FOIA Number: 2007-1550-F

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WHITE HOUSE STAFFING MEMORANDUM

Date: 5/9/00 ACTION / CONCURRENCE / COMMENT DUE BY: ASAP

Subject: DRAFT EO ON ACCESS TO HIV/AIDS DRUGS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☑	☐	LOCKHART	☐	☑
PODESTA	☑	☐	LEWIS	☐	☐
ECHAVESTE	☑	☐	MARSHALL	☐	☐
RICCHETTI	☑	☐	MOORE	☐	☐
LEW	☐	☐	NASH	☐	☐
BAILY	☐	☐	NOLAN	☑	☐
BERGER	☑	☐	REED	☑	☐
BLUMENTHAL	☐	☐	SPERLING	☑	☐
BRAIN	☑	☐	STREETT	☐	☐
BURSON	☑	☐	TRAMONTANO	☑	☐
CAHILL	☑	☐	UCELLI	☑	☐
EDMONDS	☐	☐	VERVEER	☐	☐
FRAMPTON	☐	☐	SANDY THURMAN →	☑	☐
IBARRA	☐	☐	_____	☐	☐
JOHNSON, B.	☐	☐	_____	☐	☐
JOHNSON, J.	☑	☐	_____	☐	☐
LANE	☐	☐	_____	☐	☐

REMARKS: COMMENTS TO STAFF SECRETARY

RESPONSE:

Staffing Form 3/3/00

Office of the Staff Secretary
Ext. 62702

DRAFT

Executive Order
(May 8, 6:50pm)

ACCESS TO HIV/AIDS PHARMACEUTICALS AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act, section 104 of the Foreign Assistance Act of 1961, as amended (22 USC 215(1)(b)), and section 301 of title 3 of the United States Code, and in accordance with the executive branch's policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Sec. 1. Policy:

a. In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as defined in the Trade and Development Act of 2000, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

   i) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country, and

   ii) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

b. The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis, including through efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health care services; and encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

Sec. 2. Rationale:

This order recognizes that:

(1) since the onset of the worldwide HIV/AIDS epidemic, approximately 34,000,000 people living in sub-Saharan Africa have been infected with the disease;
(2) of those infected, approximately 11,500,000 have died;
(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and
(4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

Therefore,

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis on HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective U.S. response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and to remove the stigma of the disease, and should place a priority on delivery of basic health care products and services that can be used to treat the illness and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those afflicted with the disease;

(6) an effective U.S. response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;

(7) American innovative capacity in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these sectors will be a critical element in any successful program to respond to the HIV/AIDS crisis in sub-Saharan Africa;

(8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;

(9) individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations; and

(10) successful initiatives will require close partnerships and cooperation between governments, international organizations, non-governmental organizations and the private sector, and greater consideration should be given to financial, legal and other incentives that will promote cooperation toward the goal of improving prevention efforts, as well as treatment and health care support.

Sec. 3. Scope: This order prohibits the U.S. Government from taking action pursuant to section 301 of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit U.S. Government officials from evaluating, determining, and/or expressing concern about whether such a law or policy promotes

access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit U.S. Government officials from consulting with or otherwise discussing with sub-Saharan African Governments whether such law or policy meets the above conditions. Moreover, this order does not prohibit the U.S. Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the TRIPS Agreement.

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Talking Points on EO Regarding Limitation of Trade Actions in Connection with Sub-Saharan Measures Promoting Access to HIV/AIDS Pharmaceuticals and Medical Technologies

- Today the President will sign an executive order that instructs U.S. trade officials to refrain from taking actions against laws and policies of sub-Saharan African governments that are designed to ~~facilitate distribution of~~ increase access to HIV/AIDS pharmaceuticals and medical technologies.
- More specifically, the order will limit U.S. trade actions where sub-Saharan measures (a) promote access to HIV/AIDS drugs and technologies and (b) are consistent with the central WTO agreement on intellectual property rules, the Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPs).
- The President's action will provide certain sub-Saharan African countries with added flexibility in crafting policies that will promote access to drugs and medical devices for affected populations. The President's action is necessary because certain laws affecting intellectual property rights could hinder access to HIV/AIDS drugs and technology or could increase their price.
- At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors will be protected by requiring that beneficiary sub-Saharan African countries comply with applicable WTO rules – most notably the Agreement on Trade-Related Aspects of Intellectual Property Rights.
- Thus, to the extent that sub-Saharan African countries comply with their WTO obligations, they stand to benefit from the order in important ways. However, if they do not, they may face trade actions initiated by the United States.
- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:
  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;
  - to promote practices that will prevent further transmission ~~and infection~~ of HIV;
  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and
  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

have become

- The President's action today will help combat the worldwide HIV/AIDS ~~epidemic, which has resulted in~~ approximately 34,000,000 people in sub-Saharan Africa ~~being~~ infected and, of those, approximately 11,500,000 have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

pandemic

~~Each day~~, 5,500 men, women & children in SSA die of AIDS since the pandemic began

Q1: What does the Order do? How will it help the HIV/AIDS crisis in sub-Saharan African countries?

A:

- Under this Order, beneficiary sub-Saharan African governments will be provided with flexibility to bring life-saving drugs and medical technologies to affected populations.

- They will be provided with this flexibility because the U.S. Government will not seek the revocation or revision of any intellectual property policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals and that provides adequate and effective intellectual property protection consistent with international intellectual property standards. These standards are established by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights or "TRIPS Agreement." [For background information on the TRIPS Agreement, see Q14.]

- In other words, under the Order the United States will not invoke its domestic trade law remedies to get sub-Saharan governments to change their intellectual property laws if two important conditions are met. The first is that the laws in question promote access for people living with HIV/AIDS ~~victims~~ to needed ~~drugs~~ treatments and medical devices and technology. And the second is that the laws must be consistent with the rules established in the TRIPS Agreement.

- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:

  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;

  - to promote practices that will prevent further transmission of HIV ~~and infection~~;

  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and

  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

Q2: Why is the President issuing this Order?

A:

- The President is issuing the Order for several reasons. First, he is deeply concerned about the HIV/AIDS pandemic sweeping through Africa. [For details on the pandemic, see Q6.] He has taken numerous steps to fight the spread of AIDS, and this Order is intended to add to the

Administration's efforts in this critical area. [For details on the Administration's efforts in this regard see Q7.]

- Second, the President had hoped that Congress would include provisions in the pending Trade and Development Act of 2000 [containing the Africa-CBI provisions]. Senators Feinstein and Feingold proposed an amendment to the act that would have instructed U.S. trade officials not to take action against sub-Saharan intellectual property laws that are designed to promote access to AIDS drugs and medical technologies and that are consistent with international intellectual property standards. This amendment, though, was not included in the Conference Report for the bill. Thus, building on the work of Senators Feinstein and Feingold, the President decided to issue an Order that will implement the policy.

- Third, for some time [at least since the end of last year] the Administration has been carrying out a policy that essentially is mirrored by the Order. Formalizing this policy through an Executive Order serves to underscore the depth of U.S. concern about the HIV/AIDS crisis problem in Africa.

- And fourth, the President determined that the Order, operating in conjunction with the Africa-CBI provisions will help our African partners make important advancements. Together, these actions will strengthen African economies, enhance African democracy, and expand U.S.-African trade. They also will enable the United States to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world.

Q3: Will the Order allow foreign countries to steal U.S. AIDS drugs for manufacturing?

A:

- The Order in no way diminishes obligations owed by sub-Saharan countries to the United States with regard to intellectual property protection. The United States will continue to insist that our trading partners, including sub-Saharan African countries, meet their international obligations to provide basic intellectual property protection. This includes patent, copyrights, trademarks and other intellectual property rights.

- Thus, if a sub-Saharan African country has committed to provide U.S. companies and inventors with patent protection, it must continue to do so. The Order would not allow such countries to deny patent-holders rights they enjoy under international rules.

- The Order makes clear that the minimum degree of protection to be provided by sub-Saharan countries is based on the World Trade Organization TRIPS Agreement. This agreement establishes minimum international norms for patents, copyrights, trademarks, and the like. Countries that fail to meet the standards established in the agreement would not be permitted to take advantage of the Order.

press for laws or policies that would implement a higher standard than the TRIPS agreement in these situations.

Q6: Why was the Order necessary? Why African countries and why now?

A:

- The Order recognizes that there is an extraordinary human health crisis occurring now in sub-Saharan Africa. This is one of the gravest health crises in the world.
- The numbers are staggering. Approximately 34,000,000 people in sub-Saharan Africa have been infected with the ~~disease~~ and, of those infected, approximately 11,500,000 have died. Approximately 5,500 people in sub-Saharan Africa die every day from this illness. ~~These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.~~

Q7: Do you believe that this will solve the AIDS crisis in Africa? What else is the Administration doing?

A:

- The Order will not by itself solve the AIDS crisis in Africa. It will, however, give sub-Saharan countries added ability to fight the spread of AIDS. It will give them additional flexibility to determine how best to get drugs and treatments to people who need them.
- Today's action is an integral part of a broad-based Administration effort to stem the rising tide of HIV infection and to help care for the millions of men, women, and children in Africa and around the world who are already sick with AIDS.
- The Administration's comprehensive global AIDS strategy also includes:
  - an intergovernmental working group, chaired by the White House AIDS Office and the National Security Council, charged with coordinating a government-wide response;
  - working to secure a $100 million increase in funding for global AIDS programs that the President included in his FY2001 budget request; last year the President also requested and secured a $100 million increase in our global AIDS effort enabling the USG to more than double its HIV programs in sub-Saharan Africa;
  - encouraging similar increased AIDS-related foreign aid from other G8 countries;
  - encouraging countries in Africa and around the world receiving debt relief under HIPC to redirect these funds toward HIV prevention and AIDS care programs;

- pushing for a new tax cut to help spur the development and distribution of vaccines for AIDS and other diseases;

- calling on the World Bank and other multilateral development banks to dedicate additional low-interest loans to expand AIDS education and other prevention programs as well as to build health care infrastructure; and

- helping to galvanize support from the business, labor, foundation, and religious communities.

Q8: Is the Administration no longer concerned with the protection of intellectual property rights in Africa?

A:

- The Administration continues to seek full implementation of intellectual property commitments made to the United States by our trading partners.

- In particular, the Administration has pressed many of our trading partners to meet their obligations through negotiations and, where necessary, through other trade-enforcement mechanisms. These include initiating investigations into suspect practices under Section 301 of the Trade Act of 1974 [the principal U.S. trade investigation and sanctions law] and Special 301 [USTR's annual report to Congress on the most egregious intellectual property practices around the world], as well as initiating dispute-settlement proceedings in the WTO.

- The United States under the Clinton Administration remains the most active enforcer of intellectual property rights in the world. The Order will not prevent future actions against sub-Saharan governments that fail to meet their international obligations. The Order does so by specifically requiring these countries to meet their WTO obligations. If a country fails to do so, the United States can take action against their offending measures.

- In this way, the Order strikes a proper balance between the need to enable sub-Saharan African governments to promote access to HIV/AIDS pharmaceuticals and medical technologies and the need to ensure that intellectual property rights are protected.

Q9: What is meant by a beneficiary country?

A:

We mean those sub-Saharan African countries that are determined to be beneficiaries under The Trade and Development Act of 2000 [containing the Africa-CBI provisions]. The Order is limited to sub-Saharan countries identified in that act. The countries that have been so designated are:

(1) Republic of Angola (Angola).

(2) Republic of Botswana (Botswana).

(3) Republic of Burundi (Burundi).

(4) Republic of Cape Verde (Cape Verde).

(5) Republic of Chad (Chad).

(6) Democratic Republic of Congo.

(7) Republic of the Congo (Congo).

(8) Republic of Djibouti (Djibouti).

(9) State of Eritrea (Eritrea).

(10) Gabonese Republic (Gabon).

(11) Republic of Ghana (Ghana).

(12) Republic of Guinea-Bissau (Guinea-Bissau).

(13) Kingdom of Lesotho (Lesotho).

(14) Republic of Madagascar (Madagascar).

(15) Republic of Mali (Mali).

(16) Republic of Mauritius (Mauritius).

(17) Republic of Namibia (Namibia).

(18) Federal Republic of Nigeria (Nigeria).

(19) Democratic Republic of Sao Tome and Principe (Sao Tome and Principe).

(20) Republic of Sierra Leone (Sierra Leone).

(21) Somalia.

(22) Kingdom of Swaziland (Swaziland).

(23) Republic of Togo (Togo).

(24) Republic of Zimbabwe (Zimbabwe).

(25) Republic of Benin (Benin).

(26) Burkina Faso (Burkina).

(27) Republic of Cameroon (Cameroon).

(28) Central African Republic.

(29) Federal Islamic Republic of the Comoros (Comoros).

(30) Republic of Cote d'Ivoire (Cote d'Ivoire).

(31) Republic of Equatorial Guinea (Equatorial Guinea).

(32) Ethiopia.

(33) Republic of the Gambia (Gambia).

(34) Republic of Guinea (Guinea).

(35) Republic of Kenya (Kenya).

(36) Republic of Liberia (Liberia).

(37) Republic of Malawi (Malawi).

(38) Islamic Republic of Mauritania (Mauritania).

(39) Republic of Mozambique (Mozambique).

(40) Republic of Niger (Niger).

(41) Republic of Rwanda (Rwanda).

(42) Republic of Senegal (Senegal).

(43) Republic of Seychelles (Seychelles).

(44) Republic of South Africa (South Africa).

(45) Republic of Sudan (Sudan).

(46) United Republic of Tanzania (Tanzania).

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OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Debbie

FROM: Cheryl

COMPANY:

DATE:

FAX NUMBER: 6-2215

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RE:

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

NOTES/COMMENTS:

Attached pls. find Sandy's comments, and pls. call me with questions @ 6-2959.

Thank you!

Cheryl

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

Document No. _____

WHITE HOUSE STAFFING MEMORANDUM

Date: 5/9/00 ACTION / CONCURRENCE / COMMENT DUE BY: ASAP

Subject: DRAFT EO ON ACCESS TO HIV/AIDS DRUGS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	✓	☐	LOCKHART	☐	✓
PODESTA	✓	☐	LEWIS	☐	☐
ECHAVESTE	✓	☐	MARSHALL	☐	☐
RICCHETTI	✓	☐	MOORE	☐	☐
LEW	☐	☐	NASH	☐	☐
BAILY	☐	☐	NOLAN	✓	☐
BERGER	✓	☐	REED	✓	☐
BLUMENTHAL	☐	☐	SPERLING	✓	☐
BRAIN	✓	☐	STREETT	☐	☐
BURSON	✓	☐	TRAMONTANO	✓	☐
CAHILL	✓	☐	UCELLI	✓	☐
EDMONDS	☐	☐	VERVEER	☐	☐
FRAMPTON	☐	☐	FROM SANDY THURMAN	✓	☐
IBARRA	☐	☐	_____	☐	☐
JOHNSON, B.	☐	☐	_____	☐	☐
JOHNSON, J.	✓	☐	_____	☐	☐
LANE	☐	☐	_____	☐	☐

REMARKS: COMMENTS TO STAFF SECRETARY

RESPONSE:

Office of the Staff Secretary

DRAFT

Executive Order
(May 8, 6:50pm)

ACCESS TO HIV/AIDS PHARMACEUTICALS AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act, section 104 of the Foreign Assistance Act of 1961, as amended (22 USC 215(1)(b)), and section 301 of title 3 of the United States Code, and in accordance with the executive branch's policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Sec. 1. Policy:

a. In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as defined in the Trade and Development Act of 2000, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

   i) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country, and

   ii) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

b. The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis, including through efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health care services; and encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

Sec. 2. Rationale:

This order recognizes that:

(1) since the onset of the worldwide HIV/AIDS epidemic, approximately 34,000,000 people living in sub-Saharan Africa have been infected with the disease;
(2) of those infected, approximately 11,500,000 have died;
(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and
(4) ~~access to~~ the availability of safe and effective ~~therapeutics~~ treatments for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

Therefore,

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis on HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective U.S. response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and to remove the stigma of the disease, and should place a priority on delivery of basic health care products and services that can be used to treat the illness and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those afflicted with the disease;

(6) an effective U.S. response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;

(7) American innovative capacity in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these sectors will be a critical element in any successful program to respond to the HIV/AIDS crisis in sub-Saharan Africa;

(8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;

(9) individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations; and

(10) successful initiatives will require close partnerships and cooperation between governments, international organizations, non-governmental organizations and the private sector, and greater consideration should be given to financial, legal and other incentives that will promote cooperation toward the goal of improving prevention efforts, as well as treatment and health care support.

Sec. 3. Scope: This order prohibits the U.S. Government from taking action pursuant to section 301 of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit U.S. Government officials from evaluating, determining, and/or expressing concern about whether such a law or policy promotes

access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit U.S. Government officials from consulting with or otherwise discussing with sub-Saharan African Governments whether such law or policy meets the above conditions. Moreover, this order does not prohibit the U.S. Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the TRIPS Agreement.

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*** ACTIVITY REPORT ***
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ST. TIME	CONNECTION TEL/ID	SENDER NAME	NO.	MODE	PGS.	RESULT
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*05/05 11:09			6355	AUTO RX ECM	1	NG 01'54
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					0	STOP
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	69260					
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05/09 16:19	96907560		1093	TRANSMIT ECM	4	OK 01'44

called in changes to Hal

May 9, 2000

Senator Dianne Feinstein
United States Senate
Washington, D.C. 20510-0504

Dear Senator Feinstein:

I am pleased to inform you that today I will sign an Executive Order that is intended to help make HIV/AIDS-related drugs and medical technologies more accessible and affordable in sub-Saharan African countries. The Executive Order, which is based in large part on your work in connection with the Trade and Development Act of 2000, makes formal for the U.S. government the approach the Administration has been pursuing for some time in this area. It also directs other steps to be taken to address the spread of HIV and AIDS in Africa, one of the worst health crises the world faces.

As you know, the worldwide HIV/AIDS epidemic has taken a terrible toll in terms of human suffering and the number of lives lost. Nowhere has the suffering been as great as in Africa, and nowhere is HIV/AIDS spreading more rapidly than in Africa. Approximately 34,000,000 people in sub-Saharan Africa have been infected with the ~~disease~~ and, of those infected, approximately 11,500,000 have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

To help those countries most ~~afflicted~~ by HIV/AIDS fight this terrible disease, the Executive Order directs the U.S. government to refrain from seeking, through negotiation or otherwise, the revocation or revision of any law or policy imposed by a sub-Saharan government that promotes access to HIV/AIDS pharmaceuticals and medical technologies. This order will give sub-Saharan governments the flexibility to bring life saving drugs and medical technologies to ~~afflicted~~ populations. At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors are protected by requiring sub-Saharan governments to provide adequate and effective intellectual property protection consistent with World Trade Organization rules. In this way, the order strikes a proper balance between the need to enable sub-Saharan governments to ~~facilitate distribution of~~ HIV/AIDS pharmaceuticals and medical technologies and the need to ensure that intellectual property rights are protected.

I know that you preferred for this policy to be included in the Conference Report on the Trade and Development Act of 2000, as did I. However, through this Executive Order, the policy this Administration has pursued with your support becomes the formal policy of the U.S. government. The Executive Order will ~~facilitate~~ efforts by African countries to build a better infrastructure to fight diseases like HIV/AIDS as they build better lives for their people. At the same time, the Trade and Development Act of 2000 will strengthen African economies, enhance African democracy, and expand U.S.-African trade. Together, these steps will enable the United States to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world.

Thank you for your leadership on this critically important issue.

Sincerely,

William J. Clinton

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Hal Shapiro

FROM:

COMPANY:

DATE:

FAX NUMBER: 6-2223

TOTAL NO. OF PAGES INCLUDING COVER:

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RE:

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NOTES/COMMENTS:

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Talking Points on EO Regarding Limitation of Trade Actions
in Connection with Sub-Saharan Measures Promoting Access
to HIV/AIDS Pharmaceuticals and Medical Technologies

- Today the President will sign an executive order that instructs U.S. trade officials to refrain from taking actions against intellectual property laws and policies of sub-Saharan African governments that are designed to increase access to HIV/AIDS pharmaceuticals and medical technologies for people who need them.

- More specifically, the order will limit U.S. trade actions where sub-Saharan measures (a) promote access to HIV/AIDS drugs and technologies and (b) are consistent with the central WTO agreement on intellectual property rules, the Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPs).

- The President's action will provide certain sub-Saharan African countries with added flexibility in crafting policies that will promote access to drugs and medical devices for affected populations.

- At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors will be protected by requiring that beneficiary sub-Saharan African countries comply with applicable WTO rules – most notably the Agreement on Trade-Related Aspects of Intellectual Property Rights.

- Thus, to the extent that sub-Saharan African countries comply with their WTO obligations, they stand to benefit from the order in important ways. However, if they do not, they may face trade actions initiated by the United States.

- In addition, the Order states that the U.S. will take several positive steps to address the HIV/AIDS crisis. These include encouraging all sub-Saharan African countries:

  - to implement policies designed to address the underlying causes of the HIV/AIDS crisis;

  - to promote practices that will prevent further transmission of HIV;

  - to stimulate development of the infrastructure necessary to deliver adequate health care services; and

  - to encourage policies that provide an incentive for public and private research on and development of vaccines and other medical innovations that would contribute to combating the HIV/AIDS crisis facing Africa.

- The President's action today will help combat the worldwide HIV/AIDS epidemic, which has resulted in approximately 34,000,000 people in sub-Saharan Africa being infected and, of those, approximately 11,500,000 have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

Office of HIV/AIDS Policy

Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Tel. (202) 690-5560

☐ Room 736-E

Fax. (202) 690-6584
Fax. (202) 690-7560

TO: Michael / Sandy

FAX:

FROM: Deborah von Zinkernagel
Deputy Director for Policy

(This fax contains _____ page(s) + cover)

Background piece on
Low cost drug plg for
Africa — ours alone

We can refine if useful, Dustin's staff
report got us working on this.

Author: Eric Goosby at ~OPHS_DC
Date: 2/23/00 11:02 AM
Priority: Urgent
Receipt Requested
TO: Deborah Von Zinkernagel
CC: Glen Harelson
Subject: Drugs/Africa

This is an off the top of the head compilation of essential drugs. This is not considered a comprehensive list, nor does it cover parasitic drugs or immunizations, most of which are in adequate supply in most contries.

e

OVERVIEW

The needs in Africa are extraordinary. The problem of medical care delivery in the setting of no or few resources is evident. The compilation of useful medications is predicated on the following assumptions:

1. Poor medical infrastructure for the majority of the population
2. Very limited resources to put toward medical diagnostic and treatment needs
3. Clear need for grass roots based community responses to HIV in each geographic area
4. Hospice, palliative care needs remain largely unmet
5. Transportation infrastructure is limited and fixed for the near future
6. Treatment of opportunistic infection is largely not occurring
7. Tb and malaria continue to impact heavily on the populations in Af.
8. Creation of an autonomous medical clinic with surveillance capability . The surveillance capability would focus on describing the epidemic in the immediate area in and around the clinic. This autonomous clinic would expand to adjacent areas, eventually leading to a comprehensive network of medical capabilities in the country.. Consultation and referral capability would need to be developed.
9. Stigma and prejudice remain a major barrier to accessing high risk populations and once identified, tested and brought into medical care.
10. Prevention interventions need to be based at the medical facility
11. Treatment of STD/TB/malaria and prenatal services are integral to impacting HIV spread

Annotated Formulary (does not include drugs for parasitic infections or immunizations)

1. Dapsone ($0.19/tab)
   This drug is used to profiles against the development of the most common AIDS pneumonia, Pneumocystis Carinii Pneumonia (PCP). It also prevents the development of Toxoplasmosis. Dapsone is the second drug of choice for this purpose. It should only be used in patients with normal levels of G6PD (requires blood test/ G6PD deficiency is common in Africans.

2. Isoniazid (INH: $0.02/T.B.)
   This is the primary drug used in prophylaxis for non INH resistant TB prevention and in combination with three other drugs, for treatment of active TB. It is well tolerated at 300 mg qd in patients with no history of liver disease. INH hepatitis begins to be a problem in patients over 35 yrs of age and needs to be given with monitoring of liver function tests (blood test) to patients over 35y.

3. Bactrim or Septra (trimethoprime-sulfamethoxazole sulfamethoxazole) ($0.07/tab)
   This drug is the drug of choice to prevent PCP and other common infections of the sinuses, lung and urinary tract. It also cover Toxoplasmosis.

4. Doxycycline ($0.11)
This drug is used as an alternative to chloroquine prophylaxis for malaria and in treating the common sexually transmitted disease, chlamydia. It can also be usd to treat Primary and secondary syphilis in a penicillin allergic patient (requires 30d treatment)

5. Azithromycin ($6.00/tab)
This drug is used for the treatment o chancroid, mycobacterium avium intracellularae (MAI), common bacterial pneumonias. It has the advantage of having shortened time course for therapy of pneumonia, chancroid and other bacterial infections.

6. *Ketoconazole ($2.80/tab)

Itraconazole ($5.60/100mg tab)
Fluconazole ($6.88/100mg tab)

Ketoconazole is the cheapest form of the newer antifungal agents (such as fluconazole,and itraconazole). Highly effective oral therapy for candida albicans infections of skin, vagina, and esophagus. Not as effective as other --conazoles for treatment of cyrptococcal meningitis or coccidioidomycosis.

7. Metronidazole (Flagyl) ($0.03/250tab)
This drug is effective against gingivitis, intra abdominal sepsis, Amebiasis, bacterial vagueness, trichomoniasis and clostrida.difficule colitis.

8. Nystatin Vaginal Suppositories ($0.11/each)
Used in oral thrush and vaginal thrush

9. Acyclovir ($1.08/200mg tab)

Used in the prophylaxis and treatment of herpes simplex infections of skin, sex organs, anus-rectum

10. Rifampin ($0./61/tab)

Used alone in the prophylaxis of TB known to be resistant to INH or in the the treatment of active TB in combination with Pyrazinamide, streptomycin and ethambutol.

11. Assorted Antibiotics

Ceftriaxone : one shot treatment for syphillis
Benzethine Penicillin : late latent, tertiary and Neurosyphilis
Dicloxacillin: oral medication for more severe skin infections
Keflex : oral medication for skin infections
Erythromycin: skin infections and atypical pneumonias (eg:tularemia, Q-fever,

mycoplasma,)

12. Chloroquine (quinine sulfate), Mefloquine, quinidine, proquanil

Treatment or prophylaxis for malaria.

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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	0791
CONNECTION TEL	92283997
CONNECTION ID	
ST. TIME	02/23 14:48
USAGE T	01'33
PGS.	3
RESULT	OK

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Bobb Epplin
FROM: Cheryl Bauvelt
COMPANY:
DATE:
FAX NUMBER: 228-3997
TOTAL NO. OF PAGES INCLUDING COVER: 3
PHONE NUMBER:
RE:

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

NOTES/COMMENTS:

Sorry for the delay! Pls call if you need anything else.

Cheryl (456-2959)

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Bobb Epplin

FROM: Cheryl Bauerle

COMPANY:

DATE:

FAX NUMBER: 228-3997

TOTAL NO. OF PAGES INCLUDING COVER: 3

PHONE NUMBER:

RE:

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

NOTES/COMMENTS:

Sorry for the delay! Pls call if you need anything else.

Cheryl (456-2959)

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

MR. LOCKHART: Because I don't know any HMOs or insurance companies who have one or two beneficiaries. They represent large groups. There is an economy of scale; otherwise they wouldn't be in the business. There isn't like the front row here has their health plan and the second row has their health plan; that's just not the way it works.

Q Well, federal employees choose from dozens of different plans.

MR. LOCKHART: Right, and each -- well, I guess there is. If we can get Terry to move, but he wasn't even listening so he doesn't even know what I said. (Laughter.)

Q Joe, on China. The Chinese government has said that they cannot guarantee that they will not sell in the future missile and nuclear technology to other countries like Pakistan and Iran. Do you think it will affect in the Congress PNTR or --

MR. LOCKHART: Well, we have made our position on proliferation quite clear to the Chinese, and I think as a general point we believe we are better able to make our points and to articulate our national security concerns when we are engaged and we bring China into rules-based organizations, rather than by isolating China. So can I predict an impact? No. But should it have an impact? Not according to our judgment.

Q Is the President aware of the Washington Post story the other day that honored killings are continuing still in Pakistan?

MR. LOCKHART: Yes, I'm sorry, I didn't see that. I'd have to check on that for you.

Q I think Vladimir Putin just named a Prime Minister -- any reaction to this person? I guess he was on the previous government also. Do we know anything about him?

MR. LOCKHART: I don't know in particular what we know about him. I think, as a general principle -- we have congratulated Mr. Putin for the democratic transition -- the President did, in writing -- on the occasion of his inauguration. But as a general principle, we are less interested in the people that they put forward, rather more interested in the policies, the general move toward economic reform, the cleaning up of corruption, our bilateral issues of arms control and nonproliferation. So, again, I think -- I don't have a great deal of detail about the newly-appointed Prime Minister, but what's important is they follow the general policy outline and agenda that Putin talked about.

Q Joe, do you know what the practical impact will be of the executive order the President signed today on AIDS drugs in sub-Saharan Africa, and is it a change in administration policy, or does it formalize the existing policy?

MR. LOCKHART: I think the practical impact is that it will promote the accessibility of HIV-AIDS drugs into sub-Saharan Africa. I think over the last months there's been some focus on the crisis that exists there. I mean, some 80 percent of the deaths of AIDS right now are in sub-Saharan Africa, and over 11 million people have already died, 44 million I think are infected.

The executive order finds the balance between protecting intellectual property rights and also promoting accessibility of the drugs in this area, and allowing the companies to deal with the public health crisis that they face.

Q Does this mean that what countries like South Africa are trying to do in sort of setting up I guess licensing agreements on their own to start producing AIDS drugs, maybe without the full permission of the companies involved --

MR. LOCKHART: What it does is it provides them flexibility within their own intellectual property construct, as long as they stay within the trips agreement within the WTO. I mean, I think the basic -- I think our intellectual property laws here are much more stringent than even within the WTO. And this allows sub-Saharan countries, a group of identified countries, flexibility for them to take steps in order to make these drugs more accessible.

Q Developing countries have been saying for years that intellectual property laws prevented them from getting badly-needed drugs at costs that they could afford. Doesn't this executive order prove that point?

MR. LOCKHART: I don't think that it proves that our intellectual property laws are too stringent. I think that this executive order recognizes the truly great public health crisis that exists now in sub-Saharan Africa, and I think it creates the flexibility that the countries there need to address the problem.

Q Joe, you mentioned the patients' bill of rights. Is there going to be a meeting tomorrow with the conferees?

MR. LOCKHART: It's still on, right? Let me check for you. It was tentatively set for tomorrow, and I just haven't checked since Monday. But I'll check for you.

Q One more question on prescription drugs. If you could respond to the two main criticisms of it -- the Republicans charge that it's going to be too costly, and consumer groups are saying that the administration is buckling to the pharmaceutical industry.

MR. LOCKHART: That puts us right in the middle, so I think it's normally a pretty good place. I think you'll find that the prescription drug program that the President laid out is affordable and fits within our budget framework, it pays down the debt by 2013, invests in Medicare, Social Security and our other urgent national needs.

As far as those who say we're buckling to the pharmaceutical companies, if we have, the pharmaceutical companies have shown a peculiar way of expressing their appreciation by opposing it.

Q What's the President's view of the lawsuit the DCCC filed against Tom Delay?

MR. LOCKHART: You know, I saw a couple of things on that in the paper this morning. I don't know, I haven't talked to him about it. I'll try to get his opinion.

Q Do you know, has anyone at the White House -- as you may have seen, a former White House official is quoted as saying, or wrote a piece saying he thought it was a bad idea. Did any input come from the White House --

MR. LOCKHART: No.

Q -- did DCCC check here before they did this, or was it just a --

MR. LOCKHART: Not that I'm aware. The first I saw of it was

Mr. Gore and the AIDS Drugs

VICE PRESIDENT Gore stands accused of defending pharmaceutical industry profits at the expense of South African AIDS patients. Welcome to campaign season. The AIDS activists who have heckled Mr. Gore at his early appearances, seeking to drown him out with chants of "Gore's Greed Kills," manipulate the facts in what is actually a much more complicated and interesting debate.

International trade law protects drug company patents, and for good reason. Companies invest large sums in research that often leads nowhere but sometimes produces valuable new medicines. If the industry can't recoup its investment through drug sales, here and overseas, it won't look for new drugs, and everyone will suffer—Americans and foreigners alike.

But poor countries chafe, understandably, when medicines that could save lives are priced beyond their reach. This conflict between the legitimate interests of industry and those of the developing world has no ultimate solution, but avenues of compromise can be found. More foreign aid from wealthy countries could be targeted to health care and specifically to encourage the development of medicines useful to the developing world. Developing countries could devote a larger share of their budgets to primary health care, thereby creating more of a market for useful drugs. Drug companies could more often settle for lower profit margins when selling or licensing products to poor nations, especially when the alternative is no sales at all.

In 1997 South Africa approved a new law, aimed at making medicines more affordable, that multinationals deemed a threat to patent rights. An industry lawsuit is still pending in South Africa's courts, so the law has never been implemented, and its effects remain unclear.

The two practices it might condone, to which industry objects, are compulsory licensing and parallel importing. Under the former, the government could force a multinational to grant manufacturing rights, for a fee, to a local producer; the latter would allow the import of legally produced medicines from a third country where they might be cheaper. South Africa maintains that both may be permitted under international law in certain cases. Industry for the most part dislikes both ideas.

The Clinton administration, led by Mr. Gore, has sought to protect industry's legal position. You could make a case that it should push harder to help South Africa get access to drugs it can afford. But Mr. Gore has not been as one-sided as industry—or many Republicans in Congress—would like. Last year the U.S. drug industry persuaded a Republican congressman from New Jersey, home to many pharmaceutical giants, to attach a provision to the foreign-aid bill blocking U.S. assistance to South Africa's government until the State Department explained what it was doing on industry's behalf. The congressman, Rodney Frelinghuysen, wasn't satisfied with the department's first report, so it submitted a revision, portraying itself more strongly as a champion of U.S. industry.

Language from that report—ordered up because the industry perceived the administration as too soft on South Africa and dutifully delivered by the administration to forestall a cutoff of U.S. aid—is now cited by Mr. Gore's critics on the other side as evidence that he is in industry's pocket. As we said, welcome to the campaign.

Policy Statement

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 would not object to compulsory licensing of AIDS-related drugs by South Africa provided that it is done in a manner consistent with provisions of the WTO's TRIPS agreement. Any such parallel importing of drugs should ensure their safety and efficacy and not otherwise infringe relevant patent rights.

Article 31 of TRIPS establishes specific conditions to permit what is called "unauthorized use" under exceptional circumstances, while attempting to protect the interests of the patent holder. For example, TRIPS would permit a country to compel a patent holder to grant a license, but only on a case-by-case basis, and normally only after the proposed user of the patent has been unable to obtain a license on a voluntary basis on reasonable commercial terms. This latter requirement may be waived in a "national emergency." However, even in the case of such an emergency, other conditions still apply, including a requirement to pay adequate remuneration to the patent holder and to permit the licensing decision to be subject to judicial review. In addition, the product produced under such a license should used predominately to supply the domestic market of the government authorizing such use and the license should be non-exclusive (meaning the patent-holder would still be able to voluntarily license other users) and non-assignable (meaning the licensee could not assign the license to other users).

Neither does the US Government generally support parallel importing of pharmaceuticals. The TRIPS Agreement states that a patent holder enjoys the exclusive right to make, use, sell, or import (including parallel importing) a product. However, Article 6 of the TRIPS Agreement states that disputes about "exhaustion of rights" (parallel imports) are not covered by the WTO dispute settlement procedures. Therefore, we are saying that if the SAG chooses to parallel import, such a practice could not be disputed under WTO rules, provided patent rights are not otherwise infringed. Nevertheless, we would look to a country permitting parallel imports of pharmaceuticals to ensure the safety and efficacy of such drugs.

AIDS Drugs for Africa
June 25, 1999

Context: In 1997 South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – challenged the law in South African Court, contending that this law violates the constitution of South Africa. The litigation is still ongoing.

At the same time, the U.S. Trade Representative was concerned that the ambiguity in the law could allow for actions in violation of the WTO-TRIPS agreement (the agreement reached by the 134-member WTO on protection of intellectual property). As a result, USTR named South Africa to the 301 Special Watch List. The watch list (which is not attached to sanctions) is the lowest level of three designations included in the report USTR produces every April. The report's purpose is to signal U.S. concern on intellectual property rights protection offered to U.S. goods by U.S. trading partners.

The Vice President – in his meeting with Deputy President Mbeki in August 1998 -- proposed that the two work toward a solution within a framework that would include parallel importing and compulsory licensing, so long as they were done consistent with international agreements (TRIPS). But progress of negotiations has been slow because of worries on both sides about prejudicing the outcome of the ongoing litigation.

AIDS activists have charged that the Vice President – in order to curry favor with drug companies -- has threatened severe trade sanctions against South Africa. These activists have been given credible airing in the media in spite of underlying facts that disprove their points. Namely: Early in 1999, drug company representatives pushed to raise South Africa's status on the 301 Special Watch List from the lowest level to the highest level. The highest designation – if imposed – would require South Africa to resolve the issue to U.S. satisfaction within a set period of time or face trade sanctions. As reported in a Tuesday, June 22 story in the Baltimore Sun, the Office of the Vice President strongly opposed the drug industry recommendation, and the April 30 report – rather than raising the designation -- kept South Africa on the watch list.

AIDS activists have said the Vice President has threatened trade sanctions against South Africa if they go forward with plans to produce lower-cost AIDS drugs. Is that fair?

- As co-chair of the U.S.-South Africa Binational Commission, the Vice President has made an immense personal investment of time and effort in building better U.S. ties with South Africa – working to improve health, expand trade, build the economy.

- Why would he be trying to undercut his own efforts?

- The Vice President has taken a special interest in South Africa's efforts to fight AIDS, and has kept the crisis clearly in mind as we have worked to resolve our trade differences.

- As Susan Rice, our Assistant Secretary of State for Africa, said in the press this week (Baltimore Sun, Tuesday June 22): the Vice President took the position that the health crisis in South Africa needed to be taken into account, and he led the way led the way in opposing trade sanctions pushed by the pharmaceutical industry.

- These activists – as the Washington Post said in their Thursday editorial – are "manipulating the facts." They should understand that the Vice President is one of the strongest advocates in this administration for the issues they care about.

- They should be working with him instead of against him.

The Vice President cares nothing for millions who are dying.

It would be hard to find someone in the U.S. Government with a more active record of support for the fight against AIDS in South Africa.

Since 1995, the Vice President has co-chaired with Deputy President Mbeki the U.S.-South Africa Binational Commission. In that context, he has had a central role in bringing to South Africa the best of American knowledge, effort and ideas in the fight against AIDS.

Under the auspices of the Commission, the U.S. has funded a South African effort to track the disease –you can't fight it if you can't track it. The Commission has also worked to expand awareness and improve prevention.

The Vice President has brought high-level U.S. health officials on his trips to South Africa – Secretary Shalala and Surgeon General Satcher -- where they have spoken with President Mandela's cabinet on the issue of AIDS.

Just a few months ago, Vice President Gore took Surgeon General David Satcher with him to South Africa for another meeting of the Commission.

When Vice President Gore appeared with Deputy President Mbeki last February on national TV in South Africa, he was wearing an AIDS ribbon, done in African beadwork, given to him by Mbeki after the two had spent hours the previous day in a one-on-one discussion on AIDS.

It is hard to believe that the Deputy President would present the Vice President such a gift unless they were united in partnership in the fight against AIDS.

The Vice President and Deputy President Mbeki spent a substantial part of their time at the press conference talking about the importance of raising awareness of AIDS, and the Vice

President urged leaders in every sector of South African society to add their voices to Mr. Mbeki's in the call for greater awareness and action against AIDS.

During those meetings, did the Vice President threaten trade sanctions against South Africa?

No, he did not. The Vice President proposed working toward a resolution within a framework that would include compulsory licensing and parallel importing, as long as they were done in line with international agreements.

What's the basis for the dispute?

The issue arose in 1997, when South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. The ambiguity raised concern that actions taken under that law might not be compliant with the WTO-TRIPS agreement.

In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – have challenged the law in South African Court, contending that this law violates the constitution of South Africa. This case is now being heard by the South Africa Constitutional Court. The ongoing litigation has slowed efforts to resolve it on a government to government level.

But didn't the Vice President order a sweeping new review of South African trade laws on April 30, 1999?

No, he did not. The Baltimore Sun's June 22 story pointed out this fallacy. This charge grows out of a misunderstanding of the United States Trade Representative's Annual 301 report – issued April 30, 1999.

The USTR is mandated by Congress to publish a report every year at the end of April, detailing which of America's trading partners may not be affording full protection to U.S. intellectual property rights. As a result of the passage of amendments to South Africa's Medicines Act, and the provisions that could lead to the loss of U.S. intellectual property rights, the U.S.T.R named South Africa to the "Special 301 watch list." This designation means what it says: "The U.S. is seeing some things that give it concern, signaling that concern to the South African government, and indicating that it will be watching further developments. It is the mildest designation in the report, and is not attached to sanctions.

There are two higher designations on the report -- the priority watch list, and the highest, the priority foreign country list. If a country is named a priority foreign country, it means that the country must -- within a set period of time -- resolve the trade dispute to the satisfaction of the United States or face stiff trade sanctions. South Africa is not close to that status.

But clearly , the Vice President is in the pocket of the pharmaceutical industry

No, he is not. The Pharmaceutical Research and Manufacturers argued this spring that the USTR annual report -- due to come out again at the end of April -- should designate South Africa (because of the Medicines Act) as a priority foreign country, the most severe designation. This would have required South Africa to resolve the issue to U.S. satisfaction within a short period of time, or face sanctions and a loss of foreign aid. As reported in the June 22 Baltimore Sun, the Vice President's office strongly opposed the recommendation. The U.S.T.R. agreed, and its April 30, 1999 report renewed South Africa's status on the watch list.

But the Vice President is trying to stop South Africa from doing things that are legal under WTO/TRIPS.

No, he is not. The U.S. is seeking clarification of the law – about how it will be implemented. The point of discussions has been to work with South Africa to seek assurances that actions taken under the law will be in line with international agreements.

So where does the Vice President stand?

The Vice President believes we need to use all available means to deliver high-quality, affordable medicines to those who need them. And we should do it within the legal limits established by TRIPS. Specifically, the Vice President has no objection to parallel exporting or compulsory licensing of pharmaceuticals in South Africa, so long as it is consistent with TRIPS.

But all the South Africans want to do is what is already their legal right under TRIPS.

Section 15c of the Medicines Act gives the Health Minister unspecified powers that could go beyond was has been agreed to under TRIPS.

But the State Department Report says that the Vice President was part of an effort to put pressure on the South Africans.

First, the State Department report – dated February 5 – was written in response to members of Congress who had expressed concern that the U.S. wasn't being tough enough with South Africa. They had already suspended U.S. foreign assistance to the central Government of South Africa, and said they would not restore the aid until they received a State Department report detailing what the U.S. was doing to resolve the issue. They had already rejected an earlier report – apparently for not being tough enough.

Second, the only language in the report that names Vice President Gore comes on pages 6 and 7 – under the heading "The Vice President's Plan for a Negotiated Solution." It reads as follows:

"During the August 1998 U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made the issue of intellectual property rights protection, and pharmaceutical patents in particular, a central focus of his discussions with Deputy President Mbeki. They agreed on a basis for a mutually satisfactory, Government-to-Government negotiated solution to the impasse."

That is the only mention of Vice President Gore's actions in the entire report.

Congresswoman Barbara Lee
9th District of California
U.S. House of Representatives

Fax Cover Sheet

2:30 pm.

Date: 6/16 Pages to follow: 1

To: Michael or Cheryl

From: Jennifer

Fax number: 456-2439

Message: Michael / Cheryl - My boss discussed w/ Sandy a contribution to the Presidential Mission report, so I wanted to send this draft language to you asap - Could one of you give me a call? (whoever is working on the report) Thanks!

414 Cannon HOB ♦ Washington, DC 20515 ♦ (202) 225-2661

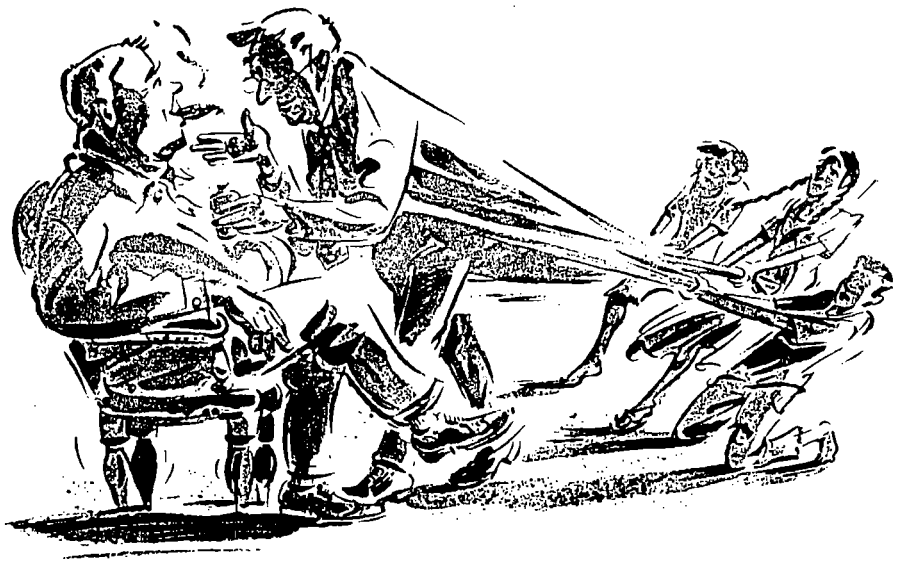
Rep. Barbara Lee
June 15, 1999

DRAFT

5. Partnerships with the Private Sector

Corporate Involvement

The United States should significantly support the involvement of the private sector in establishing a comprehensive fund dedicated to education, research and treatment of men, women, and children living with and/or exposed to HIV/AIDS in Africa. An effective public-private initiative could be seeded and leveraged with federal money, challenging private industry to contribute significant resources for this effort. As has been demonstrated in the recent $100 million "Secure the Future" initiative put forth by Bristol-Myers Squibb, private industry is interested in becoming involved in the fight against the HIV/AIDS epidemic in Africa. Given the national focus on trade partnerships with African nations, it is in their own best interest to do so. The Federal government should provide a means not only to encourage the involvement of the private sector, but also coordinate and support future private sector initiatives.



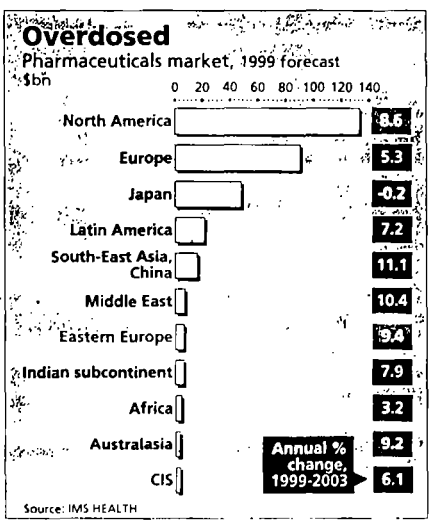
Balms for the poor

Infectious diseases hinder developing countries from developing. Making existing drugs cheaper there would help. Making entirely new drugs would help even more

PEER over the counter at a pharmacy in America, Europe or Japan and you see a wealth of drugs. Americans and Europeans spend more than $220 billion a year on prescription medicines for everything from high blood pressure to low mood—a powerful incentive for pharmaceutical companies to keep them supplied with current remedies and to concoct new ones (see chart). Of course, drugs for such diseases as river blindness and sleeping sickness are not routinely found on western shelves since there is little demand for them. But walk into a dispensary in, say, Cameroon, and you discover that such drugs are equally scarce there—not because they are not needed, but because nobody can afford them.

Lack of money not only restricts access to existing drugs and vaccines and means of dispensing them; it also offers little incentive for drug companies to develop new medicines for people in poor countries. Globally, the World Health Organisation (WHO) estimates that more than $56 billion a year is spent on health research—but less than 10% of that sum is directed toward diseases that afflict 90% of the world's population.

As Piers Whitehead of Mercer Consulting notes, large drug companies are more like supermodels than charities: they won't get out of bed and into work for less than $350m in annual sales for any given product. This is because turning a gleam in a researcher's eye into a handful of useful pills is an expensive and time-consuming business: on average, it costs $300m and takes more than a decade. Between 1975 and 1997, an impressive 1,223 new compounds were launched on the market. But as Patrice Trouiller, a consultant with Médecins sans Frontières (MSF), an aid group, points out, only 11 of them were designed for tropical diseases.



The problem is not merely one of human welfare, important though that is. Many economists, among them Jeffrey Sachs of Harvard University (see pages 17-20), believe it is also an issue of economic development. Better access to better medicines is not the only way to improve the health of poor countries, but it is a significant one. And creating new drugs and vaccines is such a technology-intensive business that the developing world is likely to remain dependent on western pharmaceutical firms for years to come.

New pills, old ills

Encouraging the development of new medicines is difficult because it requires both the push of financial incentives (to offset the risk of research in largely uncharted fields) and the pull of secure funding (to ensure that there is a paying market once the drugs are ready). Recently, however, some new ideas about how to solve these problems have emerged, based on new alliances between industry and the public sector.

One approach is that being taken by the new Medicines for Malaria Venture (MMV), which brings together public-sector organisations and drug companies under the umbrella of the WHO. Robert Ridley, director of MMV, sees the venture as a "not-for-profit virtual drug company", combining public- and private-sector research through funding collaborative discovery and development projects. Drug companies have millions of molecules in their chemical libraries created for more lucrative diseases such as cancer, along with thousands of old drugs currently used for other ailments, which could be developed for malaria at roughly a tenth of the cost of starting from scratch.

But finding the money to finance the research is not easy. MMV aims to register one new antimalarial product every five years, and is likely to need $30m a year to do so. The drug companies' gifts-in-kind are worth millions, but the bulk of the required money is still expected to come from public funds and philanthropic institutions. Initial promises of $5m have enabled MMV to begin the process of project selection, and the venture will be formally launched later this year.

Seth Berkley, head of the International AIDS Vaccine Initiative (IAVI), is hoping to do something similar for AIDS vaccines. Roughly $2 billion a year is spent on research into AIDS treatments, most of which are either too costly or too complicated for use in poor countries. But IAVI estimates that only

Flying high

COCAINE, as addicts well know, has curious effects on the body. One of them is "reverse tolerance": rather than becoming accustomed to cocaine with increasing exposure (as happens with, say, alcohol), the brain becomes more sensitive. With each hit, responses, such as fidgeting, are more exaggerated. This sensitisation is thought to be a first step in creating an overwhelming craving for the drug that eventually leads to addiction.

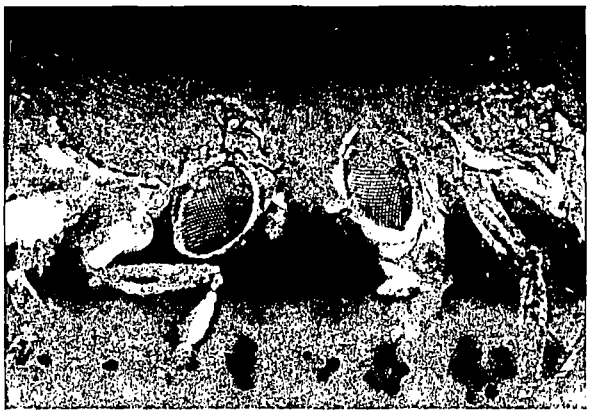
In humans, studying cocaine sensitisation is tricky since most governments have strong views on giving drugs to the uninitiated, and tend to enforce them with lengthy prison sentences. So instead researchers have turned to creatures such as the fruit fly, *Drosophila melanogaster*, to probe the cellular basis for cocaine craving. In this week's issue of *Science*, biologists Jay Hirsh, Sarah Chaney and Rozi Andretic of the University of Virginia report that an appetite for cocaine seems to be connected to the mechanisms which control circadian rhythm—the so-called "body clock".

Fruit flies, like humans, have an internal biological clock that governs their activity over a 24-hour cycle. Ms Andretic recently found that the brain makes use of a biochemical called dopamine to regulate its circadian rhythm. Other experiments on mice and flies have shown that dopamine is also involved in cocaine sensitisation. So the researchers put the two together and decided to see whether disrupting the body's internal clock might also affect cocaine craving.

When exposed to purified "freebase" cocaine, fruit flies behave surprisingly like junkies. They twitch, gnaw and groom themselves compulsively while wandering about in circles. As the drug dose rises, such erratic movements become more severe until the fly is paralysed and drops dead. Ordinarily, one cocaine hit is enough to sensitise a fly. But Dr Hirsh's team found that mutant *Drosophila* lacking genes called "Clock", "Period", "Cycle" and "Doubletime"—all of which are known to control circadian rhythm—also lack heightened responses to cocaine even after multiple doses. In fact, "Doubletime" mutants proved particularly resistant to the drug, requiring substantially higher quantities before behaving strangely.

In fruit flies, a biochemical called tyramine seems to be responsible for such drug responses, and Dr Hirsh thinks that tyramine regulation is the chemical link between these two very different processes. After a single cocaine dose, the enzyme that makes tyramine becomes more active in normal flies. In the circadian-gene mutants, however, the enzyme's activity stays steady after a dose of the drug, so tyramine levels remain low. The absence of the circadian genes, which seem to regulate the release of tyramine, prevents flies from becoming more responsive to cocaine.

Whether sky-high flies can teach scientists much about human addiction remains to be seen. Only about a fifth of the people who use cocaine actually become addicted to it: the puzzle lies in understanding what distinguishes the casual user from the hard-core addict. But if the propensity to addiction is also genetically controlled in humans, it could provide a mechanism to address the problem at the cellular level, by regulating tyramine or its vertebrate equivalent. It might then be possible to treat cocaine addiction as a disease, rather than a criminal activity.



Fruit flies on the rocks

$250m is spent creating vaccines, few of which are potentially useful for poor countries where about 95% of HIV infections occur. Dr Berkley wants to make life as easy as possible for potential vaccine developers by mustering expertise and money to help companies negotiate regulatory hurdles and organise clinical trials in developing countries.

IAVI is also trying to use the tricky issue of intellectual property to expand access to new vaccines. Patents have long been a sore point between the companies which own them and developing countries (such as South Africa) which want to get their hands on nifty new medicines and resent having to pay the premiums which patent-holders expect as a reward for their innovation. IAVI will invest in drug companies if they promise to provide their vaccines to poor countries (though not rich ones) at just above manufacturing cost, rather than including the usual hefty margin. If they do not, IAVI has the right to transfer the patent to another producer. IAVI has already struck a deal with one biotech company, Alphavax of North Carolina, along these lines and is hoping to do business with large pharmaceutical firms as well. Another proposal is to allow companies that agree to develop an HIV vaccine a limited extension to their patents on blockbuster drugs in their most lucrative markets.

A different approach, being championed by MSF, is to make a virtue of the rarity of tropical diseases in the West. Since 1983 America has offered incentives in the form of tax credits and marketing monopolies to companies willing to develop drugs for "orphan" diseases, which afflict fewer than 200,000 people and so offer markets too small to attract much attention from pharmaceutical companies. The European Commission is preparing similar legislation, and Dr Trouiller of MSF is lobbying for tropical diseases to be included in it. But although orphan drug legislation has been a boon to America's biotech companies, which can use the prospect of a market of a few million dollars to lure investors, that is scarcely loose change for large pharmaceutical firms. And since only big firms can manufacture drugs in large quantities, it is crucial to engage their interest too.

A bill now before Congress could do just that. The Lifesaving Vaccine Technology Act of 1999, introduced by Nancy Pelosi, aims to encourage drug makers to develop vaccines for malaria, tuberculosis and HIV, which together kill almost 8m people each year. The legislation proposes substantial tax credits on research and development expenses, and would cost about $25m a year.

But while the bill has received backing from both politicians and industry executives for its tax credits, it may face opposition to its explicit endorsement of "tiered pricing"—the simple idea that poor countries be charged less than rich ones for drugs. In the past, American congressmen have complained that it is "unfair" that their voters should pay 100 times more for a measles vaccine than, say, a mother in Bangladesh.

Such opposition to tiered pricing alarms drug companies, according to Amie Batson, a vaccine consultant with the World Bank. Even more worrying, says Walter Vandersmissen, head of government affairs at SmithKline Beecham Biologicals, is the prospect that rich countries might allow the import of discounted drugs from poor countries, and undercut the drug industry's sales in their profitable markets. (At the moment, America

and the European Union strictly control imports of drugs made outside their borders.)

Though many in the pharmaceutical industry are impressed by these proposals, some feel that there are now too many competing "initiatives" and that they all fall short of inspiring novel drug development. Mr Vandersmissen considers them "interesting think-tank exercises". The best way to stimulate new research, he believes, is to prove that sustainable markets can be created for relatively expensive medicines already on the shelf. This is the aim of a new international consortium, the Global Alliance for Vaccines and Immunisation, to be launched next year. It brings together the World Bank, the WHO, wealthy donor countries, poor recipient ones, philanthropic organisations and the drug industry, with the aim of improving access to existing vaccines and developing new ones.

According to Geoffrey Lamb, head of "resource mobilisation" at the World Bank, one way to finance such a programme is through a global trust fund for vaccines for needy countries. But wealthy donor governments are not keen to tie up large sums of money for long periods of time on uncertain odds. A more likely prospect, in Mr Lamb's view, is "contingent lending", in which donors promise to give money and needy countries promise to buy a vaccine if and when a useful one appears.

Ultimately, says Tim Evans, director of health sciences at the Rockefeller Foundation, rich donor countries prefer to give their money to projects (such as drug donation and immunisation programmes) which show results in a couple of years, rather than put up with the long and uncertain slog of developing new medicines. But some donors are prepared to take a more long-term view. The biggest splash has been made by the Bill and Melinda Gates Foundation. Since last December, the foundation has given $50m for malaria vaccine development, $25m for AIDS vaccine research and $100m to the Gates Children's Vaccine Programme which aims to improve access to expensive new shots against hepatitis-B, *Haemophilus influenzae* and rotavirus.

Though such contributions are welcomed by international health workers, they are, in Mr Evans's view, largely "catalytic"—enough to kickstart a reaction among drug developers and public health authorities, but not enough to sustain it. He would like to see a new group of donors: multinational corporations whose business in poor countries depends on a healthy workforce, who would benefit from novel drugs for their old ailments. In the end, developing new medicines for the world's poorest will depend on appeals to both altruism and self-interest. Balancing the two may prove the toughest trick of all for the new alliances between the public and private sector. ■

Volcanoes

Now, listen carefully

CENTURIES ago, only seers and oracles could predict when a volcano was going to vent its fury. More recently, they have been replaced by electronic sensors and computer models which are, frankly, not much better at giving warning of impending eruptions. Milton Garcés, a geophysicist at the University of Hawaii in Manoa, thinks this could soon change. In some cases, he says, a volcano will tell you when it is about to blow its top—it is just a matter of listening to it in the right way.

Vulcanologists have, in fact, been listening to volcanoes for years, but not in the way that Dr Garcés suggests. Most monitoring of volcanoes happens through the ground. The sloshing of magma deep in the heart of a volcano generates rumbles, called seismic waves, through the earth. Previous attempts to predict volcanic eruptions have been based on changes in the quality of these waves from deep, high frequency quakes to more shallow, low frequency rumblings. But this approach is unreliable. The problem, Dr Garcés thinks, is that the complex structure of the earth distorts seismic waves travelling through the ground as they encounter different layers of rock and soil.

Sound waves above the ground, in contrast, pass through the air with relatively little interference, so they should be much easier to interpret. For five years, Dr Garcés and his colleagues have been listening to these external "acoustic" sounds made by volcanoes. Their latest research, about to be published in *Geophysical Research Letters*, compared seismic and acoustic monitoring of a volcano in southern Japan, and found that the sound waves gave a much clearer warning of its eruption.

Sakurajima speaks

As well as being less distorted, acoustic waves are a more direct measure of what is going on inside a volcano than seismic waves. That is because a volcanic explosion is driven by pressure changes as the volcano builds up and releases excess gas, and sound waves are nothing more than those pressure changes propagating through the air. The kinds of sound waves Dr Garcés is interested in are "infrasonic" waves, with frequencies below about 20HZ, and so beyond the range of human hearing.

In May last year, Dr Garcés and his colleagues surrounded the Sakurajima volcano with ten seismometers buried in the ground and ten microphones placed above the ground. They took readings for several days before the volcano exploded on May 19th. Two days before the explosion, there was a clear increase in the number and strength of both kinds of signals, suggesting that infrasonic signals associated with eruptions follow similar patterns to seismic signals, and can thus be used to monitor eruptions.

But when they compared the two sets of readings more closely, the researchers found the infrasonic ones to be superior. The seismic signals varied a lot from one place to another, whereas the infrasonic ones were more consistent. And just before the explosion, there were clearer changes in the character of infrasonic signals than there were in the seismic ones: the infrasonic signals switched from brief, distinct events to a sustained vibration of the atmosphere. This transition was harder to distinguish in the seismic signals, because distinct seismic events often merge into each other anyway as they resonate through the ground.

Looking at infrasonic wave patterns alone will not guarantee that volcanic eruptions can be predicted. Dr Garcés and others are also working on computer models that describe what is actually going on inside a volcano, to see if those processes produce the kinds of infrasonic waves observed. They then hope to be able to link their measurements to useful information, such as how much and what kind of stuff the volcano will spew and how powerful the eruption will be.

This approach could find widespread use. For, in order to make sure that countries comply with the Comprehensive Test Ban Treaty and do not surreptitiously set off nuclear weapons, a huge network of acoustic listening posts is being built all over the world. It will also be able to monitor misbehaving volcanoes. In another decade or so, Dr Garcés reckons that it might be possible to integrate infrasonic, seismic and other readings with a computer model to predict the time of an eruption to within a day or two. Far more reliably, in other words, than the oracles of old. ■

August 31, 1999

SENSITIVE **For U.S. Government Use Only**

South Africa
Intellectual Property Rights

ISSUE:

The SAG has undertaken to extend adequate and affordable healthcare to all South Africans. The USG supports this goal. In 1997, the South African National Assembly amended prior legislation in an attempt to ensure the supply of affordable medicines. The effect was to grant the Health Minister broad, ill-defined powers to abrogate the patent rights of pharmaceuticals companies. The pharmaceutical industry and their Congressional advocates have urged the USG to pressure the South African Government (SAG) through use of U.S. trade laws and diplomatic channels into repealing or amending the Medicines Act. At the same time, a coalition of South African and foreign pharmaceutical companies is challenging the legislation as unconstitutional in South African courts while also trying to negotiate a compromise directly with the SAG. Recently, a coalition of consumer and AIDS activists has been pressuring the USG -- especially the Vice President -- to stop pursuing the issue with South Africa in view of its HIV/AIDS epidemic.

In our efforts to resolve this issue, we have recognized that the HIV/AIDS crisis in South Africa is a special situation that may require special measures. Thus, we informed the SAG and stated publicly that while we do not believe that compromising intellectual property rights is the solution to the greater problem, contrary to our general policy, we will raise no objection to compulsory licensing or parallel importing of pharmaceuticals (described below) on the part of South Africa, as long as it is done in a way that complies with the SAG's international trade obligations under the World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS).

BACKGROUND:

Actions by the Administration

Under the Special 301 provisions of the Trade Act of 1974, the Office of the U.S. Trade Representative is required annually to identify foreign countries that deny adequate and effective protection of intellectual property rights and to issue a public report to this effect at the end of each April. South Africa was named to the Special 301 "Watch List" (the report's lowest category) in 1998 over concern about the authority granted the Minister of Health to abrogate patent rights as well as other intellectual property issues. During this year's Special 301 review, U.S. industry recommended we designate South Africa as a "Priority Foreign Country" (the report's highest category), which could have resulted in trade sanctions. We chose not to do so, however, because we had already developed a framework to resolve our differences. As a result, South Africa was maintained on the Watch List.

The framework the Administration proposed for the resolution of our differences with South Africa was through the Binational Commission, chaired by Vice President Gore and then deputy President Mbeki. The intent of the proposal was to bring together an experts group including all

relevant decision makers – trade, health, and intellectual property – to reach a mutual goal of bringing better healthcare to the people of South Africa while assuring effective and adequate protection of intellectual property. Discussions have continued since the framework's acceptance.

A number of South African officials have recently stated that the Medicines Act will only be used to compulsory license and parallel import pharmaceutical in a manner consistent with South Africa's international trade obligations. We are now working to obtain satisfactory assurances that the Medicines Act will be implemented in this manner so that this issue can be removed from our bilateral agenda.

U.S. industry has expressed concern that any government-to-government settlement at this time could undermine their efforts to negotiate a settlement with the new government.

Congress

In the closing days of last year's budget process, Congressman Frelinghuysen of New Jersey inserted into the foreign aid bill a provision that blocked U.S. aid to the central Government of South Africa until the State Department provided a report explaining the Administration's efforts to obtain the repeal of the Medicines Act. Dissatisfied with State's first report, Congress asked for a revised report. The final report contains language that portrays U.S. efforts as being more aggressive. Congressional critics of the Administration's approach and consumer and AIDS activists have now seized on this report, as well as USTR's Special 301 report, as evidence of the Administration's heavy-handedness on the issue.

On June 25, in a response to a letter from the Chairman of the Congressional Black Caucus, the Vice President responded stating that he supports "South Africa's efforts to enhance health care for its people -- including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements."

On July 21, the Office of the United States Trade Representative testified before the House Committee on Government Reform's Subcommittee on Criminal Justice, Drug Policy and Human Resources chaired by Congressman Mica. In that testimony, USTR stated that, contrary to our general approach, we will 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.

U.S. Policy

The Administration's approach to patent protection for pharmaceuticals is to ensure that the necessary incentives are provided to promote rapid innovation of new drug therapies and to safeguard the protection of the medicines that now exist. We generally do not support policies that allow for the parallel importation or compulsory licensing of pharmaceuticals because such practices compromise intellectual property rights and raise concerns about the safety and efficacy of imported drugs. Under U.S. law, compulsory licensing and parallel importing of pharmaceuticals is generally prohibited. However, the TRIPS Agreement does allow for these

practices under certain conditions. We will not object to South Africa's efforts to compulsory license and parallel import pharmaceuticals, but want South Africa to abide by the TRIPS Agreement.

Our policy approach has been responsive to both sides in this debate. On the one hand we seek to ensure that South Africa honors its international obligations with respect to intellectual property but on the other hand are demonstrating flexibility in the application of U.S. trade policy to address concerns about South Africa's HIV/AIDS crisis.

Compulsory Licensing

In this situation we are concerned that the South African Government would grant a compulsory license to one or more domestic manufacturer(s) for the purpose of allowing it (or them) to produce a patented drug for sale in the domestic market without the consent of the patent holder. TRIPS imposes a number of disciplines on compulsory licensing including, for example:

- the requirement that authorization of such use shall be considered on a case-by-case basis;
- such use shall be authorized predominantly for the supply of the domestic market;
- the right holder shall be paid adequate remuneration; and
- such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and such efforts have not been successful within a reasonable period of time.

The last requirement (but not the others) may be waived in a national emergency. However, none of these conditions are included in the Medicines Act.

Parallel Imports

Parallel imports of pharmaceuticals are pharmaceuticals that are produced by, or with the authorization of, the patent holder and intended for sale in one market, for example Kenya, but that are diverted from the designated market, away from authorized distribution channels, and imported into another market, such as South Africa, without the authorization of the patent holder. The diversion occurs in many instances because the drugs are offered for sale in the intended market at a lower price than the market to which they are diverted. It is difficult to ensure the safety and efficacy of drugs that are parallel imported because they were not handled by authorized distributors. Thus, parallel importing of pharmaceuticals is generally prohibited in the United States and the European Union as well as Kenya.

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H.R.434

Trade and Development Act of 1999 (Engrossed Senate Amendment)

SEC. 116. ACCESS TO HIV/AIDS PHARMACEUTICALS AND MEDICAL TECHNOLOGIES.

(a) FINDINGS- Congress finds that--

(1) since the onset of the worldwide HIV/AIDS epidemic, approximately 34,000,000 people living in sub-Saharan Africa have been infected with the disease;

(2) of those infected, approximately 11,500,000 have died; and

(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide.

(b) SENSE OF CONGRESS- It is the sense of Congress that--

(1) it is in the interest of the United States to take all necessary steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, especially effective global standards for protecting pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis on HIV/AIDS in sub-Saharan Africa should be the development of the infrastructure necessary to deliver adequate health care services, and of public education to prevent transmission and infection, rather than legal standards issues; and

(4) individual countries should have the ability to determine the availability of pharmaceuticals and health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic.

(c) LIMITATION ON USE OF FUNDS- Funds appropriated or otherwise made available to any department or agency of the United States may not be obligated or expended to seek, through negotiation or otherwise, the revocation or revision of any intellectual property or competition law or policy that regulates HIV/AIDS pharmaceuticals or medical technologies of a beneficiary sub-Saharan African country if the law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies and the law or policy of the country provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

TITLE II--TRADE BENEFITS FOR CARIBBEAN BASIN

Sandra Thurman 08/25/99 03:43:30 PM

Record Type: Record

To: Cheryl S. Bauerle/OPD/EOP@EOP

cc:
Subject: Activists Lock Gore Out of His Office

---------- Forwarded by Sandra Thurman/OPD/EOP on 08/25/99 03:43 PM ----------

Richard Socarides 08/25/99 03:02:35 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP@EOP

cc:
Subject: Activists Lock Gore Out of His Office

---------- Forwarded by Richard Socarides/WHO/EOP on 08/25/99 03:02 PM ----------

Doug.Case@sdsu.edu
08/24/99 02:35:00 AM

Record Type: Record

To: Richard Socarides@EOP

cc:
Subject: Activists Lock Gore Out of His Office

PRESS RELEASE -- For immediate release
CONTACTS: John Riley: (212) 795-9673
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On-site cell phones: (917) 653-7267 and (917) 797-9203

Activists Lock Gore Out of His Office,
Criticizing Proposed S. Africa AIDS Drugs Deal

Washington, DC, August 23 - Five activists were arrested today after locking down the Old Executive Office Building a block from the White House, the site of the office of Vice President Al Gore, to protest elements of a U.S.-South Africa deal on pharmaceutical access which has not yet been made public. The demonstration lasted for over an hour and

firemen were called to cut the activists' chains. The protesters, members of the group AIDS Drugs for Africa, were handcuffed together with their hands inside pipes to make it difficult to remove them from the entrance of the building.

The proposed agreement would resolve a two-year dispute-during which the U.S. has brought trade sanctions against South Africa-over a 1997 South African law allowing the country to manufacture or import inexpensive versions of high-priced U.S.-patented drugs, powers which are fully legal under World Trade Organization rules. According to the activists, leaked information indicated that Gore-the Chair of the U.S.-South Africa Binational Commission-is insisting on an agreement which would only allow South Africa to use these cost-saving measures for drugs against AIDS, not for other disesases. While the deal has not been signed, it is in the final stages of negotiation. The protesters charge that the Gore proposal would unfairly limit South Africa's right to produce and import important drugs at affordable prices, critical for a country with very restricted health care funds.

"Gore has already tried to save his reputation by asking Congress to spend $100 million on AIDS in Africa and other poor nations - none of which would even go for purchasing anti-HIV drugs," said protester Linda Lu. "This deal is a ruse as it is unlikely to pass Congress given budget caps and constraints, and is intended to appease human rights watchers while winking at pharmaceutical companies."

Since June, AIDS activists have been dogging Gore at campaign stops around the country. While Gore has repeatedly made public offers to meet with protesters, he has not responded to verbal and written requests for such a meeting.

According to the Wall Street Journal, talks to resolve the U.S.-South Africa dispute intensified soon after the first protests. The activists stated that leaked information in July had indicated that the U.S. was ready to offer South Africa a deal allowing that country to only do parallel importing (importation of inexpensive versions of drugs from sources other than the manufacturer). Then a later leak-expanding on a public statement made by Gore a week after the controversy ignited-indicated that the Administration was willing to allow compulsory licensing (domestic manufacture of patented drugs), but only if South Africa signed an agreement pledging to comply with international trade law. As a result of these leaks, the Pharmaceutical Research and Manufacturers of America increased its lobbying and Gore recently reversed his position again, insisting on an agreement which would only allow South Africa to use the parallel importing and compulsory licensing for AIDS drugs.

Shortly after the second leak, an official of the U.S. Trade Representative's office, Joe Popovich, told a Congressional hearing that the administration is not willing to relax its trade policy to allow for compulsory licensing and parallel importing. He went on to say that because of the spread of HIV, the may be willing to relax the trade policy for HIV and AIDS drugs only.

Activists say the forthcoming deal implies that this concession will be granted only to South Africa.. In recent months, American trade officials have applied negative pressure to other developing nations attempting to access AIDS medications and other life-saving treatments under provisions of the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property) Agreement.

"The U.S. signed the TRIPS agreement, and now Gore is trying to limit the exercise of its provisions," said Marshal Weaver of AIDS Drugs for Africa. "South Africa has 3 million people with HIV, and infection rates are increasing exponentially. South Africa has the right to produce generic AIDS drugs and buy from generic manufacturers. The U.S. has curbed that right."

The United States, through Gore and US Trade Representative Charlene Barshefsky, has repeatedly claimed that the South African law violates intellectual property rights.

"No American official has been able to say exactly what part of international trade agreements are being violated by South Africa. Meanwhile, the US has not interfered with parallel importing of drugs by the UK, Canada and the Netherlands," said Anna Lynne of AIDS Drugs for Africa. "The TRIPS agreement states in clear language that patents for essential resources may be circumvented when it is in the public interest in the case of national emergency. And that same agreement in no way restricts parallel importation."

South Africa cannot afford AIDS treatments at name-brand prices. Generic versions of the same medications can be produced at about one-tenth of the cost. Pharmaceutical companies, whose lobbyists are close Gore associates and who donate generously to his campaign coffers, have sued South Africa to block the 1997 Medicines Law.

Activists from the group AIDS Drugs for Africa say they will escalate their protests until the United States stops pressuring developing nations to refrain from exercising their rights. In recent weeks, two open letters have been sent to the Vice President urging him to end U.S. government pressure on South Africa. One letter was signed by a global list of over 200 public health experts, AIDS leaders, human rights, religious, labor and development leaders, and concerned citizens; the other by South Africa's HIV/AIDS Treatment Action Campaign, a coalition that mounted two large demonstrations last month at U.S. consulates in that country. Gore's obstruction of South Africa's efforts has been criticized by such prominent personalities as civil rights leader Rev. Jesse Jackson, consumer advocate Ralph Nader and syndicated columnists Arianna Huffington, Molly Ivins and David Corn. And today, an editorial in The New York Times called on the administration to change its position on this issue.

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

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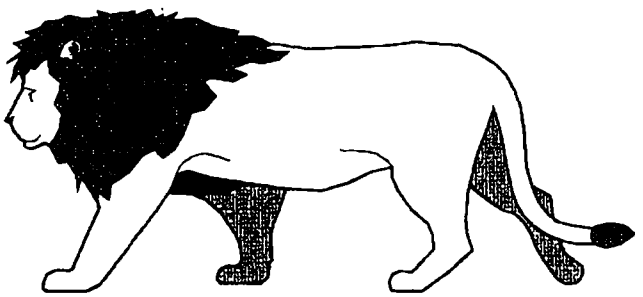
DATE: Wednesday, August 18, 1999



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

TO:

Name	Organization	Tel	Fax
B. Schwartz	USTR	395-9159	395-4505
D. DiPaolo	USTR	395-4685	395-3891
A. Robinson	USDOC	482-5148	482-5198
J. Babbitt	OVP	456-9513	456-9500
J. Urban	USPTO	(703) 305-9300	(703) 305-8885
T. Walsh	EB/IPC		647-1537
S. Thurman	White House	456-2437	456-2439
N. Carter-Foster	OES/EID	647-2435	736-7336
C. Reintsma	AID/AFR	712-4018	216-3233

SUBJECT: Press report FYI

(Note: The copy is very bad, you can access the article on the internet at www.bday.co.za)

BUSINESS DAY - AUGUST 18, 1999

STARS AND STRIPES by Simon Barber

SA between a rock and a hard place on Trips arrangement

JUSTIFYING its decision to keep SA on its list of intellectual property violators, the office of the US trade representative said in April: "SA's medicines act appears to grant the health minister ill-defined authority to issue compulsory licences, authorise parallel imports and potentially otherwise abrogate patent rights."

Last month, representative's intellectual property commissar, Joe Papovich, told a congressional committee that "contrary to our general approach, we raise no objection to compulsory licensing or parallel importing of pharmaceuticals on the part of SA, as long as it is done in a way that complies with Trips", the World Trade Organisation (WTO) agreement on intellectual property.

This was a concession. Hitherto, it had been the official policy of the US government, mandated by Congress in the Uruguay Round Agreements Act, to press Trips signatories, like SA, to provide patent protections stronger ("Trips-plus") than those they had agreed to in the treaty, Trips being an untidy compromise from the US standpoint. Under Trips, governments are specifically, though conditionally, allowed to assign patent rights to domestic third parties (compulsory licensing) for the public good and may not be challenged in the WTO if they allow patented items to be imported through channels not authorised by the patent-holder.

However, the representative's office has applied the screws to a number of countries for threatening to exercise these rights. Now, it seemed, SA was to be given a special break "contrary to our general approach".

Though not hiding its unease, the trade representative had little choice after US Vice-President Al Gore had written to James Clyburn — chairman of the congressional black caucus — that "I want you to know from the start that I support SA's efforts to enhance health care for its people, including the country's efforts to engage in compulsory licensing and parallel importing of pharmaceuticals, so long as they are done in a way consistent with international agreements".

Gore adopted this formula to inoculate himself against non-mainstream AIDS activists who were dogging his presidential election campaign with charges that he was a stooge of the the drug industry. They claimed that, as chairman of the US-SA binational commission, he was bullying Pretoria into forswearing the use of parallel imports and compulsory licensing as a means to obtain cheap AIDS medicine for SA's poor, who were therefore dying for ... want of AZT and other such death-delaying HIV palliatives.

The US drug industry was appalled by Gore's apparent wobbliness and the precedents it might set, especially since he was also suggesting that all SA had to do to satisfy official US concerns was to issue a statement approved by the trade representative's office, pledging compliance with Trips.

Not only was this an abandonment of policy, but it put Pretoria under no obligation to remove the root of all the trouble, the still potentially operative language of section 15(c) of the 1997 Medicines and Related Substances Amendments Act, which gives the country's health minister carte blanche to violate existing, Trips-compliant, SA patent law.

Section 15(c) has been challenged in the Pretoria High Court by the SA Pharmaceutical Manufacturers Association and 41 co-petitioners — among whom are several SA companies and the local subsidiaries of US and European companies.

The litigants are currently negotiating an out-of-court settlement with the health minister, Manto Tshabalala-Msimang, who raised hopes of a compromise by stating that she saw the industry as a partner rather than an antagonist, as her predecessor allegedly had done.

At a closed-door meeting last week with Gore's people, trade representative officials and White House AIDS tsarina Sandra Thurman, the US companies urged the country's administration not to do anything that would interfere with the pending court settlement in SA.

"We need to be clear this is a South African issue to be settled in SA," said participant Tom Bombelles of Pharmaceutical Research and Manufacturers of America. "It is important that the process be allowed to proceed on its own."

Bombelles' fear, though he avoided saying so for the record, was that if the US officially agreed 15(c) could live, so long as clarified by a statement and supporting regulations, the SA government would not feel obliged to relinquish the clause, whose removal, Miryenna Deeb of the SA medical association, said this week was a non-negotiable demand on the part of the litigants. Deeb argued that so long as article 15(c) survived, government could prevent drug companies asserting their rights under existing SA Trips-plus patent law.

The trade representative's office, whose constituencies are the US industry and Congress and which, though officially a White House agency, could not care a hoot about Gore's travails on the campaign trail, is refusing most pedantically to accept the draft statements Pretoria has been sending it. Meanwhile, Gore's people have suggested short-circuiting the representative's objections with a political agreement signed by Gore and President Thabo Mbeki which would be announced and presented, like Gore's earlier formula, to its officials as fait accompli. Interestingly, Trade and Industry Minister Alec Erwin is said by diplomats to be eschewing the political route, preferring to settle the matter face to face with Charlene Barshefsky, the office's head. Also, the sources say, he is not prepared to talk in the context of getting SA removed from the list, which he sees as a WTO-inconsistent unilateral US mechanism for browbeating lesser nations.

That is pregnant because the office has said its listing of SA is subject to a review — that is, negotiation next month. SA will evidently not be taking part, unless the US agrees to couch the context differently.

Erwin's approach is correct, even if a little brash about the listing process, which virtually all US trading partners have to endure. The important point is that a deal with the representative, whose interests and policy are permanent until Congress tells it otherwise, is far more valid than one with a presidential candidate who lets himself be cowed by a handful of noisy but unrepresentative AIDS activists. Gore may be more amenable at this moment than the trade representative. However, Gore is impermanent.

The trade representative, whoever appoints its boss, is forever.

Health and Trade Announcement
December 1, 1999

Question: What are the implications of the agreement between USTR and HHS?

Answer:

- Under this new arrangement there will be a more directed interaction between USTR and HHS on health-related intellectual property issues.

- When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.

- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property, consistent with international trade treaties, is sufficiently flexible to respond to public health crises.

Question: Does this mean USTR is globalizing its recent understanding with South Africa?

Answer:

- Through consultations with HHS, USTR will ensure that the unique health demands of individual nations are given careful consideration in the application of U.S. trade policy.

- We will make determinations on a case by case basis after a thorough analysis of each individual situation once a foreign government has expressed concerns to us.

Question: What was the understanding with South Africa?

Answer:

- Under the understanding both governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. This will permit South Africa to engage in compulsory licensing, parallel importing, *inter alia,* consistent with existing international trade law.

Question: What is the Administration's response to claims that the TRIPS Agreement should be amended because it conflicts with developing countries' efforts to address health issues?

Answer:

- We do not believe that TRIPS interferes with health policy. In fact, HHS and USTR agree that sound public health policy and intellectual property protection are mutually supportive. As seen in the case of South Africa, TRIPS allows the flexibility for developing countries to respond to public health crises.

Sr Comp
Lic.

To: Ms. Sandra Thurman

Suite Room 1509

212-417-4082

From Lon Tom Murray

2 pages

HHS INTERNAL DOCUMENT

Questions and Answers, Protection of Intellectual Property and Health Policy

Background: United States Trade Representative Charlene Barshefsky and Health and Human Services Secretary Donna E. Shalala today announced their intention to develop a cooperative approach on health-related intellectual property matters to ensure that the application of U.S. trade law related to intellectual property by USTR remains sufficiently flexible to respond to public health crises. Recognizing that health emergencies may require special measures, USTR and HHS are working together to establish a process for analyzing the health issues that arise in the application of U.S. trade-related intellectual property law and policy. The exact process by which HHS will analyze and evaluate USTR requests for assistance has not yet been fully described.

Does this approach signal a shift in US Trade Policy to be more accommodating of health issues such as AIDS?

I would refer this and any other questions on Trade Policy to the USTR. DHHS will simply provide consultation to USTR at its request.

Did USTR come to HHS with this idea or did HHS approach USTR?

USTR approached HHS, and a dialogue was begun between HHS and USTR.

What will this new arrangement actually mean in terms of HHS input into US Trade Policy?

USTR may receive requests from some countries to relax protection of intellectual property to make drugs more available in a public health emergency. USTR will consult with HHS on such a request, and HHS, after reviewing the situation, will provide information as to the nature of the public health problem. USTR will consider this information, but only the USTR will decide to what extent the application of US trade law might be modified.

Will HHS certify or otherwise confirm that an actual health emergency exists in a specific country?

No. HHS will provide expert consultation on the pertinent health issues in that country, and it will be up to USTR to decide whether or not a flexible approach to intellectual property protection will be applied.

Will this possibly mean a modification of the TRIPS agreement?

No. The United States is a signatory to TRIPS, but we believe that US Trade Law and TRIPS are sufficiently flexible to permit sound public health approaches to a given

problem in any country with whom the U.S. is a trading partner. We believe that public health policy and intellectual property protection can be mutually supportive.

Who will actually provide information to the USTR on health-related trade issues?

The Department will draw on expertise from various HHS agencies in consultation with multi-lateral partners. The review and response will be coordinated through the Office of International and Refugee Health, a staff office to the Secretary. It is likely that CDC, NIH, HRSA, and FDA will be the main sources of expertise.

Was the recent agreement worked out with South Africa a result of a consultation process between USTR and HHS?

No. The USTR acted independently in the case of South Africa. However, it was as a result of the recent events in South Africa that the need for health input in trade policy became apparent.

Could outcomes resulting from USTR requests to HHS related to international trade policy affect domestic issues?

It is possible that certain of the problems identified as emergencies abroad may be similar to those found in this country. However, the solutions are likely to be quite different, and we do not anticipate that decisions made by USTR in the consideration of health emergencies in other countries will be applicable here in the United States.

It is likely that many nations will consider many different problems as health emergencies. Will there be a separate office set up in HHS to handle the subsequent consultation requests from USTR?

No. At this point, HHS will provide analyses on an ad hoc basis and then later determine if additional resources will be needed to respond to requests from USTR. We are announcing today the intention to work together, and we are currently developing the review and response process.

What will constitute a public health emergency?

As we have stated, we have announced our intention to develop a process of responding to USTR requests for information. We will be working on this process with USTR in the coming weeks.

What will be the impact of this consultation process be on the NIH's policies for protection of US-developed intellectual property and its' licensing to private parties?

None whatsoever.

Health and Trade Announcement
December 1, 1999

Question: What are the implications of the agreement between USTR and HHS?

Answer:

- Under this new arrangement there will be a more directed interaction between USTR and HHS on health-related intellectual property issues.

- When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.

- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property, consistent with international trade treaties, is sufficiently flexible to respond to public health crises.

Question: Does this mean USTR is globalizing its recent understanding with South Africa?

Answer:

- Through consultations with HHS, USTR will ensure that the unique health demands of individual nations are given careful consideration in the application of U.S. trade policy.

- We will make determinations on a case by case basis after a thorough analysis of each individual situation once a foreign government has expressed concerns to us.

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Answer:

- Under the understanding both governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. This will permit South Africa to engage in compulsory licensing, parallel importing, *inter alia*, consistent with existing international trade law.

Question: What is the Administration's response to claims that the TRIPS Agreement should be amended because it conflicts with developing countries' efforts to address health issues?

Answer:

- We do not believe that TRIPS interferes with health policy. In fact, HHS and USTR agree that sound public health policy and intellectual property protection are mutually supportive. As seen in the case of South Africa, TRIPS allows the flexibility for developing countries to respond to public health crises.

Question: What is the U.S. view of proposals to patents on drugs designated by the WHO as essential drugs?

Answer:

- o We oppose proposals to deny patents on drugs designated by the WHO as essential. The vast majority of the drugs designated as essential by the WHO are not under patent anywhere in the world. ~~Clearly, patent protection is not standing in the way of access to these essential drugs.~~

Question: We understand that the Thai Government is under pressure to issue compulsory licenses on HIV drugs such as ddI.

Answer:

- o The Thai Government has not approached us about the situation you describe. If the Thai Government does indeed approach us on this issue, USTR will certainly consult closely with them and with HHS before determining the best course of action.

Question: Isn't it true that the USG imposed trade sanctions on Thailand in 1998 because it attempted to reduce the costs of medicines?

Answer:

- o Recently there have been articles stating that Thailand enacted a patent law in 1992 in response to U.S. threats to restrict trade preferences.
  - ~~In fact,~~ In 1993 the USG restored certain trade preferences to Thailand that had been revoked in 1988, pursuant to U.S. trade law, over concerns about the lack of intellectual property protection in Thailand.

- o It has also been inaccurately stated that the USG in 1998 threatened to increase tariffs on imports of Thai wood products and jewelry.
  - In fact, in 1998, the USG and Thailand agreed to a mostly copyright oriented IPR action plan which served as the basis for the restoration of duty-free treatment for Thai wood furniture and jewelry. Thailand agreed to take steps to comply with its TRIPS obligations, including to eliminate TRIPS inconsistent- compulsory licensing provisions.
  - This action in 1998 restored benefits to Thailand (mentioned above) that had been revoked in 1988.

- O It is important to note that the 1998 IPR action plan and restoration of certain benefits as the USG's attempt to focus the Thai Governments attention on the growing IP problem and to promote cooperation between our governments to improve IPR protection.

I COMO
USAS.

Press Release on USTR Letterhead USTR/HHS draft 11/24/99

THE PROTECTION OF INTELLECTUAL PROPERTY AND HEALTH POLICY

United States Trade Representative Charlene Barshefsky and Health and Human Services Secretary Donna E. Shalala today announced their intention to develop a cooperative approach on health-related intellectual property matters to ensure that the application of U.S. trade law related to intellectual property by USTR remains sufficiently flexible to respond to legitimate public health crises. In addition, Ambassador Barshefsky announced the removal of the Republic of South Africa from the special 301 "watch list."

"Recent developments in AIDS treatments give us all hope for helping those already living with HIV and for preventing new infections by interrupting maternal to child transmission. The challenge of making treatments a viable option for those who need them is one that eludes simple answers" said Secretary Shalala. "The United States will continue to work with its partner nations, multilateral organizations, industry, and affected communities to improve access to treatment."

"A modern patent system helps promote the rapid innovation, development, and commercialization of effective and safe drug therapies - therapies such as those now being deployed in the war against HIV/AIDS" said Ambassador Barshefsky. "Secretary Shalala and I believe that sound public health policy and intellectual property protection are, and must continue to be, mutually supportive."

Recognizing that health emergencies may require special measures, USTR and HHS are working together to establish a process for analyzing and evaluating the health issues that arise in the application of U.S. trade-related intellectual property law and policy. When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis in that country, USTR will seek and give full weight to the advice of HHS regarding the health considerations involved. This process will permit the application of U.S. trade-related intellectual property law to remain sufficiently flexible to react to public health crises brought to the attention of USTR. It will also ensure that the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are respected.

TRIPS provides minimum standards for protecting intellectual property rights. For example, TRIPS requires WTO members to grant time-limited exclusive rights through patents, while permitting use without the authorization of the right holder (e.g., compulsory licensing) under certain limited circumstances and conditions. The provisions of the TRIPS Agreement are being phased-in over time. January 1, 2000, is an important implementation date for developing countries. The Agreement takes special note of the least-developed countries; obligations on these countries generally do not apply until 2006.

Ambassador Barshefsky also announced that she is removing South Africa from the special 301 "watch list." The recent bilateral understanding developed with South Africa illustrates the complementary nature of sound public health and intellectual property policies. Under the September 17, 1999, understanding, both Governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. South Africa agreed that it would address health needs in a manner that fully protects intellectual property rights. Ambassador Barshefsky took this action as a result of this understanding, as well as other steps South Africa has and is taking to improve further the protection of intellectual property.

I. Comp. Lic.

Heath and Trade Announcement
December 1, 1999

Question: How does this announcement with HHS change things?

Answer:

- Under this new arrangement there will be a much more intensified interaction between USTR and HHS health-related intellectual property issues.
- When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.
- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property is sufficiently flexible to respond to legitimate public health crises.

Question: Does this mean USTR is "globalizing" its recent understanding with South Africa?

- It means that through our consultations with HHS we will determine if the South Africa type of understanding is warranted with other counties.
- We will make this determination on a case by case basis after a thorough analysis of each individual situation once a foreign government has expressed concerns to us.

Question: What was the understanding with South Africa?

- Under the understanding both governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. South Africa agreed that it would address health needs in a manner that fully protects intellectual property rights.

Question: What is the Administration's response to claims that the TRIPS Agreement should be amended because it conflicts with developing countries efforts to address health issues?

- First, we reject the notion that TRIPS in anyway interferes with sound health policies. In fact, HHS and USTR are in total agreement that sound public health policy and intellectual property protection are mutually supportive. Without IP protection, the incentive to create innovative new drugs is seriously threatened.
- Second, it cannot be established that TRIPS has had a negative impact on developing countries' efforts to address health crises, developing countries are not even obligated to implement TRIPS until January 1, 2000.

- Many countries that are facing health crises do not offer patent protection for pharmaceuticals, therefore patent protection can hardly be the cause of the problem.

Question: What is the U.S. view of proposals to patents on drugs designated by the WHO as essential drugs?

- We oppose proposals to deny patents on drugs designated by the WHO as essential. The vast majority of the drugs designated as essential by the WHO are not under patent anywhere in the world. Clearly, patent protection is not standing in the way of access to these essential drugs.

We don't have official position

- Senior officials at the WHO and at HHS do not support this proposal and do not feel it would have any positive impact on access to essential drugs.

Question: We understand the Thai Government is under pressure to issue compulsory licenses on HIV drugs such as DDI.

- The Thai Government has not approached us about the situation you describe.

- When and if the Thai Government approaches us on this issue, we will certainly consult closely with them and HHS to determine the best course of action.

Question: Isn't it true that the USG imposed trade sanctions on Thailand in 1998 because it attempted reduce the costs of medicines?

- Recently there have been articles stating that Thailand enacted a patent law in 1992 in response to U.S. threats to restrict trade preferences.

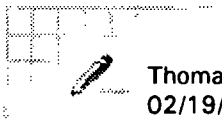
  - In fact, in 1993 the USG restored certain trade preferences to Thailand that had been revoked in 1988, pursuant to U.S. trade law, over concerns about the lack of intellectual property protection in Thailand

- It has also been inaccurately stated that the USG in 1998 "threatened to increase tariffs on imports of Thai wood products and jewelry."

  -- In fact, in 1998 the USG and Thailand agreed to a mostly copyright oriented "IPR action plan" which served as the basis for the restoration of duty-free treatment for Thai wood furniture and jewelry. Thailand agreed to take steps to comply with it TRIPS obligations, including to eliminate TRIPS inconsistent compulsory licensing provisions.

  -- This action in 1998 restored benefits to Thailand (mentioned above) that had been revoked in 1988.

- It is important to note that the 1998 "IPR action plan" and restoration of certain benefits was the USG's attempt to focus the Thai government's attention on the growing IP problem and to promote cooperation between our government to improve IPR protection.



Thomas M. Rosshirt @ OVP
02/19/99 02:17:15 PM

Record Type: Record

To: Sandra Thurman/OPD/EOP

cc:
Subject: VP's remarks on AIDS

Sandy:

On Thursday in South Africa, the Vice President gave a very moving answer to a question on AIDS in at his press conference with South African Deputy President Thabo Mbeki. The passion of his response doesn't come through in the text with the same power as it did in delivery, but I thought nonetheless you might like to see the remarks, and might have a few ideas for pushing them out.

Tom

Gore: If I could respond also. In the United States of America, the AIDS epidemic really began to hit home around 1981. Our national leaders did not really raise the alarms at that time. There are many reasons for it; I won't go into it lest my comments be misinterpreted. The point I'm trying to make is a simpler point; we did not ring the alarm bells. Our national leadership did not raise the roofs in trying to alert people to what was going on. It took some time before that happened. Now, finally, we have begun to see a little bit of progress, but we're not out of the woods yet. Here in South Africa this epidemic, which is really a pandemic, has hit with hurricane force. South Africa is blessed with a leader in Thabo Mbeki who has been speaking out forcefully, boldly and often. In order for South Africa to turn the corner, his leadership must be joined with leadership from every sector of society. Please forgive me, as a non-South African, for speaking in this way about a matter affecting your country. I'm wearing this pin because my friend, Thabo Mbeki, gave it to me this morning after a very lengthy conversation we had about HIV/AIDS last night. This is a crisis for South Africa. Listen to what Deputy President Mbeki is saying and ask the leaders of entertainment and sports and business and labor and every sector of society: Why aren't you also adding your voice to that of the Deputy President? Minister Zuma has been leading the way. Our Surgeon General, David Satcher, engaged in a very interesting and illuminating discussion with her in our Commission meeting today. Secretary Shalala, from the United States, has been actively involved in the health committee's work as well. This is a problem that must be faced at a new level of urgency. And by the way, it is not only in South Africa. South Africa keeps good statistics. Neighboring countries may not in the same way. This is a regional epidemic and a worldwide pandemic that must be faced with the kind of urgency that Deputy President Mbeki has been bringing to it.

E-COMP licensing

May 10, 2000

EXECUTIVE ORDER

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release May 10, 2000

EXECUTIVE ORDER

- - - - - - -

ACCESS TO HIV/AIDS PHARMACEUTICALS
AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act (42 U.S.C. 2421), and section 104 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b), and in accordance with executive branch policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Section 1. Policy. (a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa.

Sec. 2. Rationale: (a) This order finds that:

(1) since the onset of the worldwide HIV/AIDS epidemic, approximately 34 million people living in sub-Saharan Africa have been infected with the disease;

(2) of those infected, approximately 11.5 million have died;

(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and

(4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

(b) In light of these findings, this order recognizes that:

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis of HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective United States response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and remove the stigma of the disease, and should place a priority on basic health services that can be used to treat opportunistic infections, sexually transmitted infections, and complications associated with HIV/AIDS so as to prolong the duration and improve the quality of life of those with the disease;

(6) an effective United States response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease;

(7) the innovative capacity of the United States in the commercial and public pharmaceutical research sectors is unmatched in the world, and the participation of both these sectors will be a critical element in any successful program to respond to the HIV/AIDS crisis in sub-Saharan Africa;

(8) the TRIPS Agreement recognizes the importance of promoting effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health;

(9) individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations; and

(10) successful initiatives will require effective partnerships and cooperation among governments, inter-national organizations, nongovernmental organizations, and the private sector, and greater consideration should be given to financial, legal, and other incentives that will promote improved prevention and treatment actions.

Sec. 3. Scope. (a) This order prohibits the United States Government from taking action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. However, this order does not prohibit United States Government officials from evaluating, determining, or expressing concern about whether such a law or policy promotes access to HIV/AIDS pharmaceuticals or medical technologies or provides adequate and effective intellectual property protection consistent with the TRIPS Agreement. In addition, this order does not prohibit United States Government officials from consulting with or otherwise discussing with sub-Saharan African governments whether such law or policy meets the conditions set forth in section 1(a) of this order. Moreover, this order does not prohibit the United States Government from invoking the dispute settlement procedures of the World Trade Organization to examine whether any such law or policy is consistent with the Uruguay Round Agreements, referred to in section 101(d) of the Uruguay Round Agreements Act.

(b) This order is intended only to improve the internal management of the executive branch and is not intended to, and does not create, any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

WILLIAM J. CLINTON

THE WHITE HOUSE,
May 10, 2000.

# # #

Back to summary page

I - comp. lic

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*** TX REPORT ***
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OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: June Shih
FROM: Cheryl
COMPANY:
DATE:
FAX NUMBER: 6-6244
TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:
RE:

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

NOTES/COMMENTS:

Attached please find information on compulsory licensing and info from the UN on the children who will be on stage with the First Lady.

Sandy will prepare additional talking points on compulsory lic/South Africa when she arrives in New York.

Many thanks!

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

In September, USTR announced that we had reached a common understanding with South Africa which resulted in the setting aside of long-held differences related to patent protections for intellectual properties as they pertain to pharmaceuticals. At the center of the debate was South Africa's intent to implement compulsory licensing and parallel importation of pharmaceuticals to expand access to affordable medicines. USTR has generally opposed these practices believing they infringe on the rights of patent holders and undercut economic incentives for the development of new drugs.

South Africa reaffirmed that any future use of these practices would be in full compliance with its obligations under the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In light of South Africa's unique circumstances, including the immediate dire impact of the HIV/AIDS crisis, USTR agreed to voice no further objections to South Africa's intent to implement these practices.

Public health organizations and activist groups seized upon this issue and are currently demanding that USTR lift its opposition to these practices for all nations. Until now, USTR recognized the South Africa solution as a special case, which required special measures. Yet in conjunction with the framing of the resolution of our difference with South Africa, USTR sought to develop a cooperative approach with HHS concerning health-related intellectual property matters to ensure that the application of U.S. trade law and policies remain sufficiently flexible to respond to legitimate public health crises.

On December 1st, USTR and HHS will jointly announce the results of their efforts. The agreement reached between the agencies calls for USTR to consult with HHS, when a foreign government expresses concern that U.S. trade law or policy related to intellectual property significantly impedes its ability to address a health crisis. USTR pledges to seek and give full weight to the advice of HHS regarding the international health considerations involved. While this approach was developed specifically with the global HIV/AIDS crisis in mind, it is not limited solely to addressing that crisis.

Compulsory Licensing – refers to the use of a patent without the authorization of the patent holder, including use by government or third parties authorized by government. TRIPS imposes a number of specific and restrictive obligations related to compulsory licensing.

Parallel Importing – refers to the importing of genuine products without the authorization of the patent holder. Parallel importing permits the importation of a good from any authorized distributor worldwide, rather than limiting transactions solely through a single authorized distribution channel.

KHOMSAN SANG-SUE-MOON

Age: 14 years

Address: 7/1 Baan Mae Kee, Moo 3, Pa Sang Sub-District
Mae Chan District, Chiang Rai Province 57110, Thailand

Both parents died of AIDS. Khomsan now lives with his uncle and is in Grade 8 (the second year of secondary school). Khomsan represents not only a case of AIDS orphan but also of a child from broken family. He, however, has a very good support from his uncle. He is supported by UNICEF through their district-based project for caring for children affected by AIDS.

Author: Abigail Bing <abing@fenton.com> at Internet
Date: 18/08/1999 6:32 PM
Normal
TO: nblca@aol.com at INTERNET, Graciela Hall at UNHQ16, puiccij@un.org at INTERNET, ddesantis@unicef.org at INTERNET, jcarmichael@unicef.org at INTERNET
CC: mark@[199.245.22.2] at INTERNET
Subject: Precious Thomas
---------- Message Contents

Hello,

FYI, below find a Washington Post feature article from today, reporting on the life of Precious Thomas - the 8 year old girl who will participate in the World AIDS Day event at the UN. She sounds like an amazing person who will add significantly to the event.

A Precious Child With a Special Burden

By Lisa Frazier
Washington Post Staff Writer
Wednesday, August 18, 1999; Page A1

Precious Thomas was 2 years old and too tiny to reach the microphone from her seat next to the disc jockey at a D.C. gospel radio station.

Looking like a pretty brown doll in a frilly dress, matching hair bows and socks, she climbed onto her mother's lap, donned a headset and delivered her speech.

"I have a bad bug in my body," she began. "The bug makes me sick."

It was the first time that Precious, who lives with her mother, Rocky Thomas, in District Heights, talked publicly about life with HIV, the virus that causes AIDS. But on that Saturday morning in 1993, the articulate child with the frightening, fatal illness started down the road to an unlikely kind of celebrity.

In the Washington area, Precious, now 8, has become the public face of children with AIDS. With her hair pulled into thick, black twists and her narrow face framed by wire-rimmed glasses, she has appeared on posters and postcards. She has been swooped into the arms of more politicians, entertainers, activists and athletes than she can recognize. Speaking requests are so frequent that she has red-and-white business cards.

Precious is in demand, in part, because she is African American. HIV and AIDS have spread rapidly and disproportionately among African Americans, and nowhere is the gap more evident than among the children younger than 12 who have been infected.

Children make up a small percentage of the total AIDS caseload. But of the 4,358 AIDS cases reported among children younger than 12 in the United States through December 1998, nearly 57 percent were among African Americans. Twenty-three percent were among Hispanics.

In the District, the proportions are even more startling. All but three of the 168 AIDS cases reported among children in the same time frame were among African Americans.

As with adults, new medical treatments have extended the lives of infected children. With a new regimen that involves giving the drug AZT to pregnant women infected with HIV, fewer children have been born with the virus in recent years.

But despite laws designed to prevent the isolation and harassment that made headlines in the 1980s, the disease still carries a dreaded stigma. In many families, the secret is often guarded so closely that the truth is hidden even from the infected child, medical professionals say.

Secrecy was not in Rocky Thomas's nature.

When she learned that the 1-year-old girl she planned to adopt was HIV-positive, she shared the burden with family, friends and church. She also taught Precious about the "bad bug."

"When they're sticking her and taking her blood, she needs to know what's happening to her," Thomas said.

Part of Precious's appeal is this: Her innocence can soften even the most judgmental hearts. She can win access to places where talk of HIV and AIDS are generally off-limits -- such as African American churches.

Ask Precious why she gets so much attention, and she will tell you.

"Because I have HIV, and I talk about it," she said.

But sometimes, the load can get pretty heavy for an 8-year-old girl who can't help wondering whether she will have a future.

A Loving Home

"You forgot something, little girl," PaPa said, as Precious dashed into her family's apartment from school and headed to the refrigerator.

Dressed in blue shorts and a white shirt, her school's summer uniform, she rushed to the dining room table, threw her arms around his neck and pressed her face against his.

PaPa is 77-year-old Nathaniel Walker, who shares a Prince George's County apartment near the District with Precious and his granddaughter, Thomas.

Named Sheree Marbella Henson at birth, Precious was 2 weeks old when her drug-addicted birth mother handed her to Walker's daughter, Linda, at the time also a drug addict.

Nathaniel Walker felt sorry for the premature baby. He often drove to his daughter's home, wrapped the child in blankets and took her home with him. He and Thomas kept her for days at a time. One day, Thomas just never sent her back.

"It's hard to believe I could fit that little girl right here when we first got her," Walker said, extending his right hand as if to catch a ball.

Thomas was a newlywed who lived with her grandfather and four children -- two stepchildren and two cousins she was helping to raise.

With brown skin and deep brown eyes, the new baby was pretty and precious. So that's what everyone started calling her.

For Precious's first birthday, Thomas, a beautician, planned a Saturday bash. She bought balloons and favors, sent invitations and ordered a cake.

But the day before the party, an aunt who was baby-sitting Precious called from a hospital emergency room. Precious was sick.

Thomas rushed to her adoptive daughter's side. Four of

her customers -- some with hair still wet -- tagged along. Precious had pneumonia. The next week, Thomas learned that Precious was infected with HIV.

"I was numb," Thomas said. "All I could think about was death."

A less committed adoptive mother might have backed out of the child's life. Instead, while Precious was in the hospital, Thomas finalized the adoption.

In an odd way, Thomas had been prepared for this day. On television once in the late 1980s, she had seen Hydeia Broadbent, a beautiful African American child, then about 5, with puffy cheeks and a frilly lace dress. Hydeia, who has AIDS, spoke eloquently about the "bad bug" in her body.

Thomas had never seen an African American parent or child speak out in such a way. Hydeia and her mother left an impression, and Thomas eventually became friends with the Broadbents.

In her first few years of battling the disease, Precious was in and out of the hospital regularly. Doctors prescribed a liquid form of AZT, a bitter elixir that Precious strongly disliked. To help make the routine easier, family members would gather around Precious, clap and sing: "Medicine time, medicine time, Precious, it's your medicine time."

"She'd take her medicine and start clapping," Thomas recalled.

By age 2, curious and smart, Precious was learning to read. She memorized easily. She could recite the 39 books of the Old Testament and the parts of the digestive system. She also could explain that the "bad bug" was destroying her immune system.

That amazed Tracy Morgan, a gospel radio announcer, who stopped by Thomas's home one day in 1993 to get her hair styled. She knew little about AIDS, but Precious made her want to learn.

"No one in my family had experienced it," Morgan said. "Then she came into my life. So, I began educating myself and pretty much became a voice

speaking about it on the airwaves myself."

Before leaving that day, Morgan had some advice for Thomas: "We have got to get this child into the churches and on the radio," she said.

A Special Child

The glittery phase of the little girl's journey has been recorded in a blue plastic scrapbook:

Pictures with President Clinton, civil rights icon Rosa Parks, Attorney General Janet Reno, Nation of Islam leader Louis Farrakhan and NFL quarterback Warren Moon. Backstage meetings with entertainers Patti LaBelle, Lola Falana and Brian McKnight. Dinner with the late singer Phyllis Hyman.

It all began with the radio interview Morgan set up. Precious was invited to speak at one church, then another. AIDS organizations began calling.

"Hello, my name is Precious Thomas," she would say, opening her speech. "I am special for many good reasons. I am a child of God. My family loves me very much, and I am a beautiful, proud African American young lady. I am also special for one not-so-good reason. I am HIV-positive."

At first, Thomas rarely turned down invitations. Like the Broadbents, she wanted Precious to raise awareness about HIV and AIDS, especially among African Americans.

"I took a stand," she said. "I saw children in the hospital who were absolutely isolated. I couldn't do that to her. If you were going to be part of her life, you were going to be part of her life, whether she had the virus or not. I have never regretted that decision."

Besides, she said, Precious seemed comfortable in the spotlight. But at times, the girl couldn't help acting her age.

During a speech before the Congressional Black Caucus last year, Precious revealed that she was taking a serum that had not been approved by the Federal Drug Administration. The serum, she said, had improved

her health. Reporters gathered around her for a comment.

As the media geared up for a profound sound bite, Precious flashed her eyes at Thomas and said: "Mommy, I just need to go to the bathroom."

The interview was done.

Many groups have been charitable to Precious. The Children's Miracle Network sent her to Disney World. The Make-a-Wish Foundation gave her a birthday party at a Lanham restaurant and sent her and six family members on a Disney cruise to the Bahamas in July. Precious also was chosen to attend Camp Heartland, a safe haven outside the Twin Cities in Minnesota for children affected by AIDS.

But these days, Thomas says "no" more often to speaking requests. She set up a trust fund for Precious and bought business cards that list the child as a motivational speaker. Without a job or support from her ex-husband, Thomas said, she struggles to pay her bills.

She gave up her beauty business, she said, because caring for Precious is a full-time job. Precious is enrolled in a clinical drug trial at the National Institutes of Health in Bethesda, and the two of them frequently spend a week at a time there.

"No institution in the world is going to understand that every time my baby is sick, I have to go," Thomas said.

But Thomas and her friends say that some groups and individuals have taken advantage of Precious. Last year, a church advertised that a gospel concert would benefit Precious, but she never saw a dime, Thomas said.

"All we get is promises," Thomas said. "I try to do things with Precious to let her help this one or that one, but who's helping her?"

Precious receives Social Security, which helps to cover her private school tuition and dance lessons.

For the past year, Precious has been energetic and healthy. On any given afternoon, she is romping in the playground behind the apartment, climbing up and down the top bunk in her room, running through the house -- all

activities she could barely handle last summer. Small for her age, she wears a girl's size 5. Last summer, a toddler's size 4 was baggy.

Precious knows how to take her own medicines, a handful of pills five times a day -- at 5 and 7 a.m. and 3, 5 and 11 p.m. "I have gotten used to it," she says.

But how long the child can survive is uncertain.

"We have many, many kids born with HIV, living into their teens and beyond," said Pauline Thomas, coordinator of the Pediatric HIV/AIDS Surveillance Project for the New York City Department of Health. "The kids benefit from new treatments. But we don't know yet what their survival rate is."

When asked about her fears recently, Precious, who had been playful just minutes earlier, got quiet.

"I don't like to bring it up," she said, standing in the parking lot outside her home. "I don't want to say it."

She studied her feet, twirled her thumbs. She turned the question on the one who asked it:

"If you had HIV, what would be the scariest thing?" she asked.

Silence.

"People die from it," she said finally, staring at the pavement.

She never looked up.

Back to the top

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I - Intllctual Prop.

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Office of Services, Investment and Intellectual Property

To: NAME	AGENCY	PHONE	FAX
Sandra Thurman		62437	62438

From: Joseph Papovich (Section 19)

Phone: 395-4510_____ Return Fax: (202) 395-3891

If you have any problems receiving this fax call (202) 395-4510

Sandy, attached is the draft USTR/HHS press release. As we discussed, I'd appreciate it if you did not share this outside the government before the event. I spoke with Tom Novotny at HHS today and he will call you on Monday. Claude Burcky and I will be in Seattle next week and will be staying at the Madison Renaissance (206) 583-0300. We should also be reachable on Internet e-mail Jpapovich@ustr.gov and cburcky@ustr.gov. If cell phones will be working in Seattle, Claude can be reached at 202-329-7289.

Press Release on USTR Letterhead

THE PROTECTION OF INTELLECTUAL PROPERTY AND HEALTH POLICY

United States Trade Representative Charlene Barshefsky and Health and Human Services Secretary Donna E. Shalala today announced their intention to develop a cooperative approach on health-related intellectual property matters to ensure that the application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to legitimate public health crises. In addition, Ambassador Barshefsky announced the removal of the Republic of South Africa from the special 301 "watch list."

"Recent developments in AIDS treatments give us all hope for helping those already living with HIV and for preventing new infections by interrupting maternal to child transmission. The challenge of making treatments a viable option for those who need them is one that eludes simple answers" said Secretary Shalala. "The United States will continue to work with its partner nations, multilateral organizations, industry, and affected communities to improve access to treatment."

"A modern patent system helps promote the rapid innovation, development, and commercialization of effective and safe drug therapies - therapies such as those now being deployed in the war against HIV/AIDS" said Ambassador Barshefsky. "Secretary Shalala and I believe that sound public health policy and intellectual property protection are, and must continue to be, mutually supportive."

Recognizing that health emergencies may require special measures, USTR and HHS are working together to establish a process for analyzing and evaluating health issues that arise in the application of U.S. trade-related intellectual property law and policy. When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis in that country, USTR will seek and give full weight to the advice of HHS regarding the health considerations involved. This process will permit the application of U.S. trade-related intellectual property law to remain sufficiently flexible to react to public health crises brought to the attention of USTR. It will also ensure that the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are respected.

TRIPS provides minimum standards for protecting intellectual property rights. For example, TRIPS requires WTO members to grant time-limited exclusive rights through patents, while permitting use without the authorization of the right holder (e.g., compulsory licensing) under certain limited circumstances and conditions. The provisions of the TRIPS Agreement are being phased-in over time. January 1, 2000, is an important implementation date for developing

countries. The Agreement takes special note of the least-developed countries; obligations on these countries generally do not apply until 2006.

Ambassador Barshefsky also announced that she is removing South Africa from the special 301 "watch list." The recent bilateral understanding developed with South Africa illustrates the complementary nature of sound public health and intellectual property policies. Under the September 17, 1999, understanding, both Governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. South Africa agreed that it would address health needs in a manner that fully protects intellectual property rights. Ambassador Barshefsky took this action as a result of this understanding, as well as other steps South Africa has and is taking to improve further the protection of intellectual property.

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