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THE WHITE HOUSE
WASHINGTON

April 3, 2000

Victoria L. Sharp, M.D.
Director
HIV/AIDS
St. Luke's-Roosevelt Hospital
1000 Tenth Avenue, 1436
New York, NY 10019

Dear Dr. Sharp:

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Ingrid M. Duran
Executive Director
Congressional Hispanic Caucus Institute
504 C Street, N.E.
Washington, D.C. 20002

Dear Ms. Duran:

I am sorry that you were unable to make it to the Presidential Advisory Council on HIV/AIDS meeting. You were certainly missed!

It was a good meeting even though we bombarded the members with a tremendous amount of information in a very short time. I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Ignatius Bau, Esq.
Policy Director
Asian and Pacific Islander American Health Forum
942 Market Street, Suite 200
San Francisco, CA 94102

Dear Mr. Bau: Ignatius

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Stuart C. Burden
Senior Program Officer
Program on Global Security and Sustainability
John D. and Catherine T. MacArthur Foundation
140 South Dearborn Street, Suite 1100
Chicago, IL 60603-5285

Dear Mr. Burden: Stuart

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Stephen L. Boswell, M.D.
Executive Director
Fenway Community Health Center
Seven Haviland Street
Boston, MA 02115

Dr. Boswell Stephen —

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Joseph A. Cristina
Founder and Board Chair
Children Affected by AIDS Foundation
6033 West Century Blvd., Suite 260
Los Angeles, CA 90045

Dear Mr. Cristina: Joe

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

Big Hugs!

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Thomas Patrick Healy
40 Fifth Avenue
New York, NY 10011

Dear Mr. Healy: Tom -

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director

Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Cynthia Gomez, Ph.D.
Assistant Professor
Center for AIDS Prevention Studies
University of California, San Francisco
74 New Montgomery Street, Suite 600
San Francisco, CA 94105

Dear Dr. Gomez:

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Ms. Caya B. Lewis
National Health Coordinator
National Association for the Advancement of Colored People
4805 Mount Hope Drive
Baltimore, MD 21215

Dear Ms. Lewis: Caya

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Brent Tucker Minor
Director
Community Relations and Public Funding
Food and Friends
58 L Street, SE
Washington, D.C. 20003

Dear Mr. ~~Minor~~ Brent:

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director

Office of National AIDS Policy

p.s. Loved the card + photo!

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. John Perez
Executive Director
Region 8 States Council
United Food and Commercial Workers Union
6280 Manchester Boulevard
Buena Park, CA 90622

Dear Mr. Perez: John

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Ms. Valerie Reyes-Jimenez
Peer Educator
139 West 93rd Street, 3A
New York, NY 10025

Dear Ms. Reyes-Jimenez: Valerie –

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

Mr. Phillip P. Burgess, R.Ph.
National Director of Pharmacy Affairs
Walgreens Company
200 Wilmot Road
Deerfield, IL 60015

Dear Mr. Burgess:

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE
WASHINGTON

April 3, 2000

The Honorable Ronald V. Dellums
President
Healthcare International Management Company
1825 I Street, NW, Suite 400
Washington, D.C. 20006

Dear Mr. Dellums:

I hope you have recovered from your first meeting of the Presidential Advisory Council on HIV/AIDS. There is always so much information to digest in such a short period of time!

I look forward to working with you in the coming months to move the Council's agenda forward. Please feel free to call me anytime if I can be of help in anyway.

I look forward to seeing you soon.

Sincerely,

Sandy

Sandra L. Thurman
Director
Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR DELIA COHEN, SPECIAL ASSISTANT TO THE PRESIDENT AND DIRECTOR OF CORRESPONDENCE AND PRESIDENTIAL MESSAGES

From: Sandra L. Thurman
Presidential Envoy for AIDS Cooperation and Director, Office of National AIDS Policy
(202) 456-2437

Date: Oct 12, 2000

Subject: Letter to the President

The Presidential Advisory Council on HIV/AIDS requested that our office help transmit this letter to the President.

Please let me know if you have any questions or if we can help in preparing a response.

Thank you.

THE WHITE HOUSE

WASHINGTON

Memorandum for Dan Burkhardt

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

Date: May 31, 2000

Subject: **Letter to the President**

The Presidential Advisory Council on HIV/AIDS requested that our office help transmit this letter to the President.

Please let me know if you have any questions or if we can help in preparing a response.

Thank you.

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

May 24, 2000

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20503

Dear Mr. President:

As members of your Advisory Council on HIV/AIDS, we are writing to express our strong support for efforts to provide comprehensive care to HIV positive individuals as early as possible in their disease through the use of Medicaid Section 1115 waivers. There is no question that early intervention can decrease HIV-related morbidity and mortality. Section 1115 waivers, if implemented appropriately, will also expand the number of low-income Americans who are able to receive high quality medical care from providers with an expertise in HIV treatment.

There are important program components that will ensure quality care for HIV-infected individuals participating in a state Medicaid expansion waiver. Evidence clearly demonstrates that those who are HIV infected live longer and higher quality lives when they receive care from providers who have significant HIV experience. We urge the Administration to take steps to assure that those providing care in the context of HIV expansion waivers have sufficient experience in HIV treatment. This should be an intrinsic aspect of each successful waiver.

Moreover, the availability of HIV-experienced providers will, in part, depend upon the provider reimbursement mechanisms in the waiver program. Since experienced HIV providers, by definition, serve large numbers of HIV patients, they are likely to have a caseload that consists almost exclusively of relatively high cost patients. It is important that the financing of care, especially in a capitated system, be adequate to cover the costs associated with delivering the standard of care for HIV disease.

In addition, we strongly urge that you abandon the notion that an expansion of HIV services through Medicaid must be accomplished using the current administrative definition of cost neutrality. In some states, existing cost neutral requirements present a substantial barrier to the implementation of HIV expansion waivers and ultimately limit the benefits of these programs. For example, the

736 Jackson Place, NW
Washington, DC 20503
Tel.: (202) 456-2437
Fax: (202) 456-2438

recently granted Maine waiver caps the number of enrolled individuals. We fear that the burden of cost neutrality will fall hardest on those states with large numbers of potential enrollees and the fewest resources. These are the states most in need of an expansion. We therefore urge that your administration reassess the current definition of cost neutrality in order to eliminate the substantial barrier that it represents.

Finally, we appreciate the efforts of the Health Care Financing Administration, the Office of National AIDS Policy, the Office of the Vice President, the Office of Management and Budget and the Department of Health and Human Services to extend Medicaid coverage for HIV disease. With your support, large numbers of low-income Americans in the early stages of HIV disease, who are currently unable to receive medical care because of Medicaid eligibility restrictions, will have access to evolving treatments and technologies for HIV disease management. Access to such care will greatly improve the prognosis of thousands of individuals living with HIV.

Sincerely,

Ronald V. Dellums

Ronald V. Dellums
Chair

cc: Vice President Al Gore
Sandra Thurman, Office of National AIDS Policy
Jack Lew, Office of Management and Budget
Donna Shalala, Secretary, Dept. of Health and Human Services
Eric Goosby, M.D., Dept. of Health and Human Services
Nancy-Ann DeParle, Health Care Financing Administration
Tim Westmoreland, Health Care Financing Administration
Jeanne Lambrew, Health Care Financing Administration

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 18, 1999

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR AND TODD SUMMERS, DEPUTY DIRECTOR

From: Daniel C. Montoya, Executive Director

RE: Letter to the President Addressing FY2000 Budget Proposal to Congress

Attached is a letter to the President from the Presidential Advisory Council on HIV/AIDS dated October 18, 1999. The letter addresses funding concerns in five main areas: HIV Prevention, the Ryan White Care Act, the Housing Opportunities for People with AIDS program, the National Institutes of Health, and The Global AIDS Initiative: Leadership and Investment in Fighting an Epidemic. Please transmit this letter to the President.

Thank You.

736 Jackson Place, NW
Washington, DC 20503

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR DAN BURKHARDT, DEPUTY ASSISTANT TO THE PRESIDENT AND DIRECTOR OF CORRESPONDENCE AND PRESIDENTIAL MESSAGES

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

Date: Oct 18, 1999

Subject: Letter to the President

The Presidential Advisory Council on HIV/AIDS requested that our office help transmit this letter to the President.

Please let me know if you have any questions or if we can help in preparing a response.

Thank you.

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 18, 1999

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR AND TODD SUMMERS, DEPUTY DIRECTOR

From: Daniel C. Montoya, Executive Director

RE: Letter to the President Addressing FY2000 Budget Proposal to Congress

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Thank You.

736 Jackson Place, NW
Washington, DC 20503

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 18, 1999

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

As you begin negotiations with Congressional leaders on an omnibus appropriations agreement for FY 2000, we are writing to request your strong support and forceful advocacy for the highest possible funding levels for both domestic and international HIV/AIDS programs.

We want to again thank you for your support for record increases in HIV/AIDS funding in FY 1999, including $156 million in targeted funding to address HIV/AIDS among African-Americans and other communities of color through the Congressional Black Caucus HIV/AIDS Initiative. Our hope is that, with the full $349 million requested for this Initiative in FY 2000, your Administration will be able to build upon the solid foundation laid this year, and will be able to expand the Initiative to more fully address the unique needs of other communities of color, including Latinos, Asian/Pacific Islanders and Native Americans.

As you know, the impact of HIV disease on our nation cannot be mitigated in a single year or even a few years. In response to this long-term crisis, in addition to your support for full funding of the Congressional Black Caucus HIV/AIDS Initiative, at a minimum, we also request your support for the Senate's proposed increases in the following areas:

- $5.0 million increase for HIV prevention at the Centers for Disease Control and Prevention (CDC) and $131 million increase for substance abuse treatment at SAMHSA. Absent a cure or vaccine, well-targeted and sustained HIV prevention programs and guaranteed access to substance abuse treatment for those who request it are our best hope for stemming the tide of new infections. As you know, the majority of the estimated 40,000 HIV new infections each year are among people of color, gay and bisexual men, and injection drug users and their partners.

- $199 million increase for the Ryan White CARE Act, including $36 million for Title I, $30 million for Title II: Care Services, $75 million for ADAP, $45.7 million for Title III, $7.0 million for Title IV, $4.0 million for the AIDS Education Training Centers, and $1.2 million for Part F: Dental Reimbursements. The most recent federal statistics showing a 20% decline in AIDS-related deaths between 1997 and 1998 demonstrate that ensuring access to health care and HIV drug treatments through the Ryan White CARE Act saves thousands of lives each year.

736 Jackson Place, NW
Washington, DC 20503

• $7.0 million increase for the Housing Opportunities for People with AIDS (HOPWA) program. By stabilizing individuals' lives and facilitating access to consistent care, HIV support services such as those funded through the CARE Act and Housing Opportunities for People with AIDS program improve both the overall health outcomes and quality of life of people living with HIV disease.

• 13% increase in funding for biomedical research at the National Institutes of Health, including a corresponding increase in funding for HIV/AIDS research coordinated through the Office of AIDS Research. The Council reiterates its strong support for research on microbicides and a vaccine, in particular.

• At least $100 million to fully fund The Global AIDS Initiative: Leadership and Investment in Fighting an Epidemic (LIFE), including $35 million for the Department of Health and Human Services, $55 million for U.S. Agency for International Development and $10 million for the Department of Defense. We urge you to ensure that such funding increases are reflected in the final budget and these increased funding levels serve as the baseline for additional future funding increases that are clearly needed to respond to this growing global crisis. This funding increase lays the groundwork for United States leadership in the global response to AIDS.

Each of the federal programs identified above is critical to the nation's comprehensive approach to HIV/AIDS in the coming fiscal year. Thank you for your consideration of our request.

Sincerely,

R. Scott Hitt, M.D.
Chair

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, DDS
Mr. Terje Anderson
Ms. Regina Aragon
Ms. Barbara Aranda-Naranjo, PhD., RN
Ms. Judith Billings
Mr. Charles Blackwell
Mr. Nicholas Bollman
Jerry Cade, MD
Lynne M. Cooper, D. Min.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
Ms. Phyllis Greenberger
Nilsa Gutierrez, MD
Mr. Bob Hattoy
Mr. B. Thomas Henderson
R. Scott Hitt, MD, Chair
Michael Isbell, JD
Mr. Ronald Johnson
Mr. Jeremy Landau
Alexandra Mary Levine, MD
Mr. Steve Lew
Mr. Miguel Milanes
Ms. Helen Miramontes
Rev. Altagracia Perez
Michael Rankin, MD
Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Sean Sasser
Mr. Benjamin Schatz
Ms. Denise Stokes
Rep. Charles Quincy Troupe
Bruce Weniger, MD

DRAFT AGENDA
OECD COUNTRY CONTACT GROUP MEETING ON
HIV/AIDS TECHNICAL COOPERATION IN AFRICA
November 16-17, 1999
Venue: TBD

Donor representatives arrive the day prior to the meeting: November 15.

November 16, 1999

8:30 am **Continental Breakfast**

9:00 am **PLENARY**: Welcome and Introductions
Opening Remarks:
Ms. Sandy Thurman, Director, ONAP, The White House
Dr. Peter Piot, Director, UNAIDS

9:30 am **PLENARY:** Update on the International Partnership Against AIDS in Africa.
[A plenary discussion of the IPAA, outstanding issues, the December meeting, and plans for next year]

12:00 pm **Lunch**

1:00 pm **PLENARY** : Discussion of the purpose and desired outcomes of the technical resource strengthening aspect of the meeting.
UNAIDS and USAID speakers

1:30 pm **PLENARY**: "Goals, principles, and strategic framework for improved HIV/AIDS technical support for Africa"
[Purpose: to ensure that everyone is discussing the issue from a common framework based on concept papers distributed ahead of the meeting]
Speakers: TBD

2:45 pm **Break**

3:00 pm **PLENARY**: "Operational challenges experienced by donors in providing HIV/AIDS technical support"
[Purpose: to identify the key issues related to responding to country needs, organizing and delivering technical assistance, empowering Africans and African institutions, long term sustainability and capacity building, etc].
Speakers: TBD

4:30 pm **PLENARY:** Discussion of breakout sessions for the next day and general discussion.

5:00 pm **ADJOURN**

November 17, 1999

8:30 am **Continental Breakfast**

9:00 am **Meet in PLENARY and then into BREAKOUT GROUPS:** Common theme: "How to harmonize technical support approaches"
Group A: Technical themes areas (e.g., BCC, multisectoral, STDs, etc)
Group B: Mechanisms
Group C: Regional role and linkage to countries

11:00 am Report back if breakout sessions

12:00 pm **Lunch**

1:00 pm **PLENARY**: "How to build African institutions and capacity: lessons to date"
[Purpose: to discuss this special goal and need underlying donor efforts]. Speakers chosen to discuss their perspective on the issues (could include a representative from a university, African network, political institution, etc e.g., University, RATN, CHRCS or SADC, etc).

2:00 pm **BREAKOUT GROUPS**: Common theme: "The Way Forward"
Based on discussions from Day One's breakout groups identify concrete next steps to harmonize donor supported technical assistance in-country and regionally by discussing:

Group A:	Donor HQ, country and regionally-based strategies
Group B:	Establishing and maintaining strategic relationships (beyond just donors)
Group C:	Long term training and capacity building

4:00 pm **PLENARY**: Report back and discussion; discussion of the report to the December 1999 Secretary General meeting

5:00 pm **PLENARY:** Closing and summary of next steps
Ms. Sandy Thurman, ONAP
Dr. Peter Piot, UNAIDS

6:00 pm **ADJOURN**

NOTE: WE WOULD CONTINUE ON NOVEMBER 18 IF NECESSARY

(especially if the discussion of the IPAA on the first day runs longer)

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

MEMORANDUM FOR SANDRA THURMAN, PRESIDENTIAL ENVOY FOR AIDS COOPERATION, DIRECTOR

FROM: Daniel C. Montoya, Executive Director

RE: Letter to the President addressing the Gephardt-Pelosi Early Treatment for HIV Act of 2000.

Attached is a letter to the President from the Presidential Advisory Council on HIV/AIDS dated October 11, 2000. The letter addresses adding the Gephardt-Pelosi Early Treatment for HIV Act of 2000 to H.R. 5291, the Beneficiary Improvement and Protection Act of 2000 (BBA Giveback Bill).

Please transmit this letter to the President.

Thank You.

736 Jackson Place, NW
Washington, DC 20503
Tel.: (202) 456-2437
Fax: (202) 456-2438

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR DAN BURKHARDT, DEPUTY ASSISTANT TO THE PRESIDENT AND DIRECTOR OF CORRESPONDENCE AND PRESIDENTIAL MESSAGES

From: Sandra L. Thurman (S)
Presidential Envoy for AIDS Cooperation and Director, Office of National AIDS Policy
(202) 456-2437

Date: Oct 12, 2000

Subject: Letter to the President

The Presidential Advisory Council on HIV/AIDS requested that our office help transmit this letter to the President.

Please let me know if you have any questions or if we can help in preparing a response.

Thank you.

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

October 11, 2000

The Honorable William Jefferson Clinton
The White House
Washington, D.C.

Dear Mr. President:

On behalf of the Presidential Advisory Council on HIV/AIDS (Council), I am writing to request your strong support for current Congressional efforts to provide states the option of expanding Medicaid eligibility to low-income, uninsured persons in the earlier stages of HIV/AIDS by adding the Gephardt-Pelosi Early Treatment for HIV Act, to H.R. 5291, the Beneficiary Improvement and Protection Act of 2000 (BBA Giveback Bill). As you know, this is a policy long advocated by members of the Council, perhaps most passionately by our former colleague and mutual friend Tom Henderson. In addition, this is an approach which Vice President Gore announced three years ago that the Administration would vigoursly pursue; one which parallels the breast cancer proposal included in your FY 2001 budget request.

Three years ago the Council underscored the inherent contradiction between the goal of early care and treatment for HIV/AIDS and current Medicaid eligibility rules that require HIV-infected individuals to have a disabling AIDS condition before they are eligible for the program. In our recent report, we urged that you act swiftly to remove cost neutrality rules that have interfered with states' efforts to provide such care using the 1115 waiver process. However, since the release of our report, Congress appears ready to consider the Early Treatment for HIV Act as part of H.R. 5291. This would represent a more comprehensive and long-term solution by providing this same policy as a state option. We urge your strong support of this important legislation.

In addition to enhancing the quality of life and health for persons living with HIV/AIDS, early care and treatment is also effective in reducing the cost of HIV/AIDS care over the long term. By helping to protect the immune system, potent anti-retroviral therapy significantly decreases susceptibility to opportunistic infections and other AIDS-related diseases. This, in turn, reduces acute illness, hospitalizations, disability and lost productivity. Recent studies also indicate that anti-retroviral therapy reduces the risk of HIV transmission to others.

Despite the value of early care for HIV disease, the Department of Health and Human Services estimates that one-half to two-thirds of persons living with HIV/AIDS in the United States are currently not in care. As you know, poor people of color are at greater risk for HIV infection and are more likely to be uninsured. The Early Treatment for HIV Act is therefore critically important to our shared goal of eliminating racial and ethnic disparities in health outcomes.

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Washington, DC 20503
Tel.: (202) 456-2437
Fax: (202) 456-2438

We strongly urge you to support the Early Treatment for HIV Act and push for its enactment during "endgame" negotiations with the 106th Congress. Thank you for your consideration.

Sincerely,

Ronald V. Dellums
Chair

cc: The Honorable Albert Gore, Vice President of the United States
The Honorable Daniel Patrick Moynihan
The Honorable William V. Roth, Jr.
The Honorable Richard A. Gephardt
The Honorable John D. Dingle
The Honorable Sherrod Brown
The Honorable Charles B. Rangel
The Honorable Nancy Pelosi
The Honorable Donna E. Shalala, Secretary, U.S. Department of Health and Human Services
Sandra L. Thurman, Presidential Envoy for AIDS Cooperation, Director, Office of National AIDS Policy
Jacob J. (Jack) Lew, Director, Office of Management and Budget, The White House
Christopher C. Jennings, Deputy Assistant to the President for Health Policy, The White House
Jeanne Lambrew, Associate Director for Health and Personnel, Office of Management and Budget, The White House
Eric Goosby, M.D., Director, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services
Marsha Martin, Ph.D., Special Assistant to the Secretary, U.S. Department of Health and Human Services
Michael Hash, Acting Administrator, Health Care Financing Administration, U.S. Department of Health and Human Services
Tim Westmoreland, Director, Center for Medicaid and State Operations, Health Care Financing Administration, U.S. Department of Health and Human Services
Presidential Advisory Council on HIV/AIDS Members

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Fax: (202) 456-2438

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

May 24, 2000

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR

FROM: Daniel C. Montoya, Executive Director

RE: Providing Comprehensive Care to HIV Positive Individuals Through Medicaid 1115 Waivers

Attached is a letter in support for Medicaid 1115 Waivers as a means to provide early and comprehensive care to HIV positive individuals.

Please transmit this letter to the President.

Thank You.

736 Jackson Place, NW
Washington, DC 20503
Tel.: (202) 456-2437
Fax: (202) 456-2438

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

May 24, 2000

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20503

Dear Mr. President:

As members of your Advisory Council on HIV/AIDS, we are writing to express our strong support for efforts to provide comprehensive care to HIV positive individuals as early as possible in their disease through the use of Medicaid Section 1115 waivers. There is no question that early intervention can decrease HIV-related morbidity and mortality. Section 1115 waivers, if implemented appropriately, will also expand the number of low-income Americans who are able to receive high quality medical care from providers with an expertise in HIV treatment.

There are important program components that will ensure quality care for HIV-infected individuals participating in a state Medicaid expansion waiver. Evidence clearly demonstrates that those who are HIV infected live longer and higher quality lives when they receive care from providers who have significant HIV experience. We urge the Administration to take steps to assure that those providing care in the context of HIV expansion waivers have sufficient experience in HIV treatment. This should be an intrinsic aspect of each successful waiver.

Moreover, the availability of HIV-experienced providers will, in part, depend upon the provider reimbursement mechanisms in the waiver program. Since experienced HIV providers, by definition, serve large numbers of HIV patients, they are likely to have a caseload that consists almost exclusively of relatively high cost patients. It is important that the financing of care, especially in a capitated system, be adequate to cover the costs associated with delivering the standard of care for HIV disease.

In addition, we strongly urge that you abandon the notion that an expansion of HIV services through Medicaid must be accomplished using the current administrative definition of cost neutrality. In some states, existing cost neutral requirements present a substantial barrier to the implementation of HIV expansion waivers and ultimately limit the benefits of these programs. For example, the

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Tel.: (202) 456-2437
Fax: (202) 456-2438

recently granted Maine waiver caps the number of enrolled individuals. We fear that the burden of cost neutrality will fall hardest on those states with large numbers of potential enrollees and the fewest resources. These are the states most in need of an expansion. We therefore urge that your administration reassess the current definition of cost neutrality in order to eliminate the substantial barrier that it represents.

Finally, we appreciate the efforts of the Health Care Financing Administration, the Office of National AIDS Policy, the Office of the Vice President, the Office of Management and Budget and the Department of Health and Human Services to extend Medicaid coverage for HIV disease. With your support, large numbers of low-income Americans in the early stages of HIV disease, who are currently unable to receive medical care because of Medicaid eligibility restrictions, will have access to evolving treatments and technologies for HIV disease management. Access to such care will greatly improve the prognosis of thousands of individuals living with HIV.

Sincerely,

Ronald V. Dellums

Ronald V. Dellums
Chair

cc: Vice President Al Gore
Sandra Thurman, Office of National AIDS Policy
Jack Lew, Office of Management and Budget
Donna Shalala, Secretary, Dept. of Health and Human Services
Eric Goosby, M.D., Dept. of Health and Human Services
Nancy-Ann DeParle, Health Care Financing Administration
Tim Westmoreland, Health Care Financing Administration
Jeanne Lambrew, Health Care Financing Administration

O-PHCHA

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

July 27, 2000

MEMORANDUM FOR: Sandra L. Thurman

FROM: Daniel C. Montoya
Executive Director

RE: PACHA Report

I just wanted to send you a quick note and bring you up to speed with the progress we've been making on the PACHA report.

First of all, with respect to a time frame, we're expecting to have a final, print-ready version of the report by August 14th. If all goes as planned, I will then get a copy of the report to you during the week of August 14th. I have involved and received feedback from Matthew Murguia, Paul Gaist, and May Kennedy and you will be getting a more complete and final draft version on which to comment. Unfortunately, this will all be happening the same week of the Democratic National Convention. While I realize that you will be extremely busy that week, in light of our time constraints for getting the report printed, I would appreciate any time you can make to review the report. Moreover, I would be happy to send an additional copy of the report to anyone you feel might provide further insight.

Secondly, I have attached to this memo a copy of the POTUS/VPOTUS scheduling requests for Thursday, September 21st (or alternatively, Friday, September 22nd). It is my understanding that the President will be in Washington on both of those days. Please review the scheduling request and let me know if there is anything that I should add or change. Most importantly, please notice the people that I have listed as "recommenders" – these are people that we thought would be supportive of this proposed meeting between PACHA and the President. So far, we have not contacted any of these people although I would be happy to do so after hearing back from you.

Finally, I have also attached the Final 100 Days recommendations that the Council has compiled thus far. The members of the Council believe that these are issues which could most likely be addressed before the end of the Clinton Administration. I would appreciate it if you could provide me with some input regarding the feasibility of each of the recommendations given the relatively limited time that we have remaining.

Since I am traveling, please feel free to call me at my new cell phone number: (202) 285-5539.

Thank you for your help with making the PACHA report one of which we can all be proud.

736 Jackson Place, NW
Washington, DC 20503

THE WHITE HOUSE

WASHINGTON

SCHEDULING PROPOSAL July 26, 2000

_____ Accept _____ Regret _____ Pending

TO: STEPHANIE STREETT
Deputy Assistant to the President and Director of Scheduling

FROM: Sandra L. Thurman, Director, Office of National AIDS Policy

Daniel C. Montoya, Executive Director, Presidential Advisory Council on HIV/AIDS (PACHA)

REQUEST: POTUS request to take part in presentation of final PACHA report for Clinton Administration

BACKGROUND: In 1995, under Executive Order 12963, the President created the Presidential Advisory Council on HIV/AIDS under the Department of Health and Human Services. Since that time, the Council has issued annual reports to the Clinton Administration expressing the Council's recommendations for policies concerning HIV/AIDS prevention and services.

As the Council prepares for its last months serving under the Clinton Administration, it has compiled a final progress report detailing its hopes for the conclusion of the President's term and recommendations for the next administration.

DATE AND TIME: Thursday, September 21, 2000 (alternate date: Friday, September 22)
Time TBD

DURATION: 1 hour

LOCATION: The Roosevelt Room

PARTICIPANTS: Invited:
The President
The Vice President
Secretary Albright
Secretary Cuomo
Secretary Shalala
Secretary Summers
Sandra L. Thurman
Daniel C. Montoya
PACHA Chair, Ronald V. Dellums
PACHA members

OUTLINE OF EVENTS:	The Chair of the Presidential Advisory Council on HIV/AIDS will make some brief introductory remarks. Subsequently, PACHA members will overview and present the President with their final report. Following the presentation, the President will make some short remarks regarding the Council and the significance of the final report after which the Vice President will also make some remarks on the report. Finally, there will be a short question and answer session.
REMARKS:	Yes. A draft from the Office of National AIDS Policy will be submitted to speechwriting for review and revision.
MEDIA:	Yes
FIRST LADY:	No
VICE PRESIDENT:	Yes
RECOMMENDED BY:	Sandra L. Thurman, Director, Office of National AIDS Policy Daniel C. Montoya, Executive Director, Presidential Advisory Council on HIV/AIDS Maria Echaveste, Assistant to the President and Deputy Chief of Staff Bruce Reed, Assistant to the President for Domestic Policy and Director of the Domestic Policy Council, Office of Policy Development Kenneth Bernard, Special Advisor to the APNSA, International Health Affairs, National Security Council Julian Potter, Associate Director, Public Liason
CONTACT:	Cheryl Bauerle, Office of National AIDS Policy, 6-2959 Greg Smiley, Presidential Advisory Council on HIV/AIDS, 5-1442

THE WHITE HOUSE

WASHINGTON

SCHEDULING PROPOSAL July 26, 2000

_____ Accept _____ Regret _____ Pending

TO: Elizabeth Cotham:
Office of the Vice President, Scheduling

FROM: Sandra L. Thurman, Director, Office of National AIDS Policy

Daniel C. Montoya, Executive Director, Presidential Advisory Council on HIV/AIDS (PACHA)

REQUEST: VPOTUS take part in presentation ceremony of final PACHA report for Clinton Administration

BACKGROUND: In 1995, under Executive Order 12963, the President created the Presidential Advisory Council on HIV/AIDS under the Department of Health and Human Services. Since that time, the Council has issued annual reports to the Clinton Administration expressing the Council's recommendations for policies concerning the prevention and services of HIV/AIDS.

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PACHA Chair, Ronald V. Dellums
PACHA members

OUTLINE OF EVENTS:	The Chair of the Presidential Advisory Council on HIV/AIDS will make some brief introductory remarks. Subsequently, PACHA members will overview and present the President with their final report. Following the presentation, the President will make some short remarks regarding the Council and the significance of the final report after which the Vice President will also make some remarks on the report. Finally, there will be a short question and answer session.
REMARKS:	Yes. A draft will be submitted by the Office of National AIDS Policy to the Office of the Vice President.
MEDIA:	Yes
RECOMMENDED BY:	Sandra L. Thurman, Director, Office of National AIDS Policy Daniel C. Montoya, Executive Director, Presidential Advisory Council on HIV/AIDS David Beier, Chief Domestic Policy Advisor for the Vice President Leon Fuerth, Assistant to the Vice President for National Security Affairs Philip DuFour, Office of Mrs. Gore Julian Potter, Associate Director, Public Liason
CONTACT:	Cheryl Bauerle, Office of National AIDS Policy, 6-2959 Greg Smiley, Presidential Advisory Council on HIV/AIDS, 5-1442

Mailbox of Greg Smiley

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To: **Greg Smiley at ~OPHS_DC; rraragon@pacbell.net at INTERNET; cgomez@psg.ucsf.edu at INTERNET; Btminor59@aol.com at INTERNET; barbutti@aol.com at INTERNET; jedelheit@templeisrael.com at INTERNET; emily@mosaica.org at INTERNET; angela@mosaica.org at INTERNET; Matthew_Murguia@opd.eop.gov at INTERNET**

cc:

From: **Daniel_C._Montoya@opd.eop.gov**

Subject: **100 Days Recs**

1 Attachments

Thanks for everyone's input. As you can see we still need to flesh these out some more. I will work with ONAP and the final editors for their input. In the meantime, these will be in the draft we receive on Friday and y'all can comment on our conference call on Tuesday.

RECOMMENDATIONS FOR THE LAST 100 DAYS:

1. Take a leadership role in Congressional negotiations regarding FY 2001 HIV/AIDS appropriations and reauthorization of the Ryan White CARE Act.

2. Facilitate Presidential meeting with corporate leaders to talk about public-private partnerships on domestic and global AIDS issues in order to inspire major multi-national corporations to assume greater role and responsibility in global pandemic given the global economic and security issues.

3. Support the elimination of U.S. immigration restrictions given their discriminatory nature based upon unscientific and politically motivated policy with no public health value.

4. Eliminate budget neutrality rules that act as a barrier to states? ability to expand Medicaid eligibility to individuals in the earlier stages of HIV/AIDS.

5. Distribute scientific information regarding the efficacy of needle exchange programs to state and local health officials, grantees and sub-grantees in an effort to support local community?s efforts to implement these life-saving programs using non-federal dollar.

6. Participate in World AIDS Day events to highlight global nature of pandemic.

7. Facilitate Presidential meeting of global religious leaders to discuss HIV/AIDS issues, especially the need to fight sexism, homophobia and racism, which contribute to high-risk behavior.

8. Facilitate White House youth focused events prior to end of Administration, or conversely, implement some key elements of the recently-released youth report.

9. Issue revised, scientifically-based guidelines for HIV infected health care workers.
10. Incarcerated populations ? Daniel is checking on this.

11. Vaccine development? Something about the Bumpers Institute/Center? ? Will Check with Alexandra and Helen

12. Appoint US AIDS Envoy to coordinate efforts between the domestic, economic and national security councils.?? ? Will check with ONAP

Remember: They should be something he can do in the last 100 days ? even if doing so requires substantial political will. The list should not be too long.

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR BRUCE REED
CHRIS JENNINGS
DANIEL MENDELSON
LAURA EFROS

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

Date: October 13, 1999

Subject: **Resolution by Presidential Advisory Council on HIV/AIDS Regarding Pelosi Vaccine Bill**

Attached is a copy of a resolution just approved by the Presidential Advisory Council on HIV and AIDS relative to the Pelosi vaccine bill. They are certainly interested in having the Administration supportive of efforts to promote industry engagement in vaccine research.

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR BRUCE REED
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PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 5, 1999

The following resolution was unanimously adopted by the Presidential Advisory Council on HIV/AIDS during their 14th meeting on Tuesday October 5, 1999

RESOLUTION IN SUPPORT OF H.R. 1274 THE LIFESAVING VACCINE TECHNOLOGY ACT

The development, testing, and implementation of a vaccine against HIV will require the concerted and coordinated effort of relevant branches of the Federal government, as well as the strong commitment of private-sector industry. Numerous financial impediments currently discourage the pharmaceutical industry to participate fully in the generation of vaccines against AIDS, malaria, TB, and other catastrophic infections.

The Lifesaving Vaccine Technology Act of 1999 (H.R. 1274) would provide tax credit for qualified research and development costs associated with generation of these vaccines, similar to the research and development credits which are currently provided to other types of technology. Further, since the vast majority of HIV-, TB-, and malaria-infected individuals reside in resource-poor areas of the world, the Act also requires companies that use the tax credit to establish a good faith plan for the widest possible global access to any efficacious vaccine which may be developed.

The Presidential Advisory Council on HIV/AIDS strongly supports the intent of H.R. 1274, and hereby urges the Administration to support and work strongly toward passage of this Act in the Congress.

736 Jackson Place, NW
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Barbara Aranda-Naranjo, PhD, RN
Ms. Judith Billings
Mr. Charles Blackwell
Mr. Nicholas Bollman
Jerry Cade, MD
Lynne M. Cooper, D. Min.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
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Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Sean Sasser
Mr. Benjamin Schatz
Ms. Denise Stokes
Rep. Charles Quincy Troupe
Bruce Weniger, MD

Presidential Advisory Council on HIV/AIDS

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June 11, 1999

Presidential Advisory Council on HIV/AIDS
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Charles Blackwell
Jerry Cade
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Bob Fogel
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Tom Henderson
Mike Isbell
Jeremy Landau
Alexandra Levine
Helen Miramontes
Altagracia Perez
Alexander Robinson
Benjamin Schatz
Bruce Weniger

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Joseph Edelheit
Nilsa Gutierrez
Scott Hitt
Steve Lew
Michael Rankin
Sean Sasser

AD HOC SUBCOMMITTEES

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

October 5, 1999

MEMORANDUM FOR SANDRA THURMAN, DIRECTOR AND TODD SUMMERS, DEPUTY DIRECTOR

FROM: Daniel C. Montoya, Executive Director

RE: Resolution in support of H.R. 1274 "The Lifesaving Vaccine Technology Act of 1999"

Attached is a resolution in support of H.R. 1274 "The Lifesaving Vaccine Technology Act of 1999". During the 14th meeting of the Presidential Advisory Council on HIV/AIDS (October 4-5, 1999) the Council unanimously voted to support the intent of this legislation.

Please transmit this resolution to the President.

Thank You.

736 Jackson Place, NW
Washington, DC 20503

HEALTH GLOBAL ACCESS PROJECT COALITION
c /o HIV/AIDS Human Rights Project
545 Manhattan Avenue
New York, NY, 10027

HEALTH GAP COALITION

May 14, 1999

Dear Member of PACHA:

This envelope contains a copy of the letter from the Health Gap Coalition, sent by email to Mr. Montoya, Ms. Thurman, and Dr. Hitt, and all Council members, requesting the opportunity to present to the full Presidential Advisory Council on access to medications needed by HIV infected people in the developing world. There are methods permitted by the World Trade Organization that would significantly increase access to these medications. However, current U.S. governmental trade policy is being used to pressure countries in the developing world from utilizing these methods.

In addition to the Health Gap Coalition letter, enclosed you will find background materials on these issues:

A: An overview of the *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS Agreement), including Article 31, from the World Trade Organization, which describes the conditions in which compulsory licensing is permitted.

B: *Frequently Asked Questions About Compulsory Licensing* provided by the Consumer Project on Technology.

C: An article from the *Bangkok Post*, September 5, 1998, describing U.S. pressure on Thailand to amend its pharmaceutical patent law so that compulsory licensing would be disallowed.

D: A section in the *1998 U.S. Appropriations Bill (Public law 105-277)* that prohibits funds for the Republic of South Africa, unless it terminates sections of a pharmaceutical bill that would allow compulsory licensing of essential medications.

E: An *U.S. State Department report* on U.S. government efforts to pressure South Africa to terminate the compulsory licensing sections of that bill.

F: A statement from Representative Marion Berry of Arkansas from the *Congressional Record* of April 27, 1999 regarding U.S. governmental efforts to prohibit compulsory licensing of pharmaceuticals in developing countries, while passing a bill to extend use of compulsory licensing for a domestic purpose.

G: An article from the *Chicago Tribune*, April 28, 1999 describing international efforts to increase access to antiretrovirals and other HIV related medications, and pharmaceutical and U.S. government efforts to oppose these efforts.

We think that these materials are informative, and explain the complicated issues involved. The Health Gap Coalition would welcome the opportunity to present at PACHA, along with other interested parties, to these access and trade policy issues.

Please feel free to reach us at the Health Gap address, or by email (*Esawyer@igc.apc.org*, or *DXH05@health.state.ny.us*) or by telephone (*ES: 212 8645672; DH: 212 8667755*). Thank-you for your time.

Sincerely,

Dennis DeLeon, David Hoos, Eric Sawyer

for the Health Gap Coalition

HEALTH GLOBAL ACCESS PROJECT COALITION
c /o HIV/AIDS Human Rights Project
545 Manhattan Avenue
New York, NY, 10027

HEALTH GAP COALITION

May 11, 1999

Dear Ms. Thurman, Mr. Montoya, and Dr. Hitt:

We are writing as members of the Health Gap Coalition to strongly urge the President's Advisory Council on HIV/AIDS to host a presentation at its June meeting on compulsory licensing. Compulsory licensing and related measures would make anti- HIV medications significantly more available to HIV-infected people in developing countries. We believe that there is a great urgency for our government's position to be examined in the forum of PACHA, with the aim of developing recommendations for action by the Administration and Congress. A presentation is planned at the International Subcommittee for June 5, on these issues, but we think it is important that the full Council have the opportunity to attend.

The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) is an international trade agreement of the World Trade Organization (WTO), of which the U.S. is a member. TRIPS permits domestic use of a patent or other intellectual property under specific circumstances by compulsory licensing. For example, this can apply to a pharmaceutical if price, or other factors, make it essentially unavailable. The U.S. government incorrectly describes WTO and World Intellectual Property Organization (WIPO) regulations as not permitting such compulsory licensing, and insists on more restrictive protection of pharmaceuticals as the price of granting favored trade status to other countries.

The government of Thailand was preparing to permit local production of ddI, under its patent law which permits compulsory licensing. With the threat of withdrawal of favored nation trade status, the U.S. government is pressuring the Thai government to forbid such production. Plans to permit production of the systemic antifungal fluconazole have also been scuttled. In addition, U.S. government officials have repeatedly threatened the Republic of South Africa with loss of favored nation trading status, if it does not repeal a law that would permit the government to license domestic firms to manufacture generic versions of essential medications, including antiretrovirals. As has been widely reported in the media, South Africa may have up to 4 million people who are HIV infected, a true national health emergency.

The above examples demonstrate the urgency of a presentation of these essential trade issues. If the United States did not obstruct measures that are fully legal under international trade agreements, potentially millions of people world-wide could have access to medications that have been truly life saving in this country. For this reason, we request the opportunity to contribute to this presentation to you, as a body advisory to U. S. AIDS policies. We will be mailing more detailed written materials explaining the background of these issues.

Dennis DeLeon , David Hoos, M.D., Eric Sawyer
for the Health Gap Coalition

cc: members of the President's Advisory Council on HIV/AIDS

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An overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

Main features of the TRIPS Agreement

The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property. The areas of intellectual property that it covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks including service marks; geographical indications including appellations of origin; industrial designs; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

The three main features of the Agreement are:

(i) **Standards**. In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions, must be complied with. With the exception of the provisions of the Berne Convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement between TRIPS Member countries. The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the Paris Convention and to the Berne Convention. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne and Paris-plus agreement.

(ii) **Enforcement**. The second main set of provisions deals with domestic procedures and remedies for the enforcement of intellectual property rights. The Agreement lays down certain general principles applicable to all IPR enforcement procedures. In addition, it contains provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures, which specify, in a certain amount of detail, the procedures and remedies that must be

interests of third parties (Article 30).

The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33).

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1).

If the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood that the protected process was used are met (Article 34).

Article 31 of TRIPS

Compulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licences only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. Certain of these conditions are relaxed where compulsory licences are employed to remedy practices that have been established as anticompetitive by a legal process. These conditions should be read together with the related provisions of Article 27.1, which require that patent rights shall be enjoyable without discrimination as to the field of technology, and whether products are imported or locally produced.

Layout-designs of integrated circuits

Article 35 of the TRIPS Agreement requires Member countries to protect the layout-designs of integrated circuits in accordance with the provisions of the IPIC Treaty (the Treaty on Intellectual Property in Respect of Integrated Circuits), negotiated under the auspices of WIPO in 1989. These provisions deal with, *inter alia*, the definitions of "integrated circuit" and "layout-design (topography)", requirements for protection, exclusive rights, and limitations, as well as exploitation, registration and disclosure. An "integrated circuit" means a product, in its final form or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and/or on a piece of material and which is intended to perform an electronic function. A "layout-design (topography)" is defined as the three-dimensional disposition, however expressed, of the elements, at least one of which is an active element, and of some or all of the interconnections of an

Frequently asked questions about compulsory licenses

version 1.0a
January 20, 1999

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1. What is a compulsory license.

Compulsory licenses are licensees that are granted by a government to use patents, copyrighted works or other types of intellectual property. The United States government has several specific statutes for compulsory licensing covering a wide range of topics, as well as more general authority for compulsory licensing under antitrust and eminent domain laws. Other countries have their own approaches to compulsory licensing.

Compulsory licenses are an essential government instrument to intervene in the market and limit patent and other intellectual property rights in order to correct market failures. The authority to issue a compulsory license is important, even when the right isn't exercised, because it may temper the exercise of market power or the abuse of a patent.

2. Why do governments issue licenses to use intellectual property?

Governments issue compulsory licenses to broaden access to technologies and information in order to achieve a number of public purposes. For example, National Public Radio (NPR) recently was granted compulsory licenses for noncommercial educational broadcasting use of the repertoires of the American Society of Composers, Authors and Publishers (ASCAP) and Broadcast Music, Inc. (BMI). The Clean Air Act provides for compulsory licensing of patents related to air pollution. Antitrust authorities seek compulsory licenses as remedies for problems of monopoly or anticompetitive practices. The National Institutes of Health is examining compulsory licenses in order to facilitate broader dissemination of biotechnology "research tools." Many countries have provisions in laws for compulsory licensing if the patent owner refused to make the invention available (failure to "work" the patent), for dependent patents, or for various public interest reasons, such as to correct cases where pharmaceuticals are "available to the public in insufficient quantity or at abnormally high prices." (France).

Patents and other intellectual property rights are creations of government policy. In writing about a German compulsory license related to the development of interferon, Michael Kern wrote: "One should not forget that patents represent a interventionist instrument, ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patents may be required, when the community welfare is [no] longer served."

3. What is the status of compulsory licenses under International Law?

Nations currently have the right to issue compulsory licenses on patents and copyrights. The Paris Convention for the Protection of Industrial Property plainly states "each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

The World Trade Organization provisions on intellectual property are contained in the

agreement on trade related aspects of intellectual property, known as TRIPS. The TRIPS provides for compulsory licenses of patents in Article 31, but also provides a number of restrictions on the use of compulsory licenses. The North American Free Trade Agreement (NAFTA) has its own provisions for compulsory licensing of patents, which are somewhat more restrictive than those in the TRIPS. In earlier drafts of the OECD's proposal for a Multinational Agreement on Investments (MAI), there was language to limit compulsory licensing of patents much more severely. Compulsory licenses would only be used "to remedy an alleged violation of competition laws." After broad opposition to the MAI, negotiations were suspended.

4. What are the disputes over compulsory licensing?

The Pharmaceutical Research and Manufacturers Association (PhRMA) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) are actively lobbying the United States and the European Union trade officials to support international treaties and policies that would ban or restrict the use of compulsory licensing for medicines.

The United States uses considerable bilateral pressure to stop developing countries from using compulsory licensing for pharmaceuticals. For example, the US is actively pressuring South Africa and Thailand against the use of compulsory licenses of pharmaceuticals to treat AIDS or tropical diseases.

It is anticipated that disputes concerning compulsory licensing will eventually come before the WTO in the dispute resolution framework. Pubic health organizations want the WTO to recognize the primacy of public health concerns in the resolution of these disputes, and for the WTO to consult with the World Health Organization (WHO). PhRMA and the IFPMA want these disputes to be framed as commercial disputes, and they oppose the involvement of the WHO.

5. What medical technologies will be affected by compulsory licensing?

Each country will have its own priorities for compulsory licensing. In the United States and Europe, there is much interest in compulsory licensing for broad biotechnology patents, research tools, dependent patents, and as a remedy for unreasonable prices. In developing countries there is much interest in the use of compulsory licensing to obtain lower prices pharmacueticals for AIDS, tropical illnesses, various vaccines and other essential medicines.

To find out a lot more about compulsory licenses, see: http://www.cptech.org/ip/health/cl/.

Return to CPT home page] | page on IP and health | page on compulsory licensing

HEALTH

NGOs rally against patent law changes

Call on US to stop pressuring Thailand

Anjira Assavanonda

Activists from non-governmental organisations yesterday demanded that the US administration stop pressuring Thailand to amend its pharmaceutical patent law.

Some 30 demonstrators who rallied in front of the US embassy yesterday were from the Thai NGO Coalition on Aids, the Coordinating Committee for Primary Health Care of Thai NGOs, and another two groups of local and international NGOs working on HIV/Aids and other health issues in Thailand.

The controversial Patent Law Amendment Bill, which is expected to have strong impact on foreign drugs sold in Thailand, was due for its second reading in Parliament yesterday.

In their first petition lodged with US Trade Representative Charlene Barshefsky, the protesters demanded that the US administration stop pressuring Thailand to delete some important provisions on its authority on compulsory licensing of pharmaceutical products, and also to disband a pharmaceutical patent law committee.

The petition also called on the United States to allow other manufacturers to have the right to produce expensive patented drugs, and to allow them to be sold at their generic equivalents to bring down prices.

Classifieds

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"In the wake of the economic crisis, pressure from the US towards a small country like ours will unnecessarily place an additional burden and deprive our people of access to good health," the petition said.

Another petition was submitted to Donna Shalala, secretary to the Health and Human Services Department, calling on the agency to investigate the consumer price for ddI (didanosine), a US government-patented drug used in the treatment of HIV- /Aids. The drug was licensed on an exclusive basis to one company, Bristol-Myers Squibb.

According to this petition, Thailand can obtain ddI for 50 baht for a 100mg tablet, while the standard regime of ddI for an average Thai adult with HIV/Aids is two 100-mg tablets twice a day. This means a patient will have to spend 200 baht per day.

The protesters compared ddI to AZT, which is listed as an essential drug, and is available at a cheaper price to many Thai Aids sufferers through government or private insurance programmes. Unlike AZT, ddI is available only from Bristol-Myers Squibb, and it is so expensive that it is not included on the list of essential drugs. The drug is not covered by public health insurance.

"If Bristol-Myers Squibb, which has not paid for the research and development of the drug, is permitted to maintain its monopoly on ddI and permitted to charge high prices, we will be unable to purchase the drug and may die," said the protesters.

Saree Ongsomwang of the Coordinating Committee for Primary Health Care of Thai NGOs said if the amendment bill passed Parliament, it meant multinational drug companies would maintain their monopoly on production and marketing of drugs, and drug prices would remain high.

She cited two drugs which are effective in the treatment of cryptococcal meningitis, one of the more serious infections among Aids victims in Thailand. The drugs are Diflucan (Fluconazole), produced by Pfizer, and Amphotericine B, produced by Bristol-Myers Squibb. The cost of one-year treatment with Fluconazole at the current market price is in the region of 100,000 baht or US$2,500, which is unaffordable by an average Thai family.

The demonstrators yesterday brandished placards with protest messages such as "Drug business - a huge market for the US, but a burden for Thailand"; "Where is free trade in drug marketing?"; "Stop drug price monopoly"; and "Enough double standard of the US government."

One HIV patient among the demonstrators said Thai HIV/Aids patients would face more hardship if the government yield to US pressure.

"In the near future, a number of new drugs are going to be invented for HIV/Aids treatment. If such law is passed, we won't be able to obtain these drugs at cheap prices. How long do we have to suffer under the new patent law which cannot be changed? What should the government think of first between trade aspects and people's lives?" she said.

An official from the US embassy's Commerce Department accepted the petition yesterday, but refused to give any response.

Ms Saree said the groups would come back to hear the answer in six weeks. They also planned to meet a special House committee on the patent law amendment to discuss the problem.

Previous News [Business] Outlook Next

Info-Policy-Notes | News from Consumer Project on Technology

April 7, 1999

US law requires US Department of State to seek repeal of South African law on essential medicines

Vice President Gore plays key role in dispute

I found the following provision buried in last year's 423,911-word appropriation bill. This legislation requires the US government to seek the repeal, suspension or termination of legislation in South Africa that authorizes parallel imports and compulsory licensing of medicines. These are mechanisms the government of South Africa is trying to use to obtain less expensive pharmacuetical drugs to combat a health care disaster. According to the US Department of State, the author of this provision is Rep. Rodney P. Frelinghuysen (R-NJ), a big booster of the pharmaceutical industry based in his state.

How bad are things in South Africa?

It is estimated that 3.2 million South Africas are HIV positive, including a staggering 45 percent of the military. One in five South African pregmant women test positive for HIV.

In the face of this horror, the US Congress and the Clinton/GoreAdministration is determined to prevent South African from using its rights under international law and the WTO/GATT agreement to obtain cheaper sources of essential medicines.

This is the provision in the US appropriations bill:

<----------Excerpt from PL 105-277---------->

*Public Law 105-277 - 105th Congress

An Act

Making omnibus consolidated and emergency appropriations for the fiscal year ending September 30, 1999, and for other purposes. <<NOTE: Oct. 21, 1998 - [H.R. 4328]>>

Be it enacted by the Senate and House of Representatives of the United States of America in <<NOTE: Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999.>> Congress assembled,

[snip]

Provided further, That none of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997: [snip]

<----------End Excerpt from PL 105-277---------->

(OVER)

The disputes over the South African legislation have been focused on two issues, parallel importing of drugs, which would permit South Africa to seek the cheapest world price for a drug (a practice that is common in England and other members of the European Union), and compulsory licensing.

Under compulsory licensing, which is permited by the World Trade Organization under Article 31 of the TRIPS agreement on intellectual property, South Africa can issue a compulsory license for AIDS drugs like AZT, ddI or ddC, if it follows certain safeguards, and pays a government set royalty to the patent owner. For some drugs this reduces the price by 70 to 95 percent, depending upon manufacturing costs. Several of the drugs that are candidates for compulsory licensing, including AZT, ddI and ddC, were developed by the US National Institutes of Health (NIH).

Vice President Gore plays a large role in this dispute, as theUS Chair of the US/South Africa Binational Commission (BNC).According to the Vice President Gore's staff, on every occasion that Vice President Gore has meet with Thabo Mbeki, his South African counterpart, Gore has pressed South Africa on the intellectual property issues relating to pharmaceuticals. The Gore/Mbeki commission is considered a key instrument to pressure South African not to use compulsory licensingof HIV/AIDS drugs.

For more information about this issue, see http://www.cptech.org/ip/health http://lists.essential.org/pharm-policy http://www.cptech.org/march99-cl

For the pharmaceutical industry perspective, see the PhRMA 301 submission to the United States Trade Representative (the document the US Department of State has been providing to AIDS groups who ask about US policy.)

http://www.phrma.org/issues/nte/safrica.html

Jamie Love <love@cptech.org>
Consumer Project on Technology
202.387.8030
http://www.cptech.org

US Department of State report

U. S. GOVERNMENT EFFORTS TO NEGOTIATE THE REPEAL, TERMINATION OR WITHDR AWAL OF ARTICLE 15(C) OF THE SOUTH AFRICAN MEDICINES AND RELATED SUBSTA NCES ACT OF 1965

United States Department of State

Washington, D. C. 20520

February 5, 1999

Dear Mr. XXXXXXX:

On behalf of the Secretary, I am herewith submitting a revised report on steps taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(C) of South Africa s Medicines and Related Substances Control Amendment Act No. 90 of 1997 required by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105 277)

I hope you find this report useful to you. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Barbara Larkin
Assistant Secretary
Legislative Affairs

Enclosure:
As Stated

The Honorable
XXX XXXXX,

Committee on XXXXXXXXX XXXXXXXX,
House of Representatives.

U. S. GOVERNMENT EFFORTS TO NEGOTIATE THE REPEAL, TERMINATION OR WITHDRAWAL OF ARTICLE 15(C) OF THE SOUTH AFRICAN MEDICINES AND RELATED SUBSTANCES ACT OF 1965

The intellectual property rights protection issue surrounding Article 15(c) of the December 1997 amendments to the South African Medicines and Related Substances Act of 1965 ("Medicines Act") is a top priority for the United States Government s (USG s) economic relations with the Republic of South Africa. Resolving this bilateral trade conflict has been and remains a vital component of our bilateral commercial relationship. All relevant agencies of the U.S. Government - -
the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) - have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(c) that we believe are inconsistent with South Africa s obligations and commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The Administration understands the South African Government s wish to fulfill its commitment to make medicines more affordable for its people. Although Article 15(c), as it now stands, would authorize abrogation of pharmaceutical patents and would permit parallel imports, both WTO inconsistent actions, the South African Government to date has not allowed parallel importation of a U.S. patented pharmaceutical nor has it suspended any patents or other intellectual property rights held by U.S. pharmaceutical producers. The U.S. Government has nonetheless made clear that it will defend the legitimate interests and rights of U.S. pharmaceutical firms. In our multi level, broad based discussions with the SAG, USG officials have explained that abrogating intellectual property rights of pharmaceutical firms is not a viable means of accomplishing SAG objectives to make medicines more affordable for South Africans. We have often reiterated that such action on the SAG s part will have a long term deleterious impact on the development of new, critically important drugs and on the availability of these drugs in South Africa. Until and unless the South African

Government addresses our concerns, our efforts will continue on several fronts.

Preempting Adoption of the Amendments

Even before the South African parliament adopted the 1997 amendments, the State Department with the full support of USTR, Commerce/USPTO and pharmaceutical industry representatives, instructed the Embassy in Pretoria to deliver strong demarches opposing the undermining of patent protection and potential abrogation of South Africa s international commitments and obligations.

In June 1997, the Embassy in Pretoria, echoing testimony by U.S. pharmaceutical companies operating in South Africa, presented USG views at a parliamentary hearing on the proposed amendments to the Medicines Act. Embassy officials stressed the position that the USG would never abide abrogation of patent protection or acquiesce in parallel importation of patented medicines. U.S. Ambassador James Joseph has made frequent public statements and multiple private demarches to high-ranking South African officials against the legalization of parallel imports since mid 1997. Ambassador Joseph met with the members of the parliamentary Health Committee during their consideration of this draft of the amendments to the Medicines Act. The parliamentarians listened intently to his arguments for why the bill would be problematic. As a result, the legislators withdrew the proposed amendments from parliamentary consideration with the intent of modifying them.

During the July 1997 U.S.-South Africa Binational Commission meeting, Secretary of Commerce Daley again voiced opposition to the proposed amendments to South African Trade and Industry Minister Erwin. Minister Erwin assured Secretary Daley that U.S. concerns would be alleviated by a "revision" of the bill that would be presented to parliament later in 1997. They agreed to establish an ad hoc working group on intellectual property issues to resolve the controversy raised by the proposed amendments to the Medicines Act and obligations set forth TRIPS Article 39.

While the objectionable language contained in the original proposed amendments was removed as promised, the

South African Government s revised amendments, which parliament ultimately passed in October 1997 and President Mandela signed into law in December 1997, contained a new provision, Article 15(c), that is so ambiguous as to make the new bill worse than the earlier version. Article 15(c) seems to permit the South African

Minister of Health to abrogate pharmaceutical patent rights and/or permit parallel importation of patented pharmaceutical products.

Introduction of "New" Amendment

When U.S. Government officials in Washington and Embassy staff repeatedly requested clarification on the impact of Article 15(c), during early 1998, South African Government officials gave their assurances that there was no intention to use the authority of 15(c) to abrogate patents. South African Health Minister Zuma and her senior staff have stated repeatedly that the SAG has no intention of using the powers conferred by the bill to abrogate patent rights. Nevertheless, U.S. Government experts determined that provisions of 15(c) authorize action clearly inconsistent with South Africa s obligations under TRIPS .
At the State Department s instruction, the Embassy in Pretoria has, ove r
the past year, disseminated widely within the South African Government the U.S. Government view that 15(c) authorizes conduct that would violate TRIPS. On the parallel import issue, however, U.S. Government attorneys note that under the terms of the TRIPS agreement, disputes related to parallel importation are not subject to WTO dispute settlement procedures.

Since the passage of the offending amendments in December 1997, U.S. Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry, Foreign Affairs, and Health, to convince the South African Government to withdraw or amend the offending provisions of the law, or at the very least, to ensure that the law is implemented in a manner fully consistent with South Africa s TRIPS obligations.

During early 1998, Embassy officials and the Assistant U.S. Trade Representative for African Affairs made repeated requests to review the implementing regulations for Article 15(c) in order to ensure that application of the amendment would be consistent with South Africa s TRIPS obligations

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and commitments. However, the regulations for 15(c) have never been shared with the U.S. Government, nor have they ever been formally published and implemented. South African officials said a pending legal challenge of the amendments by pharmaceutical manufacturers precludes them from providing the USG with documents which could prejudice the case.

An International Effort

In early 1998, the Embassy in Pretoria approached the Swiss and EU member embassies in South Africa to suggest a joint effort to protest the provisions of Article 15(c) since European pharmaceutical companies could be adversely affected by the amendments, and some are party to the pending litigation. Although European Governments preferred to let the U.S. Government take the lead in demarching the South African Government on pharmaceutical patent protection, French President Chirac raised France s concerns during his July 1998 state visit to South Africa and the Swiss and German presidents also raised the issue privately with Deputy President Mbeki.

The United States Government Makes its Case

Assistant U.S. Trade Representative for Africa Rosa Whitaker traveled to South Africa in the Spring of 1998 and raised U.S. Government concerns with both the Minister of Health and the Minister of Trade and Industry. She reiterated our request to review the draft implementing regulations. Her personal intervention reinforced the Embassy s clear message to the South African Government that the United States would not abide actions inconsistent with WTO obligations.

The ad hoc working group on intellectual property created at the July 1997 BNC held its first meeting in March 1998. The two hour conference call meeting did allow the U.S. delegation - including representatives of the Departments of State, Commerce, the U.S. Patent and Trademark Office and the Office of the U.S. Trade Representative -- to eliminate several lingering misunderstandings and clarify once more U.S. Government views. However, since only officials of the South African Department of Trade and Industry attended the conference

call, the South African delegation was not in a position to answer questions on the Medicines Act authoritatively nor were they empowered to negotiate on matters related to the amendments to the Act, since the Medicines Act is the bailiwick of the South African Department of Health.

Special 301 Watch List

On April 30, 1998, with the full endorsement and support of the Department of State, the United States Trade Representative designated South Africa a Special 301 "Watch List" country during USTR s annual worldwide review of intellectual property rights protection. This designation was based largely on the potential impact of Article 15(c), not only in the South African market but also due to its global precedent and the undermining of WTO principles. The State Department joined with other USG agencies with trade responsibility to insist on this designation in the hope that this special attention would spur

South Africa to change or withdraw Article 15(c)

Withholding GSP

The Department of State, USTR, and the Department of Commerce developed an Administration decision to withhold preferential tariff treatment from certain South African exports in the early summer of 1998. On June 30, the White House announced that four items, for which South Africa had requested preferential tariff treatment under the Generalized System of Preferences (GSP) program, would be held in abeyance pending adequate progress on intellectual property rights protection in South Africa. This action was widely reported in the South African press, but SAG reaction was muted.

Securing South African Assurances

In March 1998, Secretary of Commerce Daley met with South African Health Minister Zuma to underline USG resolve to ensure South Africa would not use the provisions in 15(c) to undermine pharmaceutical patent rights or allow parallel imports.

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Dr. Ian Roberts, a senior official from the South African Department of Health, visited Washington in May 1998 and met with U.S. Government patent experts and congressional staff, and attended a USTR-chaired U.S. Government interagency meeting attended by State Department officials. At this meeting, U.S. Government officials reiterated the U.S. demand that South Africa comply with its international obligations to ensure adequate and effective protection to pharmaceutical patents. Dr. Roberts repeated South African Health Minister Zuma s pledge that it was not the SAG s intention to use Article 15(c) to abrogate patents or open the floodgates to parallel imports.

Repeated Efforts to Resolve the Issue

An Embassy official traveled to Midrand, South Africa to speak at the June 1998 "Pharmecon SA 98" pharmaceutical industry conference. The official s remarks reinforced in a public forum the strong negative U.S. views on Article 15(c) and made clear the possible ramifications of the Article s implementation, including trade sanctions.

In July 1998, Assistant U.S. Trade Representative for African Affairs Rosa Whitaker met with the South African Charge d Affaires in Washington to stress once again the U.S. Government s concerns about pharmaceutical patent protection and parallel importation in South Africa. She also repeated the U.S. Government s position that South

Africa s requests for preferential tariff treatment on four key exports would be held in abeyance pending adequate progress on intellectual property rights protection.

During his September 1998 trip to South Africa, Commerce Secretary Daley made pharmaceutical patent protection a key item in his discussions with South African Trade and Industry Minister Alec Erwin. Daley reemphasized the U.S. Government position on Article 15(c) and reminded Minister Erwin of South Africa's s obligations under the TRIPS agreement.

The Vice President s Plan for a Negotiated Solution

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. Suspended GSP benefits would be restored as progress was made in these negotiations. This basis was developed and unanimously supported by all interested U.S. Government agencies. USTR was identified to lead the U.S. Government s negotiation efforts.

Initial discussion between the Assistant U.S. Trade Representative for Services, Investment and Intellectual Property and the Deputy President s legal advisor took place in September 1998 and follow-on talks were conducted in November. During these discussions, the South African officials attempted to persuade the U.S. Government to intervene with the U.S. pharmaceutical industry to suspend or terminate its pending legal challenge to the offending provisions of the South African Medicines Act. The State Department, together with the Commerce Department and USTR, decided that such an action might undermine the leverage that U.S. companies were exerting through their legal challenge. U.S. officials told the South Africans that since the U.S. Government is not a party to the litigation, the USG was unable to agree to this request. A subsequent round of face-to-face negotiations between USTR officials and Deputy President Mbeki s advisors is tentatively scheduled to be held in Cape Town just prior to the February 1999 Binational Commission meeting.

A "New" Medicines Law

Meanwhile, during the fall of 1998, the South African

parliament drafted and considered a new medicines law that would replace the existing Medicines Act, including the offending amendments. The State Department s Economic Minister Counselor in Pretoria met with a key Mbeki advisor in September 1998 to advocate the removal of Article 15(c) provisions from the new proposed law. In October 1998, at the State Department s suggestion, the Embassy dispatched an economic officer to Cape Town to monitor the committee and full chamber debates. He forcefully advocated the U.S. position and advised parliamentarians that the new law should not include provisions that jeopardize patent rights. Despite these strenuous efforts, a new medicines

bill was passed including provisions identical to Article 15(c), in November 1998.

Health Minister Opens Negotiations with Industry

Shortly after the new law was passed, South African Health Minister Zuma began discussions with pharmaceutical industry executives. Their dialogue has offered hope for an eventual settlement of the pending litigation and satisfactory resolution of the pharmaceutical patent protection issue. On December 4, 1998, the Assistant U.S. Trade Representative for Services, Investment, and Intellectual Property sent a letter to Deputy President Mbeki s legal advisor Mojanku Gumbi noting the USG s interest that the discussions lead to a mutually agreeable settlement. As a way of spurring the discussions, he informed Gumbi that the USC would be prepared to release a significant portion of the withheld GSP benefits should such a settlement be reached. Progress has been slow, but we understand talks are continuing.

In November 1998, the State Department s Economic Minister Counselor in Pretoria met with South African Department of Foreign Affairs officials to discuss resolution of the pharmaceutical patent controversy. The South Africans were eager to find a satisfactory solution to the ongoing dispute before the upcoming February 1999 Binational Commission meeting. Embassy officials reiterated the U.S. position and noted that USTR officials talks with Mbeki advisors were the appropriate venue for seeking a negotiated settlement.

Secretary Daley paid a return visit to South Africa in December 1998. In his meetings with Deputy President Mbeki and Trade and Industry Minister Erwin during that visit, pharmaceutical patent protection was the most important bilateral issue under discussion. Deputy President Mbeki was hopeful that recent discussions between the pharmaceutical manufacturers and the South African Minister of Health would yield a solution. Secretary Daley noted the possibility of negative consequences should progress on resolving this most important

issue stall.

The Embassy closely monitored the Zuma-pharmaceutical industry discussions, which continued through December 1998. Pharmaceutical industry officials have indicated

that these talks have reached a sensitive stage and that further U.S. Government efforts at this time could be counterproductive. The Embassy and Washington agencies have therefore deferred to the U.S. pharmaceutical industry to take the lead. In mid January, the Assistant U.S. Trade Representative for Services, Investment and Intellectual Property sent a letter to Legal Advisor Gumbi suggesting that specific discussion of pharmaceutical patents and Article 15(c) be put aside while Health Minister Zuma negotiates with the interested pharmaceutical manufacturers. The pharmaceutical companies' discussions with Minister Zuma continue and their constitutional court challenge in South Africa remains pending. USTR officials and Mbeki s advisors plan to meet in February 1999.

Latest Efforts

In January 1999, in the context of preparing for the February 1999 U.S.-South Africa Binational Commission, the State Department s Economic Minister Counselor in Pretoria raised the pharmaceutical patent protection issue with Deputy President Mbeki s economic advisor. Despite the Minister Counselor s reiteration of the U.S. position, as well as a description of the ramifications of the suspension of aid to South Africa in the USG s FY 1999 appropriations law, Mbeki s advisor said the SAG was not considering repeal of the offending language in the either the Medicines Act or the new bill.

As indicated in previous sections, several adversely affected U.S. pharmaceutical manufacturers have filed a constitutional court challenge to the amendments to the Medicines Act in South African courts. While the case remains pending, the South African Government is adamant that government-to-government discussions not prejudice the outcome. U.S. Government attorneys share this view. Thus, our efforts are, in part, circumscribed by the ongoing litigation as well as a desire to be responsive to U.S. industry s request to allow its current efforts time and opportunity to be effective. We hope the State Department s and other agencies efforts to convince the South African Government to fulfill its international obligations and commitments on intellectual property rights together with a domestic legal challenge will provide sufficient incentive to achieve the suspension or removal of Article 15(c).

Next Steps

The State Department, its Embassy in Pretoria, the Commerce Department and USTR will monitor closely the ongoing discussions between the pharmaceutical industry and the South African Minister of Health. We will continue our unflagging efforts to convince the South African Government to either repeal Article 15(c) or make it consistent with the TRIPS agreement, and thus eliminate the possibility that any abrogation of U.S. pharmaceutical patent rights in South Africa. Should there be an actual violation of any U.S. pharmaceutical patent right (e.g., patent abrogation) this Administration will respond forcefully in accordance with appropriate trade remedy legislation.

CPT home page CPT Intellectual Property page CPT on IP and Health Care

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US House of Rep passes compulsory licensing of broadcast TV signals

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•To: Multiple recipients of list RANDOM-BITS <random-bits@essential.org
> •Subject: US House of Rep passes compulsory licensing of broadcast TV
 signals •From: James Love <love@cptech.org> •Date: Wed, 28 Apr 1999 13
:27:25 -0400 •Organization: http://www.cptech.org •Sender: jamie@essent
ial.org

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- As the White House pressures Africa and Thailand
on compulsory licensing of essential medicines, the
US House of Representatives approved by a vote of
422 to 1 legislation for the compulsory licensing of
broadcast television programs.

- Representative Marion Berry (D-Ark) comments on
both issues.

Washington - April 28, 1999. Yesterday the U.S. House of Representatives voted 422 to 1 to extend a compulsory license for the rebroadcast of network television programing. The legislation (HR 1554) "extends for five years (through Dec. 31, 2004) the compulsory license for satellite carriers to retransmit superstations and distant signals" and reduces the fees for the compulsory license from 27 cents-per-month per to 19 cents-per-month per subscriber.

This legislation has zipped through the US Congress following a temporary blackout of popular television shows such as sitcom Alley McBeal, that prompted satellite television viewers to press the US Congress for changes in the law to make broadcasts more widely available to satellite television subscribers.

This comes right at the time that the US government's trade and

foreign policy establishment is pressing less developed countries to abandon compulsory licensing on essential medicines. The following comments by Representative Marion Berry (D-ARK) discusses the two issues as a contrast in what we do and what we want others to do.

Jamie Love <love@cptech.org>

April 27, 1999
Congressional Record - Ex
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COMPULSORY LICENSING IS NOT AN ASSAULT ON INTELLECTUAL PROPERTY RIGHTS

HON. MARION BERRY

of arkansas

in the house of representatives

Tuesday, April 27, 1999

Mr. BERRY. Mr. Speaker, I am thankful that today, by an overwhelming majority of 422 to 1, the House of Representatives passed H.R. 1554, the Satellite Home Viewer Act of 1999, which I supported. This legislation ensures that many of my constituents will continue to receive television network programing. The bill extends for five years compulsory licenses, which require superstations and distant broadcast stations to allow their signal to be retransmitted by satellite carriers. In order to promote competition, the bill sets specific prices at which the intellectual property owners, or broadcasters, will be paid for having their signal rebroadcasted.

It is ironic that even as we vote to allow compulsory licensing today, we are interfering in another country's attempt to address a public health crisis through giving consumers access to international markets and through the use of compulsory licensing. It is estimated 3.2 million South Africans are HIV positive, including 45 percent of its military. One in five South African pregnant women test positive for HIV. Access to affordable medicine is also a critical issue for the elderly and others suffering from chronic diseases and medical conditions. Prescription drugs are not currently an option for many patients in South Africa, where the drugs often cost more than they do in the United States. The 1997 per capita income in South Africa was

estimated to be only $6,200 annually.

To address the problem, President Mandela and the South African Government enacted a law in 1997 to reform the country's prescription drug marketplace. The law amends the South African Medicines Act to allow prescription drugs to be purchased in the international marketplace where prices are lower. It would also allow compulsory licensing in some cases. Regulations implementing the law have not been implemented while the law is being constitutionally challenged in South African courts by drug makers in their country.

However, the pharmaceutical industry has persuaded the United States government to work to have the South African law repealed. In February, the United States Department of State released a report titled, U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965.

While special interest groups have tried to convince members of Congress and the administration that implementation of the South African Medicines Act would cause violations of international intellectual property rights agreements, I have seen no evidence that such violations are likely to occur. Compulsory licensing is not an assault on intellectual property rights. Instead, it is part of the copyright and patent systems which enable the interest of the public to be served. Compulsory licensing is permitted under Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In fact, French law authorizes compulsory licensing when medicines are ``only available to the public in insufficient quantity or quality or at abnormally high prices.''

Today, the House of Representatives wisely exercised its power to continue the use of compulsory licensing in the broadcast industry to allow consumers to have access to broadcast signals, that in many instances they would otherwise be unable to receive. Certainly, the United States government should recognize the need of a government to allow

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its citizens to have access to needed medicine in order to address a public health crisis and should not interfere with the situation in South Africa.

FROM CHICAGO TRIBUNE

THIRD WORLD BATTLES FOR AIDS DRUGS
U.S. FIRMS OPPOSE GENERIC LICENSING

By Merrill Goozner, Washington Bureau.
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Section: NEWS
Page: 1

Though the AIDS epidemic is taking its steepest toll in some of the poorest regions of the world, the U.S. government and the nation's pharmaceuticals industry are fighting efforts to make the latest life-saving drugs more widely available there.

The battle pits the drug firms and their desire to maintain exclusive control of the manufacture and marketing of their patented medicines against the intentions of some countries to issue licenses for those drugs to local firms, allowing them to make generic versions that are more affordable.

Last year, for instance, President Nelson Mandela raised hopes among South Africa's burgeoning AIDS population when he signed into law a measure designed to make more affordable some of the new miracle drugs that slow progression of the disease.

Under the law, the South African government could begin issuing licenses to local firms to manufacture low-cost generic versions of patented anti-AIDS drugs.

While the World Trade Organization jealously guards intellectual property rights among its member nations, its global rules of trade do allow for what is known as "compulsory licensing" if it is done to combat a national emergency.

In a country with more than 3 million HIV cases, where one-quarter of pregnant mothers in the poorest provinces are HIV-positive, the new South African compulsory licensing law would seem to meet the WTO's national-emergency guidelines.

The South African law was designed to "ensure through either global market forces or local market forces that medicines become affordable for the people of South Africa," said Ian Roberts, special assistant to the government's health minister.

But the law angered the U.S. pharmaceuticals industry, which fears that widespread licensing of its products will lead to a global "gray market" in low-priced drugs and undermine its profits and incentive to spend on costly research.

It pressed its allies in the U.S. government to swing into action against the South African law. They quickly complied. In Congress, Rep. Rodney Frelinghuysen (R-N.J.) inserted a rider in last October's appropriations bill that temporarily cut off foreign aid to South Africa as a way of

pressuring the State Department to take more forceful action against the law.

U.S. Trade Representative Charlene Barshefsky, saying the South African law was too broad and might be applied to other medicines, denied South Africa special tariff breaks on its exports to the U.S., a move designed to pressure the government to repeal the law. Vice President Al Gore also raised the issue when he visited Mandela earlier this year.

So far, South Africa has refused to back down. That has prompted dozens of American and European pharmaceuticals giants to challenge the law in a South African court, where they recently won a temporary injunction.

"In the West, companies are killing themselves to come up with the next Viagra (Pfizer Inc.'s erectile dysfunction treatment) while the developing world doesn't have access to basic medicines," said Nathan Ford, who works in the London office of the international physicians aid group, Doctors Without Borders. "In many of these countries, tuberculosis and AIDS drugs are priced at Western market levels."

The pharmaceuticals industry considers compulsory licensing "a form of patent piracy," said Thomas Bombelles, of the Pharmaceutical Research and Manufacturers Association, the industry trade group. "It's stealing."

Joe Papovich, assistant U.S. trade representative for intellectual property issues, said: "We're negative toward compulsory licensing. We think companies that have the rights to new inventions should have the right to market them the way they want."

Physicians with not-for-profit groups who labor in poor countries where clinics have been inundated with AIDS patients are using the compulsory licensing issue to pressure the global pharmaceuticals industry to come up with ways of making its high-priced wonder drugs available where needed most.

These groups say the issues surrounding the affordability of AIDS drugs apply equally to treatments for malaria, tuberculosis and meningitis, which kill millions of people each year in the less developed world.

The exotic double- and triple-drug therapies that keep HIV-positive people from developing full-blown AIDS cost more than $10,000 a year per patient in the advanced industrial world and are virtually unheard of in poor countries. Drugs for treating the chronic infections that kill AIDS sufferers can cost $100 to $150 a month in developing countries--more than the average worker's monthly salary.

For example, AZT, a drug made by Glaxo-Wellcome that has been proven effective in inhibiting transmission of HIV from pregnant women to their fetuses, costs about $240 a month in South Africa. Indian drug firms manufacture a generic version of the drug that costs $48 a month.

Jamie Love, director of the Washington-based Consumer Project on Technology, estimates the price of most AIDS-related drugs could be reduced 50 percent to 90 percent if local firms were allowed to produce generic versions to counter national health emergencies.

AIDS activists, not-for-profit clinics and some health ministers from developing countries have pressed the World Health Organization to take up the licensing issue. A draft of a resolution that will be considered by world health ministers next month in Geneva commands developing countries "to explore their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs."

As part of its campaign to forestall widespread compulsory licensing, the drug industry is raising concerns that poorly monitored use of the latest HIV inhibitors might create resistant strains of the virus. Patients taking these drugs must follow a complex daily regimen, and the pills can have unpleasant side effects such as nausea and diarrhea.

"If you just parachute in and give medicines that make them feel sick when they're not sick yet, they won't take them regularly and that can do more harm than good," said Bombelles, of the Pharmaceutical Research and Manufacturers Association.

But physicians who work in these countries call those complaints a false issue. Mark Biot, a Belgium-based physician who oversees Doctors Without Borders' worldwide AIDS efforts, said clinics in most of the larger cities of the developing world would be fully equipped to handle AIDS patients if they had access to affordable tests and drugs.

Biot recently returned from Thailand, where people begin lining up outside Bamrasnaradura Hospital in central Bangkok at 3 a.m. for the weekly AIDS clinic run by his group.

"This is not an undeveloped country," he said. "They have labs and the real opportunity to treat people who are HIV-positive or have opportunistic infections."

The clinic is seeing an increasing number of people who have recently stopped using the combination of AZT and Videx or didanosine (ddI), a reverse transcriptase inhibitor made by Bristol-Myers Squibb. The two drugs taken in combination slow the onset of AIDS.

Because of the Asian financial crisis, those drugs were removed from the government's essential medicines list and are no longer distributed at subsidized prices, according to Biot.

A spokeswoman for Bristol-Myers said the company still supplied the government with Videx but refused to discuss negotiations over its price.

Nearly two-thirds of the world's 33 million HIV-infected people live in the impoverished countries of sub-Saharan Africa. About 6 million live in the poor countries of Asia.

"We have an obligation on life-saving drugs," said Joseph Saba, a director at the United Nations AIDS program (UNAIDS). "If we're going to bind these countries to comply with global trading

treaties, then we have to figure out how to provide drugs needed for public health and life-saving drugs at an affordable price."

UNAIDS has set up pilot programs to bring AIDS-fighting drugs to four countries--Uganda, Ivory Coast, Chile and Vietnam. But the $1 million program, which does receive free drugs from the pharmaceuticals firms, barely scratches the surface in these countries.

What the pilot programs have taught UNAIDS officials is that access to cheaper drugs is only the first step in developing a successful strategy to treat AIDS. In Uganda, for instance, which has 1 million people with HIV, the virus that causes AIDS, "there are no hospitals, no pharmacists, no trained doctors. We have to improve the entire system," Saba said.

But many developing countries do have health-delivery systems capable of treating HIV-infected people. In Thailand, where nearly a million Thais are infected with HIV, a coalition of local not-for-profit groups last fall began pressuring the Thai government to license local firms to manufacture the drugs that hinder the virus' ability to multiply inside the body.

The activists claim the U.S. government pressured the Thai government to abandon its efforts to license the drugs to local manufacturers.

Papovich, who oversees intellectual property issues at the U.S. Trade Representative's office, said he could not recall discussions about compulsory licensing of drugs. He said the U.S. threatened Thailand's special tariff breaks because it failed to curb piracy of copyrighted goods like CDs and software.

But the U.S. trade representative's recently published annual report on Foreign Trade Barriers tells a different story. The report said U.S. businesses were upset that a new Thai pharmaceuticals law might allow compulsory licensing of drugs.

"It's painfully clear U.S. trade representatives are not used to community groups questioning what they do," said Ron McGinnis, director of AIDS programs at the Global Health Council, in Washington. "People now want to know how trade policies affect access to care."