

Patients over Profit:



Treatment Access for All

Patients over Profit: Treatment Access for All
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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.



Targets

Gilead Sciences

Demands

- 1) Make good on your price promises: Register your drugs in all 97 Access Program countries; seek temporary waivers until registration is complete.
- 2) Publish affordable prices for middle-income countries, particularly those excluded in Southeast Asia, Eastern Europe, the Caribbean, and Latin America.
- 3) Offer a voluntary open license to governments and companies to produce generic versions of Tenofovir & Truvada in the Global South.
- 4) Research and develop pediatric formulations and establish recommended pediatric dosing ranges.

Locations

Corporate HQ: Foster City, CA
President and CEO, John C. Martin, PhD.
333 Lakeside Drive; Foster City, CA. 94404
(p) 650.574.3000 ; (f) 650.578.9264

Other factories/offices: (Details at www.gilead.com/wt/sec/worldwide)
CA: San Dimas, CA
NC: Durham

Abbott Laboratories

Demands

- 1) Publish affordable prices for both new and old Kaletra in all low- and middle-income countries, particularly those excluded in Southeast Asia, the Caribbean, Latin America and Eastern Europe.
- 2) Make good on your price promises: Register both new and old Kaletra in all ACCESS countries; seek temporary waivers until registration is complete.
- 3) Offer a voluntary open license to governments and companies to produce generic versions of Kaletra in the Global South.
- 4) Make pediatric formulations: half-dose tablet and syrup that is more palatable and doesn't require refrigeration

Locations

Corporate HQ: Abbott Park, IL
Chairman and CEO, Miles D. White
100 Abbott Park Road, Dept 392 Bldg. AP61-2
Abbott Park, IL 60064.
(p) 847-937-6100 or General: 847-937-3417
(f) 847-937-1511 or General: 847-938-6277

Other factories/offices: (Details at <http://abbott.com/corporate/unitedstates.cfm>)
CA: San Diego, Redwood City, Santa Clara, South Pasadena

GA: Norcross
IL: Abbott Park, North Chicago, Downers Grove
MA: Worcester, Bedford
MI: Sturgis, Wyandotte
NJ: East Windsor, Whippany
NY: Glens Falls
OH: Columbus
TX: Austin, Dallas, Irving
UT: Salt Lake City
VA: Altavista

Demands

1) Put patients over profits: Publicly take Intellectual Property Rights (IPRs)—already governed by the WTO—off the table in negotiations with Southern Africa, Thailand and all other nations in the Global South.

2) Publish US proposed text for the entirety of both FTAs so that the US, Thai, and Southern African people have a chance to hold public consultations on the proposed agreement before any trade agreement moves ahead.

Location

600 17th St., NW, Washington, DC 20508

General Target:

Rob Portman, U.S. Trade Representative

Ph: 202.395.6890 F: 202.395.4549

Plus...

Southern Africa Targets:

Florizelle Liser, Assistant U.S. Trade Rep. for Africa

Ph: 202-395-9514 F: 202-395-4505

Victoria Espinel, Acting Assistant USTR for Intellectual Property

F: 202-395-3891

Thailand FTA Targets:

Barbara Weisel, Assistant U.S. Trade Rep. for Asia-Pacific and Pharmaceutical Policy

Ph: 202.395.6813 F: 202-395-9515

Victoria Espinel, Acting Assistant USTR for Intellectual Property

F: 202-395-3891



Putting Profit before Patients: Gilead Sciences

In recent years, the price of first-generation AIDS drugs used in first-line combination antiretrovirals has fallen dramatically, from US\$10,000 to US\$200/patient/year.¹ But with growing resistance to these drugs and side effects, there is an urgent need for newer drugs.

Among these critical new second-generation drugs are Gilead's Tenofovir (brand name Viread) and Truvada. Sadly, people living with AIDS in the Global South continue to die because these essential drugs are neither available nor affordable in the places they are most needed. Meanwhile, Gilead seeks public acclaim for its philanthropic program that claims to make drugs available to people living with AIDS around the world, when in fact leaving too many to die.

Background

Gilead Sciences is among the most profitable companies in the US. Gilead's 2005 sales will likely hit \$2 billion when accounting is completed—the majority of revenue coming from HIV medications, sales of which are up over 50%. While company profits run at over 30% of sales (likely well over \$600 million in '05), research and development accounts for less than 15%, lagging behind marketing and administrative costs.²

Gilead's 'Access' Program

Launched in September 2003, Gilead claims to be offering discounted prices to 97 countries, including all of Africa.³ However, Gilead has failed to actually make these drugs available in most of the countries where they claim to be offering price reductions—thus garnering positive publicity while people in the Global South die because drugs are inaccessible.

Drugs

Tenofovir (TDF/brand name Viread)

A widely prescribed antiretroviral, recommended by the WHO as a key part of combination therapy, it is in a category of HIV medicines called nucleoside reverse transcriptase inhibitors (NRTIs), which prevent HIV from altering the genetic material of healthy T-cells and prevent the cells from producing new virus.

Truvada

A combination of Gilead's NNRTI antiretrovirals Tenofovir and Emtricitabine (TDF+FTC) that requires only once a day use (though must be combined with other medications)

SGAC DEMAND #1: REGISTER Tenofovir and Truvada and MAKE THEM ACCESSIBLE

Make good on your price promises: Register your drugs in all 97 Access Program countries; seek temporary waivers until registration is complete!

Use of Gilead's drugs in the Global South, like any drugs, requires registration with country drug regulatory agencies (NDRAs)—the equivalent of the US FDA—or it requires negotiation of temporary waivers at the NDRA. Out of the 97 Gilead Access Program countries, according to the WHO, Tenofovir has only been registered in 6 countries and Truvada in only 3.⁴ While Gilead claims to have sent dossiers to 20 more countries, these do not include any in Africa—a problem Gilead claims is not theirs to solve, but up to a South African company, Aspen Pharmacare, to whom it licensed production and marketing in Africa. While Gilead may claim that it's Aspen's responsibility to register the drugs, Aspen's limited capacity to do so in a timely manner and the state of emergency facing these countries make false the claim that Gilead is offering discounted drugs to all of Africa.

Added to the deadly delay in making these drugs available, Gilead refuses to offer equitable pricing to 34 middle income countries excluded from the “Access” program. Of these countries, Tenofovir is registered in only Brazil and Truvada in none.⁵

Neither Truvada nor Tenofovir has received WHO pre-qualification due to, in large part, Gilead’s non-cooperation when it comes to paperwork. WHO Pre-qualification would greatly facilitate registration of Gilead’s drugs with national regulatory agencies.

SGAC DEMAND #2: BETTER PRICING, MORE COUNTRIES

Establish affordable pricing for all low- and middle-income countries, particularly those excluded in Eastern Europe, Southeast Asia, and Latin America.

The discounted “Access” price of Tenofovir is currently US\$208/patient/year and Truvada is currently US\$318—higher than many first generation drugs.

A great many countries, though, are simply left out—5 countries classified by the World Bank as “lower income,” including India, are ineligible for Gilead’s program. Of the 54 “lower-middle income” countries like Brazil and Thailand, 33 are not eligible for Gilead’s Access Program. In these countries, which include tens of millions of people living on less than \$2 a day, drugs are priced out of reach—often at US prices unless negotiated on a drug-by-drug basis. For example, after repeated negotiations in Brazil, Tenofovir still costs an exorbitantly high US\$2,555/patient/year.

SGAC DEMAND #3: VOLUNTARY OPEN LICENSING

Offer a voluntary open license to governments and companies to produce generic Tenofovir and Truvada in the Global South.

Both the active ingredient in Tenofovir, invented by Czech and Belgian scientists, and Truvada, “owned” by Emory University, were developed by scientists outside of Gilead. Gilead, however, is single-handedly able to set prices and exercise the patent rights to these drugs.

In addition to registering the drugs, Gilead must issue a voluntary, open license—explicitly allowing governments and companies to produce and provide affordable generic versions in the Global South, where Gilead shows no marketing interest. This will bring prices down through fair competition and enable more suppliers to actually deliver the drugs (not just promises).

SGAC DEMAND #4: PEDIATRIC FORMULATIONS

Research and develop pediatric formulations and establish recommended pediatric dosing ranges.

Millions of children die with no access to these drugs because there is currently no pediatric formulation or dosing ranges for Tenofovir or Truvada. The adult formula of Tenofovir has a high toxicity in children.

TAKE ACTION ON GILEAD NOW

Contact Gilead: President and CEO, John C. Martin, PhD.; Gilead Sciences, Inc., 333 Lakeside Drive; Foster City, CA. 94404; (p) 650.574.3000 ; (f) 650.578.9264

Contact the CEO and demand real, affordable access. Here are some talking points:

- Out of 97 Access countries, Gilead has shamefully registered in only 3 (for Truvada)/ 6 (for Tenofovir). It must commit to registering their drugs in all 97 countries and turn their phantom acts of goodness into reality.
- Poor people around the world need affordable drugs, so you need to provide affordable prices for all low- and middle income countries currently excluded from your program!
- Trying to blame your failure to register in Africa on Aspen is unacceptable—Gilead can’t claim to offer discounted drugs in Africa if you haven’t even bothered to do the paperwork!
- Gilead’s lack of any pediatric formulation of its drugs is unacceptable—creating a pediatric formulation and dosing ranges is a basic step that would save lives.

1 MSF: Backgrounder for WTO Hong Kong Ministerial on Second-line Antiretrovirals. 10 December, 2005.

2 Gilead Sciences, Third Quarter Earning Report, www.gilead.com

3 Gileadaccess.org

4 TDF: Bahamas, Gambia, Kenya, Rwanda, Uganda, Zambia; Truvada: Ghana, Kenya, Uganda

5 World Health Organization, <http://ftp.who.int/htm/AMDS/drugsdatabase.pdf>



Putting Profit before Patients: Abbott Laboratories

In recent years the price of first-line AIDS drugs has fallen dramatically, from US\$10,000 to US\$175/patient/year.¹ But with growing resistance to these first-line drugs and side-effects, there is an urgent need for new “second-line” drugs. Unfortunately affordable global access to these drugs is nearly non-existent.

Abbott’s Kaletra (a combination of drugs Lopinavir and Ritonavir [LPV/r]) is among these critical second-line drugs. Abbott received FDA approval in October, 2005 for a new version of Kaletra that makes huge improvements for use in resource-poor settings. This newer version of Kaletra:

- does not require refrigeration
- can be administered without regard to meals
- requires fewer pills per day (2-4 tablets a day vs 3-6 capsules)

Sadly, this new formulation—perfect for saving lives in Africa and other regions—is not getting to people living with AIDS in the Global South. Instead of getting affordable drugs to people dying in need, Abbott has focused on seeking public acclaim for its largely illusory ‘Accelerated Access Initiative’ while making this drug available only in wealthy markets in the US and Europe.

Background

Abbott Laboratories is among the top drug companies in the world, with \$19.7 billion in sales in 2004 and \$3.2 billion in profits, a 17.5 percent increase over the previous year. Marketing and administrative costs accounted for more than \$4.9 billion of Abbott’s operating expenses while research and development accounted for just under \$1.7 billion. The company spent \$27.6 million on lobbying over the past seven years.² Abbott’s CEO is paid over \$5 million a year.³

In 2000, due to the high cost of AIDS drugs, a tiny percentage of people in developing countries had access to life-saving HIV/AIDS treatment. With patent monopolies under increasing scrutiny and the call for generic competition growing, a handful of drug companies (later including Abbott) sought to protect their reputation and their profits by launching a project called the Accelerating Access Initiative (AAI) in conjunction with UNAIDS. While companies promised to cut drug costs, many activists criticized the project as simple PR.

SGAC DEMAND #1: AFFORDABLE PRICING For NEW KALETRA, MORE COUNTRIES

Immediately establish affordable prices for new Kaletra for all low- and middle-income countries, which includes many in Southeast Asia, the Caribbean, Latin America, and Eastern Europe left out of Abbott’s program.

Despite having a new version that is essential for use in the Global South, Abbott has yet to even offer a price for the improved Kaletra in poor and middle-income countries. According to industry experts, the production of new Kaletra in tablets is less costly than the older Kaletra capsules, yet Abbott has told Brazil to expect new Kaletra to be priced at 10% more than the old.

Since 2001 Abbott has offered lower prices for old Kaletra—currently at \$500/patient/year. However, this price is offered to only 69 countries—leaving out millions who live in countries not deemed poor enough by Abbott. The WHO and UNAIDS recently asked companies to expand the program to a wider group of countries grappling with HIV/AIDS where little or no discounts on pricey drugs had been offered. Based on UNAIDS/WHO proposals, there are now about 110 countries that should be eligible for the program, but Abbott has refused to expand its program.

Further, Abbott is among the worst transgressors of charging high prices outside the ACCESS program. These “middle income” countries like Brazil and Thailand include tens of millions living on less than \$2 a day, yet according to Doctors Without Borders the price of Kaletra in middle-income countries outside Africa is on average 7.4 times more expensive than in low- income countries (average of \$672 vs. \$4,998).⁴

SGAC DEMAND #2: REGISTER KALETRA & MAKE IT AVAILABLE

Make Good on Your Promises: Register Kaletra in all ACCESS countries; seek temporary waivers until registration is complete!

Use of Kaletra in the Global South, like any drug, requires registration in country drug regulatory agencies (NDRAs)—the equivalent of the US FDA—or it requires negotiation of temporary waivers. Registration of drugs is the responsibility of the manufacturer, yet since receiving FDA approval in October 2005, Abbott has not moved to register or get temporary waivers for the much-needed new form of Kaletra in any of the access countries. The company says it does not plan to do so until after completing registration in Europe—where profits are higher. With no generic versions available, this means this life saving drug is simply not available throughout Africa and the Global South. Even the old form of Kaletra is registered in only 54 of the 69 ACCESS countries where a lower price has been “offered.”⁵

SGAC DEMAND #3: VOLUNTARY OPEN LICENSING

Offer a voluntary open license to governments and companies to produce generic Kaletra in the Global South.

There are currently no widely-available generic versions of new Kaletra—and we know that generic production has the potential to decrease prices up to 95%! A few generics of the old version are available only in India. Increasingly, though, new patent laws and “data exclusivity” laws pushed by drug companies and the US government in poor countries are making marketing of generic drugs difficult or impossible.

Abbott has so far refused to provide licenses for Kaletra to interested generic producers, including producers in Brazil. A voluntary, open license would allow governments and other companies to make affordable generic medicines and bring prices down through fair competition.

SGAC DEMAND #4: PEDIATRIC FORMULATIONS

Create a half-dose tablet and syrup that is more palatable and doesn't require refrigeration.

The current pediatric version of Kaletra (a syrup) tastes so bad and must be taken in such large quantities by children that it makes them sick. In addition, it must be refrigerated and so cannot reach rural populations. A small tablet and/or concentrated syrup version would move toward addressing this problem.

TAKE ACTION ON ABBOTT NOW

Contact Abbott: Chairman and CEO, Miles D. White, 100 Abbott Park Road, Dept 392 Bldg. AP61-2
Abbott Park, IL 60064. (p) 847-937-6100 or 847-937-3417 (f) 847-937-1511 or 847-938-6277

Contact the CEO and demand real, affordable access. Here are some talking points:

- Resource poor nations in Africa and elsewhere are the first places new Kaletra should be available—besides greed why would Abbott wait to make it available and affordable?
- Abbott has to make new Kaletra available at the same price as the old!
- Abbott must expand its Access program to include millions dying without access to treatment in Southeast Asia, the Caribbean, Latin America, and Eastern Europe!
- Abbott must offer open and voluntary licenses to produce Kaletra and allow for generic production.
- A pediatric formulation of Kaletra that doesn't make kids sick and doesn't have to be refrigerated is needed to save the lives of the 500,000 children currently in need of ARVs.

¹ Doctors Without Borders/MSF, “Backgrounder for WTO Hong Kong Ministerial on Second-line Antiretrovirals.” 10 December, 2005.

² Center for Public Integrity, *Pushing Prescriptions*, 2005, www.publicintegrity.org/rx.

³ On average over 6 years, Forbes Magazine; www.forbes.com/static/execcpay2005/

⁴ Doctors Without Borders/MSF, 2005, www.accessmeds-msf.org.

⁵ WHO ADMS data: *Excluded countries include Bangladesh, Bhutan, Cameroon, Central African Rep., Chad, Guinea Bissau, Libya, Maldives, Mali, Myanmar, Nepal, Sao Tome & Principe, Sudan, and Yemen.* 25 October, 2005.



Putting Profit before Patients: US-Southern Africa Trade Agreement

Trade negotiations between the United States and the South African Customs Union (SACU) – comprised of Botswana, Lesotho, Namibia, South Africa, and Swaziland – have recently restarted. If the US gets its way, however, corporations are likely to gain significant new rights at the expense of people living with HIV and AIDS.

HIV/AIDS, Trade, and Southern Africa

South Africa is home to over 3.5 million HIV-positive people – the most in the world – while the SACU countries have the highest HIV-prevalence rates in the world. Whereas pharmaceutical companies are currently producing drugs that have significantly reduced AIDS death rates in wealthy countries, people in poorer countries cannot afford market prices for treatments that cost upwards of \$15,000 per year. Low cost generic versions of these drugs, however, have reduced prices by up to 95% – making it actually feasible for Southern Africa countries to treat their HIV-infected populations.

In trade negotiations, however, the US government is promoting new intellectual property rights for corporations that would rule out production of affordable new generic medications—making costs of expanded treatment prohibitively expensive. There is no need for expanded intellectual property rights, since they are already governed by the WTO. Indeed, under pressure the US signed the 2001 Doha Declaration that clarified the ability of nations to use trade law flexibilities to ensure access to medicines. Yet because drug companies did not get what they wanted at the WTO, the US is now pushing these new damaging provisions on a bilateral basis—including currently with Southern Africa.

The US government has refused to release the draft text of its FTA proposals, keeping US and Southern Africa populations in the dark and limiting democratic review and civil society participation. Based on public US positions on FTAs, however, it is clear that the US government is seeking to:

- Extend patent terms beyond the basic 20 years agreed to at the WTO.
- Restrict SACU nations' right to make or import affordable generic medications.
- Stop SACU nations from using trade law flexibilities to protect public health – provisions the US agreed to in the Doha Declaration on public health.
- Prevent the SACU governments and companies from using clinical trial data collected by drug companies to show that equivalent generic drugs are safe and effective.

What We Want from the US Trade Representative

- Put patients over profits: publicly take Intellectual Property Rights (IPRs)—already governed by the WTO—off the table in negotiations with SACU and all other nations in the Global South.
- Publish US proposed text for the entire FTA so that the US and Southern Africa people have a chance to hold public consultations on the proposed agreement before any trade agreement moves ahead.

WHO TO CONTACT

USTR: 600 17th St., NW Washington, DC 20508
Rob Portman, US Trade Representative
Ph: 202.395.6890 F: 202.395.4549
Florizelle Liser, Assistant US Trade Rep. for Africa
Ph: 202.395.9514 F: 202.395.4505



Putting Profit before Patients: US-Thai Trade Agreement

The United States and Thailand are negotiating a Free Trade Agreement (FTA) that threatens to undermine Thailand's ability to buy and produce low-cost generic versions of life-saving medicines. At the Chiang Mai negotiation round in January 2006, 10,000 Thai activists—half of them living with HIV/AIDS—converged on the meeting and forced their way in to demand that their lives be valued over corporate profit.

HIV/AIDS, Trade and Thailand

While there is still no cure for HIV disease, death rates from AIDS have been slashed in the US and other wealthy nations through effective antiretroviral therapy. In poorer parts of the world, paying market prices for these drugs is simply not an option. Low cost generic versions of these drugs, however, have reduced prices by up to 95%. This has made it possible for Thailand to create a program of government-subsidized antiretroviral drugs that now reaches 80,000 of 170,000 Thai people living with HIV and AIDS. And the program is working—AIDS deaths are 1/3 of what they were a year ago!

Nonetheless, the US government is pushing intellectual property provisions for a new FTA at the expense of people's lives – provisions that would keep the costs of new drugs in Thailand prohibitively expensive by ruling out generic competition. There is no need for bilateral deals that expand intellectual property rights, since they are already governed by the WTO—of which Thailand is a member. Indeed, under pressure the US signed the 2001 Doha Declaration that clarified the ability of nations to use trade law flexibilities to ensure access to medicines. Yet because drug companies did not get what they wanted at the WTO, the US is now pushing these new damaging provisions on a bilateral basis.

The US government has consistently refused to release the draft text of its FTA proposals, keeping US and Thai populations in the dark and limiting democratic review and civil society participation. Based on public US positions on FTAs, however, it is clear that the US government is seeking to:

- Extend patent terms beyond the basic 20 years agreed to at the WTO.
- Restrict Thailand's right to make or import affordable generic medications.
- Stop Thailand from using trade law flexibilities to protect public health – provisions the US agreed to in the 2001 Doha Declaration addressing public health and medicines.
- Prevent the Thai government and companies from using clinical trial data collected by drug companies to show that equivalent generic drugs are safe and effective.

Student Global AIDS Campaign Demands:

- Suspend the negotiations on the FTA as demanded by Thai activists.
- Put patients over profits: Publicly take Intellectual Property Rights (IPRs)—already governed by the WTO—off the table in negotiations with Thailand and all other nations in the Global South.
- Publish US proposed text for the entire FTA so that the US and Thai people have a chance to hold public consultations on the proposed agreement before any trade agreement moves ahead.

WHO TO CONTACT

USTR: 600 17th St., NW Washington, DC 20508

Rob Portman, US Trade Representative

Ph: 202.395.6890 F: 202.395.4549

Barbara Weisel, Assistant U.S. Trade Rep. for Asia-Pacific and Pharmaceutical Policy

Ph: 202.395.6813 F: 202-395-9515



Take Action



Take Action for TX!

(with thanks for some ideas from ActUP NY)

Treatment Access (TX) for people living with AIDS around the world depends upon access to affordable drugs—and that depends, in part, on US activists bringing it home to our government and our drug companies!

So, what can you do? Remember taking action can take on many forms. Talking with your friends, family, and people you go to school with—that's taking direct action. So is taking over the office of the CEO of the nearest drug company to demand affordable prices for people dying around the world. So is writing a letter to your member of congress asking them to stop bad trade deals.

So, in that spirit, here are some suggestions. Even better, make up your own! Some actions are totally risk free, while others carry some risks and will require legal advice and support. But, whatever you do, don't just sit there—take action today... or at least tomorrow.

No-Risk Actions

1. Do a phone- or fax-zap on Gilead, Abbott, or the USTR's office.
2. Write letters or send post cards to the US Trade Rep or the CEOs of Abbott & Gilead demanding national leadership in response to the AIDS crisis.
3. Organize a postcard mail-in campaign to a local legislator asking them to lobby the US Trade Rep to put people living with HIV and AIDS over profit and stop the SACU and Thai FTAs.
4. Phone in to local radio talk shows and discuss access to treatment for AIDS globally; organize on your campus so that the station is flooded with calls throughout the program.
5. Organize a teach-in on treatment-related issues on your campus or, better yet, do outreach to others by doing teach-ins at other local colleges and high schools.
6. Write letters to the editor of your local newspaper/magazine, discussing the greed that pharma corporations are demonstrating in failing to provide affordable drugs and pushing bad trade deals on poor countries.

Low-Risk Actions

1. Organize a peaceful picket with signs and creative chants in front of an important target—one of Gilead or Abbott's factories or a government building. Make sure to invite the media (email erin@fightglobalaids.org or mkavanagh@globaljusticenow.org for help).
2. Wheatpaste attention-grabbing posters or fliers around your community demanding action—especially if you are near one of the pharmaceutical headquarters.
3. Hold a vigil with candles every night for a week in front a good target like a Gilead or Abbott factory or a government building—mourn the death of millions who could be saved by affordable drugs.
4. Build a mock graveyard of tombstones (of people who have died from government/drug company neglect) and place it in prominent location on your campus. Get passers by to take some sort of action—write a letter, make a call.

Not-So-Low-Risk Actions

1. Organize a big demonstration that blocks traffic and marches through your town or city demanding action from one of our targets.
2. Hang a banner from a prominent location (highway overpass, tall building, church steeple, etc.).
3. Stage a massive die-in (a form of street theater in which demonstrators lie down in the streets symbolically in memory of those who have died from HIV disease).
4. Take over the office(s) at one of the drug companies or government agents and refuse to leave until your demands have been met.
5. Interrupt/disrupt a speaking event of a politician or company executive and demand that they take action on these issues.
6. Fill a casket with bloody bones (check with local restaurants and meat markets) and place it in front a prominent location—even better if it's in front of a good target.
7. Interrupt a local live newscast with AIDS-treatment-specific information.



Do A TX Zap!

(From ActUP NY's YELL Zine: www.actupny.org/YELL/zine/)

A Zap via phone, fax, or letter is a great way to get our Treatment Access (TX) demands across to our targets. Look at the fact sheets on each of the targets for phone, fax, and addresses and remember to include our demands!

Phone

A phone zap is when a number of people call a target to make a demand. Phone zaps serve a double purpose: they let your target know how many people support your demands, but they also make it hard for your target to conduct business as usual because they keep the phone lines busy, making it hard for an office to function. To conduct a phone zap, find out the phone number(s) of your target, write a sample script with your demands and some facts about the issue, and put it on a flyer with the phone numbers. Give it to as many people as possible, and start calling.

Fax

A fax zap is similar to a phone zap because it is both a way of communicating your demands and a way of inconveniencing your target by keeping their fax machine busy. To do a fax zap, give out a sheet with your demands on it and your target's fax number and have people fax it whenever they want, as often as they want. Another way of doing this if you only have access to one fax machine, is to feed one copy of your flyer through the fax machine. As it comes through, tape on another copy to form a loop. Once the loop is created you may either be able to set the fax machine to automatically redial and keep sending over and over or you may have to stand there and keep dialing.

Letter

The point of a letter zap is to show, by generating a flood of mail, how many people support your demands. There are two ways to do a letter zap. The first is to have lots of people write individual letters to your target - this is particularly powerful because it gives a human voice to your demands. Sometimes it's not possible to get enough people to actually write individual letters, so the other way to do a letter zap is to write a form letter to your target outlining your demands and make a lot of copies. All people have to do is sign the letters. It helps to have each person individually put the address and their own return address on the envelopes because if the letters are obviously all the same they won't be opened. Letter zaps can also be done via email.



Do TX Pickets, Protests or Street Theater!

Getting out there to the streets is a fun and effective way to both get our message out and put pressure on our Treatment Access targets. Check out the fact sheets on each of the targets for demands. Many chapters are actually located near a factory or office of one of our target drug companies or government targets (check out the targets section of TX Access guide).

There's many different high-profile events or actions you can hold—some that require many people and some only a few.

Ideas include:

- **Hold a peaceful moving picket or a night-time vigil** in front of one of the targets. This can be especially effective if there are lots of people or, with just a few people, if you repeat the action often (like every day for a week).
- **Create a great photo-op.** ACTUP, for example, has done actions like lining up hundreds of shoes representing people who have died in front of decision-makers' offices or delivering a 30 foot long spine to politicians. Focusing on treatment, visuals could include lining up hundreds of empty prescription bottles outside a pharma office or bringing a coffin full of prescription bottles and leave it in front of the target. Make sure to call the media!
- **Do some street theater.** This January, SGACers and others pulled out 30 people—one dressed up as a drug company executive, another as a Grim Reaper representing the Thai FTA, and then 25 others, playing HIV+ Thais, were "killed" by the FTA and piled into body bags with signs saying "killed by the FTA." Then they were "eulogized" with speeches about trade and AIDS. The news photographers ate it up and it made international news!

Target

Make sure that you are clear about who the target is, and what the demands are. If you are trying to influence a target, how will they know about it (is it at their office? Will you send them photos or press clippings?).

Media

Think about what the press story will be and why media will want to come (what's new, why will they care?). Have good visuals at your demo with clear messages on them. Make your press announcements catchy and do follow-up calls!

Turnout

Think about your goals—do you need a lot of people or can you be effective with fewer? Set a specific turn-out goal, then get at least twice that many commitments—keep a list! Consider things like assigning dorm captains to bottom-line turn out, doing classroom presentations, and knocking on doors and making phone calls.

Prep

Make a list of all the roles for the day and all the props, megaphones, stages, signs, etc. you'll need. Walk through the "scenario" to make sure everyone will know what to do, where to go. Plan how you're going to end the event, don't just let people drift off.

More ideas? Check out some of the most creative at: www.actupny.org and www.ruckus.org

Check out SGAC's advocacy guide for more tips or call/email the national coordinator!



More Reading

FAQ: HIV & AIDS TREATMENT ACCESS

(with thanks to MSF accessmed-msf.org and HealthGAP Healthgap.org)

ARVs & Treatment

Is antiretroviral treatment necessary to combat HIV/AIDS?

Yes. A few years after infection with HIV, the virus weakens the patient's immune system to the point where the first "opportunistic infections" appear. HIV itself does not kill, it is opportunistic infections – such as tuberculosis and pneumonia – that do. Medicines to treat most opportunistic infections are available (though they are often too expensive for the majority of patients). But treating opportunistic infections is only a temporary solution, since HIV continues to attack the immune system. After one infection is cured, others inevitably follow. Antiretroviral (ARV) drugs are needed in order to combat HIV directly and are an important part of a comprehensive approach to addressing the epidemic. They do not cure AIDS, but can improve a patient's quality of life and prolong survival when taken consistently. Over the last six years, the introduction of ARVs in Europe and the US has cut AIDS deaths by over 70%. In Brazil, the use of ARVs cut AIDS mortality by 51% from 1996-1999. Treatment is also a powerful incentive to get tested, providing a strong boost to prevention efforts. We cannot afford to wait to extend treatment.

Should treatment take precedence over prevention activities?

Prevention and treatment are BOTH essential and complementary components of combating disease. Field experience has shown that prevention efforts are boosted when treatment is also made available.

What are the barriers to access to medicines for AIDS in developing countries?

The high price of medicines is one of many barriers to providing ARV treatment for people living with AIDS in developing countries. Other barriers include political will, social stigma, health infrastructure, and insufficient funding. But until recently, the prices of ARVs were so high that wide scale treatment programs were unthinkable. Since September 2000, the injection of generic competition into the global ARV market has catalyzed a dramatic drop in drug prices. As a result, medical, academic, and political leaders are now beginning to tackle other barriers to treatment. With the prices of drugs tumbling, there is no longer any excuse to deny medical treatment to the millions who are already ill.

Is it even possible to provide free access to ARV treatment in poor countries?

Yes, an increasing number of countries around the world have programs that offer free ARV treatment. Botswana was one of the first countries in Africa to establish a national antiretroviral therapy program, beginning in 2002 and progressively expanding across the country. Treatment is provided free of charge in the public sector. This has in turn stimulated demand for voluntary HIV counseling and testing. Brazil began offering free and universal access to triple-combination antiretroviral treatment in 1996. Today about 160,000 people receive free treatment through the public health system. This includes 17 antiretroviral drugs, eight of which are domestically produced generic drugs and nine are imported brand-name drugs. The government estimates that provision of treatment early in the epidemic has saved Brazil more than US\$ 2 billion in health-care costs since the beginning of the epidemic.

Will focusing on treatment for people who are already HIV-positive detract from prevention efforts?

Treatment and prevention efforts are both necessary and complementary strategies for combating the HIV epidemic. People have little incentive to get tested to find out their HIV status without the possibility of treatment. Once people know their status, they can modify their behavior to reduce transmission. New efforts to combat the HIV pandemic must include treatment in order to be effective.

Do developing countries need second-line drugs because patients there don't adhere to medicine and so are causing the emergence of super-drug-resistant strains of HIV?

The complexity of AIDS treatment makes patient adherence a challenge in BOTH wealthy and poor settings. However, results from the few existing programs are encouraging. With limited health infrastructure, Brazil has dramatically reduced illnesses and deaths from AIDS, and enjoys treatment adherence rates that match those in the US (around 70% of patients taking their medicines properly 80% of the time). In much poorer Uganda and Côte d'Ivoire, well-run pilot projects have also demonstrated that adherence rates can match those of Europe and the US. But, in the normal course of HIV disease, patients become resistant to first line drugs in 4-7 years in both the wealthy and poor nations. As such, second generation drugs are needed in the US and Europe—and must be made available to those in the Global South.

Prices, Patents, and Generics

Are generic medicines the best way to bring prices down?

Yes. When generic competition is introduced, prices will fall—historically by up to 95%. For example, after the Brazilian government began producing AIDS drugs generically, prices dropped by 82%. In contrast, the prices of drugs with no generic competitor dropped by only 9%. Likewise, generic competition reduced the price of a triple-combination of antiretrovirals from \$10,000 to \$300 in one year.

Do patents block access to medicines?

When medicines are under patent in a country, the patent-holder has a monopoly on the drug for a minimum of 20 years and can charge whatever price will maximize profit. This prevents the entry of generic competition. In developing countries, this translates into prices that are not affordable for the patient so people die without access.

Will lowering drug prices for poor countries hurt research and development (R&D) for new medicines?

No. Profits from sales in developing countries are insignificant in creating incentives for future research and development. The U.S. drug industry is already the most profitable industry in the world. Pharmaceutical sales in the countries in question are an infinitesimal portion of total global sales (\$518 billion in 2004). All of Africa makes up just 0.4% of the global market; all developing countries combined (Africa, Asia, and Latin America) comprise less than 11.5% of global drug sales. U.S. drug companies make most of their sales (88.5%), and an even higher portion of their profits, from the rich markets of North America, Europe, and Japan. They don't need to squeeze blood from poor consumers in Thailand and other developing countries in order to bring a new medicine to the market. Finally, it is notable that companies consistently spend more on marketing and administration than on R&D.

Why not ask companies simply to donate the drugs?

Drug donations are not a long-term solution to the access crisis. Donations usually do not cover global need and are limited in time and place; they often come with burdensome restrictions on recipient health ministries; they often require extra administrative work, diverting scarce resources from health systems; they can distort rational drug use; tax deductions given for donations may cost donor countries more than other options. Considering the weaknesses, donations should neither be relied-upon, portrayed, nor promoted as the best way to improve access to medicines.

Aren't generic manufacturers stealing intellectual property and breaking the law?

No. Patents are granted on a national basis -- there is no such thing as an international patent. Therefore, if a drug is not patented in a country, it is perfectly legal for a generic company to produce or import a version of that drug in that country. Companies can also export generics to other countries where that drug is not under patent. A concrete example is the AIDS drug zidovudine (AZT). GlaxoSmithKline holds the patent for AZT in the US and Europe, but it does not have a patent for AZT in Ghana. This means that Ghana can legally produce or import a generic version of AZT, and is not in any way infringing on the patent rights of GlaxoSmithKline. In India, there is no product patent for AZT. This means that a generic company like Cipla, based in Bombay, can legally produce and export AZT to a country like Ghana.

What is compulsory licencing?

Compulsory licences allow the production or import of a generic medicine, without the consent of the patent holder. Patent-holders receive adequate compensation. Compulsory licences may be issued by public authorities for various reasons, including public health or emergency. They are neither a form of pirating, a legal loophole, nor a way of stealing intellectual property. Compulsory licences are legal under the TRIPS Agreement, are considered a regular feature of any good intellectual property legislation, and are commonly used by industrialised countries such as the US. France authorizes compulsory licences when patented drugs “are only made available to the public in insufficient quantities or quality or at abnormally high prices.” Both private entities and governments can typically apply for a compulsory licence. Countries should design fast, simple procedures for granting compulsory licences to make full use of this safeguard.

What is parallel importing?

Parallel importation allows a country to shop around for the best price of a branded drug on the global market, without the permission of the patent-holder. It is an attractive option for developing countries when the same branded medicine is being sold for different prices in different markets. For example, it would allow a country like Mozambique, where 100 units of Bayer's ciprofloxacin (500mg) costs \$740, to import the same product from India where Bayer sells it for the much lower price of \$15, due to vigorous generic competition. Many European countries, such as the United Kingdom, benefit from significant parallel trade to reduce the overall cost of medicines. Parallel importing does not involve the purchase of generics.

How much does it cost to research and develop a new drug?

An accurate answer is impossible, since companies do not divulge R&D costs per drug, and methods for calculating this figure are highly controversial. The industry estimates that R&D for each new drug ranges from \$350-\$500 million. These estimates cover many costs, including compounds that have failed, overhead, and opportunity cost. In contrast, independent estimates range from \$30-\$160 million. In addition, R&D is often funded by the public sector. According to the World Bank, half of the current R&D expenditure worldwide, estimated at \$70-\$90 billion, is funded publicly. Many of the drugs marketed by private companies were originally discovered with public funding, including the AIDS drugs stavudine (d4T), zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), abacavir, and ritonavir.

Aren't generic drugs always of lower quality than branded products? Wouldn't that be setting a double-standard for developing countries?

No. In many countries, such as India, Mexico, Thailand, Brazil, Colombia, Canada, South Korea, Argentina, Spain and the US there are strong generic pharmaceutical industries that produce quality drugs. Many of these generic drugmakers produce and export drugs under sub-contract for drug companies in North America, Europe and Japan. Generic companies in developing countries often have manufacturing plants that have been certified by foreign governments as well as their own national authorities.

Generic drugmakers, like proprietary manufacturers that make brand name drugs, should always be examined for quality and good manufacturing practices. This is the primary responsibility of national drug regulatory authorities. MSF supports testing of drugs to meet standards for quality and is advocating for UN agencies to provide support to developing countries by pre-qualifying generic producers of medicines where appropriate, as in the case of anti-retrovirals and other drugs needed in HIV/AIDS.



AIDS & Trade: Myths & Realities

U.S. Pressure on Southern Africa & Thailand Will Impede Access to Medicines

With thanks to HealthGAP (www.healthgap.org)

Although the U.S. initially won significant intellectual property concessions in a multilateral negotiations that resulted in the formation of the World Trade Organization and the passage of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), the U.S. has now turned to bilateral and regional agreements in Latin America (CAFTA, Chile, and Peru), in Southeast Asia (Singapore and now it hopes Thailand and then Malaysia), and in Africa (on-going negotiations with the Southern Africa Customs Union) to secure increased market exclusivity/monopoly rights for its research and development pharmaceutical industry.

Reeling from the negative publicity and pro-access to medicines messaging in Thailand and internationally, the Office of the U.S. Trade Representative (USTR) has mounted a public relations campaign full of distortions and omissions. The U.S.'s myths must be refuted with the truth: Southern Africa, Thailand and other developing countries have a right, indeed an obligation, to guarantee access to more affordable generic medicines in order to address its multiple public health needs.

Myth 1: The FTA will not raise the price of generic medicines in Thailand or South Africa; those medicines will continue to be available at price generic companies choose; most HIV/AIDS drugs are generic.

Reality: These reassurances contain a small truth within a big lie. It's true that an FTA will not affect pricing on drugs that are already being produced generically – that is older, first-line medicines. However, the new rules will increasingly affect the price of newer medicines, especially as drug companies increase their patent filings in Thailand and South Africa, as they seek extensions of patent terms, and as they enforce data rights for their newer medicines. Consumers in Thailand and South Africa will need and are entitled to affordable access to newer medicines at less than monopoly prices. By gaining longer patents and additional data exclusivity rights, big drug companies can continue to exclude or at the very least delay entry by generic competitors, thereby keeping the prices of medicines artificially high.

Myth 2: The U.S. is not proposing extensions of patents beyond the 20 years that is already the law in Thailand and South Africa; data exclusivity does not extend patents.

Reality: The U.S. has sought extensions of patent terms for regulatory delay (both in issuing a patent and in granting marketing approval) in all of its recent FTAs. Inside sources have confirmed that the U.S. is seeking such extensions in the Thai agreement as well and is likely to do so with SACU. The U.S. argument that data exclusivity does not extend patents is true as a matter of patent law, but in economic terms data exclusivity creates a practical right of marketing exclusivity that can delay introduction of generic products even if a patent has expired or even if there is no patent whatsoever.

Myth 3: Data exclusivity does not bar entry of generic equivalents; generic producers are free to submit their own test data and gain marketing approval.

Reality: The U.S. administration argues that it is incredibly expensive for originator drug companies to discover and prove the safety and efficacy of new drugs, but then it argues illogically that those same costs would not bar entry of a generic competitor. To the contrary, not only would it be too expensive and time-consuming for generic companies to repeat clinical trials to gain access to relatively small and poor markets like Thailand and Southern Africa, it would also be ethically improper since the safety and efficacy of the underlying product (and its equivalents) have already been established.

Myth 4: Big pharmaceutical companies must get higher profits from even small, poor countries like Thailand and those in Southern Africa in order to have incentives to invest in research and development.

Reality: Profits from sales in developing countries are insignificant in creating incentives for future research and development. The U.S. drug industry is already the most profitable industry in the world. Pharmaceutical sales in Thailand and Southern Africa are an infinitesimal portion of global sales (totaling \$518 billion in 2004) and all developing country markets combined (Africa, Asia, and Latin America) comprise less than 11.5% of global drug sales with Africa making up just .4%. U.S. drug companies make most of their sales (88.5%) and an even higher portion of their profits from the rich markets of North America, Europe, and Japan. They don't need to squeeze blood from poor consumers in Thailand and Southern Africa in order to bring a new medicine to the market.

Myth 5: Because high profits are necessary for research and development, U.S. IPR-enhancement goals represent a careful balance between current access and future innovation.

Reality: As an industry, major pharmaceutical companies spend nearly three times as much on marketing and administration as they do on research and development. Even after investing in tax-deductible R&D, drug companies typically earn 1 _ as much in profit as they spend on R&D. Moreover, much of the research conducted by industry is in pursuit of me-too drugs, marketing studies, and patent extensions. 53% of "new drugs" 1981-91 were rated by the FDA as providing little or no therapeutic gain and only 16% offered important therapeutic gains. From 1992-99, under a new review system, only 22% (170/730) of "new" drugs merited priority review at the FDA.

Rather than representing a true balance between innovation and access, U.S. trade policy represents a continuous assault on consumer interests and the human right to health, all in pursuit of super-profits for the decade's most profitable industry. Squandering precious research dollars in pursuit of block-buster drugs, trivial product changes (to gain patent extensions), and market-share for copy-cat drugs, the pharmaceutical industry is intent on maximizing its right to sell high priced produced to rich countries and rich elites in developing countries, even if that means hundreds of millions of poor people must wait decades for pharmaceutical patents to lapse and for prices finally to fall.

Myth 3: Data exclusivity does not bar entry of generic equivalents; generic producers are free to submit their own test data and gain marketing approval.

Reality: The success or failure of a pharmaceutical sector in any country depends very little on the patent law in small and poor countries – success depends on a technological infrastructure and access to patent protections and marketing opportunities in rich countries. Indian pharmaceutical companies have become increasingly innovative even before the new Indian Act and most of their prospective innovation is oriented towards penetration of the First World market. Moreover, after passage of the TRIPS Agreement, which set new standards for intellectual property rights, diminished local working requirements (requirements of local production of patent products), and enhanced

Big Pharma's importation rights, many countries including Peru, Chile, and South Africa experienced a significant disinvestment in their local pharmaceutical industries.

Myth 7: Big drug companies won't bother to register their new products in countries like those in Southern Africa or Thailand unless they are given data exclusivity (U.S.T.R. cites Jordan in this regard).

Reality: Even with small quantity sales, major drug companies still have incentive to sell drugs at a profit to middle-class and rich elites in smaller markets. Moreover, Big Pharma has been registering and selling its brand-name drugs in dozens of countries without data-exclusivity for the past 25 years. In addition to seeking data exclusivity monopolies, drug companies typically have underlying patent-based monopoly rights to their newest medicines, which already erect strong barriers against generic competition.

Of course, the larger problem is that Big Pharma often neglects to register its newest products in poor country markets because the volume of sales is not worth the effort. This is a major problem in drug companies' so-called AIDS-drugs access programs where companies make proud announcements of price reductions in low-income (not middle-income) countries and then neglect to register their products (or even to seek temporary import permissions from drug regulatory agencies). For example, Gilead has registered Tenofovir and Truvada in only a handful of access countries (6/97 and 3/97 respectively). Likewise, Abbott has not sought registration of its new single-dose, non-refrigeration Kaletra formulation in any of its 68 access countries.

Myth 8: Only a few drugs are affected so people should not be worried.

Reality: Although it is true that data exclusivity will not apply to all drugs, it does apply to the newest medicines, many of which represent therapeutic breakthroughs, and, if implemented in the manner wanted by the U.S., will apply to most new medicines brought to market in Southern Africa and Thailand in the future. There's no reason that people should not have access to affordable versions of the newest and most effective medicines even if those drugs are relatively few in number.

Myth 9: The World Trade Organization's TRIPS Agreement requires Southern African nations and Thailand to adopt data exclusivity provisions.

Reality: The U.S. administration is misrepresenting the standards required by the TRIPS Agreement. The relevant portion of the TRIPS Agreement, Art. 39.3, only requires protection of undisclosed data against "unfair commercial use" – basically theft or commercial espionage. Nowhere does it state that exclusive rights must be provided for a given period. In fact, TRIPS makes clear that countries may decide for themselves what constitutes "unfair commercial use" and that there are many possible approaches to satisfy this requirement. Permitting a drug regulatory authority to do its job – assuring the quality, safety, and efficacy of medicines – is not unfair commercial use; it is a mandated public service. Prior to 1994, the U.S. tried to get its strict interpretation of data exclusivity into the TRIPS Agreement and failed – negotiators simply rejected its proposal. The TRIPS Agreement, as clarified by the Doha Declaration, ensures the primacy of public health and further ensures that intellectual property rules do not interfere with promoting "access to medicines for all." Furthermore, the Trade Promotion Authority Act of 2002, §2102(b)(4)(C) requires the U.S. to uphold the Doha Declaration. The USTR is defying this requirement.

Myth 10: The proposed FTA would permit Southern African nations and Thailand to take measures it considers necessary to protect public health, particularly with regard to the epidemics of HIV/AIDS, TB, and malaria.

Reality: The exact language of the U.S. proposal creates ironclad protection for pharmaceutical test data with no textual exceptions for registering medicines produced domestically or imported pursuant to compulsory licenses or government use orders. While patents that block access to medicines can be remedied through compulsory licenses

and other TRIPS-compliant safeguards, there is no such explicit recourse for data exclusivity. The U.S. is using vague assurances about rights to protect public health for “epidemics such as HIV/AIDS, tuberculosis and malaria to offset explicit language that takes away such rights. “Sign this contract, but rely on my good intentions in an unsigned postcard” doesn’t work when you buy a used car and it shouldn’t work in trade agreements either.

Myth 11: U.S. is willing to meet with civil society opponents to “clear up misunderstandings.”

Reality: The U.S. insists that its FTA negotiations and all negotiating positions and documents be kept secret. It did not even distribute its proposed IPR provisions to Thai negotiators until the very last moment. Moreover, civil society groups in the U.S. have met with the USTR on many occasions to raise objections to its TRIPS-plus provisions in free trade negotiations as have some members of Congress. Contrary to clearing up misunderstandings, these meetings have consistently confirmed that the USTR is more interested in imposing an ever higher standard of intellectual property protections on developing countries. Each successful negotiation becomes a new step toward even stronger IPRs.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS): A severe immunological disorder caused by the retrovirus HIV, resulting in a deficient immune response that is manifested by increased susceptibility to opportunistic infections, such as tuberculosis, *Pneumocystis carinii* pneumonia, cryptococcal meningitis. It is transmitted primarily by exposure to contaminated body fluids, especially blood and semen. 95% of the 36 million people with HIV/AIDS live in developing countries. In sub-Saharan Africa, home to two thirds of people with HIV/AIDS, 0.1% of patients receive anti-AIDS treatment.

ANTIRETROVIRALS (ARV): Drugs used to treat HIV/AIDS which stop the virus from replicating. Although they do not cure HIV/AIDS, they can improve patients' quality of life and prolong survival when taken consistently.

BIOEQUIVALENT: Drugs containing the same active ingredient (e.g. the generic version and the originator's), in the same amount and pharmaceutical form, which have proved to be absorbed and/or excreted in the same way, and can therefore be expected to have the same effects on the human body.

COMBINATION THERAPY: (DRUG COCKTAIL OR TRIPLE THERAPY): HIV/AIDS drug therapy using a combination of drugs, usually one protease inhibitor or non-nucleoside combined with two other drugs.

COMPULSORY LICENSING: provisions in patent laws that allow public authorities to grant licenses to a third party without the consent of the patent holder. Patent-holders receive adequate compensation. Compulsory licenses may be issued on various grounds of general interest, including public health, and are a common feature of patent law. For example, France authorizes them when patented drugs "are only made available to the public in insufficient quantities or quality or at abnormally high prices."³² Compulsory licenses are neither a form of pirating, a legal loophole, nor a way of stealing intellectual property. Rather, they are part of any good intellectual property legislation, and ensure that a government can counter the negative effects of patents to protect the public interest. For further information, please visit Consumer Project on Technology site: <http://www.cptech.org/ip/health/cl/>

DIFFERENTIAL PRICING: The practice of charging different prices in different markets. See equity pricing. Data exclusivity Trade terms increasingly being pushed by drug companies and the US government that would prevent governments and other companies from using the data from clinical trials and other research submitted by a drug company in the registration process. Generic drugs usually only have to prove that they are chemically identical (or in some cases bioequivalent) to existing approved drugs in order to gain registration, but under extended data exclusivity rights they would have to needlessly repeat trial.

Equity pricing Pricing policies that ensure that, from the point of view of the community and the individual, the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them. Equity pricing is based on the principle that the poor should pay less for, and have access to, products such as essential medicines. The terms "differential", "tiered", "preferential", and "discounted" pricing, and "market segmentation" are also often used to describe the practice of charging lower prices in different markets. However, they do not necessarily result in affordability or equitable access to a product. Rather, they are commercial terms for pricing practices aimed at maximising the profits of the seller. While these practices may lead to equitable access to medicines, they do not necessarily mean that even the lowest prices charged will be affordable.

FREE TRADE AGREEMENT (FTA): An agreement made between two countries (bilateral) or between several countries (multilateral) that sets the terms by which the goods and services produced by one country may be sold in another. Increasingly, these agreements are coming to cover vast new topics that are well outside the area of simply exchanging goods—including everything from ownership of water resources to the ability to produce generic medicines.

Generic drug A pharmaceutical product usually intended to be interchangeable with the innovator product, which is not protected by a patent in the country or is licensed. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary name.

HUMAN IMMUNODEFICIENCY VIRUS (HIV): The retrovirus that weakens the immune system, particularly by causing the death of many CD4+ T cells which coordinate the immune system's response to intruders. After a number of years (typically 5 - 10), this weakening of the immune system leaves the body open to attack from opportunistic infections, eventually leading to the development of Acquired Immune Deficiency Syndrome (AIDS).

INTELLECTUAL PROPERTY (IP): This term covers a number of different legal rights that are awarded by states to persons in return for some valuable "creative" activity. Two well known examples of intellectual property are patents, which may be awarded to protect inventions, and copyright. A patent allows its owner to stop anybody else from making use of their invention, unless given permission (in return for a payment for example). Intellectual property rights only last for a limited period of time, for example, 20 years for patents, 70 years for copyright. See patent protection.

MOTHER TO CHILD TRANSMISSION (MTCT): transmission of HIV from mother to child during pregnancy, at the time of birth, or through breast milk. In the absence of any therapeutic intervention, transmission occurs approximately 25 - 35% of the time. Short courses of antiretroviral therapy such as AZT and nevirapine can reduce this risk by 50% or more, while longer duration treatment with a combination of antiretrovirals can almost eliminate the risk of transmission.

NUCLEOSIDE/NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs): drugs, sometimes referred to as "nukes," which when used in combination with other anti-HIV drugs—usually a total of 3 drugs—can block the replication of HIV in a person's blood. NRTIs work by providing faulty versions of the building blocks (nucleotides) used by HIV's reverse transcriptase enzyme to convert RNA to DNA—preventing the incorporation of HIV's genetic material into health cells and thus preventing production of new virus. NRTIs include emtricitabine (Gilead's Emtriva), tenofovir (Gilead's Viread) and the combination tenofovir + emtricitabine (Gilead's Truvada) as well as other important drugs like stavudine, abacavir, lamivudine.

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs): drugs, sometimes referred to as "non-nukes," which when used in combination with other anti-HIV drugs—usually a total of 3 drugs—can block the replication of HIV in a person's blood. NNRTIs work by attaching themselves to HIV's reverse transcriptase enzyme and prevent the enzyme from converting RNA to DNA—preventing the incorporation of HIV's genetic material into health cells and thus preventing production of new virus. NNRTIs include nevirapine, efavirenz, and delavirdine.

OPPORTUNISTIC INFECTION (OI): an illness that takes advantage of HIV's weakening of the immune system to cause disease. Many OIs occur almost exclusively in people with HIV (e.g., cryptococcal meningitis, pneumocystis carinii pneumonia, toxoplasmosis), while others are simply more likely to cause disease in people whose immune system have been weakened by HIV (e.g., candidiasis, herpes, tuberculosis).

PARALLEL IMPORTATION: importation of patented products without the approval of the patent-holder. Parallel importation allows a country to shop around for the best price of a branded drug on the global market. It is an attractive option for developing countries when the same branded medicine is being sold for different prices in different

markets. Parallel importing does not involve the purchase of generics. It would allow a country like Mozambique, where 100 units of Bayer's ciprofloxacin (500mg) costs \$740, to import the same product from India where Bayer sells it for \$15 (lower price is due to generic competition in India).³¹ Many European countries, such as the United Kingdom, allow parallel trade to reduce the overall cost of medicines.

PATENT (PATENT PROTECTION): title that confers upon the creator of an invention (product or process) the sole right to make, use, import and sell that invention for a set period of time. Patent protection lasts at least 20 years from the date the patent application was filed. The TRIPS agreement requires patent protection to be available for inventions in all fields of technology in all WTO Member States. This provision is essentially aimed at pharmaceutical products, for which certain developing countries, as well as developed countries, had refused to grant patents. Patent protection has been an incentive for research and development of new drugs, but questions remain as to whether the patent system will ensure investment in medicines needed by the poor.

PROTEASE INHIBITOR: a drug often used in combination with other anti-HIV drugs—usually a total of 3 drugs—that can block the replication of HIV in a person's blood. PIs works by inhibiting HIV protease, an aspartyl enzyme essential for the replication of the virus. Protease inhibitors include lopinavir and ritonavir (combined as Abbott's Kaletra) amprenavir, indinavir, nelfinavir, saquinavir.

REGULATORY APPROVAL (REGULATORY AUTHORISATION): government authorisation of the production and marketing of a drug following proof of its safety and efficacy. This is a process distinct from patenting and takes place on a national level.

TRIPS: WTO's Agreement on Trade Related Aspects of Intellectual Property Rights. For more information, please visit the TRIPS material on the WTO website: http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

TRIPS SAFEGUARDS: Precautionary measures included in the TRIPS agreement to ensure affordability and availability of patented technologies in cases of patent abuse or emergency situation. These safeguards include compulsory licensing, exceptions to exclusive rights and other measures which promote generic competition, and extension of the transitional period. Parallel importation of a patented drug from countries where it is sold more cheaply can also be authorized by governments.

WTO: World Trade Organization



Treatment Access by the Numbers

40 million people living with HIV & AIDS

6.5 million people in “immediate need” of treatment

1 million people with access to treatment

< 50 preventable Mother to Child Transmissions of HIV in the US

630,000 preventable Mother to Child Transmissions of HIV in the Global South

2.3 million children under 15 living with HIV & AIDS

660,000 children in need of treatment

13 years life expectancy has decreased because of AIDS in Southern Africa, to 49

2010 year by which the US and Group of 8 wealthiest nations promised universal access to treatment in Africa

30-35 predicted life expectancy in Southern Africa by 2010

Late 19th century during which this was last the life expectancy

0 chance that we will achieve universal access to treatment by 2010 if we continue with our current policies toward trade and drug companies

Sources: CDC, 2005; UNAIDS, 2004 and 2005; US Census Bureau, 2004; WHO, 2005.



Resources for Action



Open Letter to Gilead Sciences

January 2006

John C. Martin, PhD
President and CEO
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
via fax to (650) 578-9264

Dear Dr. Martin,

We write today on behalf of Student Global AIDS Campaign—an organization with over 85 chapters at colleges and high schools throughout the country, committed to bringing an end to HIV and AIDS around the world. We are writing to express our deep concern over Gilead's inaction on making the essential antiretrovirals Tenofovir and Truvada accessible and affordable to the millions of people living with HIV and AIDS in low- and middle-income countries.

We understand that, since its inception in 2003, Gilead's Access Program has expanded its reach several times under pressure from activists—now including 97 countries and offering a price for Tenofovir of \$208 per person per year and Truvada of \$318 per person per year. We applaud Gilead for its stated intentions.

We are deeply concerned, however, that the promises made by Gilead are neither truly being enacted nor truly sufficient to meet the stated goals of offering no-profit prices in developing countries around the world. Instead, we have come to understand that these pledges are more often phantom promises than real distribution and that Gilead deserves little of the praise it seeks.

Many of our members—including those at Emory University—and partner groups have raised these issues with Gilead before. We are well aware of the company's inaction.

As activists concerned with truly achieving universal access to AIDS treatment—dedicated to making the US public aware of the realities of corporate action on HIV and AIDS—we are writing to demand that Gilead immediately take the following steps:

1) Make good on your price promises: Register your drugs in all 97 Access Program countries; seek temporary waivers until registration is complete.

We find Gilead's claims to be offering "no-profit" prices in 97 countries to be insincere at best, given Gilead's near complete failure to register these drugs in country—ensuring that the drugs are inaccessible. According to the WHO Tenofovir is registered in 6 countries and Truvada in 3; according to the company you have shipped dossiers to 20 more countries after much pressure. We are unconvinced, however, that 20 plus 6 equals 97. We are similarly unconvinced that Gilead can disclaim responsibility for doing the work or registering the drugs in all 97 countries by claiming your licensee, Aspen Pharmacare, is responsible. This is Gilead's responsibility and it is Gilead that should be submitting the paperwork and working with both governments and service providers on the ground to ensure that these drugs are available and affordable. Otherwise your claims are simply false.

2) Publish affordable prices for middle-income countries, particularly those excluded in Southeast Asia, Eastern Europe, the Caribbean, and Latin America.

While we appreciate that Gilead has included 97 countries in its Access Program, this still leaves many in need whose lives Gilead should be working to save if it is to make any real claim to corporate citizenship. Five countries classified by the World Bank as “lower income,” including India, are simply left out of Gilead’s program. Of the 54 “lower-middle income,” countries, like Brazil and Thailand, 33 are not eligible for Gilead’s Access Program. In these countries, which include tens of millions of people living on less than \$2 a day, drugs are priced out of reach—often at US prices unless negotiated on a drug-by-drug basis. We find this unacceptable and urge Gilead to publish differential pricing for all of these countries.

3) Offer a voluntary open license to governments and companies to produce generic versions of Tenofovir & Truvada in the Global South.

As we have found again and again, the best way to ensure affordable access is through fair competition. We urge Gilead to offer a clear, open, voluntary license to all qualified producers along with technology transfer (if needed) and full access to registration data or rights of reference to expedite product registration. The geographical market for the open licenses should be all non-developed countries and all market groups (i.e., private sector, public sector, NGO/mission/workplace sectors). Given Gilead’s disinterest in marketing Tenofovir and Truvada in these countries, this would be a clear step and would do much more than simple claims of “non-enforcement” to ensure real, affordable access.

4) Research and develop pediatric formulations and establish recommended pediatric dosing ranges.

Millions of children have no access to these drugs because there is currently no pediatric formulation or dosing ranges for Tenofovir or Truvada. The adult formulation of Tenofovir has been shown to have a high toxicity in children. The simple calculus that the world’s HIV-positive children do not represent a sufficient “market share” to deserve research and formulations is cruel and we urge Gilead to reverse this lapse.

Given Gilead’s lack of action to date, we are writing to make our expectations clear and our intention to draw attention to these failures clearer. We urgently hope that Gilead will decide to make good on its promises and expand its efforts to provide real, affordable access. To do so would save the lives of many. But Gilead’s efforts must be more than publicity, talk, and obfuscation. We expect real action immediately.

We look forward to hearing your response and to setting up a time for further discussion of these issues. Thank you for your attention and your time.

Sincerely,

Matthew Kavanagh, National Coordinator

National Steering Committee:

Traci Ackron, DePaul University

Cameron Lefevre, Penn State University

Erin Burns, Guilford College

Meheret Melles, University of Maryland

Grant Gordon, University of Chicago

Polly Peterson, Olympia High School

Andrew Kohan, George Washington University

Sara Renn, University of Louisville

Sharon Kim, University of Chicago

Brooke Slick, Shepherd University



Open Letter to Abbott Laboratories

January 2006

Miles D. White
Chairman and CEO
Abbott Laboratories
100 Abbott Park Road,
Dept 392 Bldg. AP61-2
Abbott Park, IL 60064

via fax to 847-937-1511

Dear Mr. White,

We write today on behalf of Student Global AIDS Campaign—an organization with over 85 chapters at colleges and high schools throughout the country, committed to bringing an end to HIV and AIDS around the world. We are writing to express our deep concern over Abbott's inaction on making the essential antiretroviral Kaletra—in its new and old forms—accessible and affordable to the millions of people living with HIV and AIDS in low- and middle-income countries.

We understand that, since its participation in the ACCESS initiative, Abbott's Access to HIV Care Program has currently includes 69 countries, including Africa, and a price for Kaletra of \$500 per person per year. We applaud Abbott for its stated intentions.

We are deeply concerned, however, that the promises made by Abbott are neither truly being enacted nor truly sufficient to meet the stated goals of offering no-profit prices in developing countries around the world. New Kaletra is especially essential, since its non-refrigerated tablet form would be critical in making Kaletra useful in resource-poor settings. Unfortunately, we have come to understand that—especially as relates to new Kaletra—access promises are more often phantom pledges than real distribution and that Abbott deserves little of the praise it seeks.

Many of our members and partner groups have raised these issues with Abbott before. We are well aware of the company's inaction. As activists concerned with truly achieving universal access to AIDS treatment—dedicated to making the US public aware of the realities of corporate action on HIV and AIDS—we are writing to demand that Abbott immediately take the following steps:

1) Publish affordable prices for new Kaletra in all low- and middle-income countries, which includes many in Southeast Asia, Eastern Europe, the Caribbean, and Latin America left out of Abbot's program.

Despite having a formulation that is essential for use in the Global South, Abbott has yet to even offer a price for the improved version of Kaletra in low- and middle-income countries. We urge you to do so immediately.

While we appreciate that Abbott has included 69 countries in its Access Program, this still leaves many in need whose lives Gilead should be working to save if it is to make any real claim to corporate citizenship. Since the AAI was launched five years ago, millions more people living in at least 40 more countries, are in immediate need of affordable access. Abbott has been urged by UNAIDS, the WHO, and activists around the world to expand the program to include 110 other countries—nations covered by programs of other US corporations. We urge Abbott to do so.

Millions who live in countries not deemed poor enough by Abbott are in need. These “middle income” countries like Brazil and Thailand include tens of millions living on less than \$2 a day, yet according to Doctors Without Borders the price of Kaletra in middle-income countries outside Africa is on average 7.4 times more expensive than in low-income countries (mean: \$672 vs. \$4,998). We urge abbot to publish affordable prices for these countries as well.

2) Make good on your price promises: Register both new and old Kaletra in all ACCESS countries; seek temporary waivers until registration is complete.

We find Abbott’s claims to be offering “no-profit” prices in 69 countries to be insincere at best, given that the most useful form of the drug has not been registered in any of them. Abbott’s plan to not even pursue registration and marketing in Africa until after completing registration in Europe makes no sense to us—and shows obvious disregard for lives in the 69 countries Abbott claims to care about.

It is Abbott’s responsibility to submit the paperwork and work with both governments and service providers on the ground to ensure that Kaletra is available and affordable.

3) Offer a voluntary open license to governments and companies to produce generic versions of Kaletra in the Global South.

As we have found again and again, the best way to ensure affordable access is through fair competition. We urge Abbott to offer a clear, open, voluntary license to all qualified producers along with technology transfer (if needed) and full access to registration data or rights of reference to expedite product registration. The geographical market for the open licenses should be all non-developed countries and all market groups, i.e., private sector, public sector, NGO/mission/workplace sectors. Given Abbott’s clear focus on US and European markets, this would be a clear and easy step toward making these essential drugs affordable in the Global South.

4) Make pediatric formulations: half-dose tablet and syrup that is more palatable and doesn’t require refrigeration

Reports from providers are that the current pediatric version of Kaletra (a syrup) is unpalatable for children and must be taken in such large quantities children that it makes treatment difficult at best. A small tablet and/or concentrated syrup version would solve this problem. The simple calculus that the world’s HIV-positive children do not represent a sufficient “market share” to deserve appropriate formulations they is cruel and we urge Abbott to reverse this lapse.

Given Abbott’s lack of action to date, we are writing to make our expectations clear and our intention to draw attention to these failures clearer. We urgently hope that Abbott will decide to make good on its promises and expand its efforts to provide real, affordable access. To do so would save the lives of many. But Abbott’s efforts must be more than publicity, talk, and obfuscation. We expect real action immediately.

We look forward to hearing your response and to setting up a time for further discussion of these issues. Thank you for your attention and your time.

Sincerely,

Matthew Kavanagh, National Coordinator

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Sharon Kim, University of Chicago

Cameron Lefevre, Penn State University
Meheret Melles, University of Maryland
Polly Peterson, Olympia High School
Sara Renn, University of Louisville
Brooke Slick, Shepherd University



Open Letter to the Office of the US Trade Representative

January 2006

Name

Title

Office of the US Trade Representative

600 17th St., NW

Washington, DC 20508

Dear [Target Here],

We write today on behalf of Student Global AIDS Campaign—an organization with over 85 chapters at colleges and high schools throughout the country, committed to bringing an end to HIV and AIDS around the world.

We write to express our deep concern over the US Trade Representative's efforts to negotiate a free trade agreement with the Southern African Customs Union. While there are many concerns raised by our members and partners around the world about the proposed trade deal, we are writing today to urge you in the strongest terms to exclude intellectual property from negotiations over any such agreement.

South Africa is home to over 3.5 million HIV-positive people – the most in the world – while the SACU countries have the highest HIV-prevalence rates in the world. Whereas pharmaceutical companies are currently producing drugs that have significantly reduced AIDS death rates in wealthy countries, most people in this region cannot possibly afford market prices for treatments that cost upwards of \$15,000 per year. Low cost generic versions of these drugs, however, have reduced prices by up to 95% – making it actually feasible for Southern Africa countries to treat their HIV-infected populations.

In trade negotiations, however, efforts to expand intellectual property rights for corporations could rule out production of affordable new generic medications—making costs of expanded treatment prohibitively expensive. There is no need for new intellectual property rights, insofar as they are already governed by the WTO, of which all SACU countries are members. Indeed, we are well aware that the US signed the 2001 Doha Declaration that clarified the ability of nations to use trade law flexibilities to ensure access to medicines.

As such, we are writing to ask you to live up to that pledge and assure that trade agreements with nations in the Global South—especially that with SACU nations—put patients over profit. **We are writing to ask that the USTR publicly take intellectual property rights (IPRs)—already governed by the WTO—off the table in negotiations with SACU.**

In addition, we also request that you publish US proposed text for the entire FTA so that the US and Southern Africa people have a chance to hold public consultations on the proposed agreement before any trade agreement moves ahead.

We look forward to your response.

Sincerely,

Sample Op-Ed

From nuclear weapons to bio-terrorism, modern technology has frighteningly destructive capabilities. Yet technology can also improve millions of lives, making them longer, healthier, and more productive. Advances in antiretroviral medication can significantly improve the lives of the world's 40.3 million HIV positive individuals. However, while the technology to create enough medication exists, pharmaceutical companies consistently create barriers to universal treatment. While nearly 8,500 people die from AIDS daily, pharmaceutical companies dictate standards for which nations may access affordable drugs, while preserving their monopolies on life-saving medication through free trade agreements.

Antiretroviral drugs are proven to extend the lives of HIV positive individuals. Following the introduction of antiretroviral medication in the United States in 1996, AIDS deaths plummeted by seventy percent. Yet the rest of the world is not as fortunate: In June 2005, UNAIDS and the World Health Organization estimated that only 15% of the 6.5 million people in “developing and transitional countries” who urgently needed antiretroviral drugs received them.

As more HIV positive people are living longer with treatment, a “second generation” of AIDS medications is needed to combat resistant strains of the HIV virus. In a United Kingdom study, 335 of 2,357 HIV positive individuals demonstrated resistance to one or more antiretroviral drugs. The study suggests HIV becomes increasingly resistant over time: While an average of 14% of positive individuals demonstrated resistance to antiretrovirals between 1996 and 2003, 19% of positive individuals experienced resistance to medication between 2002 and 2003. As the HIV virus evolves, so must the technology to combat it.

When effective, convenient medications do exist, they often do not reach the people who need them most. Truvada, a once-a-day HIV medication manufactured by Gilead, results in less anemia and fatigue than a similar, twice-a-day drug. Gilead touts the convenience of Truvada, declaring it a “particularly suitable option[] in resource-limited settings.” Yet in “resource-limited settings” are often where the medicine is least available. Gilead claims to offer discounted AIDS medication in 97 poor nations, but some of the countries in most dire need of reduced-cost HIV medication are, ironically, not poor enough to qualify for them. India's HIV rate has surged from several thousand in the early 1990s to approximately 5.1 million in 2003. Yet because this country is “middle-income,” Gilead does not offer discounted antiretroviral medications there.

Because pharmaceutical companies wield incredible political power, free trade agreements heavily favor them, preserving monopolies on drugs. During the 2002 election cycle, the pharmaceutical industry gave a hefty \$29,441,951 in campaign contributions, according to the Center for Responsive Politics. Less than surprisingly, free trade agreements cater to the pharmaceutical companies' demands for intellectual property rights protections, which restrict the development and distribution of generic drugs. In the Free Trade Agreement of the Americas, nations that have permission to manufacture generic HIV medications are forbidden to export them to neighboring countries. Therefore, nations lacking the infrastructure to develop and distribute their own generics cannot—by law—access cheaper generics from another nation. Because of free trade provisions, geography can determine whether or not an individual receives life-saving medication.

Sample Op-Ed (continued)

Will private corporations continually overpower democratically-elected governments to hold the power of life or death over millions of people? Has corporate greed conclusively superceded humanitarian needs? To eradicate the ever-changing threat that HIV presents to individuals, families, and society itself, we must infuse technology with humanity. On a microscopic level, the virus is evolving; will our society evolve enough to stop it?

Erin Burns
Student Global AIDS Campaign

Sample Letter to the Editor

Check out the original article here: http://abbott.com/news/patents_mw.cfm

In his article “Drug patents are good for our health,” Mr. Miles White, CEO of Abbott Laboratories, defends his company’s opposition to the manufacture of a generic version of Abbott’s HIV treatment, Kaletra, in Brazil. The pharmaceutical industry, he argues, needs profits to pursue research and development of newer, better drugs.

With all due respect to Mr. White, especially given his humble status as 260 of Forbes’ 500 highest paid executives, the pharmaceutical industry isn’t exactly strapped for cash.

Abbott’s confrontation with Brazil represents a disturbing trend of unfettered corporate greed. Brazil already pays Abbott \$107 million annually so it can distribute Kaletra free of charge to HIV positive individuals. In 2002, the combined profits for the ten drug companies in the Fortune 500 (\$35.9 billion) were \$2.2 billion more than the profits for all the other 490 businesses put together (\$33.7 billion). That same year, pharmaceutical companies made 18.5% profit, while the all Fortune 500 companies had a median profitability of three percent.

As for the research and development Mr. White so ardently defends, the latest medications are certainly necessary to combat the increasingly resistant HIV virus. By an industry spokeswoman’s admission, however, advertising and marketing takes up a considerable amount of the industry’s budget, equating to roughly half of the money spent on research and development. Additionally, the pharmaceutical industry has spent \$125,291,328 on campaign contributions since 1990.

Mr. White shouldn’t have to defend the pharmaceutical industry’s need to pursue research and development—but he should own up to the industry’s prioritization of exorbitant executive salaries, self-promotion, and campaign contributions over stopping the spread of HIV.

Erin Burns
Student Global AIDS Campaign



MEDIA ADVISORY

MEDIA ADVISORY

MEDIA ADVISORY

Outside Abbott Pharmaceutical Headquarters, Student Activists Demand Internationally Accessible AIDS Medications

WHAT: Demonstration demanding more readily accessible HIV medication internationally, involving a game of hopscotch representing the number of people who have died from AIDS and a petition delivery

WHEN: 12:00-1:00pm, January 31

WHERE: Abbott Pharmaceutical Headquarters, 100 Abbott Park Rd., Abbott Park, IL 60064

WHO: Faber University Student Global AIDS Campaign chapter

ABBOTT PARK, ILLINOIS – January 31, 2005 – Members of the Faber University Student Global AIDS Campaign chapter will urge Abbott Laboratories to make HIV medications more readily available internationally, delivering a petition signed by two thousand students and playing a massive game of hopscotch with three hundred and fifty steps, which symbolize the number of people who died from AIDS during the executives’ lunch hour.

The students are playing hopscotch to remind Abbott’s executives that they have the power to curb AIDS’ impact on the millions of children impacted by the pandemic. Antiretroviral drugs—such as Kaletra, which Abbott manufactures—can prolong the lifespan of people living with HIV by delaying the onset of AIDS. Unfortunately, children’s doses of the drugs are often not readily available. Kaletra, for instance, has yet to be developed in a pediatric formulation.

While many in “developed” nations have access to affordable HIV treatment, the vast majority of the rest of the world does not. In the United States, antiretroviral treatment has decreased mother-to-child HIV transmission to under 50 cases a year. But in sub-Saharan Africa, 550,000 children contract the virus from their mothers annually. Worldwide, 15 million children have lost at least one parent to AIDS.

Contact: Chad Blackwell
(555) 555-4876
cblackwell@faber.edu
www.fightglobalaids.org

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PRESS RELEASE

PRESS RELEASE

PRESS RELEASE

Outside Abbott Pharmaceutical Headquarters, Student Activists Demand Internationally Accessible AIDS Medications

FOR IMMEDIATE RELEASE

Contact: Chad Blackwell
(555) 555-4876
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www.fightglobalaids.org

ABBOTT PARK, ILLINOIS – January 31, 2005 – Members of the Faber University Student Global AIDS Campaign chapter today urged Abbott Laboratories to make HIV medications more readily available internationally, delivering a petition signed by two thousand students and playing a massive game of hopscotch with three hundred and fifty steps, which symbolized the number of people who died from AIDS during the executives' lunch hour.

“We’re playing hopscotch, a kids’ game, to remind Abbott’s executives that they have the power to curb AIDS’ impact on the millions of children who are orphaned or infected by this pandemic,” said Sandra Calzari, the president of the Faber Student Global AIDS Campaign chapter. **“Right inside this building, Abbott has an on-site childcare center. How would the parents of those kids feel if their children didn’t have access to medicines that could save their lives?”**

Antiretroviral drugs—such as Kaletra, which Abbott manufactures—can prolong the lifespan of people living with HIV by delaying the onset of AIDS. Unfortunately, children’s doses of the drugs are often not readily available. Kaletra, for instance, has yet to be developed in a pediatric formulation.

While many in “developed” nations have access to affordable HIV treatment, the vast majority of the rest of the world does not. In the United States, antiretroviral treatment has decreased mother-to-child HIV transmission to less than 50 cases per year. But in sub-Saharan Africa, 550,000 children contract the virus from their mothers annually. Worldwide, 15 million children have lost at least one parent to AIDS.

The Student Global AIDS Campaign members, who delivered a petition signed by two thousand students and the president of Faber University supporting their efforts, encouraged Abbott employees to join them in their “game” and distributed information about the realities of AIDS medicine access.

“We are not powerless in the face of the AIDS pandemic,” said John Hoffman, a freshman member of SGAC. **“Pharmaceutical companies, like Abbott, can influence international policy and negotiate with governments to provide affordable drugs to millions. We’re here to ensure they do that.”**

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About SGAC and GJ

The Student Global AIDS Campaign

SGAC is a national student and youth movement with chapters at high schools, colleges, and universities across the United States committed to bringing an end to HIV and AIDS in the U.S. and around the world through education, informed advocacy, media work, and direct action.

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Global Justice

Global Justice, SGAC's parent organization, mobilizes a powerful movement of students and young people in the U.S., in partnership with youth internationally, to promote solutions to the world's most pressing social problems. We produce an immediate impact by promoting policies that strengthen global communities, and long-term change by empowering young people to become global justice activists for life. We achieve these goals through student owned and led campaigns, leadership development, advocacy, and education.

www.globaljusticenow.org