers in India and Brazil often refrain from submitting their products for FDA approval because they would then have to honor U.S. patent law, which may prevent their drug from being sold in many countries. The PEPFAR review process also requires FDA-approved drugs to be registered in each of the countries for which it is procured.[41] Such extensive red tape further deters generic drug manufacturers from entering into the process.

Furthermore, there is no evidence suggesting that WHO standards are sub par or that trusting the WHO's recommendations would create place drug consumers at risk. On the contrary, a myriad of well-respected organizations and institutions have accepted WHO standards. Doctors Without Borders uses a number of the generic ARVs that have been pre-qualified by the WHO.[42] The Global Fund (to which the U.S. is a contributor) and other initiatives also depend heavily on generic ARVs approved by the WHO's prequalification project.[43] Dr. Lembit Rago, the WHO official who leads the drug assessments, maintains that the institution's set of standards is rigorous and was developed using "absolutely the same principles" as the FDA. He also explained that he borrowed his inspectors from regulatory agencies in Canada, France, Germany, Sweden and Switzerland.[44]

If WHO assessments have gained such widespread acceptance, why does the Bush Administration refuse to acknowledge their legitimacy? Critics contend that the U.S. insists on a separate, lengthy review process so that brand-name drug companies can reap large profits from PEPFAR at the expense of the more cost-effective generic manufactures. Rago himself revealed that as soon as his office approved certain generic pills from India, "a very cold wind began to blow from the U.S. It is no secret that Pharma is lobbying against us in a big way."[45]

The Need for Reform

One of the most essential drugs that the FDA has not yet approved is the generic drug introduced by Cipla in 2001 that set in motion the sharp rise in competition between brand-name and generic drug manufacturers. Often sold under the name of Triomune or Triviro, it is produced by several companies in India. In 2003, the WHO pre-qualified the drug, along with several other combination therapies.[46] Yet the ARV drug still remains out of the hands of thousands of patients because of PEPFAR's strict regulations.

Prominent U.S. politicians have spoken out against the current system's sluggish acceptance of generics, particularly Rep. Henry Waxman (D-Calif.), Sen. Edward Kennedy (D-Mass.), and Sen. John McCain (R-Ariz.).[47] In March 2004, Kennedy and McCain sent a letter to the White House asking that Bush accept WHO-approved generics. "We should wait no longer to provide safe and effective low-cost medications to the developing world, and again, urge you to reconsider the administration's actions. Make no mistake, delays will cost lives," the letter said.[48]

In response to such criticism, the U.S. announced in May 2004 that the FDA would create a "fast-track" approval process for international makers of generic ARVs. But critics maintain that the process is far from expedient. In 2004, almost all ARVs administered through the program were still from well-known companies that make name-brand drugs.[49] In 2005, less than 11% of PEPFAR's ARV budget was spent on generics.[50]

Yet the Bush administration has continued to perpetuate the myth that PEPFAR has significantly increased its purchase of generics. In May 2006, PEPFAR released a report entitled *Bringing Hope: Supplying Antiretroviral Drugs for HIV/AIDS Treatment*, in which a graph indicates that 70% of PEPFAR drug procurements in 2004-2006 were of generics. But this statistic is based on data from just four grant recipients whose ARV purchases total $4.3 million, which was only a small portion of the overall ARV drug budget during that time frame.[51] In reality, only about 27% of its PEPFAR's ARV funds were actually spent on cheaper generic alternatives in 2006.[52] This touting of this distorted statistic to give the appearance of progress further illustrates the government's reluctance to commit to any real change in PEPFAR policy.

The issue grows even more dismal when distinguishing between first- and second-line ARVs. Nearly all generic ARVs approved so far are drugs for first-line drugs, which are usually only effective for about four years. Each year, more than 10% of the population living with HIV becomes resistant to these drugs and must move on to second-line ARVs, most of which are brand-name drugs.[53] In 2005, the average price low-income countries paid for second-line treatments was $1,700 per patient, while first-line drugs cost approximately $144. Second-line treatment currently costs 10 times the price of first-line drug therapy.[54]

In 2006, Doctors Without Borders reported that 16% of its African AIDS patients needed to switch to second generation drugs, but that putting only 2.5% of patients on second-line drugs used up 30% of its drug budget.[55] Although fewer than 10% of PEPFAR patients currently need second-line drugs, this number will increase.[56] As second-line generic ARV manufacturers currently face the same hurdles that initially prevented first-line ARVs from entering the market, it is important to note that generic drug access must expand to include these second-line drugs.

The Case of South Africa

South Africa's recent court case illustrates the way in which patents, generics, IP law, and WTO regulations all collide in a country's fight for cheap drug access. In 1997, South Africa's Health Minister, Dr. Nkosazana Dlamini-Zuma, introduced the "Medicines and Related Substances Control Act." This legislation gave the Ministry of Health discretion to authorize parallel importing and compulsory licensing of ARVs in critical situations. Though the Act conformed to the TRIPS code, the Pharmaceutical Research and Manufacturers of America (PhRMA) claimed that it violated both the Patents Act and the Constitution of South Africa and accused South Africa of stealing patented drugs. The case was brought a case before South Africa's High Court, with the U.S. government backing PhRMA.

During this time period, PhRMA lobbied in Washington, particularly focusing on U.S. Trade Representative (USTR) Charlene Barshefsky and Al Gore, the Vice President at the time.

Barshefsky responded by withholding preferential trade treatment for some South Africa products in the summer of 1998 and by placing South Africa on USTR's "Special 301 Watch List" in March 1999.[57] These events proved that the Global South's fear of practicing compulsory licensing was valid, as South Africa was subjected to international pressure for its decision to engage in compulsory licensing.

Due to intense pressure from activists, Gore and the Clinton Administration eventually shifted its position, choosing to support South Africa and instructing the USTR to ease its pressure on South Africa.[58] As international public opinion and the Clinton Administration's stance began to align with South Africa, the pharmaceutical companies dropped their lawsuit in April 2001. In December 2003, the South African government reached an agreement with drug manufacturers GlaxoSmithKline and Boehringer Ingelheim, in which the two companies agreed to expand the licensing of their patented AIDS drugs to three generic manufacturers in South Africa and other African countries. GlaxoSmithKline also agreed to cap royalty fees at no more than 5% of net sales.[59]

A New Trend

Fearing that they could become embroiled in similar conflicts all around the world if other countries decided to follow South Africa's example, pharmaceutical companies have begun to make private drug agreements with individual country governments in order to avert further use of compulsory licensing. When it appears that a country is going to issue a compulsory license without their consent, transnational pharmaceutical companies prefer to cut a deal rather than agree to a voluntary license or be forced to accept the government's issue of a compulsory license. The companies prefer to donate money and drugs to clinics in low-income countries than see the patent system weakened.[60] Big Pharma also fears that if the system is weakened through compulsory licensing, a domino effect could arise; the Global South could begin to demand lower prices for all patented drugs, not just for AIDS drugs.[61]

One of the earlier examples of such deals occurred in December 2003, when pharmaceutical giants Glaxo and Boehringer-Ingelheim quietly agreed to grant licenses to produce AIDS drugs to four generic companies from India and South Africa. In return for being allowed to sell the drugs anywhere in sub-Saharan Africa, the companies agreed to turn over 5% of sales to Glaxo and Boehringer.[62] The case of Brazil provides another apt illustration of Big Pharma's strategy in action. When Brazil and Abbott Laboratories clashed over Brazil's right to issue a compulsory license for the drug Kaletra, the situation was eventually resolved by a 2005 agreement between the two parties, in which Abbott agreed to sell its drug to Brazil at a reduced price that would purportedly allow Brazil to save 259 million over six years.[63]

Such deals do not take place solely between drug companies and countries in the Global South. During the anthrax scare in 2001, the U.S. government began the process of revoking Bayer's patent on Cipro, a drug that would provide treatment for anthrax exposure. Eventually Bayer agreed to discount Cipro for a large quantity procurement.[64]

Pharmaceutical companies have also begun to partner with humanitarian programs. In October 2003, a foundation organized by former President Bill Clinton announced an agreement with Indian and South African generic makers to sell ARVs for approximately $140 per patient per year if large orders were guaranteed, payment was in cash, and the drug maker did not have to pay the legal and lobbying costs of getting each drug licensed in each country. In May 2007, the Clinton Foundation negotiated a price reduction deal in which generic drug manufacturers Cipla and Matrix agreed to cut the price of second-line ARVs by an average of 25% in low-income countries and by 50% in middle-income countries.[65] In July 2007, the Clinton Foundation announced another drug agreement that would reduce the prices of ARVs for the Zambian government by 2009 and is predicted to save Zambia over $100 million between two and three years.[66]

Looking Ahead

Agreements such as those brokered by the Clinton Foundation and UNAIDS are steps in the right direction, as they directly increase the amount of HIV/AIDS patients receiving ARVs. Other positive signs include increased awareness of the issues surrounding ARV access, which has been seen in the WTO declarations, decisions of individual governments, growing pressure from advocacy groups, and media coverage of important developments, such as the South Africa court case.

There remains, however, a great deal of progress to be made. Africa Action calls on the U.S. to use its political influence to lead the WTO in safeguarding the right of countries in the Global South to issue compulsory licenses. The U.S. must also cease to use the strong-arm tactics it has employed in the past to protect Big Pharma and should encourage other countries to do the same. Furthermore, the government must work to ensure that the money it dedicates to combating AIDS around the world is used in the most effective way possible to ensure treatment access for all who need it. The U.S. must cease to prioritize the profits of Big Pharma over the lives of people living with HIV/AIDS.

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