



Campaign Overview



Dear SGACers,

Welcome to the Student Global AIDS Campaign’s national action toolkit on Treatment Access. Today, 40 million people are living with HIV and AIDS, but only 1 million of them have access to the effective treatments that, for those who can afford it, makes living decades HIV-positive a possibility. While we saw big reductions in drug prices a few years ago, people living with HIV and AIDS in the Global South are facing a new and growing crisis of affordable access to the “second-generation” of drugs that are essential for treatment as resistance and side-effects inevitably set in.

Access to treatment is fundamentally an issue of justice and human rights. One’s ability to pay market prices to multinational pharmaceutical corporations should not dictate life or death. Entire nations should not face economic and social devastation from HIV and AIDS while wealthier nations are able to use treatment to fight the pandemic.

In these pages you’ll find lots of (we hope) helpful information and suggestions on how you can take action to demand affordable AIDS drugs for all. Our government and US companies play an essential role and, as the SGAC mission says, this is the crisis of our generation. It is up to us to make it clear to those in power that everyone deserves the chance to live.

We look forward to hearing from you—if you have questions, ideas, or we can help—as we move ahead in this national campaign to put patients over profit.

In solidarity,

Andrew, Brooke, Cameron, Erin, Grant, Mimi, Polly, Sara, Sharon and Traci
SGAC National Steering Committee



Patients over Profit: Treatment Access for All

Today the total number of people living with HIV stands at over 40 million, double the number in 1995. In 2005, there were close to five million new HIV infections worldwide, over 3 million of these in sub-Saharan Africa alone. In the same year, three million people died of AIDS-related diseases; more than half a million were children.¹

In the United States and other wealthy nations, HIV and AIDS are increasingly becoming chronic and treatable through medical advances. Life-extending drugs are available to those with the money, insurance, or government support necessary to pay for them and today many individuals have survived—and even thrived—with HIV for upwards of two decades. After the introduction of anti-retroviral therapy in the US in 1996, the HIV-related death rate declined by 70%.²

The good news is that over 1 million people worldwide now have access to effective treatment. But this falls far short of the World Health Organization's goal of reaching 3 million by 2005. **Today, fewer than 1 in 6 people in "immediate need" of treatment have it.**³

In 2005, 99% of AIDS deaths were outside North America and Western Europe yet, except for a few individual nations, these remain the only regions in the world where most people in need of antiretroviral treatment are able to receive it. In Sub-Saharan Africa only 11% of the 4.7 million in need of treatment have it. In Asia, only 14% have access.⁴

Recently the Group of 8 wealthiest nations met in Scotland and pledged universal access to HIV/AIDS treatment by the year 2010. Yet, this pledge has almost no chance of success unless we substantially change the way our government and our companies do business!

Since the fall of 2000, prices of "first generation" antiretroviral drugs have become more affordable in the Global South—AIDS therapy can now cost just \$200 per patient per year compared to \$10,000 four years ago. Under pressure from activists, many drug companies have voluntarily reduced prices. The most effective and important element in bringing first-generation prices down, however, has been through generic production and competition.

In the normal course of HIV disease, though, patients (in both rich and poor countries) often become resistant to older "first line" drugs four or five years into treatment. New "second generation" drugs are now available to meet this challenge, yet in much of the Global South people cannot receive treatment. Why? These newer drugs, available almost exclusively from big-name drug companies, cost up to 30 times as much as first line drugs and, often, aren't even available where they're most needed!

What Needs to Happen?

Drug Companies must make good on their promises and make drugs *available and affordable* for those living in poverty in the Global South!

Medicines registered and sold at affordable prices in low and middle-income countries.

Drug Companies must *let generic drugs save peoples lives* in the Global South!

Open licenses to allow fair competition through government and corporate generic production in low- and middle-income countries, which can reduce costs up to 95%.

The US Government and Trade Agreements need to *put people's lives over drug company profits!*

Rules that protect public health must trump corporate patent and data rights.

SGAC's Treatment Access Campaign

Pharma Companies, Keep Your Promises! Generics Now to Save Lives!
Trade Justice that Puts Public Health over Pharma Profits!

1) Drug Companies must make good on their promises and make drugs available and affordable for those living in poverty in the Global South!

The pharmaceutical industry is among the top in the US economy in profits—with hundreds of billions of dollars in sales and many companies raking in 15-30% profits year after year. Drug companies try to justify high prices by saying they have high research and development costs. In reality, however, after accounting for tax breaks, public funding, and other support drug companies spend just 1.3 cents out of every dollar from sales on innovation!⁵

In the hopes that governments will not break their patents in southern countries and to thwart bad publicity, pharmaceutical companies have made many promises in the last few years to provide affordable AIDS drugs in poor countries. In reality, however, second generation drugs are neither available nor affordable despite drug company pledges. Why?

Availability: Drug companies have published “differential pricing” plans that would provide reduced prices for essential second line drugs in poor countries—Gilead Sciences, for example, promises affordable prices in 97 countries. In order for a drug to be available for use in a country, though, the company must register the drug with the national drug regulatory agencies (NDRAs) and provide data showing its safety and effectiveness—as companies do in the US with the Food & Drug Administration (FDA). In many cases, though, the multinational drug companies have simply not bothered to register their drugs in the countries where they claim to be offering affordable prices. As such, the life-saving medicines are not available and the pricing plans are phantom promises.

Prices: Even if the drugs were available, millions of people in dire need are excluded because companies do not offer affordable pricing to most “middle income” countries. Many of these countries—like Brazil and India, for example—have no hope of paying market prices for name-brand AIDS drugs, yet are ineligible for discounted prices.

Children: Over a half-million children died last year because of HIV and AIDS—nearly all in the Global South. Because these children are not important “profitable” consumers, though, most second line AIDS medications have not been tested on kids and are not available in dosages for them. Sometimes this is as simple as making a pill that can easily be split in half. Where they are available, pediatric formulations usually cost many times as much as adult dosages—for less of the same drug!

Numbers

US Drug company sales
per year:*
\$218 billion

Portion in Africa:
0.4%

Research & Development
Spending:
\$38 billion

Spending on Marketing:
\$60 billion

Spending on lobbying the
US government:
\$116 million

Spending on Research &
Development in Africa:
\$18 million

*Sources: Pharmaceutical Research
and Manufacturers of America (PhRMA);
Center for Public Integrity, 2004.

2) Drug Companies must let generic drugs save peoples lives in the Global South!

We know that, far and away, the best way to reduce prices on life-saving medications is through generic production. AIDS treatment has only been possible in some of the world's most impoverished regions because generic competition led to dramatic price drops—from \$15,000 per person per year to just \$200. Research in Uganda by Doctors Without Borders and Oxfam, for example, demonstrated the essential nature of generics. Despite the fact the big five pharmaceutical companies had agreed under the Accelerated Access Initiative to reduce the prices of ARVs, it wasn't until generic equivalents from India were brought in that prices actually fell to affordable rates in the country.⁶

Big Pharma, though, has resisted the production of generics. The reality is that allowing governments and drug companies to produce generic drugs in poor countries wouldn't begin to touch massive drug company profits. Indeed, the drugs aren't even being sold in many of these countries.

Voluntary open licenses: In 2001 Bristol Myers Squibb, under pressure from students and NGOs, agreed to relax its patent protection on the drug d4T, allowing generic companies to produce the drug in Africa. Similarly, today drug companies should put people's health over profit. Often patent laws prevent the production of low-cost generic. So too do emerging corporate rights to "data exclusivity," which can prevent makers of "follow on" drugs from using previous research to show that their drugs are effective and safe.

An open license is essentially an agreement to allow governments and generic companies in the Global South who are qualified to create generic versions of life-saving drugs. Instead of picking and choosing one company to transfer the monopoly to or a few companies who would share an oligopoly, the patent holder agrees to set standards with respect to good manufacturing practices (quality) and then lets the producers opt-in into the license.

Some companies have tried to say they won't enforce patents in some countries, but this can (and has been) rescinded at some point when the company changes its mind—leaving generic producers high and dry. Other companies have offered limited licenses only in those countries they know don't have the capacity to actually produce generic drugs. Instead, there must be real effort to save lives by encouraging low-cost generic production through clear, open licenses in areas in need.

3) The US Government and Trade Agreements need to put people's lives over drug company profits.

The US government is currently negotiating trade deals with Southern Africa and Thailand that promise to block the development of life-saving, low-cost drugs.

International trade is currently and primarily governed through the World Trade Organization (WTO), which was established in 1994. The WTO has a membership of 149 countries and is governed by a series of agreements. Countries desire to join the WTO because it offers the opportunity to participate in a system of "free trade" where, ideally, all barriers will be removed from channels of trade and everyone will have an equal advantage to participate in the world market. In reality, rich countries are often demanding more access to poorer countries people and markets while poorer countries are reluctant to comply out of concern for their domestic economies, environment, traditions and public health.

TRIPS and the Doha Declaration: One of the agreements that govern international trade at the WTO is called Trade Related aspects of Intellectual Property Rights (TRIPS), which covers protections that countries must offer including areas like copyrights, trademarks, and patents.

During and after the negotiations of TRIPS, developing countries lobbied against the strong protection for

Intellectual Property Rights (IPRs) that TRIPS provided. In particular, they worried that providing strong IPRs to drug patents would make it difficult for poorer countries to provide necessary medicines to their citizens living and dying of HIV/AIDS, malaria, tuberculosis, and other diseases.

In response to this concern, in 2001 WTO members (including the US) issued the Doha Declaration, stating that developing countries should not be limited by TRIPS in their efforts to protect public health, specifically including access to medicines. Pressured by the pharmaceutical industry, the US government fought this declaration. When it lost, the US began an end-run around the declaration on a country-by-country basis by negotiating bilateral treaties with IPRs beyond what is provided in TRIPS—referred to as the US’s “TRIPS plus” agenda. Such efforts are clearly evident in recent trade agreements, such as the Central American Free Trade Agreement (CAFTA), negotiated between the United States and developing countries.

That agenda includes:

- **Extending Drug Patent terms beyond the basic 20 years agreed to at the WTO.** Pharmaceutical companies argue that patents compensate them financially for the Research and Development (R&D) they invest in each drug. In reality, the public pays for half of R&D expenditures worldwide, and independent estimates of what drug companies spend on R&D is less than half of what drug companies claim they spend.⁷
- **Restricting the circumstances where countries can issue compulsory licenses.** CLs allow a country to override a patent in very limited circumstances to meet a pressing public need—a mechanism the US has historically used for military and other priorities.
- **Preventing use of test data on the patented drug to prove that its generic counterpart is also safe.**⁸ When a generic drug becomes available, countries normally affirm its safety and effectiveness through looking at the data available from the patented drug and requiring the new drug simply prove it is chemically the same. Without the use of previous test data, though, new research would have to be conducted. Known as “data exclusivity”, this requirement will slow down or prevent access to the cheaper drug since many generic companies and governments do not have the technological capacity or funding to test these drugs on their own.

Expanded intellectual property rights will benefit only corporations—whose profits will be maximized at the real cost of peoples lives. The world has already spoken through the Doha Declaration, and IPRs are already governed by the WTO. Yet, the United States’ trade agenda affirms its preference for drug companies’ profits over providing access to treatment for millions of people.

1 UNAIDS, Global Summary of the AIDS Epidemic, 2005, www.unaids.org/Epi2005/doc/report.html

2 Highleyman, Mortality Trends: Toward a New Definition of AIDS, San Francisco AIDS Foundation, 2004/2005, www.thebody.com/sfaf/winter05/definition.html. Though note uneven nature of treatment in the US—HIV/AIDS is still the leading cause of death for African American women ages 24-34 (Henry J. Kaiser Family Foundation, The HIV/AIDS Epidemic in the United States, HIV/AIDS Policy Fact Sheet, 2005) and death rates are much higher among poor Americans (United Press International, “The poorest more likely to die from AIDS,” Nov 1, 2005, www.upi.com/ConsumerHealthDaily/view.php?StoryID=20051101-051047-7558j)

3 World Health Organization, Antiretroviral therapy coverage in low- and middle-income countries, June 2005, www.who.int/hiv/facts/cov0605/.

4 WHO, June 2005.

5 Light and Lexchin, “Foreign free riders and the high price of US medicines,” *British Medical Journal*, 22 October 2005.

6 www.oxfam.org.uk/what_we_do/issues/hivaids/downloads/arvaccessuganda.pdf

7 Medecins Sans Frontiers. Frequently Asked Questions, 2005, www.accessmed-msf.org/campaign/faq.shtm.

8 Medecins Sans Frontiers, Provisions in CAFTA Restrict Access to Medicines, February 3, 2004, www.msf.org.