

The logo for the Student Global AIDS Campaign features the words "Student Global" in a smaller font above "AIDS" in a large, bold font, with "CAMPAIGN" in a smaller font below. A red and white AIDS ribbon is integrated into the design, passing through the letters of "AIDS".

**Student Global
AIDS
CAMPAIGN** | **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/excepay2005/

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