



## Global Public Health: Access to Essential Medicines

By Robert Weissman, Essential Action

One in five adult South Africans, one in seven Kenyans, and one in four Zimbabweans has HIV/AIDS. Former U.S. Surgeon General David Satcher has likened the HIV/AIDS epidemic in Africa to the plague that decimated Europe in the fourteenth century.

Existing treatments, which enable many people with HIV/AIDS in the U.S. and other industrialized countries to live relatively healthy lives, are unavailable to all but a few people in Africa. Until recently, lifesaving HIV/AIDS drug cocktails cost \$10,000-\$15,000 a year in many African countries—vastly out of reach for all but a small handful of the growing African population with HIV/AIDS.

For millions of HIV-infected people, there is a crying need to make lifesaving drugs more available—and quickly. It is crucial that rich countries provide adequate funding for the new Global Fund to Fight AIDS,

Tuberculosis, and Malaria. The fund has made an initial round of grants, pledging \$1.5 billion in support for projects over a five-year period—the bulk of the \$1.9 billion currently at the Global Fund's disposal for this time period. Yet this amount is puny compared to the need: The Global Fund needs roughly \$10 billion a year to address the AIDS pandemic and other infectious diseases wracking Africa and poor countries elsewhere, according to public health experts.

With pharmaceuticals constituting such a huge component of the cost of treating people with HIV, the price of drugs will remain a crucial factor in determining whether, and how

many, people with HIV/AIDS receive treatment, irrespective of the level of donor support for the Global Fund to fight AIDS. Brand-name drug companies have responded to negative publicity on drug pricing by announcing some concessionary deals on some of their products. But these price reductions are limited in scope and have done little to make drugs available to HIV-positive people in poor countries.

A vital tool to help achieve affordability of essential medicines is the option of compulsory licensing. Compulsory licensing enables any government to

instruct a patent holder to license the right to use its patent to a company, government agency, or other party. Zimbabwe, for example, could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Zimbabwean firm would then manufacture the drug for sale in Zimbabwe under a generic name, and it would pay a reasonable royalty to Bristol-Myers Squibb on each sale.

Compulsory licensing lowers prices to consumers by creating competition in the market for the patented good. Its impact is similar to the introduction of generic competition at the end of a drug's patent term—prices come tumbling down. Compulsory licensing can lower the price of medicines by 95% or more.

Compulsory licensing is permitted under the international trade rules established by the General Agreement on Tariffs and Trade (GATT) and administered by the World Trade Organization (WTO). It is regularly used in industrialized countries, including the United States. One of the GATT agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), contains the international rules that the WTO enforces regarding intellectual property (patents, copyrights, and trademarks). Industry, especially the pharmaceutical sector, exercised heavy influence over the TRIPS agreement negotiations, and many public interest advocates generally believe that the TRIPS agreement inappropriately favors corporations.

In general, the TRIPS agreement requires countries to adopt U.S.-style patent systems, which apply both to products and processes and last for 20 years. This has compelled many developing countries—which had followed the lead of virtually every industrialized country in enacting weak patent rules while they were still industrializing (many European countries did not recognize patents until the 1970s)—to refashion their patent rules dramatically.

But despite the TRIPS document's biases and the requirements that it imposes on signatory countries, the agreement does permit compulsory licensing. Even so, multinational pharmaceutical companies object to the practice, which they perceive as curtailing corporate profits. Under pressure, the Clinton administration retreated from its longstanding, aggressive opposition to developing country efforts to undertake compulsory licensing. The Bush administration has continued the revised Clinton policy but, like the Clinton administration, continues to pose serious obstacles to effective utilization of this crucial policy instrument.

### Key Points

- Combinations of available pharmaceuticals—too expensive for nearly all of the infected people in the developing world—could enable many afflicted with HIV/AIDS to live relatively normal lives.
- Recent multinational pharmaceutical company offers of price reductions have not succeeded in making lifesaving AIDS medicines available to those in need in developing countries.
- Compulsory licensing policies could help developing country governments make essential medicines more affordable to their citizens.

## Problems with Current U.S. Policy

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Despite the legality of compulsory licensing and despite the public health emergency enveloping much of the developing world, until mid-1999 the U.S. actively opposed developing country efforts to implement compulsory licensing or other measures to make HIV/AIDS drugs more affordable and available in low-income countries. The U.S. position suddenly changed in June 1999, following AIDS activist protests that disrupted the early presidential campaign of Al Gore. During the November-December 1999 WTO meetings in Seattle, the Clinton administration announced it would offer special treatment for health-related intellectual property disputes, taking into account health issues as well as commercial concerns. However, efforts to incorporate the new Clinton policy into the Africa Growth and Opportunity Act floundered and even threatened to impede passage of the act. So the Clinton administration issued an executive order stipulating that the U.S. would not challenge TRIPS-compliant policy measures to make AIDS medicines available anywhere in Africa.

In February 2001, with ever-heightening attention on the AIDS crisis and growing interest in what posture President Bush would adopt regarding controversial intellectual property issues, the new administration indicated that it would continue the Clinton administration's policy of permitting initiatives to make AIDS medicines more available, as long as those efforts were TRIPS-compliant. But Clinton's executive order is limited to sub-Saharan Africa and only covers AIDS medicines. This illustrates a pervasive problem in Washington's position, even after the 1999 policy shift: the treatment of compulsory licensing as an exceptional policy tool to be used only in emergency circumstances, even though the WTO TRIPS agreement considers compulsory licensing a standard part of the intellectual property regime.

Despite the executive order, both Clinton and Bush have exerted direct pressure on countries seeking to advance compulsory licensing and related policies. The mixed messages conveyed by U.S. actions, along with confusion fostered by the pharmaceutical industry over what is permissible under WTO rules, has intimidated most developing countries and left them wary of political consequences if they exercise their right to promote compulsory licensing.

In June 2001, African countries at the TRIPS governing body (known as the TRIPS Council) forced a historic discussion on intellectual property and access to health technologies. That meeting created momentum for a declaration on TRIPS and public health, which was eventually issued at the November 2001 WTO Ministerial meeting in Doha, Qatar. In the Doha Declaration, countries "affirmed that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." The declaration specifically mentioned each country's right to pursue compulsory licensing.

The WTO also pledged at Doha to rectify an irrational TRIPS provision that would particularly undermine a

developing country's ability to institute effective compulsory licensing. Although TRIPS rules permit a country to assign a drug import license to a manufacturer outside the country, the licensee must have both permission to produce the drug in the country where its factory is based and permission to export the drug from that country. Thus, even if Zambia were to issue a compulsory drug license to a manufacturer in Canada, the Canadian manufacturer would be blocked from producing and exporting the drug if a brand-name company had a patent for that drug in Canada.

The Doha Declaration obligates TRIPS members to address this problem in 2002. All parties recognize that some kind of exception to this irrational provision will need to be created through clarification, reinterpretation, or amendment of TRIPS rules. However, the U.S. is working aggressively to limit the scope of the exception, suggesting for example that it should only apply to the poorest countries or to those afflicted with the most extreme health care emergencies. If the ultimate resolution reflects the U.S. position, many developing countries will find themselves unable to make effective use of compulsory licensing. (The U.S. position, incidentally, would also inhibit the U.S. or any other rich country's ability to assign compulsory licenses overseas. This would, for example, have made it much harder for the U.S. to assign a license to Indian producers for the anti-anthrax drug Cipro, something Washington considered doing in the wake of September 11.)

The U.S. is also working in diverse international trade negotiating fora to increase the monopoly protections afforded by patents and to diminish the ability of countries to initiate compulsory licensing and parallel importing. For example, the U.S.-Jordan Free Trade Agreement, completed in fall 2000, sharply limits the grounds for compulsory licensing, and the published summary of the U.S. negotiating position for the intellectual property portion of the proposed Free Trade Agreement of the Americas (FTAA) contains a variety of measures that would effectively extend patent terms, interfere with compulsory licensing, and otherwise undermine efforts by poor countries to make medicines more accessible. Generally, the inclusion of intellectual property provisions in multiple-country trade agreements (like the FTAA) makes it much harder to ratchet down international patent protection obligations. Even if changes were made so that the WTO TRIPS agreement became less restrictive, for example, this move would have little impact on countries that had separate intellectual property obligations—if they were equivalent to or more severe than the WTO mandates—under the FTAA or other international trade agreements.

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### Key Problems

- The inclusion of intellectual property provisions in multiple-country trade agreements makes it much harder to advance public health priorities.
  - Washington continues to work to limit developing countries' options to adopt intellectual property policies that could make HIV/AIDS drugs more affordable.
  - The U.S. government is seeking to renege on commitments, made at the WTO Ministerial meeting in Doha, Qatar, to facilitate poor countries' access to essential medicines.
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# Toward a New Foreign Policy

Addressing the HIV/AIDS crisis in Africa and around the world will require a massively accelerated prevention effort. It will also require revitalizing developing countries' decimated public health systems and making quality health care much more widely available. This, in turn, will require major new investments in public health and the abandonment of structural adjustment requirements to collect user fees from people seeking health care.

In May 1999 the World Health Assembly, the policy-making body of the World Health Organization (WHO), passed a resolution that declared public health concerns "paramount" in intellectual property issues

related to pharmaceuticals. Although Washington had vociferously opposed earlier efforts to obtain passage of a similar resolution that said public health concerns should take priority over commercial matters, the U.S., after insisting on minor changes, voted in support of the 1999 resolution. It is now time for Washington to bring its foreign policy into full compliance with the accepted notion that public health protection is the most important goal in shaping pharmaceutical patent policy.

First, the U.S. should agree to work on good-faith implementation of the Doha Declaration by promoting a pro-health reso-

lution of the issues surrounding pharmaceutical exports. Washington should encourage a TRIPS interpretation that would enable health technology exports from countries with patents on a relevant product or process to countries where the product or process either is not patented or has been compulsorily licensed. The legal mechanism to facilitate these exports should be automatic and not limited by any conditions related to the importing countries (e.g., the country's size or wealth, technological or manufacturing capacity, or extent of disease prevalence). This automatic, unconditional process is necessary to deliver on the promise of the Doha Declaration and to rationalize the TRIPS regime to permit countries to use compulsory licensing in appropriate contexts.

Second, the U.S. should stop seeking expansion of TRIPS (TRIPS-plus) in international trade agreements

like the FTAA. There should be no overlapping or more expansive intellectual property provisions in new trade agreements.

Third, Washington should broaden the executive order about AIDS medicines, which recognizes that health issues deserve special consideration in intellectual property disputes. The U.S. should accept compulsory licensing and related measures as integral parts of the intellectual property system and crucial to delivering essential medicines in poor countries. The executive order should be expanded to cover all health-related technologies, not just those related to HIV/AIDS, and all parts of the world, not just Africa.

Fourth, the U.S. should immediately license to the WHO all of the HIV/AIDS drugs that have been developed with government funding and for which the U.S. government holds patent or other intellectual property rights. Existing law permits Washington to take such steps. With a license, the WHO could contract with private generic makers to produce the medicines and distribute them widely in the developing world. Since many of the most important HIV/AIDS remedies were developed with significant U.S. government funding, Washington controls rights to many important HIV/AIDS treatment pharmaceuticals.

Finally, it should be reiterated that although access to essential medicines is of critical importance, more must be done to prevent the transmission of HIV/AIDS and to improve treatment for those infected. Rich countries, led by the U.S., must provide much more substantial support to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and African governments must do more to support AIDS education and prevention efforts and to avoid stigmatizing people with the disease. Washington should also lead an international effort to cancel the foreign debts of the poorest countries, since debt servicing siphons off funds from investment in public health. Likewise, the U.S. should work to change World Bank and International Monetary Fund structural adjustment policies—such as requiring copayments from indigent patients—since these policies make it more difficult for those with HIV/AIDS to gain access to medical care.

*Robert Weissman <rob@essential.org> is editor of Multinational Monitor magazine and codirector of Essential Action, a corporate accountability group. He is coauthor of Corporate Predators: The Hunt for MegaProfits and the Attack on Democracy (Monroe, ME: Common Courage Press, 1999; see <http://www.corporatepredators.org/>).*

## Key Recommendations

- The U.S. should agree to work on good-faith implementation of the Doha Declaration regarding the TRIPS agreement and public health.
- The U.S. should cease efforts to incorporate intellectual property protections—especially those that go beyond TRIPS—into new trade agreements.
- Washington should license to the World Health Organization all HIV/AIDS drugs that the U.S. government has played a substantial role in developing in order to ensure widespread distribution in the developing world.

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# Citizen-Based Agenda



Citizen movements organizing across national borders are increasingly a key factor in reshaping global affairs policy at both the national and international levels. To further its own mission to reform U.S. foreign policy—"making it a more responsible global partner and global leader"—Foreign Policy In Focus (FPIF) is committed to strengthening and advancing citizen movements concerned with global affairs. As part of that effort, we are drafting profiles of many of the most prominent citizen-based global affairs agendas.

## Democratizing Access to Essential Medicines

Two factors—the rapid spread of the HIV virus throughout Africa and new efforts by pharmaceutical companies to enforce patent laws through free trade rules—have combined to fuel a new international campaign to increase access to essential, lifesaving medications by developing countries and the world's poor. The movement, which brings together Africa policy institutions, trade reform groups, consumer groups, and public health organizations, demands more balanced policies regarding pharmaceutical patent and trade rules by governments and multilateral organizations. These groups point out that more than 90% of all death and suffering from infectious diseases occurs in the developing world and that 20% of the world's population uses 80% of manufactured medicines. The main argument is that public health policy should not be held hostage to market forces and on restrictive patent laws. With respect to trade and patent laws, citizen groups advocate: less-restrictive interpretations of the new Trade-Related Intellectual Property Rights Agreement (TRIPS), creation of a working group within the World Trade Organization (WTO) that provides a public health framework for rulings on key features of WTO agreements, and policy reforms by the U.S. and other governments that institute legal forms of relief from patent restrictions on lifesaving medicines. To address the AIDS crisis and the spread of infectious diseases, citizen groups advocate increasing funds for health care research and pressuring governments to require pharmaceutical firms to reinvest a larger percentage of their profits into R&D for treatment of communicable diseases through vaccines and medicines. With the AIDS crisis devastating impoverished Africa, citizen groups have succeeded in making access to essential, lifesaving medicines a major global affairs issue—one that challenges the dictates of unmitigated free trade and the power of the world's largest pharmaceutical firms.

—FPIF Editors

## Sources for More Information

### Organizations

#### Africa Action

110 Maryland Ave. NE, #509  
Washington, DC 20002  
Voice: (202) 546-7961  
Fax: (202) 546-1545  
Email: [apic@igc.org](mailto:apic@igc.org)  
Website: <http://www.africapolicy.org/>

#### Consumer Project on Technology

Box 19367  
Washington, DC 20036  
Voice: (202) 387-8030  
Fax: (202) 234-5176  
Website: <http://www.cptech.org/>

#### Health GAP (Global Access Project)

4851 Catharine Street  
Philadelphia, PA 19143  
Voice: (215) 474-9329  
Fax: (215) 893-4374  
Email: [info@healthgap.org](mailto:info@healthgap.org)  
Website: <http://www.globaltreatmentaccess.org/>

#### Medicins Sans Frontieres

(Doctors Without Borders)—USA  
6 East 39th Street, 8th Floor  
New York, NY 10016  
Voice: (212) 655-3764  
Fax: (212) 679-7016  
Email: [doctors@newyork.msf.org](mailto:doctors@newyork.msf.org)  
Website: <http://www.msf.org/>

### Publications

"Developing Country Group's Paper: paper submitted by a group of developing countries to the TRIPS Council, for the special discussion on intellectual property and access to medicines," June 20, 2001, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/paper\\_develop\\_w296\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm).

Essential Action, "Comments on the Free Trade Area of the Americas," draft text, August 22, 2001, available at <http://lists.essential.org/pipermail/ip-health/2001-August/001761.html>.

"Fighting AIDS in Africa," (editorial), *New York Times*, February 25, 2001.

Barton Gellman, "A Turning Point That Left Millions Behind: Drug Discounts Benefit Few While Protecting Pharmaceutical Companies' Profits," *Washington Post*, December 28, 2000, available at [http://www.washingtonpost.com/wp-dyn/world/issues/aidsinafrica/A56492\\_2000Dec27.html](http://www.washingtonpost.com/wp-dyn/world/issues/aidsinafrica/A56492_2000Dec27.html).

Health GAP, "Critical Issues Surrounding an International Fund for HIV/AIDS and Other Infectious Diseases," October 10, 2001, available at [http://www.globaltreatmentaccess.org/content/press\\_releases/01/101001\\_HGAP\\_PP\\_Fund.pdf](http://www.globaltreatmentaccess.org/content/press_releases/01/101001_HGAP_PP_Fund.pdf).

Letter from Consumer Project on Technology, Essential Action, Medicins Sans Frontieres, Oxfam International, Health GAP Coalition, and the Third World Network to the World Trade Organization's TRIPS Council, January 28, 2002, available at <http://www.cptech.org/ip/health/art30exports.html>.

Letter to Secretary of Health and Human Services Tommy Thompson from Ralph Nader, James Love, and Robert Weissman requesting that DHHS provide the WHO, UNICEF, and other public health organizations access to U.S. government-funded medical inventions, March 28, 2001, available at <http://www.cptech.org/ip/health/econ/CPTthompson03282001.html>.

Stephen Lewis, "J'accuse: The West Is Willfully Turning Its Back on the Greatest Human Tragedy of Our Age, Says the Former Deputy Head of UNICEF," *Globe & Mail* (Canada), January 26, 2001.

Oxfam, "WTO Patent Rules and Access to Essential Medicines: The Pressure Mounts," June 2001, available at <http://www.oxfam.org.uk/policy/papers/wtorules/wtorules.htm>.

Tina Rosenberg, "Look at Brazil: Patent Laws Are Malleable. Patients Are Educable. Drug Companies Are Vincible. The World's AIDS Crisis Is Solvable." *New York Times Magazine*, January 28, 2001, available at <http://www.nytimes.com/library/magazine/home/20010128mag-aids.html>.

### Websites

#### Allafrica.com: Health

<http://allafrica.com/health/>

#### Health Gap

<http://www.healthgap.org/>

#### HIVInSite Daily News

<http://hivinsite.ucsf.edu/ads/>

#### Treatment Action Campaign

<http://www.tac.org.za/>