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Compulsory Licensing [1]

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Drug Makers Fight Off Challenge to AIDS Drug Export Prices

As Vice President Al Gore seeks the Democratic presidential nomination, he is often greeted at campaign stops by rowdy demonstrators chanting, "Gore's greed kills."

The protesters represent public health and gay advocacy groups who want the United States to drop its opposition to South Africa's attempts to purchase or manufacture less expensive anti-AIDS drugs. By attracting the attention of reporters covering the vice president, the activists hope to make the public aware of South Africa's high rates of AIDS and HIV infection and a U.S. trade policy that protects the market and profit margins of U.S. pharmaceutical manufacturers.

LOBBYISTS & ADVOCATES

A coalition formed by the gay advocacy group Act Up and the Ralph Nader-sponsored Consumer Project on Technology enlisted help from public health organizations, including Medecins Sans Frontieres and Health Action International, to lobby the Clinton administration, Congress and federal trade officials. Those groups find themselves lined up against the huge pharmaceutical industry trade group that maintains an in-house lobbying staff supplemented by the services of a variety of lobbying and public relations firms.

At issue is the Clinton administration's opposition to trade practices called parallel importing and compulsory licensing. In an attempt to control an AIDS outbreak, South Africa legalized the two practices in a 1997 law known as the Medicines Act.

Parallel importing would allow South Africa to purchase AIDS drugs at lower prices from sources other than the manufacturers. Compulsory licensing would permit South African companies to manufacture generic versions of the drugs in return for royalty payments to patent holders.

Parallel importing and compulsory licensing have been part of the debate on Capitol Hill over the House-passed African Growth and Opportunity Act (HR 434), which is intended to promote U.S. trade with sub-Saharan Africa by reducing duties on exports from those nations. According to the Office of National AIDS Policy, that region accounts for more than 80 percent of AIDS deaths.

Complaining that the trade bill did not address the prevalence of AIDS in Africa, Rep. Jesse L. Jackson Jr., D-Ill., introduced a competing bill that would permit low-cost imports and production of generics.

But the administration and leading AIDS drug producers call the South African law too vague and contend it may violate international trade agreements. The opponents argue that the sale of AIDS drugs needs to be profitable to support research and development of future drugs and low-cost AIDS vaccines.

The Washington-based Pharmaceutical Research and Manufacturers of America challenged the law in South African courts. At the same time, the drug companies have been lobbying the South African government to clarify and change the law. The drug makers suspended their lawsuit last week when the South African health minister agreed to redraft the law next year.

Manufacturers association spokesman Mark Grayson said the group also is working with U.S. trade agencies and

the vice president's office and is making its case to members of Congress.

The drug manufacturers' lobbying campaign began in 1997 with a letter to the U.S. trade representative objecting to the Medicines Act. Later that year, representatives of Bristol-Myers Squibb Co., Merck & Co. and other drug companies met with the South African ambassador to the United States.

The manufacturers also enlisted the help of Secretary of Commerce William M. Daley to press the issue.

More recently, the manufacturers successfully lobbied the U.S. trade representative to add South Africa to a list of countries under scrutiny for intellectual property rights violations. In April, the trade representative's office also announced it would review South African trade practices.

With backing from the pharmaceutical industry, the fiscal 1999 omnibus appropriations law (PL 105-277) withheld U.S. aid to South Africa until the secretary of State issued a report detailing the steps being taken to win repeal or suspension of the Medicines Act.

The resulting report released in February said the State Department had worked with the trade representative's office, the Commerce Department and the pharmaceutical industry to oppose South African trade practices.

Turning to 'direct action.' Supporters of South Africa's effort to get less expensive drugs have no similar lobbying success to brag about.

Jamie Love, director of the Consumer Project on Technology, pressed his side's case with Gore's staff and members of Congress, especially members of the Congressional Black Caucus. Love and Nader wrote letters to Gore, Secretary of State Madeleine K. Albright and Rep. James E. Clyburn, D-S.C., chairman of the black caucus, and met with Sandra Thurman, director of the White House AIDS policy office.

Love maintains a site on the World Wide Web and a discussion group on the Internet.

Love worked with Jackson in the drafting of the lawmaker's HOPE for Africa Act (HR 772), the trade bill offered as an alternative to the House-passed bill. But Jackson's legislation, which would allow African countries to use parallel importing and compulsory licensing, has shown no signs of movement.

Act Up and other advocacy groups turned to what Eric Sawyer, co-founder of New York Act Up, calls "direct action." They arranged protests, disrupted campaign speeches and staged marches in the nation's capital to protest the administration policy on anti-AIDS drugs.

Before the House passed the African Growth and Opportunity bill, Act Up blocked access to the drug manufacturers association's Washington headquarters and brought 1,000 people to the capital for a one-day lobbying assault on Capitol Hill.

The group also urged its members to write letters, call their representatives, attend demonstrations, call journalists and raise money for the lobbying effort.

Unhappy with Gore's response to its entreaties, Act Up planned additional protest activities for Oct. 1 — which the group designated a national day of action against pharmaceutical companies — and on World AIDS Day, Dec. 1.

— Mary S. Dabrymple

Lobbyists & Advocates appears Mondays. Contact advocates@cq.com or call Randy Wynn at (202) 822-1455.



Love



FAX TRANSMISSION

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To: Cheryl Baverle
AIDS Policy Office

Date: 10/4/99

Fax #: 62439

Pages: 8
(Including cover sheet)

From: Donna M. DiPaolo
Deputy Director for IP

Subject: 10/6 DEMONSTRATION

MESSAGE:

per telcon



**ACT UP/DC Mourns the death
of founder Steve Michael**
Learn more about this activist
and why he fought so hard for
I-59

HOPE FOR AFRICA ... NOT NAFTA

Demand medications for all nations

Join ACT UP and Demonstrate
Oct 6 in D.C. - END MEDICAL
APARTHEID
- ACT UP
- September 27, 1999

Common Mistakes by Reporters covering US/South Africa dispute

Contrary to reports in USA Today,
the Chicago Tribune, and a few
other news outlets, South Africa
did not back down in the trade
dispute.
- James Love CPTech
- September 23, 1999

Letter asking US to WHO access to drugs developed with US tax dollars

Give the WHO the right to
use health care patents that
the US government has rights
to under 35 USC Sec 202 (c)(4),
for government owned
inventions.
- James Love CPTech
- September 3, 1999

Accord reached With

WHAT IS HAPPENING WHAT IS NEW

AIDS DRUGS FOR ALL NATIONS - DEMO OCT. 6

ACT UP
September 30, 1999

Protesters Demand U.S. Trade
Representative Barshefsky
Extend South African Trade
Agreement on Medicines to All
Nations! 30 million with HIV
worldwide denied access to
lifesaving treatment!
Wednesday, October 6 o 12
noon o Dozens of Arrests
Expected Farragut Square, 17th
St NW & "Eye" St; march to
USTR, 17th St, NW & G St

CLINTON VETO'S DC's APPROPRIATION

THE WHITE HOUSE
September 28, 1999

However, I have decided to veto
this bill because Congress has
added a number of unacceptable
riders that prevent local
residents from making their own
decisions about local matters.
Congress has interfered in local
decisions in this bill in a way that
it would not have done to any
other local jurisdiction in the
country. For example, this bill
bars the District from spending
its own funds to seek voting
rights for the citizens of the
District of Columbia.

ACLU INFORMATION ON I-59

The ACLU has committed to
fighting the 'social riders'
imposed on the DC
appropriations bill. Join them in
urging the President to veto the
DC appropriations.

DC COUNCIL URGES CONGRESS AND CONTROL BOARD TO RESPECT DEMOCRACY

DC COUNCIL
September 20, 1999

To declare, on an emergency



How to Contact Us | Press Releases | Text of Initiative 59 |
ACT UP/DC Home Page

...demand medicine for every nation...

ACT UP Philadelphia
 for Immediate Release
 September 26, 1999

Wednesday, October 6:
 Noon, EST * Washington DC, USA
 Farragut square * 17th & Connecticut NW

US Trade Representative Charlene Barshevsky holds the world hostage for life-saving drugs>bring the dead to barshevsky's door.....

Philadelphia: Buses leave 8am, Broad and Walnut, lunch provided
 Transportation also available from NYC and other locations

.....end medical apartheid worldwide..... 90% of people with HIV worldwide have no access to lifesaving drugs.

Poor nations seek to manufacture affordable generic versions of expensive drugs, and also shop around the globe for the best price. These legal and common trade practices are used by the United States and many other whiter, wealthier nations without fear of punishment.

Rather than supporting these efforts, the US Government threatens developing nations with sanctions and demands changes in the laws of sovereign countries.

As the top trade official of the United States, Charlene Barshevsky plays big stick for the drug companies -- the world's most profitable industry and top contributor to politicians.

For poor nations populated mostly with people of color, the racist trade policies of the US are a death sentence.

Barshevsky and her big business buddies would rather let millions die from AIDS than give away the big secret: many drugs cost pennies to manufacture.

On Friday, September 17, AIDS activists in the U.S. and South Africa (where 1 in 8 people is HIV+) forced Vice President Al Gore to back down from his attempts to derail South Africa's intentions to provide life-saving medication. He instructed Charlene Barshefsky, the United States Trade Representative, to cease her obstructions of South African's efforts.

But the rest of the world is still held hostage by racist US trade policies. -- business as usual leaves millions dead --

- We demand that the deal made with South Africa
- become U.S.trade policy for all nations
- We must stop interfering with the efforts of

OCTOBER 6th Demonstration in D.C. - ACT UP/DC

<http://www.actupdc.org/africa/Demo-oct-6.html>

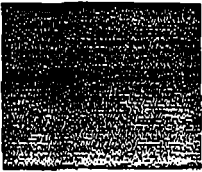
- sovereign nations to save lives.

info: 215.731.1844 jdauids@critpath.org

REMINDER: Please call your Senators at 202.224.3121 and ask them to oppose the Africa Growth and Opportunity Act.¹ You don't have to know who your Senators are -- just give your zip code and they will connect you to the right office.

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D.C.
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ACTION OCT. 6 - Protesters Demand U.S. Trade Representative Barshefsky Extend South African Trade Agreement on Medicines to All Nations

CONTACT: Julie Davids, 215.731.1844
cell: 267-231-4637
page: 215.212.9050

Protesters Demand U.S. Trade Representative Barshefsky Extend South African Trade Agreement on Medicines to All Nations 30 million with HIV worldwide denied access to lifesaving treatment Wednesday, October 6 o 12 noon o Dozens of Arrests Expected Farragut Square, 17th St NW & "Eye" St; march to USTR, 17th St, NW & G St

1000 people with HIV/AIDS and their supporters from ACT UP Philadelphia and the Health GAP Coalition will march and rally on Wednesday, demanding an end to US trade policy that threatens and enforces sanctions against countries utilizing legal methods for accessing essential medications. A larger-than-life puppet depicting US Trade Representative Charlene Barshefsky as a marionette whose strings are pulled by drug industry executives, "blood money," dollar bills featuring Barshefsky's image, and empty pill bottles symbolizing the effect of USTR bullying of nations hard-hit by HIV/AIDS will be featured. Civil disobedience is anticipated.

Charlene Barshefsky uses the trading power and markets of the United States to restrict developing countries from accessing life saving medicines via WTO authorized trade practices. Barshefsky, collaborating overtly with drug manufacturers, routinely instigates penalties and sanctions against poor nations utilizing compulsory licensing or parallel importing. A former timber industry lobbyist, Barshefsky has made heavy-handed enforcement, at the bidding of industry, a hallmark of her rule of USTR.

"The requests for international sanctions coming from PhRMA, the drug company lobby, are uncritically adopted by Barshefsky's office," said Paul Davis of ACT UP Philadelphia, referring to USTR's Special 301 Watch List. "PhRMA is dictating the trade policy of this country. Barshefsky parrots the drug company lie that increasing access to drugs in developing nations will destroy pharmaceutical research. Not only is the majority of drug development in the United States heavily subsidized by U.S. tax payers, most drug companies spend far more on advertising and marketing than research. The pharmaceutical industry is the planet's most profitable industry*, and it is calling the shots for Barshefsky. Big Pharma would let millions die rather than letting the secret out – drugs are cheap to make." [*Fortune 500 web page]

90% of HIV cases occur in nations with virtually no access to effective treatments, thus virtually ensuring the suffering and early death of 30 million people. In Zambia, the chance that a 15-year-old will die of AIDS is 60%, according to Callisto Madavo, Regional Director of the World Bank.

After a series of protests, including a 700 person demonstration at a Gore fundraiser in Philadelphia, Barshefsky was recently directed by Vice President Gore to remove all U.S. obstructions to South Africa's compulsory licensing and parallel importing efforts. One in eight South Africans is living with HIV. However, according to Clinton/Gore Administration sources, the agreement with South Africa is an "exception," and the USTR will continue U.S. efforts to block developing countries efforts to produce essential medicines. Protesters demand that all nations be permitted to exercise their rights to provide life-saving medicines, and demand that USTR support countries seeking greater access to medications at the WTO ministerial in Seattle this Fall. Barshefsky is expected to advocate for the weakening of WTO agreements permitting compulsory licensing and parallel importing, particularly with regards to medication.

"Essential medications are not luxuries. They are life-saving, and countries are permitted to manufacture them under international treaties," said Willie Parker, director of the ACT UP Gospel Choir. "We will raise our voices to say 'no more' to a public servant using our tax dollars to kill millions, simply because this Administration cares more for drug company whims than human lives."

Over the past six months, protesters have followed Vice President Gore around the country, accusing him of "Medical Apartheid," siding with the pharmaceutical industry in the battle to guard its patent rights at the expense of human lives. They pledge that disruptions and protests will not cease until the Administration transforms trade policy to support access to essential medications, rather than pharmaceutical companies placing profit before human lives.

"Saving lives in Thailand, Brazil and India is just as vital as saving lives in South Africa," explained Chris Kimmenez of ACT UP Philadelphia. "The United States must cease its harassment of sovereign nations that are taking legal measures to provide essential medications. The U.S. has failed to implement our own laws that could pave the way for drug access," he added, referring to the unused Bayh-Dole legislation (37CFR 404.7), which would allow the U.S. to issue production rights for medications whose patents are held by federal health and research agencies.

Protesters will distribute a new report documenting USTR's role in limiting access to essential medications, including:

1. Thailand, home to approximately one million people with AIDS, where the US government has pressed the government to give up compulsory licensing, parallel imports and price controls on pharmaceuticals. At Bamrasnaradura Hospital in Bangkok, Thailand, only twenty out of two thousand patient who seek treatment each month can afford the triple drug cocktails that have become the standard of care in developed countries. (Health Action International: Essential Medicines and Compulsory Licensing, Nathan Ford and Daniel Berman, 1999; www.haiweb.org/campaign/cl/mtgsum.html)
2. In India, where more than 700 million people live in dire poverty, the US

government has lobbied against compulsory licensing of essential medicines and strong-armed the passage of harmful legislation.

3. Throughout Central and Latin America, the US has lobbied against the use of compulsory licensing and parallel imports of essential medicines. On Wednesday, September 8, people with HIV, diabetics and their allies protested across Brazil. While their nation's constitution guarantees access to medicine as a human right, the production of generic medication through compulsory licensing has been all but eliminated in recent years due to US pressure bankrupting public health programs and leaving millions without treatment.
4. In Egypt, the US government has reportedly threatened to cut off \$500 million in US Economic aid, if the Egyptian government joins in developing country lobbying efforts on pharmaceutical policies and the WTO.

Compulsory licensing is the process whereby a country issues a permit for manufacturing a generic version of a patented product, paying a royalty to the patent-holder. Parallel importing is the process of shopping around the globe for the best price for a patented product. Both practices are legal and routinely utilized by many industrialized nations. However, Barshefsky takes numerous unilateral actions against poor countries to protect drug manufacturers' monopoly on their products. Most 'essential medicines' are inexpensive to manufacture, and were typically researched and developed largely with U.S. tax dollars.

Compulsory licensing finds its legal basis in Article 31 of the World Trade Organization's TRIPS agreement. It states that Member States may "use the subject of a patent without the authorization of a right holder, including use by the government or third parties authorized by the government," when justified in the public interest.

Michael Kantor, Barshefsky's predecessor, noted that "TRIPS specifically sets out a considerable number of conditions under which compulsory licensing may be utilized for use by those countries wishing to impose limits on intellectual property within its own borders... [and] to exclude entirely from the scope of patentable subject matter a range of inventions, including... surgical and therapeutic methods... The innovator pharmaceutical companies were not enthusiastic supporters of these provisions, but they were accepted nevertheless by this Administration." (Feb 1, 1996 letter; www.cptech.org/pgharm/cl.html)

Parallel importing is specifically excluded from the TRIPS amendment, meaning that it is impossible for such measures to be in violation of TRIPS.

"Barshefsky flouts international trade agreements like racist sheriffs used Jim Crow laws," said Roy Hayes, ACT UP Philadelphia member who will risk arrest Wednesday, "She interprets the law as she sees fit, then unleashes her dogs and guns to block human rights."

Demands of the Health GAP Coalition

1. The U.S.T.R. and other relevant department heads must cease actions interfering with efforts by poor countries to increase access to essential medicines; the announced terms of Gore's arrangement with South Africa must become U.S. global trade policy;

"Is Ambassador Barshefsky a corporate lapdog, or a killer pit bull for big

pharma? Public USTR documents threaten sanctions against countries that stand up for their legal right to provide medication." asked ACT UP Philadelphia member Paul Davis. "We demand that Charlene Barshefsky implement policies that value human lives more than drug company profits," he continued.

2. The USTR must support, rather than oppose, the campaign of poor nations, including Venezuela, Uganda, and Sri Lanka to broaden the Trade Related Aspects of Intellectual Property (TRIPS) agreement during the WTO Ministerial in Seattle in November to more explicitly exempt essential medicines from the patent system for countries unable to afford "Apartheid prices."
3. The USTR must remove South Africa from the 301 Watch List, which targets nations for a wide array of U.S. trade sanctions.

"South Africa was placed on the 301 Watch List during its trade dispute with Gore and Barshefsky over the use of compulsory licensing and parallel importing. If the dispute has been settled like Gore wants us to believe, then South Africa should be removed from the list," said ACT UP Philadelphia's Asia Russell



THE WHITE HOUSE
WASHINGTON

MEMORANDUM TO PHIL DUFOUR

From: Sandy Thurman
Date: June 18, 1999
Re: Talking Points

The Vice President has absolutely no objection to compulsory licensing of pharmaceuticals in South Africa so long as it is consistent with TRIPS (Trade Related Aspects of Intellectual Property, from the World Trade Organization). We must work toward assuring access to affordable high quality drugs to all who need them.

In 1997, South Africa's General Assembly passed legislation granting broad powers to the Health Minister with respect to pharmaceutical patents. This raised serious concerns regarding whether this new law was consistent with existing World Trade Organization regulations. As a consequence, more than 40 companies from around the world filed suit against the South African government. Unfortunately, the pending law suit slowed negotiations between the United States and South Africa intended to resolve the issue. However, this in no way undermines our position on compulsory licensing or our commitment to working with the South Africans to help provide the most affordable medicines possible.

Access to affordable drugs is just one of many challenges in providing care to people with HIV in Africa. While compulsory licensing is an important issue, it must be considered in the broader context of the development and support of a health care continuum that includes both prevention, social services and treatment. This is the focus of our Administration's work on the global battle against AIDS -- particularly in Africa.

More than any Administration in the past, our Administration has worked diligently to build a new partnership with Africa. A vital part of this new partnership is helping to respond to this serious and growing pandemic.

Through the White House AIDS Office, we have lead several recent fact finding missions to sub-Saharan Africa and are now in the process of finalizing an AIDS Initiative for Africa.

This Administration has been a leader in the battle against AIDS and we will continue to be.

INTERNATIONAL

No treatment:
AIDS patient

No Money, No Meds

South Africa needs access to cheap AIDS medicine, but drug companies want a say in what they get and how they get it. Now Al Gore is caught in the cross-fire.

BY MARCUS MABRY

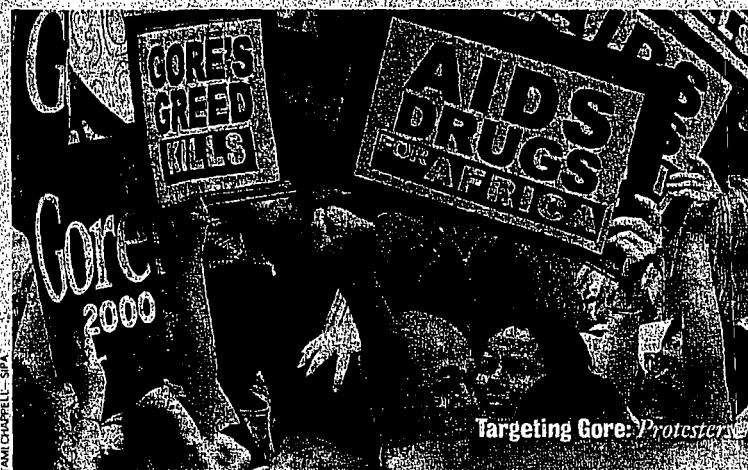
VERONICA MNGOMA, A 35-YEAR-old mother of three, was diagnosed with AIDS more than a year ago. But doctors at Rietvlei Hospital, in South Africa's impoverished Eastern Cape province, didn't do anything about it. They didn't even tell Mngoma there are treatments that could prolong her life. Why not? On the \$33 a week Mngoma earned working in a furniture factory, she couldn't pay for AIDS drugs anyway. "If we told [her] there was treatment but you can't af-

ford it, that would be cruel," says Rietvlei Supt. Nigel Hoffman. Now Mngoma's bony limbs are covered in scales, and she has trouble walking. Talking is a chore. She opens her mouth, filled with yellow sores, and fights to tell a reporter, "I worry about my children."

Is it right to put a price tag on survival? South Africa's government thinks not: It wants to bypass Western pharmaceutical firms and produce AIDS drugs on its own, or to import them at the cheapest possible cost—perhaps from so-called patent-pirate countries. That, in turn, has whipped up

emotions in Washington, where trade officials and corporate lobbyists are determined to protect intellectual-property rights. AIDS activists have taken up the South African cause: protesters from ACT UP, the confrontational AIDS lobby group, are now dogging the campaign of Al Gore, casting him as the leading villain in the dispute.

This is not a narrow bilateral issue, nor is it a simple one. Ninety percent of the world's 33 million HIV/AIDS cases are in Africa, Latin America and Asia. The vast majority of infected people in those areas



Targeting Gore: Protesters

The High Cost of Good Health

Expensive drugs have eased the AIDS crisis in the wealthier countries. But in poor ones, new infections—and the death toll—keep growing.

North America	890,000	44,000	\$22,251
Caribbean and Latin America	1,730,000	205,000	\$3,940
Europe and Central Asia	770,000	110,000	\$2,510
North Africa and Middle East	210,000	19,000	\$2,070
Sub-Saharan Africa	22,500,000	4,000,000	\$510
East Asia and Pacific	580,000	200,000	\$970
South Asia	6,700,000	1,200,000	\$380
Australia and New Zealand	12,000	600	\$19,830

Total cases of HIV/AIDS
New Infections in 1998
GNP per capita, 1997

ALL DATA ARE ESTIMATES. SOURCES: UNAIDS/WHO; WORLD BANK

can't afford the cocktails of miracle drugs that can make AIDS a chronic disease rather than a death sentence. Those cocktails usually include protease inhibitors such as Crixivan, produced by Merck, and other antiretrovirals, such as AZT, produced by Glaxo Wellcome. In the United States, the combination can cost \$750 a month, a fortune in a country like South Africa, where 8 percent of the country's 38 million people are infected with AIDS—and the annual per capita income is \$6,000.

In late 1997 South Africa decided to take action. It passed legislation that would empower the government to secure cheap, effective drugs. Theoretically, the law would allow small local companies to produce their own versions of drugs patented by the pharmaceutical giants—perhaps at much lower costs. The government would also be allowed to import AIDS drugs from other countries, such as India and Argentina, that don't enforce intellectual-property rights.

The law was condemned by the South African drug industry, which is largely

made up of subsidiaries of Western drug multinationals. The companies quickly took the government to court, arguing that the South African legislation threatens their patents—and with them, the revenues needed to fund the costly development of such drugs in the first place. Besides, the companies contend, complex AIDS treatments are unlikely to be administered effectively in South Africa. "It's much more complicated than getting pills to people," says Tom Bombelles of the Pharmaceutical Research and Manufacturers of America, an industry trade group. The AIDS drug regimens need to be closely monitored, he says. Yet in South Africa, "the whole health system is in a shambles."

U.S. officials initially hoped that quiet diplomacy might resolve the dispute. Gore, who heads the U.S.-South Africa Binational Commission, told Pretoria last August that the law was too vague and had to comply with international trade regulations. (South Africa insists that it does, and points out that Western countries take the same meas-

ures when it suits them.) Apparently that wasn't tough enough for Rodney Frelinghuysen, a Republican congressman from New Jersey whose district includes several drug companies. He attached a provision to last year's budget that blocked U.S. aid to South Africa until the State Department explained how it was helping his corporate friends. State's final report said Washington was "engaged in an assiduous, concerted campaign" to change the law and specifically cited Gore's diplomatic pressure on Pretoria. When AIDS activists got hold of the report, they launched a counteroffensive—against Gore.

Last week noisy protesters from ACT UP staged their fourth demonstration in a month—at a \$1,000-a-plate fund-raiser outside a swanky Philadelphia hotel. (Gore's people say only a handful of protesters have shown up at most campaign events.) Conservative commentator Arianna Huffington took up the attack, dubbing the VP "Pharmacologic Al," and Ralph Nader's lobbyists have also put pressure on Gore, who insists that he supports inexpensive AIDS drugs for South Africa, has some credible allies. The AIDS Action Council, the largest AIDS

lobby group in the United States, believes the protests against the veep are misdirected. "This is like blaming Roosevelt for the Holocaust," says Council director Daniel Zingale.

The blame game could go on for quite a while. The drug industry's challenge to the new law is tied up in South Africa's Constitutional Court, and no one expects a resolution until next year. Nevertheless, activists in South Africa and the United States are planning more protests. And drug companies are threatening to take their investments out of South Africa.

Meanwhile, the doctors at Rietvlei do what they can. "If Africa had access to these medicines, then it would be Africa's responsibility to find a way to make them work," says Rietvlei Superintendent Hoffman. Until then, he will continue to keep his HIV-infected patients in the dark about the existence of drugs that could save their lives. It seems a small kindness, but right now it's about all he has to offer.

With DEBRA ROSENBERG and JOHN BARRY
in Washington

THE WHITE HOUSE

Office of the Press Secretary
(Seattle, Washington)

For Immediate Release

December 1, 1999

REMARKS BY THE PRESIDENT
TO THE LUNCHEON IN HONOR OF THE
MINISTERS ATTENDING THE MEETINGS
OF THE WORLD TRADE ORGANIZATION

The Four Seasons Hotel
Seattle, Washington

3:05 P.M. PST

THE PRESIDENT: Thank you very much. Ambassador Barshefsky, thank you for your remarks and your work. Ladies and gentlemen, we have a very large delegation from our administration here today, and I hope it's evidence to you of our seriousness of purpose. I thank the Commerce Secretary, Bill Daley; the Agriculture Secretary, Dan Glickman; our SBA Administrator, Aida Alvarez; my National Economic Councilor Gene Sperling; Ambassador Esserman; and my Chief of Staff, John Podesta, all of whom are here and I thank them.

I want to say that I agree that Mike Moore is the ideal person to head the WTO, because he has a sense of humor -- and, boy, do we need it right now. (Laughter.) Did you see the gentleman holding up the big white napkin here before we started? He was doing that to get the light for the television cameras. But he was standing here hold the napkin and Mike whispered to me, he said, well, after yesterday, that could be the flag of the WTO. (Laughter.) We'll have rolling laughter as the translation gets through here.

Let me begin by saying welcome to the United States and to one of our most wonderful cities. We are honored to have you here on a very important mission. Today I want to talk a little bit about the work that we're all here to do: launching a new WTO round for a new century -- a new type of round that I hope will be about jobs, development and broadly shared prosperity; and about improving the quality of life, as well as the quality of work around the world; an expanded system of rule-based trade that keeps pace with the changing global economy and the changing global society.

Let me begin by saying that seven years ago when I had the honor to become President of the United States, I sat down alone and sort of made a list of the things that I hoped could be done to create the kind of world that I wanted our children to live in, in the new century -- a world where the interests of the United States I thought were quite clear: in peace and stability; in democracy and prosperity.

To achieve that kind of world, I thought it was very important that the United States support the increasing unity of Europe, and the expansion of the European Union; that we support the expansion of NATO and its partnership with what are now more than two dozen countries, including Russia and Ukraine; that we support the integration of China, Russia, and the Indian subcontinent in particular, into the large political and economic flows of our time; that we stand against the ethnic and religious conflicts that were still consuming the Middle East and Northern Ireland, then Bosnia and later Kosovo; that we do what we could to help people all over the world to deal with such things,

including the tribal wars in Africa.

And I thought it was important that we give people mechanisms by which they could work toward a shared prosperity, which is why we wanted to finish the last WTO round; why we are working hard with our friends in Europe on a Stability Pact for the Balkans; why we know economics must be a big part of the Middle East peace process; why we have an Asian-Pacific Economic Forum, where the leaders meet; why we've had two Summits of the Americas with our friends in Latin America; why we're trying to pass the Africa and Caribbean Basin Trade Initiatives; and why I believe it is imperative that we here succeed in launching a new trade round that can command broad support among ordinary citizens in all our countries and take us where we want to go.

There are negative forces I have tried to combat, in addition to the forces of hatred based on ethnic or religious difference: the terrorists, the problems of disease and poverty, which I hope that the large debt relief initiative that we are pushing will help to alleviate.

But in the end, all of these changes in my view will only give us the world we want -- where the poorest countries have children that can at least live through childhood, and where the boys as well as the girls can go to school, and then have a chance to make a decent living; where countries with governance problems can work through them; where wealthy countries can continue to prosper but do so in a way that is more responsible to helping those who still have a long way to go economically; and where, together, we can meet our common responsibilities to human needs, to the environment, to the cause of world peace -- we will not get that done unless we can prove, for all of our domestic political difficulties and all of our honest differences, we still believe that we can have an interdependent global economy that runs alongside our interdependent international information society.

And we are called upon here to meet against a background of a lot of people coming here to protest. Some of them, I think, have a short memory -- or maybe no memory -- of what life was like in most of your countries not so very long ago. So let me say again, I condemn the small number who were violent, and who tried to prevent you from meeting.

But I'm glad the others showed up, because they represent millions of people who are now asking questions about whether this enterprise in fact will take us all where we want to go. And we ought to welcome their questions, and be prepared to give an answer, because if we cannot create an interconnected global economy that is increasing prosperity and genuine opportunity for people everywhere, then all of our political initiatives are going to be less successful. So I ask you to think about that.

When I hear the voices outside the meeting rooms, I disagree with a lot of what they say, but I'm still glad they're here. Why? Because their voices now count in this debate. For 50 years -- one of the reasons I said we needed a leader like Mr. Moore, with a sense of humor, because for 50 years global trade, even though there were always conflicts -- you know, the United States and Japan, they're our great friends and allies. We're always arguing about something.

But to be fair, it was a conflict that operated within a fairly narrow band. For 50 years, trade decisions were largely the province of trade ministers, heads of government, and business interests. But now, what all those people in the street tell us is that they would also like to be heard. And they're not so sure that this deal is working for them.

Some of them say, well -- and by the way, they're kind of like we

are; a lot of them are in conflict with each other, right? Because a lot of them say, well, this is not a good thing for the developing countries. They haven't benefited as much as they should have, while the wealthy countries have grown wealthier in this information society.

Others say, well, even if you're growing the economy, you're hurting the environment. And still others say, well, companies may be getting rich in some of these poorer countries, but actual working, laboring people are not doing so well. And others have other various and sundry criticisms of what we have done.

I would like to say, first of all, I think we need to do a better job of making the basic case. No one in this room can seriously argue that the world would have been a better place today if our forebears over the last 50 years had not done their work to bring us closer together. Whatever the problems that exist, in whatever countries represented here -- whatever the legitimacy of any of the criticism against us -- this is a stronger, more prosperous world because we have worked to expand the frontiers of cooperation and reduce the barriers to trade among people. And we need to reiterate our conviction that that is true. If we were all out here going on our own, we would not be as well off in the world as we are.

Secondly, at the end of the Cold War, I am sure everyone in this room has been struck by the cruel irony that in this most modern of ages -- when the Internet tells us everything, as Mr. Moore said; when we are solving all the problems of the human gene and we will soon know what's in the black holes in the universe -- it is truly ironic when the biggest problems of human societies are the oldest ones, those rooted in our fear of those who are different from us -- different races, different ethnic groups, different tribes, different religions. All over the world, people consumed by differences.

When people are working together for common prosperity in a rule-based system, they have big incentives to lay the differences down and join hands to work together. So if we just make those two points to our critics, I think it's very important. Number one, the world is a better place than it would have been, had we not had the last 50 years of increasing economic cooperation for trade and investment. And number two, the world of the future will be a safer place if we continue to work together in a rule-based system that offers enormous incentives for people to find ways to cooperate and to give up their old hatreds and their impulses to violence and war.

Now, having said that, we now have to say: what next? I think we have to acknowledge a responsibility, particularly those of us in the wealthier countries, to make sure that we are working harder to see that the benefits of the global economy are more widely shared among and within countries -- that it truly works for ordinary people who are doing the work for the rest of us.

I think we also have to make sure that the rules make sense and that we're continuing to make progress, notwithstanding the domestic political difficulties that every country will face. We all benefit when the rules are clear and fair. I think that means we have to cut tariffs further on manufactured goods and set equally ambitious goals for services. I think we should extend our moratorium on e-commerce. I think we should treat agriculture as we treat other sectors of the economy.

But we all have domestic political constraints. Everybody knows that. I think we have to leave this luncheon saying, in spite of that, we're going to find some way to keep moving forward because the world will be a better place and the world will be a safer place.

Now, let me offer a few observations of what I hope will be done. First, I think we have to do more to ensure that the least developed countries have greater access to global markets, and the technical assistance to make the most of it.

Director General Moore has dedicated himself and this organization to extending the benefits of trade to the least developed countries and I thank you for that, sir. Here in Seattle, 32 developing nations are moving toward admission to the WTO. EU President Prodi and I have discussed this whole issue and I have assured him, and I assure you, that the United States is committed to a comprehensive program to help the poorest nations become full partners in the world trading system. This initiative, which we are working on with the EU, Japan and Canada, would enhance market access for products from the least developed countries consistent with our GSP preference access program and our Africa and Caribbean Basin Initiatives -- which, I am glad to report, are making good progress through the United States Congress.

Building on our recent collaboration with Senegal, Lesotho, Zambia, Bangladesh and Nigeria, we would also intensify our efforts to help developing countries build the domestic institutions they need to make the most of trade opportunities and to implement WTO obligations. This afternoon, I will meet with heads of international organizations that provide trade-related technical assistance and ask them to help in this effort.

And I will say this. I do believe, after the Uruguay Round, when we set up this system, that we did not pay enough attention to the internal capacity-building in the developing nations that is necessary to really play a part in the global economy. And I am prepared to do my part to rectify that omission.

We also must help these countries avert the health and pollution costs of the industrial age. We have to help them use clean technologies that improve the economy, the environment and health care at the same time. And I will just give one example.

Today is World AIDS day. And today, the USTR, our trade representative, and the Department of Health and Human Services are announcing that they are committed to working together to make sure that our intellectual property policy is flexible enough to respond to legitimate public health crises.

Intellectual property protections are very important to a modern economy, but when HIV and AIDS epidemics are involved, and like serious health care crises, the United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need. I hope this will help South Africa and many other countries that we are committed to support in this regard.

More generally, this new round should promote sustainable development in places where hunger and poverty still stoke despair. We know counties that have opened their economies to the world have also opened the doors to opportunity and hope for their own people. Where barriers have fallen, by and large, living standards have risen and democratic institutions have become stronger. We have to spread that more broadly.

So secondly, I want to say what I said at the WTO in Geneva last year. I think it is imperative that the WTO become more open and accessible. While other international organizations have sought and not shied from public participation -- when that has happened, public support has grown. If the WTO expects to have public support grow for our endeavors, the public must see and hear and, in a very real sense,

actually join in the deliberations. That's the only way they can know the process is fair, and know their concerns were at least considered.

We've made progress since I issued this challenge in Geneva last year, but I believe there's more work to be done -- from opening the hearing-room doors to inviting in a more formal fashion public comment on trade disputes.

Now look, let me just say, I know there's a lot of controversy about this. And as all of you know, I'm about to enter the last year of my presidency. I will not be around to deal with the aftermath. But I'm telling you, I've been in this business a long time. And in the end, we all serve and function at the sufferance of the people -- either with their active support, or their silent acquiescence. What they are telling us in the streets here is, this was an issue we used to be silent on. We're not going to be silent on it anymore. We haven't necessarily given up on trade, but we want to be heard.

The sooner the WTO opens up the process, and lets people representing those who are outside in, the sooner we will see fewer demonstrations, more constructive debate, and a broader level of support in every country for the direction that every single person in this room knows that we ought to be taking into the 21st century. So we can do it a little bit now and a little bit later. We can drag our feet, or we can run through an open door. But my preference is to open the meetings, open the records, and let people file their opinions.

No one -- no sensible person -- expects to win every argument, and no one ever does. But in a free society, people want to be heard. And human dignity, and political reality, demand it today.

Third, as I have said repeatedly, I believe the WTO must make sure that open trade does indeed lift living standards -- respects core labor standards that are essential not only to worker rights, but to human rights. That's why this year the United States has proposed that the WTO create a working group on trade and labor. To deny the importance of these issues in a global economy is to deny the dignity of work -- the belief that honest labor fairly compensated gives meaning and structure to our lives. I hope we can affirm these values at this meeting.

I am pleased that tomorrow I will sign the ILO Convention to Eliminate the Worst Forms of Child Labor. And I thank the United States Senate on a bipartisan basis for supporting us in this. I believe the WTO should collaborate more closely with the ILO, which has worked hard to protect human rights, to ban child labor. I hope you will do this.

Let me say in all candor, I am well aware that a lot of the nations that we most hope to support -- the developing nations of the world -- have reservations when the United States says, we support bringing labor concerns into our trade debate. And I freely acknowledge that, if we had a certain kind of rule, then protectionists in wealthy countries could use things like wage differentials to keep poorer countries down -- to say, okay, you opened your markets to us, now we'll sell to you. But you're selling to us and we want to keep you down, so we'll say you're not paying your people enough.

The answer to that is not to avoid this labor issue -- not when there's still child labor all over the world; not when there are still oppressive labor practices all over the world; not when there is still evidence in countries that ordinary people are not benefiting from this. The answer is not to just throw away the issue. The answer is to write the rules in such a way that people in our position, the wealthier countries, can't do that, can't use this as an instrument of protectionism. We can find a way to do this.

But there is a sense of solidarity all over the world, among ordinary people who get up every day, will never be able to come to a luncheon like this, do their work, raise their children, pay their taxes, form the backbone of every nation represented here. They deserve basic, fundamental decency. And the progress of global trade should reflect, also, in their own lives. I do not want the United States, or any other country, now or later, to be able to use this as a shield for protectionism. But to pretend that it is not a legitimate issue in many countries is another form of denial, which I believe will keep the global trading system from building the public support it deserves.

Finally, we must work to protect and to improve the environment as we expand trade. Two weeks ago, I signed an executive order requiring careful environmental review of our major trading agreements early enough to make a difference -- including the input of the public and outside experts, and considering genuinely held concerns. We stand ready to cooperate as you develop similar systems, and to integrate the environment more fully into trade policy.

We are committed to finding solutions which are win-win, that benefit both the economy and the environment -- open trade and cutting-edge clean technologies, which I believe will be the next industrial revolution. We will continue to support WTO rules that recognize a nation's right to take science-based health, safety and environmental measures, even when they're higher than international standards.

Now, I want to say something about this. Again, I know, there are some people who believe my concern and the concern of the United States about the environment is another way that somehow we can keep the developing countries down. That is not true. There are basically two great clusters of environmental issues facing the world today. First, there are the local issues faced primarily by the developing nations: healthy water systems and sewer systems, systems to restrict soil erosion and to otherwise promote the public health.

It is in everyone's interest to help those things to be installed as quickly and efficiently as possible. But the real issue that affects us all, that prompts my insistence that we put this issue on the agenda, is global warming and the related issue of the loss of species in the world as a consequence of global warming.

And the difference in this issue and previous environmental issues is this: once the greenhouse gases get in the atmosphere, they take a long time, 100 years or more, to dispel. Therefore, one nation's policy, including ours -- and we are now the largest emitter of greenhouse gases, in the United States. We won't be long, but we are now.

But we have to do something about this. And I want to say to you what I said to the people at our table. There is now clear and compelling scientific, technological evidence that it is no longer necessary for a poor country growing rich to do so by emitting more greenhouse gas emissions. Or, in plainer language, a nation can develop a middle class and develop wealth without burning more oil and coal in traditional manners. This is a sea change in the reality that existed just a few years ago. And -- let's be candid -- most people don't believe it. A lot of people in our country don't believe it.

But in everything from transportation to manufacturing to the generation of electricity, to the construction of buildings, it is now possible to grow an economy, with much less injury to the atmosphere, with available technologies. And within five years breathtaking changes in the way automobile engines work and in the way fuel is made,

especially from biomass, will make these trends even more clear.

I do not believe the United States has the right to ask India or Pakistan or China or any other country to give up economic growth. But I do believe that all of us can responsibly say, if you can grow at the same rate without doing what we did -- that is, fouling the environment and then cleaning it up -- Mr. Kono remembers -- I remember the first time I went to Tokyo over 20 years ago, people wore masks riding their bicycles around. And now the air there is cleaner than it is in my home town in Arkansas.

What is the difference now? It is not just a national issue. If you foul the atmosphere, and then you later clean it up, the greenhouse gases are still up there, and they'll be there for 100 years, warming the climate.

Now, we do not have a right to ask anybody to give up economic growth. But we do have a right to say, if we're prepared to help you finance a different path to growth, and we can prove to you -- and you accept, on the evidence -- that your growth will be faster, not smaller, that you'll have more good jobs, more new technology, a broader base for your economy -- then I do believe we ought to have those kind of environmental standards. And we ought to do it in a voluntary way with available technologies. But we ought to put environment at the core of our trade concerns.

Now, I don't know if I've persuaded any of you about any of this. But I know one thing: this is a better world than it would have been if our forebears hadn't done this for the last 50 years. If we're going to go into the next 50 years, we have to recognize that we're in a very different environment. We're in a total information society, where information has already been globalized, and citizens all over the world have been empowered. And they are knocking on the door here, saying, let us in and listen to us. This is not an elite process anymore; this is a process we want to be heard in.

So I implore you, let's continue to make progress on all the issues where clearly we can. Let's open the process, and listen to people even when we don't agree with them. We might learn something, and they'll feel that they've been part of a legitimate process. And let's continue to find ways to prove that the quality of life of ordinary citizens in every country can be lifted, including basic labor standards and an advance on the environmental front.

If we do this, then 50 years from now the people who will be sitting in all these chairs will be able to have the same feelings about you that Mr. Moore articulated our feelings for the World War II generation.

Thank you very much, and welcome again. (Applause.)

END

3:40 P.M. PST

Michael, This has not been sent out - we will want to see the executive order or at least know that it is official, Thanks

until it's over

AIDS ACTION

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FOR IMMEDIATE RELEASE:

May 8, 2000

10

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AIDS Action: White House Gets It!

Today's Executive Order Will Alleviate Suffering in Developing Countries

WASHINGTON—AIDS Action today praised President Clinton for signing an executive order that will for the first time allow developing countries to import and manufacture cheaper versions of the world's most effective AIDS drugs without fear of punishment from U.S. trade authorities.

"Americans can be proud of their president today," said Jeff Jacobs, director of government affairs for AIDS Action. "With the stroke of his pen Bill Clinton has signaled that this country is seriously engaged in the global war on AIDS. America can and should do more, but this is an important first step."

The executive order signed today will allow those countries hardest hit by AIDS to provide their citizens with powerful drugs that have been proven to lower viral load in those persons with HIV. Lowering a patient's HIV viral load is associated with dramatic improvements in overall health, as well as decreased infectiousness.

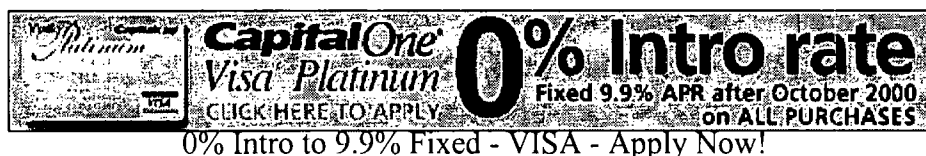
"The best medicines available to fight AIDS are outrageously expensive. Almost nobody in developing countries can afford these therapies, yet that's where the epidemic is raging," said Jacobs. "Today's action by the White House will help get these drugs to where they're desperately needed. This is great news."

"AIDS Action, in its 1998 report card on the administration's efforts to fight the AIDS epidemic, issued an "F" for international AIDS policies. Two years later there's a real sense that the White House gets it," said Jacobs. "Declaring the global AIDS epidemic a threat to national security demonstrated a heightened American commitment to solving a world problem. Though some people viewed that move with skepticism, today's action proves it wasn't just a publicity stunt."

###

AIDS Action is the national voice on AIDS, representing all Americans affected by HIV/AIDS and 3,200 community-based organizations that serve them.

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World HeadlinesSources: [Reuters](#) | [AP](#) | [Full Coverage](#)**Wednesday May 10 1:28 PM ET****Clinton Helps Africans With AIDS***By JIM ABRAMS, Associated Press Writer*

WASHINGTON (AP) - President Clinton issued an executive order Wednesday making it easier for AIDS-ravaged Africa to obtain inexpensive drugs and medical technologies.

The president took the action after nearly identical language in the order was taken out of an African trade bill that Congress is likely to pass and send to the White House this week.

The order states that the U.S. government will not seek to overturn any intellectual property law or policy imposed by a sub-Saharan African government that promotes access to HIV/AIDS pharmaceuticals and medical technologies.

"Given the devastating impact of AIDS, the United States will not require or negotiate restrictive rules in the intellectual property rights area," said U.S. Trade Representative Charlene Barshefsky.

Sen. Dianne Feinstein, D-Calif., who proposed the AIDS drugs amendment to the trade bill with Sen. Russell Feingold, D-Wis., praised the executive order as "the right thing to do."

She said it struck a balance between the need of African nations for access to AIDS drugs and the need to ensure that intellectual property is protected.

Feinstein said the order conforms to World Trade Organization rules that give countries flexibility in addressing public health concerns, in this case by assuring them access to cheap, generic AIDS drugs.

The order also states that it is U.S. policy to encourage sub-Saharan African nations to take steps to address the underlying causes of the HIV/AIDS crisis and that the United States should work with individual countries to assist them in developing effective public education campaigns.

Barshefsky noted that the United States had previously worked out an agreement with South Africa on the production and import of cheaper AIDS drugs. She said the executive order would make clear that the policy worked out in this agreement would be uniform throughout Africa.

Some 34 million people in sub-Saharan Africa have been infected with the disease since the onset of the AIDS epidemic, and 11.5 million have died, 83 percent of the world's total AIDS-related deaths.

Senate Majority Leader Trent Lott, R-Miss., on Tuesday criticized the intention of the president to substitute the dropped Feinstein amendment with an executive order.

“There seems to be a pattern now of him doing executive orders that exceed what he should be doing,” Lott said at a news conference. “That should be done legislatively ... He doesn't make the laws. And so I would hope that he would be careful about doing that.”

The trade bill, which would give African and Caribbean states significantly greater access to U.S. apparel markets, has passed the House and is expected to be approved by the Senate as early as Thursday. Clinton has strongly endorsed it.

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Top Stories Headlines[Add to My Yahoo!](#)**Wednesday May 10 2:57 PM ET**

U.S. Pledges AIDS Drug Help for Sub-Saharan Africa

By Lisa Richwine

WASHINGTON (Reuters) - The United States said on Wednesday it was retreating from a controversial policy, pushed by U.S. drug makers, in order to help make less expensive AIDS drugs available to millions of poor patients in sub-Saharan Africa.

In an executive order, President Clinton promised U.S. officials would not stand in the way of countries that sought to obtain less costly, generic AIDS medication for their poorest citizens as long as the measures complied with international trade rules.

The announcement follows a more than year-long campaign by AIDS activists who complained that the Clinton administration, including Vice President Al Gore ([news](#) - [web sites](#)), was working on behalf of U.S. drug makers to bully developing countries from pursuing generic drugs.

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Pharmaceutical companies had argued that countries' efforts to license local manufacturers to make generic AIDS drugs violated the firms' patent protections and compromised future research. U.S. officials had threatened trade sanctions against countries that pursued such licenses.

From now on, officials will take a softer stance, U.S. Trade Representative Charlene Barshefsky said, asking only that countries abide by the World Trade Organization's agreement on intellectual property. That agreement gives countries more leeway to pursue less expensive medicines, she said.

Barshefsky said the administration was announcing the "very substantial" policy change because the spread of AIDS, which the United States recently dubbed a threat to its national security, had reached crisis levels in sub-Saharan Africa. In some areas, more than 20 percent of adults are infected with the HIV virus that causes AIDS, she said.

The order "is intended to help stop the spread of HIV/AIDS in sub-Saharan Africa by making AIDS-related drugs and medical technologies more accessible and affordable," Barshefsky told reporters.

"The executive order strikes a proper balance between the needs of African countries ... and the needs to ensure that basic intellectual property rights are protected."

Clinton's order would extend an agreement reached last September with the United States and South Africa to all sub-Saharan African countries, Barshefsky said. Measures in other countries will be considered on a case-by-case basis, she said.

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THE WHITE HOUSE

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May 11, 2000, Thursday, Final Edition

SECTION: FINANCIAL; Pg. E02

LENGTH: 484 words

HEADLINE: Africa Gets **AIDS Drug** Exception; Clinton Order May Lower Prices

BYLINE: John Burgess , Washington Post Staff Writer

BODY:

President Clinton yesterday ordered that sub-Saharan Africa get special leeway in importing or manufacturing patented drugs to combat the devastating AIDS epidemic there.

Clinton acted following lobbying by African countries, which contend that patent protection is cutting them off from newly developed treatments even as the disease cuts deadly swaths across their societies. U.S. AIDS activist groups have also pressed for the action.

When U.S. patent laws are strictly enforced for **AIDS drugs**, the result is high prices, typically \$ 10,000 a year or more to treat an AIDS patient in this country. Such sums are far out of reach for African countries, which want to buy or make knockoff versions of the drugs at far lower prices. Clinton's order could make it possible, under some circumstances, for them to obtain **AIDS drugs** at lower prices.

"The executive order finds the balance between protecting intellectual property rights and also promoting accessibility of the drugs" in Africa, said White House spokesman Joe Lockhart.

The order declared that the United States would not invoke a key clause in U.S. trade law against sub-Saharan African countries concerning protection of patents on **AIDS drugs**. It would instead hold them to the less stringent standard of a World Trade Organization agreement on intellectual property protection.

The Pharmaceutical Research and Manufacturers of America, the U.S. drug industry's main trade group, criticized Clinton's order. It sets "an undesirable and inappropriate precedent, by adopting a discriminatory approach to intellectual property laws, and focusing exclusively on pharmaceuticals," said President Alan F. Holmer in a statement.

Member companies are working with African countries to combat the disease, he said, and "continue to play an essential role in pioneering applied research and development, our best hope of winning the war against AIDS. Strong intellectual property protection is the only way to encourage this research." The industry contends that without it, it won't have the huge sums of money needed to develop the drugs.

Paul Davis of ACT-UP Philadelphia, an activist group, welcomed the decision. But he faulted it for only covering sub-Saharan Africa and **AIDS drugs**. "There are more killers than HIV/AIDS and lots of folks

have AIDS in other countries," he said.

Last year, the White House negotiated a deal with South Africa to exempt it on AIDS issues from the provision known as Section 301 of a 1974 trade law. Yesterday's order extends that policy to sub-Saharan Africa as a whole, where, according to the White House, 11.5 million people have died of AIDS, about 83 percent of the world total for the disease.

Under WTO rules that will apply to the countries, certain health circumstances allow countries to order that certain drugs be licensed for local use or imported from third countries.

LANGUAGE: ENGLISH

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Clinton Aims to Get Africa More AIDS-Drugs Access

Dow Jones Newswires

WASHINGTON — President Clinton issued an executive order aimed at making drugs to fight AIDS more accessible and more affordable for Africa.

The action, "strikes the proper balance between the need of African countries to respond to the HIV/AIDS crisis through availability of effective drugs at affordable prices, and ensure that basic individual property rights are protected," U.S. Trade Representative Charlene Barshefsky told reporters after the order was announced.

Under the order, the U.S. will no longer seek to impose increasingly tough standards for protection of intellectual property rights in the area of HIV/AIDS-related drugs and medical technology on sub-Saharan countries. Instead, the U.S. will enforce the minimum standards now imposed by the World Trade Organization agreement on intellectual property rights, Ms. Barshefsky said.

The executive order essentially accomplishes what a failed amendment to the Africa and Caribbean trade bill attempted to write into law.

"The fact that the amendment did not survive conference was disappointing, and led the administration to issue essentially the same policy in executive-order form," Ms. Barshefsky said. She said she doesn't expect a legal challenge.



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Elizabeth Marum) points
Alyson

Subject: re: fwd: Re: cu.s. dept of commerce and aids/malawi - a poss...

Date: Tue, 1 Jun 1999 17:18:24 -0400

From: "Paul Delay" <pdelay@usaid.gov>

To: "Barbara de Zalduondo" <bzalduondo@usaid.gov>,

"Elizabeth Marum" <Elizabeth=Marum%HPN%LILONGWE@usaid.gov>

CC: <AROSS@AFR-SD.ORG>, "Hope Sukin" <hosukin@usaid.gov>,

<"internet[IHUSAIN@AFR-SD.ORG]"@usaid.gov>, "Joan LaRosa" <jlarosa@usaid.gov>

Elizabeth, great response!! I spoke briefly with Sally this morning. Not sure I gave the big picture but I went through the four areas where we have had dialogue with the drug companies and the pros and cons of each approach. The four areas were:

1. Preferential tiered pricing of drugs (The problems include grossly inequitable access, even with significant preferred pricing, no lab support or training, would lead to suboptimum use and probable resistance, etc),
2. Drug donations (same problems as above but even more so and clearly not sustainable)
3. Drug Company Foundations which support training, community activities and some infrastructure (probably the most benign of the drug company interventions)
4. Compulsory licensing versus continuing to push enforcement of the Treaties on Intellectual Property Rights (TRIPS) This is a hot one now with lots of activist involvement. The pros and cons are fairly complex, and the USG does not have a single policy on this, unfortunately.

Paul R. De Lay, Chief, HIV-AIDS Division
Tel: 202 712 0683; FAX 202 216 3046;
Internet: pdelay@usaid.gov

Original Text

From: Barbara de Zalduondo@G.PHN.HN@AIDW, on 06/01/1999 5:10 PM:
To: Elizabeth Marum@HPN@LILONGWE
Cc: Alex Ross@AFR-SD.OFF@AIDW, Hope Sukin@AFR-SD@AIDW,
internet[IHUSAIN@AFR-SD.ORG], Joan LaRosa@HPN@LILONGWE, Paul
Delay@G.PHN.HN@AIDW

Yay Elizabeth!!! Comprehensive, concrete, compelling, and I especially like the airplane metaphor - another Marum citation to add to briefings up here. Just wanted to say thanks and congrats.
- Brazey

202-216-3046

Barbara O. de Zalduondo, Ph.D.
(Under Z in the F2 Directory)
USAID G/PHN/HN/HIV-AIDS
Tel: 202-712-1325; Fax:

internet: bzalduondo@usaid.gov

From: Paul Delay@G.PHN.HN@AIDW, on 06/01/1999 1:03 PM:
To: Alan Getson@G.PHN.HN@AIDW, Amy Bloom@G.PHN.HN@AIDW, Barbara de
Zalduondo@G.PHN.HN@AIDW, Clifton Cortez@G.PHN.HN@AIDW, David L
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Heisler@G.PHN.HN@AIDW, Jaynell Smith@G.PHN.HN@AIDW, John
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fyi

Paul R. De Lay, Chief, HIV-AIDS Division
Tel: 202 712 0683; FAX 202 216 3046;
Internet: pdelay@usaid.gov

From: "Elizabeth Marum" <emarum@malawi.net>, on 06/01/1999 11:02 AM:
To: internet["Sally Miller" <Sally_Miller@ita.doc.gov>]
Cc: Joan LaRosa@HPN@LILONGWE, Paul Delay@G.PHN.HN@AIDW

Hello, Sally-- how nice to hear from you. I've heard much about
you and Bruce from Jane, and I hope one day we'll have a chance
to meet.

Let me first tell you that not only have I met with Sandy Thurman,
but also I was the one who did a lot of the planning for the in-
country events relating to her two trips to Uganda.

Now, to respond to your questions: I like option # 1 much more
than option # 2. Although I am committed to working hard to make
sure that we provide better care to the millions of Africans already
living with HIV infection, our first priority must be prevention of new
infections. Workplace programs can be quite effective, and
anything you can do to encourage this initiative is great.

The problems that I see with the donation of AZT to the very poor
countries in Africa such as Malawi, Zambia, Uganda, etc are the
following:

1. Many people in these countries don't have access to clean
water, enough food, and simple antibiotics for opportunistic
infections. Simple infections such as syphilis remain undiagnosed
and untreated. Even tuberculosis is under-diagnosed and under-
treated. In this environment, to talk of AZT and other anti-retrovirals
is like supplying airplanes to villages with no roads, no bicycles, no
fuel, no mechanics, no pilots....etc. Personally, I believe we have
to work harder to get some basic needs first.
2. Another big barrier is that most people in these very poor
nations who are HIV infected do not know it-- so they don't even
know that they should be on drugs. One of the main projects I'm
working on here in Malawi (and worked on in Uganda) is increasing
the availability of HIV testing and counseling. I was at the largest
hospital in Malawi an hour ago-- they have almost no HIV test kits
in the hospital, and have no idea when more will be delivered. The
few test kits remaining are being saved to test blood before
transfusions. This is another critical need which, in my opinion,
needs attention before drugs are donated. Abbott has a new,
simple, rapid HIV test kit called "Determine". If you could get
Abbott to donate large quantities of these test kits, it would be a
great service to the people of Africa.
3. The third major problem is-- who gets the drugs? In Uganda,
there has been a program supported by UNAIDS for the last six
months, whereby anti-retroviral therapy is available at a slightly
reduced price. Though this sounds great, unfortunately to date the
only people who are benefitting are those who live in the capital city
(Kampala) and who can afford not only the drugs but also the lab

work and doctors fees. Even if the drugs were free, the costs of the recommended routine lab tests and the costs of paying a doctor skilled in caring for someone on the drugs is considerable. Gender access is another big problem. Before I left Uganda in April I kept trying to find out what percentage of people benefitting from the program were women. No one would tell me, I think because they are embarrassed, but I heard unofficially that it might be as high as 80% or more of the beneficiaries are men. And yet we know that more than 50% of the people living with HIV infection in Uganda and other poor countries are women. I have Ugandan friends who are getting the drugs through this program, and I'm so glad that they are getting access. But even they are feeling great ambivalences about such a program which benefits only a tiny percentage (and mostly men) of those who desperately need help. The sad truth remains that, even in Uganda which probably has more AIDS home care programs than anywhere else in Africa, most people with AIDS do not even get simple drugs such as antibiotics, creams for rashes, and anti-fungal treatments.

4. A fourth major problem is logistics. In many African countries, systems for distribution of drugs, lab tests, and even condoms are very inadequate. Many health centers and rural hospitals are very poorly supplied with basic needs, while drugs sit on the shelf past their expiry dates in some central warehouse in the capital city. Making sure that the drugs (and required associated lab tests) are stored properly, distributed in a timely fashion, pulled from distribution when expired, etc., is a major task for which many (most?) African countries do not have the systems in place at this time.

Now, having said all of the above, let me emphasize that this is NOT an official response from USAID-- this is my informat response directly to you. For such a potentially large program with high visibility, it would be best to get a more official response from USAID. Also, most of what I have said applies to the very poor countries such as Malawi, Tanzania, Uganda, etc., and may not be completely applicable in South Africa which has more money and more resources. I have copied on my reply the USAID Health Officer in Malawi and the USAID HIV/AIDS coordinator in Washington DC, Dr. Paul DeLay. I'm not sure I have his email address correctly, so you might want to give him a call directly. I don't have his direct phone number but if you call USAID at the Ronald Reagan building, you should be able to track him down.

In addition, as Dr. DeLay will no doubt tell you, USAID is hoping to implement some regional AIDS activities, specific to the Southern Africa region, and something like this might come under this initiative more than a country specific program. Dr. DeLay will be able to give you "the big picture response" whereas mine is more limited to the specific problems I have seen living and working in Uganda and now Malawi.

I hope this is helpful. In spite of my reservations about the drugs, I think it's great that Americans are more aware of the terrible tragedy of AIDS in Africa, and perhaps the most important impact of these initiatives and ideas is simply to increase public awareness and concern about Africa.

Sincerely,
Elizabeth Marum, Ph.D.
Technical Advisor in HIV/AIDS

USAID Malawi and CDC

Date sent: Fri, 28 May 1999 13:30:20 -0400
From: "Sally Miller" <Sally_Miller@ita.doc.gov>
To: emarum@malawi.net
Subject: cu.s. dept of commerce and aids/malawi - a possible link

> let me introduce myself. I am the director of Commerce's Office of Africa.

>

> I know of you through your sister Jane Corwin, who works with my husband, Bruce Miller, in another part of commerce.

>

> The White House AIDS director, Sandra Thurman, approached my political boss, DAS for Africa Ed Casselle, and asked our office to try to link up with the AIDS effort in two ways.

>

> the first was to think up avenues, using Levi Straus and Ford south africa videos regarding AIDS in the workplace, to reach out to other large US employers in the region to adopt similar programs.

>

> the second would involve an outreach by the Secretary to U.S. pharmaceutical firms by which the firms would be asked for a specific amount of anti-AIDS medication dosages over a specific period of time which would be given to specific entity within a specific African country. a hypothetical example, would be WRT drug company, 3 million doses of AZT to the military in country X.

>

> It is in crafting this second option that I ask for assistance. Could you identify specific potential recipient organizations in specific country/countries which could be proposed for such an effort? the thinking was that specific drug companies could thereby be challenged with a discrete request, with a set dollar figure attached - and with a concrete end-user in mind, so that there would be confidence in the medications getting to the afflicted.

>

> As an AIDS professions, how does this initiative strike you? if it needs recrafting, how would you suggest it be reshaped?

>

> I await your suggestions and reaction.

>

> Hope your long weekend is enjoyable.

>

*** TX REPORT ***

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RESULT OK



OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Philip DuFour FROM: Sandy Thurman
COMPANY: DATE: June 16, 1999
FAX NUMBER: 603-625-6760 TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:
RE:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Thanks so much for all of your help. We have *got* to get our folks on the program!

Attached please find the following documents:

1. Guidance on AIDS/Drugs/South Africa
2. ACT UP Press release
3. *Washington Post* Editorial on racism
4. Global Health Council polling data
5. Hart polling data
6. OVP/AIDS - Q/A



OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Sara Bianchi	Sandy Thurman
COMPANY	DATE:
	June 16, 1999
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
6-5557	
PHONE NUMBER:	
RE	

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

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6. OVP/AIDS – Q/A
7. Example of 75 letters
8. Gephardt/Pelosi letter
9. Leahy *USA Today* letter
10. Poz magazine article

Please page me if you need me. Thanks so much for your help!!!

Sandy

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO 0892
CONNECTION TEL 65557
CONNECTION ID
ST. TIME 06/16 21:25
USAGE T 06'39
PGS. 17
RESULT OK



OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: **Sara Bianchi** FROM: **Sandy Thurman**
COMPANY: DATE: **June 16, 1999**
FAX NUMBER: **6-5557** TOTAL NO. OF PAGES INCLUDING COVER:
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9. Leahy *USA Today* letter
10. Poz magazine article
11. Most recent POTUS memo

Hope your trip went well. This is more info than you need, but better too much than too little!

Call me or page me if you have any questions.

Big hugs.

Sandy

Call Michael
@ home.

Tom Rossini -

Sarah
45 6555-7
✓

Dufour

Mrs. Gore

Philip Hilton

Amy
Malnati

226-7975

50 new
dept relief

New Hampshire -
FAX 603
625-6760
phone 629-9158



OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO:

Philip DuFour

FROM:

Sandy Thurman

COMPANY:

DATE:

June 16, 1999

FAX NUMBER:

603-625-6760

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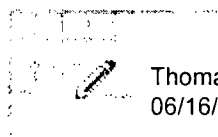
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Call me or page me if you have any questions.

Big hugs-
Sandy

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)



Thomas M. Rosshirt@OVP
06/16/99 12:07:13 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP@EOP, ziegler_jay@ustr.gov@INET@VAXGTWY

cc:

Subject:

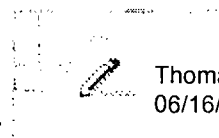
Guidance on AIDS/Drugs/South Africa

We respect the good intentions of those concerned about the problems of AIDS in Africa. The Vice President has been working diligently over many years with Thabo Mbeki -- inaugurated today as President of South Africa -- to combat the scourge of AIDS in Africa.

In the context of the U.S.-South Africa Binational Commission which they co-chair, Vice President Gore and President Mbeki have worked together to find better ways to track the disease, to promote awareness, and develop better means of prevention. Under Vice President Gore's leadership, the U.S. government has been sharing the best of our knowledge and efforts on AIDS with the Government of South Africa.

The Vice President also believes we need to use all available means to deliver high-quality, affordable medicines to those who need them. That's why he has been encouraging the efforts of the U.S. Trade Representative, the South African government, and the pharmaceutical industry to explore solutions to the dispute over patent rights.

We will continue to work with South Africa and other African nations to address the problem of AIDS in a comprehensive manner, from tracking, awareness, prevention, providing treatment, and also continuing our research -- so that 20th century treatment can be replaced by a 21st century cure.



Thomas M. Rosshirt@OVP
06/16/99 06:28:26 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP@EOP, Erica J. Barks-Ruggles/NSC/EOP@EOP

cc:

Subject: ACT UP Press release on VP protest

----- Forwarded by Thomas M. Rosshirt/OVP on 06/16/99 06:27 PM -----



Todd A. Summers @ EOP

06/16/99 05:56:46 PM

.....

Record Type: Record

To: Sandra Thurman/OPD/EOP@EOP, Philip G Dufour/OVP@OVP

cc:

Subject: ACT UP Press release on VP protest

- > PRESS RELEASE: For Immediate Release
- >
- > AIDS ACTIVISTS DISRUPT AL GORE'S ANNOUNCEMENT OF PRESIDENTIAL
- > CANDIDACY: Protestors from "AIDS Drugs for Africa" demand global
- > access to anti-HIV drugs and an end to Vice-President's bullying
- > of South Africa
- >
- > Contact: Asia Russell: 215-731-1844 x 8, pager: 215-838-2355
- > Carthage, TN-Wednesday, June 16
- >
- > AIDS activists disrupted Vice President Al Gore's announcement of
- > his presidential candidacy today on the steps of the Smith County
- > Courthouse. 15 protestors blew air horns and chanted "Gore is
- > killing Africans-AIDS drugs now" at the moment of Gore's
- > announcement, calling attention to the pivotal role the Vice
- > President has played in preventing HIV positive South Africans
- > from obtaining the drugs they need to survive.
- >
- > Gore has been widely criticized for his central role in promoting
- > controversial US trade policy on South African and other
- > developing nations. AIDS activists and trade experts charge
- > Gore with prioritizing the profit motives of the pharmaceutical
- > industry above the needs of 22.5 million people living with AIDS
- > in Africa, virtually all of whom have no access to affordable
- > medications.

- >
- > "Al Gore's devout loyalty to the drug industry is literally
- > costing millions of lives," said Emily Winkelstein from AIDS
- > Drugs for Africa, the grassroots activist group that organized
- > today's event.
- >
- > Most people with AIDS in developing nations die of treatable,
- > preventable infections such as tuberculosis and pneumonia,
- > because medications are priced out of their reach, and out of the
- > reach of their domestic governments. The average annual income
- > in South African is US \$2600, while an estimated cost of one
- > month's supply of AIDS drugs is US \$1000.
- >
- > South Africa and other developing countries have sought tools to
- > respond to the crisis in medication access, including "compulsory
- > licensing"-the granting of local licenses to produce generic
- > equivalents of patented medications when the public health is
- > threatened by lack of medication access. This practice could
- > lower drug prices as much as 90%. Compulsory licensing is legal
- > under the terms and conditions of current international trade
- > agreements, and includes provisions for royalties for the patent
- > holder.
- >
- > Gore has publicly threatened severe trade sanctions against South
- > Africa in response to the governments' efforts to enact a
- > domestic law to allow production of essential AIDS drugs through
- > compulsory licensing.
- >
- > "At the expense of human life, Gore is protecting the
- > multi-billion dollar drug industry he and his presidential
- > campaign hope to benefit from. His actions against South Africa
- > are morally reprehensible," said SharonAnn Lynch, an activist who
- > confronted Gore today. "I am outraged that Gore is siding with
- > the drug companies on an issue, where the moral imperative is
- > clear: South Africans must be allowed to take the necessary
- > steps to address the AIDS crisis in their nation." 20-26% of
- > young adults are infected with HIV in most of southern Africa.
- > In the South African military, 45% of ranks are living with HIV
- > or AIDS.
- >
- > "Gore has said that the international AIDS pandemic must be a top
- > priority for developing nations as the Chair of the South African
- > Bi-national Commission," said Anna Kramarsky, also of AIDS Drugs
- > for Africa." And all the while he has been using his position to
- > bully South African Deputy President Thabo Mbeki, threatening
- > trade sanctions if the South African government dares respond to
- > the needs of its millions of dying citizens."
- >
- > "Developing nations are being faced with an unprecedented health
- > emergency, and they must be allowed to use the range of tools
- > available to them, including compulsory licensing of necessary
- > drugs," said Mark Milano from AIDS Drugs for Africa.
- >
- > "I am outraged that Gore is using his clout as the Vice President

> to squelch the life-saving efforts of the South African
> government," said Mel Stevens. "We will follow Gore every step
> of his campaign, until he stops doing the dirty work of the drug
> companies for them."
>
> ---END---

The Washington Post

AN INDEPENDENT NEWSPAPER

Kosovo and Sierra Leone

ONE OF THE bloodiest wars of the '90s may be winding down. We refer here not to Kosovo but to West Africa's Sierra Leone. Late in May, Africans, led by Nigeria and helped by President Clinton's envoy for the purpose, the Rev. Jesse Jackson, produced a cease-fire and power-sharing talks. You missed the news? It happened with hardly any of the acclaim that marked the breakthrough in Kosovo.

The war in Sierra Leone seemed endless, unendable, horrible and duplicative of other regional wars; it unfolded in a quarter little known to Americans. Perhaps for such reasons it received only episodic attention. But how then to explain the emergence of Kosovo as a major concern of American policy and a large topic in the news? For Kosovo's war also has seemed endless, unendable, horrible and duplicative, and it also unfolded in a remote quarter.

Jesse Jackson, for one, has been inquiring into this discrepancy. He notes that where the United States is sending \$15 million to the West African organization that worked to end the Sierra Leone war, it has made a "down payment" of \$13 billion for Kosovo. He does not say, as many in Africa do, that behind the gap lies a

question of race. He does say that if American cameras brought home the pictures of Sierra Leone's misery, the American conscience would be touched and the disparities in American treatment of the two countries would narrow.

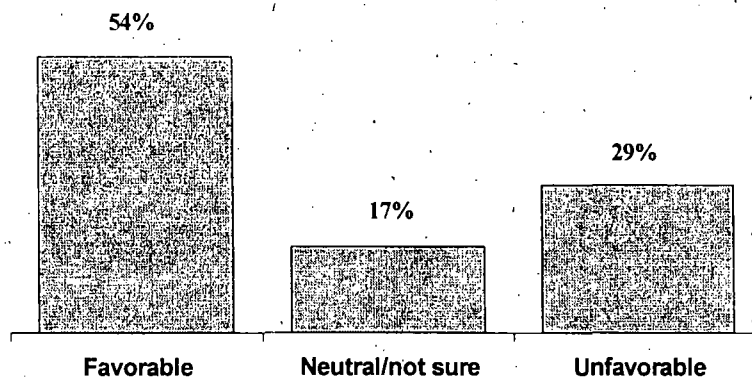
Over the decades American policy has found compelling national interest, and American media have found plenty of news, in convulsions in nonwhite countries. The American record in providing humanitarian aid to Africans is notable. Still, the traditional Eurocentric quality of American global engagement is plain and becomes even sharper when crisis flowers. Thus did the United States turn a decade's full attention on Bosnia and then Kosovo, even as successive upheavals in Somalia, Sudan, Rwanda, Zaire/Congo and Sierra Leone generally prompted a less ambitious and more selective approach.

The contrast can be explained by circumstances, but that is not good enough. A fair and sustainable policy must tap the energies and resources that ease rather than aggravate the lingering question of why the United States sometimes appears readier to help a distressed white country than a distressed black one.

NEW POLL MEASURES AMERICANS' CONCERN ABOUT WORLD-WIDE SPREAD OF INFECTIOUS DISEASES

A study sponsored by the Global Health Council (GHC) reveals that nearly 85 percent of Americans fear the global spread of AIDS, tuberculosis, and hepatitis, among other infectious diseases, according to a story headlined, "Most Fear Spread of Disease," appearing in USA Today on June 16, 1999. Ninety percent of poll respondents agree that fighting a disease at its source is the best approach, while 85 percent say that vaccines are critical. Nearly half of all Americans say they know someone with AIDS, TB, hepatitis, or malaria, and 54 percent consider themselves knowledgeable about global infectious diseases. Also, over 80 percent of respondents see AIDS as a greater threat today than it was 10 years ago, while 42 percent and 65 percent consider TB and hepatitis as growing problems, respectively. GHC officials say the survey shows that Americans are more concerned with health issues than politicians seem to believe.

Increase U.S. Assistance to Fight AIDS in Africa



Peter D. Hart Research Associates surveyed 1,411 registered voters, including 310 African Americans, by telephone between February 20 and 26, 1999, for the Children's Research and Education Institute.

American voters view the spread of AIDS in Africa as a serious problem. Although many voters have not heard much about the issue, they nonetheless believe that it is likely to have an impact here at home. A majority of Americans have a favorable view of a proposal to increase U.S. government assistance for international AIDS programs in Africa.

- ♦ The spread of AIDS in Africa is viewed as a serious problem by two-thirds (67%) of American voters, with 45% saying that it is an extremely serious problem and an additional 22% describing it as a quite serious problem.
- ♦ The same proportion (67%) believe that it is false to say that the global AIDS crisis is coming under control.
- ♦ In addition, three-quarters (75%) of voters believe that the AIDS epidemic in Africa will affect people in the United States.
- ♦ Although the issue is important, only 19% of voters say that they have read or heard a lot about it. Nearly half (48%) say that they have heard little or nothing about it.
- ♦ A 54% majority are favorable to a proposal to increase government assistance for international efforts to fight the spread of AIDS in Africa. Only 29% are unfavorable.
 - An overwhelming 83% majority of African Americans are favorable (55% strongly favorable), and only 10% are unfavorable.
- ♦ Support for greater assistance increases when it is placed in the context of an international effort. Three-quarters (76%) of voters say that they would be more likely to support assistance to help Africa deal with the AIDS epidemic if they knew that it would be a part of a larger international effort with Europe, Japan, and other countries doing their share.

OVP/AIDS – South Africa

What is the scope of the HIV/AIDS crisis in South Africa?

- 3.5 million South Africans are currently HIV positive
- There are about 1,500 new infections daily
- South Africa's GDP is reduced by 1% a year by the economic costs of AIDS

What assistance is the U.S. providing to South Africa specifically to combat AIDS?

- South Africa's Department of Health is now beginning to implement a comprehensive national plan to address the HIV/AIDS crisis in South Africa. USAID and the Department of health and Human Services have served in a consultative and complementary role in partnership with the Department of health.

NOTE: Refer to Global and Africa aid statistics as needed.

- USAIDS HIV/AIDS program in South Africa is currently funded at \$10 million over the next five years.
- The program focuses on three key areas:
 - HIV/AIDS related public awareness activities
 - Training
 - Testing of mass media messages; development of multiple public information campaigns
 - Work with community based groups, NGOs, media organizations, and others
 - Support for trade unions workplace programs, including workplace guidelines
 - a National Sexually Transmitted Diseases (STD) Reference Center
 - Joint activity between the SAG, USAID and DHHS (CDC)
 - Network of institutions working in various areas of STD prevention, diagnosis, and treatment
 - Proposed activities include surveillance, evaluation of new diagnostic techniques, and alternative health delivery systems for target populations
 - HIV/AIDS vaccine development

-- Increasing collaboration between US and South African government officials, members of academia, laboratories, pharmaceutical interests working to identify effective vaccines to counter HIV

- Work with the South African national Youth Commission has identified HIV/AIDS as a priority activity. A number of our agencies are working with that organization as its leadership formulates its implementation plans.
- We also have a focus on building greater private-public cooperative efforts. We seek greater participation of private firms in supporting local governments in their efforts. We believe that a number of trial models will showcase that successful partnerships can be built between the private sector with local governments, NGOs, and community-based organizations.

What role does the BNC play in these efforts?

- You have to remember that the structure of the BNC brings together, in some form, representation from almost every agency of our government.
- That permits the Commission to coordinate organizational activities of our own agencies to those of their South African counterparts.
- The schedule of meetings of the Commission also permit us to chart our progress and motivates accomplishments.
- During our most recent Commission meeting held in Cape Town in February, The Vice President and Deputy President Mbeki spoke at length between themselves on ways to enhance our cooperative efforts in the fight against AIDS.
- Their discussions were followed by detailed talks within the Commission's Health Working Group.
- I'm confident that the Commission will continue to play a vital role in addressing those priorities, such as the fight against AIDS, identified by the Commission's Co-Chairmen.

OVP/AIDS – South Africa

Has the Vice President or his staff met with representatives of the Pharmaceutical Research and Manufacturers of America (PhRMA)?

- Jim Babbitt, who serves as a Special Advisor to the Vice President and U.S. Executive Secretary to the U.S. – South Africa Binational Commission, met with Mr. Thomas Bombelles, Assistant Vice President – International of PhRMA, on April 13th, 1999, in the OEOP.

NOTE: Tom, I'm unaware of other meetings, but can't state that the VP or Leon have not met with PhRMA in the more distant past.

What was the purpose of that meeting?

- Mr. Bombelles requested the meeting to explain PhRMA's justification for recommending that South Africa be named as a Priority Foreign Country on the Special 301 Report under consideration by the U.S. Trade Representative.

What was the response from the Vice President's Office to PhRMA's presentation?

- Mr. Babbitt expressed disagreement with PhRMA's position. He expressed a personal view, later indorsed by the Vice President's National Security Advisor, that maintaining South Africa on the Special 301 Report's Watch List was appropriate to indicate our concern with intellectual property practices in South Africa.
- That position indicated our concerns not only with South Africa's Medicines Act and its impact on patent protections for pharmaceuticals, but also other outstanding IPR issues.
- Mr. Babbitt also encouraged a direct dialogue between PhRMA and others pharmaceutical interests with South African Minister of Health Zuma to resolve apparent differences.

Was there any follow-up to that meeting?

- PhRMA continues to provide the Vice President's Office with written statements providing their perspective on the outstanding issues.
- The Vice President's Office was represented in the interagency meetings making recommendations to the U.S. Trade Representative prior to the release of the Special 301 Report.
- The Vice President and his staff are deeply involved in our continuing efforts to resolve our differences with South Africa. We are confident that these efforts will be

successful and in keeping with the sense of partnership that has come to characterize our bilateral relationship.



FAX TRANSMISSION

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E-mail: ddipaolo@ustr.gov

To: SANDY THURNAN

Date: 10/5/99

Fax #: 62439

Pages: 5
(Including cover sheet)

From: Donna M. DiPaolo
Deputy Director for IP

Subject: S. AFRICA / IPR TALKING POINTS

MESSAGE: — please note these were
prepared for Amb. Barshetsky's
use; wording therefore may
need to be revamped.

— PRESS RELEASE IS ALSO ATTACHED

South Africa/AIDS/IPR

TALKING POINTS

- We recognize the serious health care crisis in South Africa and we appreciate that the government of South Africa is trying to improve access to quality health care for its people.
- This is a goal we and the entire Administration fully endorse and support. We believe that this goal can be achieved while promoting adequate and effective patent protection for pharmaceutical products.
- Our own goal is to chart a course that assists in improving access to affordable medicines, while not freezing the financial incentives that fuel continued research and production of new drugs.
- We believe that both of these goals are achievable, and we have been working with South Africa to ensure that the Medicines Act will be TRIPS-consistent.
- We were concerned about provisions in the Medicines Act that would have granted the Health Minister broad unspecified powers to abrogate patent rights for pharmaceuticals and to permit parallel imports.
- The South African Medicines Act does not provide for any of these conditions and no regulations have been issued that would ensure that the TRIPS Agreement's requirements would be met.
- After dialogue with South African officials through the mechanism of the Council of the Trade and Investment Framework Agreement, we have now identified common ground with respect to South Africa's implementation of the Medicines Act. South Africa has provided assurances that, as it moves vigorously forward to bring improved health care to its citizens, it will do so in a manner consistent with international commitments and that fully protects intellectual property rights.
- This understanding will enable us to set aside this issue from our bilateral trade agenda.

If asked:

- Now that this issue has been resolved, we have told the Government of South Africa that when the GSP program is reauthorized by Congress, we will implement South Africa's new GSP benefits for unwrought gold, semi-manufactured gold and Vanadium Carbides, currently held in abeyance.
- With respect to the specific intellectual property concerns at issue, we had previously

outlined Administration policy on this issue in testimony given on July 22, 1999 to the House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources. We had said that we realize that AIDS is a special case which may require special measures. Thus, while we do not believe that compromising intellectual property rights is the solution to the greater problem, contrary to our general approach, we raise no objection to compulsory licensing or parallel importing of pharmaceuticals on the part of South Africa, as long as it is done in a way that complies with TRIPS. Of course, we are also committed to working with South Africa to ensure the safety and efficacy of pharmaceutical imports. South Africa has now provided the assurances we had sought in these regards.

- With respect to the Special 301 Out-of-Cycle review (scheduled for September 1999) of South Africa, no decision has yet been made. We are continuing to discuss with South African officials a number of issues not related to the Medicines Act.

**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C.
20508**

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**FOR IMMEDIATE RELEASE
SEPTEMBER 17, 1999**

**CONTACT: 99 - 76
TOM TRIPP
HELAIN KLASKY
AMY STILWELL**

U.S. - South Africa Understanding on Intellectual Property

United States Trade Representative Charlene Barshefsky today announced that the Governments of the United States and South Africa have come to an understanding with respect to South Africa's urgent need to provide better, more affordable health care while ensuring that intellectual property rights are protected. This understanding was reached working through the mechanism of the Council of the Trade and Investment Framework Agreement (TIFA).

"The Government of South Africa is battling a very serious AIDS pandemic," stated Ambassador Barshefsky. "The United States Government fully supports President Mbeki and his Government in their effort to combat this problem and is committed to do whatever it can to help.

Both Governments also have reaffirmed their shared objective of fully protecting intellectual property rights, including their commitment to comply with the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). They recognized that this Agreement is designed to ensure high levels of intellectual property protection while enabling governments to address national social needs.

Between these shared commitments, the two governments have identified common ground with respect to South Africa's implementation of its so-called "Medicines Act." "The United States very much appreciates South Africa's assurance that, as it moves vigorously forward to bring improved health care to its citizens, it will do so in a manner consistent with international commitments and that fully protects intellectual property rights," continued Ambassador Barshefsky. "This will enable us to set aside this issue from our bilateral trade agenda. Moreover, once GSP is re-authorized by Congress, new GSP benefits granted to South Africa in June 1998 will be implemented."

Ambassador Barshefsky also welcomed a September 9 announcement by the Pharmaceutical Manufacturers Association of South Africa that it will suspend litigation over the Medicines Act.

Barshefsky observed: "I am hopeful that this suspension, coupled with progress made between our two governments, will enable all interested parties to develop together the best possible approach to addressing this serious situation, while protecting important intellectual property rights."

License to Kill

Gore guns for Third World countries trying to make cheap AIDS drugs

BY DOUG IRELAND

While Bill Clinton and Al Gore spend billions to blast the Serbs into submission, ostensibly to save lives, their international AIDS policy is politically smart-bombing Third World countries to save profits, not people with HIV. The administration, in cahoots with the pharmaceutical industry, is using economic and political blackmail to stop developing countries from making inexpensive copies of patented AIDS drugs.

Take Thailand, with nearly a million infected with HIV. The United States has been applying immense pressure to block Thai companies from producing generic versions of ddI, a nucleoside analog created by our government's own researchers and marketed worldwide exclusively by Bristol-Myers Squibb. Also targeted are Thai generic versions of Bristol-Myers and Pfizer drugs used to treat cryptococcal meningitis, an often-fatal fungal brain infection affecting some 200,000 HIV positive Thais.

At issue is an obscure portion of international trade law known as compulsory licensing, designed to expand access to patented or copyrighted products considered essential goods and services. Under rules of the World Trade Organization—of which the United States is a charter member—countries with a public health crisis can use compulsory licensing to manufacture drugs more cheaply, as long as they reasonably compensate the patent holders.

Yet the Clinton-Gore administration is adamantly opposed to compulsory licensing by other countries, even

fastest-growing infection rate—to abrogate its recent law allowing compulsory licensing of pharmaceuticals. As the Watergate saying goes, "Follow the money."

Most drugs, including antiretrovirals, are relatively inexpensive to produce. As David Scondras, an activist campaigning for lower drug pricing, wrote recently in *AIDS Treatment News*: "For example, AZT in bulk can be purchased for 42 cents for 300 mg from the worldwide suppliers; this price reflects profits not only to the manufacturer but also to the middleman bulk buyer. The same drug retails at my local pharmacy for \$5.82 per pill. This ridiculous price bears no real relation to the cost of production."

The primary reason the pharmaceutical giants are fighting so hard against compulsory licensing of AIDS drugs abroad is not because of the potential to lose profits there—

Third World people and governments can't afford to

pay U.S. prices anyway. Instead, they fear that if other countries make those drugs available to their PWAs at a tiny fraction of the retail cost, it would set off a major price-gouging scandal here, in the United States, when the true size of drug companies' markups are revealed.

Rep. Jesse Jackson Jr.'s HOPE for Africa bill (see "Keep HOPE Alive," p. 36) would prohibit the use of U.S. funds to undermine African intellectual property and competition policies designed to increase the availability of vital

medicines. But as Richard Laing, MD, a Boston University public health expert, points out, even the Jackson bill is no panacea for the continent's epidemic, since in most of sub-Saharan Africa, "where a dollar a year per person is spent on health care, the vast majority struggle to have access just to simple antibiotics, and the AIDS numbers are too big for compulsory licensing to make a difference."

The Clinton-Gore administration has engaged in a series of grotesque and secretive maneuverings to avoid having to consult with or debate public health leaders on these issues. But a March conference in Geneva, organized by Ralph Nader's Consumer Project on Technology, Doctors Without Borders and Health Action International, brought together 60 nongovernmental organizations from around the world to mobilize opposition to U.S. policy, and activists in the United States are now forging a coalition. The president's Advisory Commission on AIDS has finally consented to take up the issue this summer. Still, since Clinton has so often ignored his own commission's recommendations, it will take a major public outcry to alter U.S. policy—especially given the puissant lobbying of the multinational monopolies. ■



The VP is defending drug company monopolies.

though U.S. law permits it. Gore—currently raising money for his presidential campaign—has been the administration's point man in defending these companies' monopolies. This may come as news to the gay fatcats whom Gore is courting so assiduously, but it doesn't come out of the blue: Gore's chief domestic policy advisor, David Beier, was the main lobbyist for Genentech, a biotech behemoth. Co-chair of the U.S.-South Africa Binational Commission, Gore is pummeling South Africa—which has the world's

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EXECUTIVE OFFICE OF THE PRESIDENT
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(202) 456-2438 (fax)



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THE WHITE HOUSE

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Joseph Papovich

FROM:

Sandy Thurman

COMPANY:

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(202) 456-2438 (fax)

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR RICHARD FISHER

From: Sandra L. Thurman 
Director
Office of National AIDS Policy
(202) 456-2437

CC: Joseph Papovich

Date: May 25, 2000

Re: News Article

Thanks for your note. I have received several calls from friends in the industry as well.

Unfortunately, these remarks were taken out of context. Other news stories reflected more accurately what was actually said. I could clearly have been more circumspect in my response to press inquiries. I will always consult with you before making statements other than the ones USTR so generously provides in your talking points. However, I would greatly appreciate it if you would kindly consult with me before assuming that I would do otherwise.

I am sorry that this has caused a bit of a buss.

Thanks much-

Sandy

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Friday May 26 12:08 PM ET

U.S. Could Extend AIDS Drug Help to Asia

GENEVA (Reuters) - The United States, which recently agreed to help make cheaper AIDS drugs available in sub-Saharan Africa, may relax patent laws for Asia and former states of the Soviet Union, a White House official said on Friday.

But Sandra Thurman, director of the White House Office for AIDS policy, said there was no timetable for extending the executive order signed by President Clinton two weeks ago.

The epicenter of the AIDS epidemic is in sub-Saharan Africa, but will move to Asia in 15 years and then to the former Soviet states, where intravenous drug use is the main way of transmitting the HIV virus, she added.

The presidential order allows sub-Saharan countries to obtain less costly AIDS medication through compulsory licensing and parallel importing, as long as the measures comply with the rules of the World Trade Organization (WTO).

*Sandra Thurman
John Kim
5/31/2002*

*Sandy - please consult
with me on this
before making these
kind of statements -*

*they have
experience in
manage of how
cells for other
countries and
from industry.
Thank
Richard*

To: Richard Risher
cc Joseph Papovitch

Thanks for your note. I have received several calls from friends in the industry as well.

~~Unfortunately~~ ~~Obviously~~ these remarks were taken out of context. ~~The other~~ Other news stories reflected more accurately what was said. ~~However~~ ^{actually} I ^{clearly} will ^{more} ^{circumspect} ^{in my} ^{responses} ^{to press} ^{inquiries} ~~but~~ ^{app} I ^{will} ^{always} consult with you before making statements other than the ones USTR so generously provides in your talking points. ~~However~~ ^{However} I would greatly appreciate it if you would kindly consult ~~me~~ with me before assuming ~~the worst~~ that I would do otherwise!

I am sorry that this has caused ~~to be such a buzz~~ a bit of a buzz.

Thanks much.

Sandy

JANICE D. SCHAKOWSKY
9TH DISTRICT, ILLINOIS

Congress of the United States
House of Representatives
Washington, DC 20515-1309

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COMMENTS:

October 14, 1999

Copt

The Honorable William Jefferson Clinton
President of the United States
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear President Clinton:

Your Administration has taken significant steps to address the HIV/AIDS epidemic, both here and abroad. We believe, however, that there is more that can and must be done to address the worldwide pandemic affecting more than 33 million adults and children, 22.5 million of them in Africa. We request that you use existing authority to give the World Health Organization (WHO) the right to use HIV/AIDS patents where the United States government has rights to those inventions.

Great progress has been made in developing products to treat HIV and AIDS. Many of those products were developed with taxpayer funding, through the National Institutes of Health and grants to universities and businesses. We believe strongly that these publicly-financed products should be accessible to consumers both in the United States and in other countries. Unfortunately, without prompt and decisive action, HIV/AIDS drugs will remain unaffordable and unavailable for millions.

Under 35 USC Sec. 202(c)(4) of the Bayh-Dole Act and 37 CFR 404.7, the United States government has the authority to provide international agencies with royalty-free rights to health care products where our government holds the rights to those inventions. We believe that this authority should be used to enter into an agreement with the World Health Organization so that it can provide affordable access to HIV/AIDS drugs and products that treat other infectious diseases. The WHO is an appropriate entity since it has the knowledge to determine whether the necessary local health care delivery systems are in place to ensure prescription drugs and medical products are distributed and used effectively.

We respectfully ask that the Administration enter into negotiations with the WHO to expand access to medical inventions for which the U.S. government holds intellectual property rights. Without such action, treatment opportunities will continue to be missed because individuals and countries simply cannot afford them. We must use every tool at our disposal to help the millions of children and adults already infected with HIV/AIDS and to prevent the further spread of this and other infectious diseases.

CH

Copy

The Honorable William Jefferson Clinton
October 14, 1999
Page 2

Thank you for your leadership on this issue and for your attention to our request.

Jan Schakowsky, M.C.

Maxine Waters, M.C.

Jesse L. Jackson, Jr., M.C.

Barbara Lee, M.C.

FACT SHEET: WHAT HAS BEEN REPORTED
AIDS Drugs for South Africa

"I want to state categorically that Vice President Gore has not put pressure, has not given notice to put sanctions, on South Africa on this matter."

-- South African Ambassador to the United States, Sheila Sisulu, at the National Press Club -- July 2, 1999

"The AIDS Action Council, the largest AIDS lobby group in the United States, believes the protests against the veep are misdirected. 'This is like blaming Roosevelt for the Holocaust,' says Council director Daniel Zingale."

-- Newsweek -- July 12, 1999

"Vice President Gore would seem an unlikely target for AIDS activists. Under the Clinton administration, funding for AIDS research has soared, new AIDS medicines have dramatically reduced mortality rates, and the government is now pushing to get an AIDS vaccine by 2007."

-- Philadelphia Inquirer -- June 29

The accusation that Gore is in the pocket of the drug industry, which was starting to gain currency, now holds less water than it ever did. The industry wants a big fat stake driven through section 15c and the Vice President has not delivered. But he may have fostered something more important: ... a sane atmosphere for reasoning through why the protection of intellectual property is not necessarily incompatible with better, more affordable health care for SA's poor ..."

-- Business Day (South Africa) -- July 14, 1999

"The suggestion that the Vice President has passively condemned impoverished South Africans to hideous death by contagion – in exchange for corporate-backed campaign donations – is not even remotely fair. It is groundless and grotesque."

-- The Weekly Standard -- July 19, 1999

"Trehwhitt acknowledged that the pharmaceutical industry pushed the administration to label South Africa a "priority foreign country," which would set a deadline for it to change its disputed policy before trade sanctions would take effect. But under pressure from Gore's office, the trade representative refused to do so."

-- Baltimore Sun -- June 22, 1999

"Susan Rice, the assistant secretary of State for Africa, asserted that Gore has 'led the way' in opposing trade sanctions and other drastic actions pushed by the pharmaceutical industry... "The Vice President took the position that the health crisis in South Africa really needed to be taken into account,' Rice said."

-- Baltimore Sun -- June 22, 1999

"The AIDS activists who have heckled Mr. Gore ... manipulate the facts...."

-- Washington Post editorial -- June 24

"Vendetta Against Gore Based on Lies"

'Aids Activists distort facts when accusing US Vice President of bullying SA over drugs law'
-- Headline, Pretoria News -- July 1, 1999

"I applaud AIDS activists for bringing some long-overdue attention to Africa's AIDS crisis. But in their pursuit of Al Gore, they're barking at the wrong politician. At least he has tried to be part of the solution, while too many others only make the problem worse or pay no attention to it at all."

-- Clarence Page, Chicago Tribune -- July 4, 1999

"Internal memos between Gore and U.S. Trade Representative Charlene Barshefsky in April show that Gore actually opposed efforts by American drug companies to pressure the Clinton Administration to escalate threats of trade sanctions against South Africa."

-- Clarence Page, Chicago Tribune -- July 4, 1999

"...We in the CBC are concerned with the recent characterizations of your conversations with President Mbeki and your position on trade sanctions against South Africa – characterizations that are entirely out of line with your record."

-- Rep. James Clyburn, Chairman of the Congressional Black Caucus, referring to AIDS protestors in a June 24 letter to Vice President Gore.

"[Congressional Black Caucus Chairman James Clyburn] said he thought the AIDS activists had unfairly targeted the vice president, and now feels "my suspicions as to what this was all about seem to have been well-placed."

-- Associated Press -- June 30

"Exhibit A in the activists case against Gore is a report the state department provided Congress in February describing the administration's efforts to get 15(c) repealed or amended. Designed to appease pro-industry legislators who wanted to cut aid to SA, the report emphasized the tough line administration was taking and underplayed Gore's desire for a compromise that would enable Pretoria to achieve its social goals while remaining true to Trips."

-- Business Day (South Africa) -- June 30, 1999

Gore has long had good relations with gay rights groups, an important Democratic Party constituency, and the South Africa issue does not appear to be endangering that relationship. David Smith, spokesman for the Human Rights Campaign, one of the largest gay rights lobbying groups, described the patent matter as a "complicated issue" with "no easy solutions" and added, "To single out the vice president is not fair."

-- Washington Post -- June 18, 1999

"In the current fracas, it seems to us, Vice President Gore is attempting to keep all reasonable considerations in balance. He wants his country to sustain in principle the international patent protection regime. He wants to foreclose no potentially effective response to the infectious-diseases crisis in Africa."

-- The Weekly Standard -- July 19, 1999



THAILAND An AIDS victim at a hospice in a Buddhist temple

In the U.S. the debate erupted in public recently when Vice President Al Gore declared his candidacy for the White House. AIDS activists heckled him and brandished signs accusing him of siding with the drug companies. Gore, shaken by the ferocity of the attacks, shifted course and said he supported compulsory licensing and parallel importing, "so long as they are done in a way consistent with international agreements."

A similar struggle has been going on in Thailand, which has an estimated 1.5 million HIV infections out of a population of 60 million. Yet Thailand's ability to produce drugs locally has forced the multinational companies to drop prices. Until last year, Flucanazole, an important antibiotic used to fight a fatal form of

meningitis that accompanies AIDS, cost \$7.36 a tablet. This year the Thais began manufacturing it locally, and the price dropped to \$1. Glaxo Wellcome reduced the price of AZT to less than \$1 per tablet after Thailand began making its own version.

Pharmaceutical companies insist the high prices are necessary to finance new-drug development. That's certainly true, at least initially. Yet many of the recent breakthroughs have been paid for by U.S. taxpayers. AZT was discovered by the National Cancer Institute and given to Burroughs Wellcome (now Glaxo Wellcome). DDI was developed at the National Institutes of Health and licensed to Bristol-Myers Squibb.

To its credit, Bristol-Myers Squibb has also taken the lead in philanthropy, with an offer to give \$100 million to fight AIDS in five African countries over the next five years. A sizable chunk is earmarked to bring African doctors to the U.S. so they can be trained to carry out research and clinical trials back in Africa. But even that has raised a red flag among activists. "A lot of the companies are using the cheaper labor costs and the lack of ethical codes in developing countries as a way to get the trials done more cheaply and quickly," says Dan Berman of Doctors Without Borders. A better solution, the activists suggest, would be for drugs known to be effective to be made available at a price these regions can afford.

Ethics and AIDS Drugs

Some countries want to suspend patent and trade laws to get lower-cost medications to the poor

By WILLIAM DOWELL

THE LATEST DRUG COCKTAILS MAY SOON downgrade AIDS from a death sentence to a chronic disease—in countries that can afford the typical \$15,000 annual cost per patient. But what about the cash-starved developing world, which currently accounts for nearly 90% of new HIV infections? It's an issue that countries like South Africa and Thailand are struggling with. And a growing number of government health ministers and AIDS activists are proposing an unusual solution: rip off the drug companies.

They're not really stealing, of course, but that's the way U.S. drug companies—backed by Uncle Sam—view a tactic being employed in South Africa and elsewhere. The tactic uses a loophole in the World Trade Organization's Trade-Related Intellectual Property Rights agreement to exempt worst-hit countries from patent restrictions on essential drugs. The loophole, Article 31, authorizes emergency use of "compulsory licensing" to produce essential drugs locally as long as royalties are paid. Another tactic: parallel importing, or

buying in a country where the needed drugs are cheaper, circumventing artificially high prices set by the patent holders for some areas.

The hottest debate is in South Africa, where nearly 3.5 million of that country's 40 million citizens are HIV-infected—more than three times the U.S. rate—and 50,000 new HIV cases emerge each month. Drug prices tend to be high, a holdover from apartheid, when price premiums were needed to encourage foreign companies to override sanctions. Says Mojanku Gumbi, an adviser to South Africa's new President, Thabo Mbeki: "This is not about intellectual property rights. It's about pricing structure and segmenting of markets. We are saying that the drug companies can't make the same profits they made under apartheid."

South Africa passed a law last year that gives the Ministry of Health discretion to authorize parallel importing and compulsory licensing in critical situations. But a consortium of 40 drug companies—about a third of them American—filed a suit that has kept the law tied up.

Expensive AIDS drugs ...

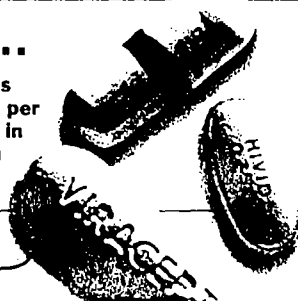
Multidrug treatment in the West runs from \$12,000 to \$15,000 or more per patient per year. The typical budget in developing countries for total health care is \$10 per person per year

... tempt poor countries to bend the rules

■ **THAILAND**
Has used competition to bring down prices of drugs such as AZT by producing some compounds locally

■ **SOUTH AFRICA**
Faced with 50,000 new AIDS cases a month, the country may resort to parallel importing to get supplies of critical drugs

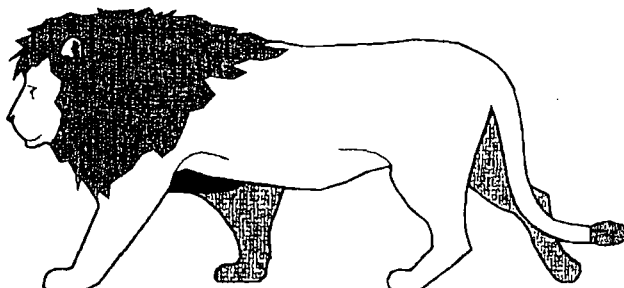
Time Magazine



U.S. Department of State
Office of Southern African Affairs

FACSIMILE

DATE: Wednesday, August 04, 1999



FROM: Michael Koplovsky -- Tel: (202) 647-9850 Fax: (202) 647-5007

TO:

<u>Name</u>	<u>Organization</u>	<u>Tel</u>	<u>Fax</u>
B. Schwartz	USTR	395-9159	395-4505
D. DiPaulo	USTR	395-4685	395-3891
A. Robinson	Commerce	482-5148	482-5198
J. Babbitt	OVP	456-9513	456-9500
J. Urban	USPTO	(703) 305-9300	(703) 305-8885
T. Walsh	State EB/IPC		647-1537
N. Carter-Foster	State OES/EID	647-2435	736-7336
S. Thurman	White House	456-2437	456-2439

SUBJECT: Draft Cable for Clearance

Attached is a draft cable with talking points on the pharmaceutical patent issue and HIV/AIDS for use by our Embassy and Consulates General in South Africa.

Please provide comments/changes/clearance by Noon, Friday August 6.

Thanks.

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DRAFT:	MK
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CLR 5:	JB
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08/04/99 647-9850
AF/S:JSEQUEIRA

AF/S:DGATTO EB/IPC:TWALSH USTR:DDIPAULO
USDOC:AROBINSON OVP:JBABBIT USPTO:JURBAN USTR:BSCHWARTZ
WH:STHURMAN OES/EID: NCARTER-FOSTER AID/AFR:CRENTSMA

PRIORITY PRETORIA, DURBAN PRIORITY,
JOHANNESBURG PRIORITY, CAPE TOWN PRIORITY
ROUTINE SADCC

E.O. 12958: N/A

TAGS: ETRD, KIPR, SOCI, SF

SUBJECT: TALKING POINTS ON PHARMACEUTICAL PATENTS
PROTECTION AND HIV/AIDS

REF: (A)PRETORIA 9433, (B)JOHANNESBURG 0472

1. (SBU) AS REQUESTED REFTELS, WASHINGTON AGENCIES PROVIDE INTERAGENCY CLEARED TALKING POINTS (PARA. 3) UPON WHICH ADDRESSEE POSTS MAY DRAW WHEN RESPONDING TO INQUIRIES ABOUT AND/OR CRITICISM OF U.S. POLICY REGARDING THE HIV/AIDS SITUATION IN SOUTH AFRICA AND PHARMACEUTICAL PATENT PROTECTION, ESPECIALLY AS THIS RELATED TO SECTION 15 (C) OF THE MEDICINES ACT AND THE ANNUAL SPECIAL 301 REVIEW.

2. (SBU) DEPARTMENT COMMENDS PAO HULL'S RECENT LETTER TO THE EDITOR OUTLINING THE U.S. POSITION AND SETTING THE RECORD STRAIGHT. WASHINGTON OFFICIALS UNIVERSALLY AGREE "WE COULDN'T HAVE SAID IT BETTER."

3. (U) BEGIN TALKING POINTS:

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-- THE SOUTH AFRICAN GOVERNMENT COMMITTED TO PROVIDING ACCESS TO ADEQUATE AND AFFORDABLE HEALTHCARE TO ALL ITS CITIZENS. THE UNITED STATES GOVERNMENT HAS EXPRESSED ITS RECOGNITION OF AND SUPPORT FOR THAT GOAL. WE ALSO RECOGNIZE THAT ASSURING THE AVAILABILITY OF PHARMACEUTICAL PRODUCTS MUST BE A KEY COMPONENT OF ANY IMPROVED HEALTHCARE SYSTEM.

-- IN 1997, THE NATIONAL ASSEMBLY PASSED AMENDMENTS TO THE MEDICINES ACT GRANTING THE MINISTER OF HEALTH BROAD, BUT UNSPECIFIED AUTHORITIES THAT ARE INTENDED TO PROVIDE MORE AFFORDABLE DRUGS TO ITS PEOPLE. THE AMBIGUITY ASSOCIATED WITH THE WORDING OF SECTION 15(C) OF THE ACT GAVE RISE TO CONCERNS THAT THESE AUTHORITIES COULD BE EXECUTED IN A MANNER CONTRARY TO INTERNATIONAL AGREEMENTS.

-- THERE IS AN INTERNATIONAL CONSENSUS FOR THE NEED TO EXTEND APPROPRIATE PROTECTIONS TO INTELLECTUAL PROPERTY RIGHTS, INCLUDING FOR PHARMACEUTICAL PATENTS.

-- THE 134 MEMBERS OF THE WORLD TRADE ORGANIZATION (WTO) ACCEPTED INTERNATIONAL STANDARDS FOR SUCH PROTECTIONS AS SET OUT IN THE TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT (TRIPS).

-- RIGHTS GRANTED PHARMACEUTICAL PATENT HOLDERS ARE INTENDED TO GUARANTEE THAT FINANCIAL INCENTIVES, WHICH ENSURE CONTINUED RESEARCH AND DEVELOPMENT OF NEW MEDICINES, ARE MAINTAINED.

-- WE BELIEVE THAT THE SOUTH AFRICAN GOVERNMENT SHARES OUR BELIEF THAT ENHANCING PUBLIC HEALTH, INCLUDING ENSURING THE PROVISION OF AFFORDABLE MEDICINES, CAN BE ACHIEVED IN A MANNER CONSISTENT WITH INTERNATIONALLY ACCEPTED STANDARDS FOR INTELLECTUAL PROPERTY RIGHTS PROTECTION.

-- THE UNITED STATES GOVERNMENT HAS EXPRESSED REPEATEDLY ITS CONCERNS OVER THE VAGUE AUTHORITY OF SECTION 15 (C) OF THE MEDICINES ACT WITH THE SOUTH AFRICAN GOVERNMENT.

-- WE HAVE SOUGHT THROUGH CANDID BILATERAL DISCUSSIONS TO ALLAY APPREHENSIONS AND TO CLEAR UP MISUNDERSTANDINGS

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ABOUT THE SOUTH AFRICAN GOVERNMENT'S INTENTIONS RELATED TO THE MEDICINES ACT.

-- IN AUGUST OF 1998, OUR TWO GOVERNMENTS AGREED TO A FRAMEWORK FOR RESOLUTION OF OUR DIFFERENCES CONCERNING SOUTH AFRICA'S MEDICINES ACT. THE PROPOSAL CALLED FOR THE CONVENING OF AN EXPERTS GROUP -- INCLUDING ALL RELEVANT DECISION MAKERS IN THE AREAS OF TRADE, HEALTH, AND INTELLECTUAL PROPERTY -- THAT WOULD WORK TOWARD THE DUAL GOALS OF PROVIDING BETTER HEALTHCARE TO THE SOUTH AFRICAN PEOPLE WHILE ENSURING ADEQUATE AND EFFECTIVE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS.

-- BILATERAL TALKS HAVE BEEN COMPLICATED BY CONCERN ON BOTH SIDES THAT THE DISCUSSIONS NOT PREJUDICE ONGOING LITIGATION IN SOUTH AFRICAN COURTS. NONETHELESS, WE ARE CONFIDENT THAT OUR CONTINUING EXCHANGE WILL RESULT IN A MUTUALLY SATISFACTORY OUTCOME.

-- OUR GOVERNMENT'S POSITION ON THE CONDUCT OF PARALLEL IMPORTATION OR COMPULSORY LICENSING OF PHARMACEUTICAL PRODUCTS UNDER THE AUTHORITY OF SECTION 15 (C) WAS MOST RECENTLY EXPRESSED BY AN OFFICIAL OF THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE IN OPEN TESTIMONY TO THE UNITED STATES CONGRESS, JULY 21, 1999.

-- "...AIDS IS A SPECIAL CASE WHICH MAY REQUIRE SPECIAL MEASURES. WE DO NOT BELIEVE THAT COMPROMISING INTELLECTUAL PROPERTY RIGHTS IS THE SOLUTION TO THE GREATER PROBLEM. CONTRARY TO OUR GENERAL APPROACH, WE RAISE NO OBJECTION TO COMPULSORY LICENSING OR PARALLEL IMPORTING OF PHARMACEUTICALS ON THE PART OF SOUTH AFRICA, AS LONG AS IT IS DONE IN A WAY THAT COMPLIES WITH TRIPS."

-- THE UNITED STATES GOVERNMENT HAS TAKEN AN ACTIVE ROLE IN DRAWING ATTENTION TO THE SCALE AND SCOPE OF THE AIDS CRISIS AS IT AFFECTS AFRICA. IT STRONGLY SUPPORTS, THROUGH WORDS AND ACTIONS, AFRICAN AND INTERNATIONAL EFFORTS TO COMBAT THE DISEASE.

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-- VICE PRESIDENT GORE AND THEN DEPUTY PRESIDENT MBEKI HIGHLIGHTED THE HIV/AIDS CRISIS DURING THE VICE PRESIDENT'S LAST VISIT TO SOUTH AFRICA IN FEBRUARY.

-- THE UNITED STATES IS THE WORLD'S LEADING DONOR FOR THE PREVENTION AND CONTROL OF HIV/AIDS IN THE DEVELOPING WORLD.

-- THIS YEAR (FISCAL YEAR '99), USAID WILL SPEND \$125 MILLION WORLDWIDE ON HIV/AIDS PREVENTION AND CONTROL, \$74 MILLION -- MORE THAN HALF -- WILL BE ALLOCATED TO SUB-SAHARAN AFRICA.

-- THE U.S. HAS SET ASIDE \$7 MILLION TO SUPPORT AIDS ORPHANS AND INFECTED CHILDREN.

-- THIS IS A CONTINUATION OF OUR LONG-TERM EFFORTS. SINCE 1986, THE UNITED STATES HAS FUNDED HIV/AIDS EDUCATION, TREATMENT, AND PREVENTION PROGRAMS ACROSS AFRICA.

-- THE UNITED STATES HAS CONTRIBUTED NEARLY \$1 BILLION TO THE CAUSE IN 38 COUNTRIES IN SUB-SAHARAN AFRICA.

-- OUR INTERNATIONAL PROGRAMS ARE FIRST AND FOREMOST AIMED AT COMBATING HIV.

-- EDUCATION IS THE CENTERPIECE OF OUR EFFORTS.

-- IN ADDITION PROGRAMS FOCUS ON: CHANGING HIGH RISK BEHAVIOR; PROMOTING CONDOM USE; CONTROLLING SEXUALLY TRANSMITTED DISEASES; IMPROVING THE POLICY ENVIRONMENT TO REDUCE TRANSMISSION OF HIV; CONDUCTING RESEARCH; PROMOTING ADVOCACY; AND MONITORING AND EVALUATING CARE AND SUPPORT ACTIVITIES.

-- SUPPORT ACTIVITIES INCLUDE COMMUNITY-BASED ORPHAN CARE AND VOLUNTARY COUNSELING AND TESTING PROGRAMS.

-- ALTHOUGH THE UNITED STATES IS SPENDING \$200 MILLION THIS YEAR ALONE ON THE DEVELOPMENT OF A VACCINE, WE ARE A LONG WAY FROM ACHIEVING THAT GOAL.

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-- WHILE NEW ANTI-HIV DRUGS DRAMATICALLY IMPROVE AND EXTEND LIFE, THEY ARE NOT A CURE.

-- PREVENTION BASED ON BEHAVIOR CHANGE REMAINS THE PRIMARY INTERVENTION AT THIS TIME.

-- WE ARE WORKING IN PARTNERSHIP WITH THE SOUTH AFRICAN OFFICIALS TO ADDRESS THE AIDS CRISIS THROUGH A VARIETY OF MEAN, INCLUDING: A \$10 MILLION, FIVE-YEAR PROGRAM TO SUPPORT THE NATIONAL GOVERNMENT AND LOCAL NGO EFFORTS TO FIGHT HIV/AIDS; COOPERATION WITH THE SOUTH AFRICAN NATIONAL YOUTH COMMISSION; ONGOING DISCUSSION IN OUR BINATIONAL COMMISSION'S HEALTH WORKING GROUP ON WAYS TO ENHANCE OUR COOPERATIVE EFFORTS TO FIGHT AIDS; AND RESOURCE EXPANSION THROUGH ENCOURAGEMENT OF PUBLIC-PRIVATE PARTNERSHIPS.

-- WE RECOGNIZE THE AIDS EPIDEMIC'S DIRE IMPACT ON AFRICA AND ITS PEOPLE, AND WE REALIZE THAT MUCH MORE MUST BE DONE TO MOBILIZE GREATER RESOURCES AND EFFORTS TO COMBAT IT.

-- ON JULY 19TH, VICE PRESIDENT GORE ANNOUNCED THAT THE ADMINISTRATION IS SEEKING FROM CONGRESS NEW U.S. RESOURCES IN THIS FIGHT TOTALING \$100 MILLION, AND CALLED FOR A RENEWED EFFORT TO ENCOURAGE OTHER PUBLIC AND PRIVATE CONTRIBUTIONS TO THE JOIN GLOBAL RESPONSE.

-- THIS NEW FUNDING WILL ALLOW US TO DOUBLE OUR EXISTING EFFORTS AND WILL BE FOCUSED ON FOUR CRITICALLY IMPORTANT FRONTS OF THE BATTLE:

- PROGRAMS TO CONTAIN THE AIDS PANDEMIC - \$48 MILLION
- SUPPORT FOR HOME AND COMMUNITY-BASED CARE - \$23 MILLION
- CARE FOR CHILDREN ORPHANED BY AIDS - \$10 MILLION
- STRENGTHENING PREVENTION AND TREATMENT THROUGH CAPACITY DEVELOPMENT - \$19 MILLION

END TALKING POINTS.

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