

Global Treatment Access Campaign

KENYA: "IF THE DISEASE CONTINUES UNCHECKED IT WILL BE LIKE EXPLODING A NEUTRON BOMB"

25% of Kenyans are HIV positive, but only 2% can afford the recommended cocktail of anti-retroviral medicines.

The World Trade Organisation (WTO), which draws more than three-quarters of its members from the developing world, sets the patent controls that have, in part, maintained current price levels.

In January Kenya must agree to extend its patent protection from the current seven years to the WTO-mandated 20 years, sealing the western pharmaceutical companies exclusive rights to anti-retroviral treatments for several generations of AIDS patients.

"We want to see patent law change entirely, to see all drugs produced locally or imported from cheaper producers, currently outside patent law. A Kenyan

drug company has offered to start making anti-retrovirals for us for free, but our hands are tied by the WTO." said Dr Sophie-Marie Scoufflaire, head of the Access to Essential Medicines campaign for Médecins sans Frontières (MSF).

"Extraordinary means call for extraordinary measures," Dr Mohammed Abdullah said. "We must [re-examine] the whole patenting issue. If the disease continues unchecked it will be like exploding a neutron bomb in our country. There will be buildings but there will be no human beings."

Even if the cost of HIV and AIDS drugs was reduced by up to 85%, as the world's leading pharmaceutical companies were suggesting, it would only bring prices down to European levels, and would make almost no difference to the number of people able to afford treatment in Kenya.

The chairman of the country's AIDS control council called the proposal of a price drop "cynical and hypocritical."

"If the international mafia - the drug companies - really mean business, they should waive their patent rights and let developing countries make the drugs themselves under their supervision. Kenya already has the capacity to make most of these drugs. It is the big five [AIDS drug companies] who are stopping us." Dr Abdullah said.

"Price reductions are just a tool of the multinationals to try to stop Africa producing its own drugs," said Dr Scoufflaire.

With the guidance Médecins sans Frontières, the Kenya Access to Essential Medicines Coalition is currently working on legislation to retain the country's right to produce generic versions of patented drugs, or to import from a third party.

SOUTH AFRICA: TAC LAUNCHES DEFIANCE CAMPAIGN AGAINST PATENT ABUSE

In October, 2000, Treatment Access Campaign (TAC), the South African AIDS activist group, launched a Defiance Campaign Against Patent Abuse by smuggling generic fluconazole, a drug that is otherwise unaffordable to poor South Africans, into the country to treat people suffering from cryptococcal meningitis and thrush.

Pfizer sells version of fluconazole under the brand name Diflucan. It is used to treat fungal infections, and is most importantly effective in treating cryptococcal meningitis, a deadly disease without treatment, and the most common AIDS-related systemic fungal infection, as well as thrush, a fungal infection that can occur in the mouth and throat that makes eating and drinking extremely difficult and often results in wasting. It can also cause painful infections in the vagina. In South Africa, is currently priced at US\$8.92 per pill. In Thailand, where Pfizer does not have exclusive marketing rights, fluconazole costs only US\$0.29 per pill. The average daily wage in South Africa is about US\$7.0.

In March, 2000, TAC and the HealthGAP Coalition challenged Pfizer to either lower its price of fluconazole or to release the patent, thereby lawfully allowing South Africa to produce a generic version of the drug or import it at lower prices from another country (parallel importing). Generic production and parallel importation are legal under international trade laws.

In response to pressure in South Africa from TAC, and in the U.S. from the HealthGAP Coalition, and from ACT-UP Paris, Pfizer announced news in April of a restricted "donation program" in a public relations move, to the Wall Street Journal, rather than to South African activists or the South African government. This remains an empty public relations stunt, as not a single pill from Pfizer has yet to have been shipped to South Africa.

Pfizer announced that fluconazole would be donated to people living with AIDS with cryptococcal meningitis who could not

afford the drug. This donation has come with such complicated restrictions that people in South Africa are still dying because of infections that are treatable and preventable with fluconazole. Pfizer has not yet finalized its agreement with the Ministry of Health, and it has not met the Health Minister's request for a lower price.

TAC challenges Pfizer, along with the South African drug companies trade group, the Pharmaceutical Manufacturers Association, to take action against TAC for defying their patent on fluconazole. TAC is prepared to defy patents on all HIV/AIDS drugs. TAC will stop defying the unjust trade laws that protect Pfizer's version of fluconazole once Pfizer has lowered the price to under R4.00 (US 50 cents) and when its "donation" is implemented without any restrictions.

TAC asks all civil society organizations to endorse and help develop the Defiance Campaign against Patent Abuse and AIDS Profiteering.



WOMAN-CONTROLLED HIV PREVENTION: A GLOBAL NECESSITY

Two decades into the AIDS epidemic, it is abundantly clear that traditional prevention campaigns which advocate for abstinence and condom use fail to reflect the complex social, economic and personal factors which effect women's sexual decision-making. Simply put: As long as condoms are the only option for stopping sexual transmission of HIV, AIDS is not a preventable disease. Microbicides are a crucial tool for empowering women and changing the landscape of new AIDS infections. A microbicide is the name given to any substance that can be used, vaginally or rectally, to prevent the transmission of HIV and/or other sexually-transmitted diseases. The battle to increase public awareness, industry interest, and government funding of microbicide research has gained critical momentum over the last year. It is absolutely critical to keep the pressure on decision-makers in government and industry.

A GLOBAL NECESSITY

Women-controlled methods of HIV prevention must be a global priority.

U.S. ACTION: Introduced last March and recently passed in the House of Representatives, the Microbicides Development Act of 2000 would increase funding at the National Institutes of Health (NIH) for the development of effective microbicides—products that can potentially save millions of lives. Specifically, the Act authorizes more money for federal microbicide research and development and instructs the NIH Director, in consultation with other relevant federal institutes and agencies, to develop a five-year implementation plan for the microbicides research program.

THE NEED FOR MICROBICIDES: THE FACTS

► In the developing world, up to 60% of all new HIV infections are among 15-24 year olds, with females outnumbering males two-to-one.

► Heterosexual transmission, within marriages, is driving the epidemic in many countries. Yet globally, only four percent of married women use condoms as their method of family planning.

► In the US, AIDS is the second leading cause of death among African American women between 25-44 and the third leading cause of death among Latinas in that age group.

► Research to develop microbicides received barely 1% of the National Institutes of Health AIDS research budget in 1998.

WOMAN-CONTROLLED HIV PREVENTION:

Contact your Senator: tell them to support the Microbicides Development Act of 2000. You can reach the Capital Switchboard at 1-800-648-3516.

Demand funding for the development of woman-controlled prevention methods.

CAMPAIGN FOR DEBT CANCELLATION FOR POOR COUNTRIES



90% of the world's people with HIV live in desperately poor countries whose governments can't afford to provide basic health care or prevention services. A key reason for this catastrophe is the campaign by the World Bank and the International Monetary Fund (IMF)—two powerful, US-controlled financial institutions—to force countries with staggering debt payments to cut back and privatize their health care, while imposing fees on poor people seeking medical services. IMF/WB policies severely limit countries' capacity to address the urgent needs of people living with HIV/AIDS, and of carrying out effective prevention programs. Until steps are taken to alleviate the crushing burden of debt, treatments for HIV and other illnesses will remain out of reach for the vast majority of those in need.

► **FACT:** Poor countries will never pay off existing debt. Failure to cancel their debts leaves them in a vicious cycle where they must continually cut domestic spending and borrow more from abroad to meet payments on past debts.

► **FACT:** Structural adjustment programs (including privatization, cuts in government spending and subsidies, and orienting economies to promote exports) have been an unmitigated disaster. In 1999 alone, these programs cost poor countries an estimated 2 trillion dollars in economic output.

► **FACT:** User fees for primary healthcare services deny access to care and preventive treatment for the poor, leading to the spread of unnecessary and preventable death and disease. They leave people with HIV/AIDS unable to get even basic health care, and undermine efforts to treat STDs, which increase the risk of HIV infection.

► **FACT:** Current plans to reduce the debt owed by developing countries do little to alleviate the real burden of this debt. The U.S. government supported plan for debt relief (the "Heavily Indebted Poor Country Initiative" or HIPC) primarily writes off only the portion of debt that is already accepted as 'not owed'. This very limited debt relief leaves most developing countries paying the same amount they do now, as these plans do not erase all the debt.

► **FACT:** The HIPC Initiative requires years of compliance with deadly structural adjustment programs before 'qualifying' for the limited debt reduction benefits.

DEBT CANCELLATION and HEALTH CARE

► Debt payments for loan-strapped countries are nearly three times the amount spent on healthcare. Per capita spending is \$22 on debt, \$14 on education and \$8 on healthcare.

► By increasing migrant labor and displacing the rural sector, structural adjustment programs cause social disruption that fuels the AIDS epidemic.


► When the World Bank mandated that Kenya impose charges of U.S.\$2.15 for STD clinic services, attendance fell by up to 60 percent.

► In Papua, New Guinea, the introduction of user fees led to a 30 percent decline in outpatient visits.

► The Meltzer Commission, a bipartisan Congressional commission, has unanimously called for the World Bank and IMF to use their resources to entirely cancel debt in poor countries.

► The U.S. Congress recently passed legislation requiring the U.S. government to oppose IMF/World Bank plans to oppose user fees for basic health care. U.S. activists must monitor vigorously to ensure that a new administration enforces this law.

\$US200 PER PERSON PER YEAR

 The World Health Organization, or other international agencies, should arrange for the procurement of antiretroviral drugs by generic pharmaceutical companies at the low prices that are now feasible.

At the expected cost of approximately \$US200* per person per year for triple combination therapy, wealthy countries, international organizations and donor agencies should be able to have a real impact when providing assistance for the fight against AIDS in developing countries. By the use of these low cost drugs and with the help of grants, providing for treatment and care for the people with HIV/AIDS in the developing countries should be a fiscally attainable goal, rather than the scare figures cited that hundreds of billions of dollars will be required.

According to public sector generic manufacturers in Thailand and Brazil, the economies of scale afforded by an international program of manufacturing and distribution would create cost reductions far beyond the price breaks announced by large pharmaceutical companies.

Debt cancellation will enable enable countries to re-invest in the clinics, training, and procurement necessary to generate access in the most rural and impoverished areas.

*From the MSF Campaign for Access to Essential Medicines report released in July 2000 at the International Conference in Durban, South Africa:

HIV/AIDS Medicines Pricing Report:

"SETTING OBJECTIVES:
IS THERE A POLITICAL WILL?"

"According to initial information, the five company/UNAIDS initiative would reduce antiretroviral prices by 85% (or 6.7 times less). This would bring the cost of antiretrovirals down to US\$2750 per year per patient. This sum is still far too expensive for the vast majority of people living in developing countries. However, generic manufacturers in Brazil and Thailand are confident of their ability to produce antiretrovirals that would result in a yearly triple combination price of US\$200."

THAI PATENT BATTLE

In Thailand activists have been fighting for cheaper access to ddI (didanosine) and d4T (stavudine). These drugs were developed by the US government's National Institutes of Health and then licensed to Bristol Myers Squibb (BMS). The license agreement included a fair pricing requirement which has never been enforced.

Instead, BMS has gone to great lengths to attempt to prevent Thailand, and other countries, from manufacturing cheap, generic versions of these drugs. In 1996, the Thai Government Pharmaceutical Organization (GPO) attempted to begin legal, generic production of ddI. While the patent for the original formulation of ddI does not exist in Thailand, and therefore generic production should be legal there, they were blocked from doing so when BMS was granted a patent for a new formulation of ddI, based on an application that had been rejected twice in the U.S.

The GPO has developed non-patented formulations of ddI and d4T, though they are still blocked from producing a generic version of the improved, buffered form of ddI. A coalition of doctors, activists and advocates is attempting to challenge the ddI patent claims in the Thai Intellectual Property Court. BMS continues to pressure the Thai government not to purchase generic d4T.

BMS has grossly abused the patent system to protect its profits and place two essential AIDS medications out of reach for many HIV-infected individuals in Thailand and around the world.

BRISTOL-MYERS SQUIBB AND DRUG PROFITEERING: THE FACTS

- ◆ d4T sales were US\$605 million in 1999; ddI sales were \$205 million dollars
- ◆ BMS charges US\$1.25 per 100 mg tablet of ddI
- ◆ In Thailand, the non-patented version of ddI is sold for \$0.80
- ◆ BMS charges US\$2.70 per 50 milligram tablet of d4T
- ◆ In Thailand, the non-patented version of d4T is sold for US\$0.38
- ◆ Total world wide sales of d4T (Zerit) had exceeded \$ 1.1 billion by 1998

FOR YEARS, THE WORLD HEALTH ORGANISATION HAS RESISTED THE DISTRIBUTION OF AFFORDABLE ANTIRETROVIRAL TREATMENTS IN POOR COUNTRIES.

Only two antiretrovirals are presently on the WHO Essential Drug List — but only for the prevention of mother-to-child transmission of HIV, not for treatment. To this day WHO refuses to concretely recognise as essential anything but prevention, leaving treatment completely aside.

In May 2000, because of pressure from delegates representing developing countries the World Health Assembly (the governing body) mandated WHO to accelerate the process to expand access to treatment and prophylaxis of HIV/AIDS. Six months later, there is not a single thing to show for this mandate.

THE DIRECTIVES REQUIRED THE WHO TO:

1. "update the existing databases, so that Member States may benefit from all the information available concerning the prices of essential medicines, including HIV drugs", and "encourage local manufacturing and importing" in compliance with international trade agreements.
2. engage in drafting TRIPS compliant model legislation so that member states could begin to implement access to the most affordable generic medicines.
3. provide assistance to manufacturers of affordable medicines so that drug registry could be accelerated and globalized.

"EXTRAORDINARY MEANS CALL FOR EXTRAORDINARY MEASURES. WE MUST [RE-EXAMINE] THE WHOLE PATENTING ISSUE. IF THE DISEASE CONTINUES UNCHECKED IT WILL BE LIKE EXPLODING A NEUTRON BOMB IN OUR COUNTRY. THERE WILL BE BUILDINGS BUT THERE WILL BE NO HUMAN BEINGS." -DR. MOHAMMED ABDULLAH, KENYA

PHARMACEUTICAL INDUSTRY: FACT AND FICTION

PHRMA - FICTION:

Compulsory licensing is an abrogation of patent rights—no better than patent theft.

THE FACTS:

Compulsory licensing is not an attack on the patent system, it is an accepted part of that system—a protection developed to remedy market failures created by the patent system, such as lack of access to an essential drug due to prohibitive cost. International agreements like the World Trade Organization's agreement on Trade Related Aspects of Intellectual Property (TRIPS) clearly address provisions and conditions for compulsory licensing. The US and other developed nations enjoy frequent access to patented products through compulsory licensing. The UK and the Netherlands are among many countries that obtain a significant percentage of their medications through parallel importing.

PHRMA - FICTION:

Compulsory licensing and parallel importing discourage the development of important new therapies by decreasing return on industry investment in research and development.

THE FACTS:

Taxpayer dollars—not industry dollars—subsidized the research and development of many candidate drugs for compulsory licensing, such as AIDS treatments like AZT and ddI. In these cases, there is no "investment" for industry to recoup, just huge profits for them to rake in. And as the developing world represents a negligible portion of the global pharmaceutical market—all of Africa constitutes only 1.5% of that market—industry claims of "reduced returns" as a result of compulsory licensing in poor countries are highly suspect. With so few sales occurring in the developing world, compulsory licensing will not erode drug company markets.

PHRMA - FICTION:

The problem of access to medication in the developing world is bigger than what can be solved through compulsory licensing and parallel importing. There's no magic bullet in correcting disparate access to medication—just giving out pills won't help.

THE FACTS:

No one is claiming that compulsory licensing alone will end to unequal access to medication and treatment. Neither compulsory licensing nor parallel importing is a panacea. But neither are the limited drug giveaway programs that garner such good reviews of the pharmaceutical industry. Compulsory licensing and parallel importing are lawful tools available now for use by countries such as South Africa and Thailand, who have the infrastructure to make and distribute desperately needed drugs that are inaccessible to dying people due to high price.

QUICK LIST OF TERMS

Compulsory licenses are licenses that are granted to a body (government, institution, or organization) under international trade law that allow them to license domestic production of a patented product, copyrighted work, or other type of intellectual property without the permission of the patent holder.

The Global Agreement on Tariffs and Trade (GATT) is an international trade treaty that regulates tariffs on traded goods. GATT includes the TRIPs (see definition).

A generic drug is a copy of a patented medicine.

Intellectual property rights refer to the rules that apply to patented products.

Off-patent refers to production of a product whose patent has expired.

Parallel importing is a trade practice whereby a government, institution, or organization imports or buys a licensed product from a third party, without the permission of the patent holder. Normally at a much cheaper price.

A patent is an official document that provides an inventor exclusive protection to make and market an invention, and the right to exclude others from making, using, offering for sale, or selling that invention. The patent provides a trademark (a mark or word) for the invention. In the U.S. and under the WTO, patents last 20 years for medicines.

The Pharmaceutical Research Manufacturers of America (PhRMA) is a lobby group representing the drug industry.

The Trade-Related aspects of Intellectual Property Rights (TRIPs) is a piece of global legislation that applies to international trade of patented products. TRIPs is a provision of GATT.

A royalty is a payment made to a patent holder for a license for a patented product (trade-marked good) by another party. It represents a percentage or share of the profits made by the sale of the patented product.

The U.S. Federal Trade Commission (FTC) is the national body responsible for oversight in patent disputes in the United States.

Voluntary licenses are licenses that are given by the patent holder to a third party, normally a royalty is given in exchange for a license.

The World Trade Organization (WTO) is an international body made up of member nations that oversees trade related aspects of international property rights.

"IF THE INTERNATIONAL MAFIA—THE DRUG COMPANIES—REALLY MEAN BUSINESS, THEY SHOULD WAIVE THEIR PATENT RIGHTS AND LET DEVELOPING COUNTRIES MAKE THE DRUGS THEMSELVES UNDER THEIR SUPERVISION. KENYA ALREADY HAS THE CAPACITY TO MAKE MOST OF THESE DRUGS. IT IS THE BIG FIVE WHO ARE STOPPING US." -MARDEN MADOKA, MINISTER OF STATE, KENYA, 11/7/00

ONLINE RESOURCES

Global Treatment Access Campaign
<http://www.globaltreatmentaccess.org>

Health Global Access Project (GAP) Coalition
<http://www.healthgap.org>

Médecins sans Frontières
Access to Essential Medicines Campaign
<http://www.accessmed-msf.org>

Treatment Action Campaign
<http://www.tac.org.za>

Consumer Project on Technology
<http://www.cptech.org/ip/health>

International Gay and Lesbian Human Rights Commission
<http://www.iglhrc.org>

International Council of AIDS Service Orgs.:
http://www.icaso.org/compulsory_english.htm