RECORD TYPE: PRESIDENTIAL (TRP NOTES MAIL)

CREATOR: Weber, J. Todd ("Weber, J. Todd" <jtw5@cdc.gov> [UNKNOWN])

CREATION DATE/TIME:21-MAR-1998 16:38:27.00

SUBJECT: FW: Dr. Jonathan Mann on AIDS Vaccines (ag)

TO: Jonathan T. Weber (CN=Jonathan T. Weber/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

TEXT:
> -----Original Message-----

> From: Weniger, Bruce

> Sent: Friday, March 20, 1998 2:50 PM

> To: 'AIDS Vaccine Circulation List'

> Subject: Dr. Jonathan Mann on AIDS Vaccines (ag)

>

>

> FYI, below is the prepared text by

> Jonathan Mann from his presentation before

> the Presidential Advisory Council on HIV and

> AIDS this last week.

>

> Regards,

>

> Bruce

>

> ++++++++++++++++++

>

> Paralysis in AIDS Vaccine Development Violates Ethical

> Principles and Human Rights

>

> Jonathan M. Mann, MD, MPH

> Dean and Professor, School of Public Health

> Allegheny University of the Health Sciences

> Philadelphia, Pennsylvania
> Founding Director, Global Program on AIDS,
> World Health Organization
> March 20, 1998
>
> There is increasing worldwide consensus that a preventive vaccine will be essential for controlling the expanding and intensifying global HIV/AIDS epidemic.
>
> There are several AIDS vaccine candidates which have been shown to be safe in humans, and some produce a variety of immune responses, including those possibly associated with protection against HIV, in a majority of recipients. If the process of vaccine development was proceeding normally - traditionally - this would lead to prompt initiation of field trials to determine protective efficacy of vaccine candidates. Yet years later, field trials of AIDS vaccine candidates are still not underway.
>
> Three reasons have been put forward to explain this unusual deviation from standard vaccine development practice. First, it has been alleged that special ethical problems exist regarding conduct of AIDS vaccine field trials. While important, none of these ethical issues are insurmountable. Secondly, the fear has been expressed that if the first vaccine trial is not highly successful, it would be impossible to conduct further trials; the global urgency and need for an AIDS vaccine make this fear

> groundless.
>
> The third issue involves disagreement within the
> scientific community about whether current candidate
> vaccines will protect. This controversy, inherent in
> development of all vaccines, has been allowed unreasonably
> to paralyze progress towards AIDS vaccine development.
> Something has gone wrong with the process, because the
> history of successful vaccine development, including recent
> vaccines such as against rotavirus and whooping cough
> (pertussis) unequivocally shows that the immune correlates
> of protection are very often unknown, both prior to field
> testing and even after approval for licensure.
>
> Some vaccines (such as against Lyme disease) have
> been found to be highly effective in field trials without
> identifying a human correlate of immunity. And smallpox
> was eradicated using a vaccine whose exact
> mode of action and protection was unknown!
>
> This raises a series of ethical and human rights issues.
> For the failure to proceed expeditiously with field trials of
> available AIDS vaccine candidates constitutes unethical
> practice and violates human rights of Americans.
>
> The key ethical concept of concern is the duty to help
> people in need, and the central human rights violations
> involve the right "to share in scientific advancement and its
> benefits", and the rights to non-discrimination and to life.
>

> The ethical duty to help involves a balance of benefits to another and the risk to self. For example, if you do not know how to swim and you see a person being swept away in a raging river, failure to jump in and try to save the person is not unethical. However, if you are a trained lifeguard and see someone drowning in a calm lake, you have an ethical duty to help.
>
> The failure to mount field trials of available AIDS vaccine candidates, in a manner consistent with traditional and current good vaccine development practice, violates the duty to help and is patently unethical. Requiring certainty about immune correlates of protection before starting field trials of AIDS vaccine candidates is unethical because it creates an unreasonable barrier to progress.
>
> To illustrate: the immune correlates of protection against rotavirus, a major cause of death in childhood worldwide, were unclear when field trials of candidate rotavirus vaccines were initiated. Field trials were started once candidate rotavirus vaccines were shown to be safe and to induce some immune responses. In a series of field trials, rotavirus vaccine proved its effectiveness and today, even while the vaccine was recently approved by the FDA advisory committee and recommended for universal childhood immunization by the federal government's Advisory Committee on Immunization Practices, the immune correlates of protection are still unknown. Proceeding to field tests of rotavirus vaccine was highly ethical, while delaying testing until all the scientific answers

> were available would have been unethical, and detrimental
> to public health.
>
> It is unrealistic and illusory to wait for universal
> consensus within the scientific community about when a
> vaccine candidate is ready for field trials. There has never
> been universal consensus about vaccines: to cite just one
> example, the names of those prominent scientists who
> declamed vigorously against polio vaccine testing have
> been forgotten, while Enders, Salk and Sabin made public
> health history. The decision about how and when to
> proceed to field trials, bearing its own burden of responsibility
> and accountability, is best placed in the hands of those
> experienced with vaccine development, including its public
> health dimensions.
>
> Human rights are also particularly relevant because the
> US government has invested so heavily and several of its
> institutions, including NIH, the Department of Defense,
> CDC and FDA, are involved in AIDS vaccine research and
> development. In this context, federal governmental failure to
> proceed to AIDS vaccine field trials, while contributing
> institutionally and financially to field trials of other vaccines
> which met essentially similar criteria vaccine development
> criteria (human safety and immunogenicity without clear
> knowledge about correlates of immunity) represents
> a clear violation of the human rights of American citizens.
>
> This human rights violation is underscored by the fact
> that the vulnerable population for HIV infection in the United

> States, the estimated 40,000 new HIV infections in 1998, will
> occur predominantly in already marginalized populations,
> thereby exacerbating pre-existing patterns of societal
> discrimination. It is as if the US government had decided
> that the AIDS epidemic could be controlled in this country
> without a vaccine. In contrast, progress towards Lyme
> vaccine development, to protect against a disease affecting
> middle and upper-class populations in this country, has
> proceeded rapidly. Very simply, if 40,000 college
> students were becoming HIV infected each year, it is
> obvious that field trials of AIDS vaccine candidates would
> have long been underway.
>
> Thus, the failure to proceed to field trials, in the
> context not of an ideal world but in the real world of
> successful vaccine development, is unethical and violates
> human rights. The failure to act, like silence, has moral
> consequences.
>
> At an institutional level, this failure stems from decisions
> and recommendations made by NIH and its AIDS vaccine
> advisory committee, both of which are headed by notable
> scientists who nevertheless lack experience with vaccine
> development and public health. This is not a plea for AIDS
> as a special case; no special dispensation is required.
> What is needed is to develop AIDS vaccine candidates
> according to procedures and mile-stone driven strategies
> which have produced highly successful vaccines which
> save millions of lives from diseases like polio, whooping
> cough and measles. It is unethical and violative of human

> rights to hold AIDS vaccine development hostage to a
> requirement for scientific exactitude which is unreasonable
> and may well be unattainable.
>
> Science is an instrument of public health. The larger
> responsibility, central to the moral authority and legitimacy
> of our government, is protection of the public health. The
> program for AIDS vaccine must be lifted above institutional
> defensiveness and parochial interests. The health of America
> and the world needs leadership - "can do" American
> leadership - to develop AIDS vaccines. Failing to proceed
> is unethical and violates basic human rights.
>
> # # #
>

RECORD TYPE: PRESIDENTIAL (TRP NOTES MAIL)

CREATOR: James Love (James Love <love@cptech.org> [UNKNOWN])

CREATION DATE/TIME:17-APR-1998 13:21:30.00

SUBJECT: Tom Kalil: Letter to Clinton Re: Amgen

TO: Thomas A. Kalil (CN=Thomas A. Kalil/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

TEXT:
Tom, do you know who in the WH I should call to talk about this issue?

Basically, it concerns allegations (from Lawerence Berkeley Lab) that

Amgen is suppressing an invention that would cut EPO doses. Jamie

Ralph Nader

P.O. Box 19312

Washington, DC 20036

Ralph@essential.org

James Love

Consumer Project on Technology

P.O. Box 19367, Washington, DC 20036

202.387.8030, love@cptech.org

http://www.cptech.org

April 16, 1998

President Bill Clinton

The White House

Washington, DC

Dear President Clinton:

We are writing to ask for an investigation concerning the possible suppression of an important public health invention. In this respect we are attaching copies of our April 16, 1998 letter to Gordon Binder, Chairman of the Board and Chief Executive Officer of Amgen Inc., the company which currently markets EPOGEN© which is Amgen's trademark for its recombinant human erythropoietin, or EPO.

Our concern is the following. Public health researchers, supported by public funds, have identified a mechanism to reduce a patient?s loss of EPO during treatment, significantly reducing the amount of EPO a patient needs to take. This invention has the potential to save consumers hundreds of millions of dollars per year, and to make EPO more broadly available to patients who cannot currently afford the drug.

The invention was developed at Lawrence Berkeley Laboratory (LBL), a national laboratory, and was supported by grants from the National Institutes of Health (NIH). According to the inventor and LBL officials involved in attempts to commercialize the invention, Amgen was approached several years ago about research which would solve an important problem in treating patents for anemia ? the natural discharge of EPO into the urine which requires patients to take large doses of EPO. This problem is particularly important for patients with immature renal systems such as infants and children. The LBL invention involves a protein binding factor which may eliminate entirely the need for the purchase of EPO for some patients, and for other patents the invention would reduce the needed doses of EPO. The inventor believes this may reduce by half the average doses needed for EPO ? a very expensive drug which can cost several thousand dollars.

LBL staff believe Amgen is hostile to the commercialization of this invention simply because it would significantly reduce demand for EPO -- a product which generated $1.16 billion for Amgen in 1997. Other U.S. and European biotechnology companies have reportedly expressed concerns that Amgen would oppose the development of the invention through costly and time-consuming litigation, and would withhold important intellectual property licenses from firms which made efforts to commercialize this invention.

Public health concerns should be paramount in determining which therapies are available to consumers. Amgen?s EPO product was made possible by decades of public funded research on EPO, and Amgen has benefited also from subsidies from EPO?s designation as an Orphan Drug and other public programs to support the biotechnology industry. Amgen is currently seeking support from public institutions to obtain additional intellectual property rights on gene research and EPO.

We are appalled at the reports that Amgen, a company which has so richly benefited from public research, would not respond responsibly to public health research that would benefit patients. The fact that the client population most affected are children underscores the ethical issues that you must address.

We ask that you investigate every aspect of this matter, to determine if there are indeed barriers to the development of the LBL invention, and if so, whether Amgen?s actions run counter to antitrust laws, and also whether are there are other remedies available to address this issue.

As part of this investigation, we specifically ask that you determine how Amgen currently benefits from government subsidies to the

biotechnology sector, and if it would be appropriate to withhold publicly supported intellectual property rights or research support for a company, if that company refuses to address legitimate and important public health concerns.

Finally, we ask that the U.S. Patent and Trademark Office, the U.S. Trade Representative, the Department of Health and Human Services and the Federal Trade Commission evaluate U.S. positions in trade negotiations on intellectual property rights, and determine if provisions on compulsory licensing that exist in the WTO, NAFTA or the proposed Multinational Agreement on Investments permit governments to adequately address public health concerns.

We also ask you to consult the World Health Organization (WHO) to determine what steps if any WHO recommends to address this or similar public health problems, and we urge the United States to support the World Health Assembly Executive Board Resolution EB101.R24, on the WHO Revised Drug strategy, that urges member states:

> (2) to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs;

We look forward to receiving a response from your office on this matter. We also invite your staff to attend a meeting on intellectual property rights and health care that will be held on May 7 and 8, 1998, in

Washington, DC. Information about this event is available on the Internet at http://www.cptech.org/may7-8.

Sincerely,

/s/
Ralph Nader

/s/
James Love

This letter is on the Internet at http://www.cptech.org/pharm/amgen.html

Ralph Nader
P.O. Box 19312
Washington, DC 20036
Ralph@essential.org

James Love
Consumer Project on Technology
P.O. Box 19367, Washington, DC 20036
202.387.8030, love@cptech.org
http://www.cptech.org

April 16, 1998

Gordon Binder
Chairman of the Board

and Chief Executive Officer

Amgen Inc.

Amgen Center

Thousand Oaks, CA 91320-1789

Via fax: 805/447-1010

We are writing to express our concern over reports that Amgen is opposed to the development of an invention that significantly reduces the amount of Erythropoietin (EPO) needed to treat anemia. The invention was developed at Lawrence Berkeley Laboratory (LBL), which was supported by the National Institutes of Health (NIH), Lung, and Blood Institute grant HL 22469, and received U.S. Patent 5625035. According to the inventor, Gisela K. Clemons, of Berkeley, CA, this dates back to research done in 1991, and the inventor and the LBL have engaged in extensive discussions with Amgen regarding the significance of the invention, and the benefits to EPO patients. According to the inventor and LBL officials involved in attempts to commercialize the invention, Amgen has declined to further test the invention, and other U.S. and European biotechnology companies have expressed concerns that Amgen would oppose the development of the invention through costly and time consuming litigation, and would withhold important intellectual property licenses from firms which made efforts to commercialize this invention.

The invention would reduce the amount of EPO needed by patients suffering from anemia, including premature infants and those with anemia due to kidney failure, AIDS related illnesses or other diseases, or surgery needs. According to the inventor, this invention may eliminate entirely the need for the purchase of EPO for some patients, and for other patients the invention would significantly reduce the needed doses

of EPO. It is possible that the invention would reduce by half, on average, the amount of EPO needed by those suffering from anemia.

As you know, the commercial development of EPO benefited from decades of government funded research on Erythropoietin. Amgen is also expecting to benefit from government funded research in other areas, and has recently approached government funded research laboratories for assistance in further research relating to the use of EPO. Amgen has benefited due to generous tax credits from manufacturing goods in Puerto Rico, the Orphan Drug Tax Credit, and the Research and Development Tax credit and from other government subsidies.

As a result of all these subsidies by taxpayers, Amgen has benefited richly from the commercial development of EPO, which produced 1997 sales of $1.16 billion. According to the Amgen 10K report, gross margins on EPO and Amgen? ?s other products are greater than 86 percent.

Researchers and licensing officials at LBL believe Amgen is opposed to the development of the new binding protean technology because such an invention might reduce by half the average doses of EPO needed by current anemia patients.

We would like to know from you if Amgen is indeed resisting the deployment of a valuable public health invention simply to protect the revenues it receives from EPO patients. If Amgen is not trying to suppress this invention in order to protect its profits, then what is Amgen doing to further develop this important discovery?

Sincerely,

/s/

Ralph Nader

/s/

James Love

This letter is on the Internet at http://www.cptech.org/pharm/amgen.html

--

James Love

Consumer Project on Technology

P.O. Box 19367, Washington, DC 20036

love@cptech.org | http://www.cptech.org

voice 202.387.8030, fax 202.234.5176

--

James Love

Consumer Project on Technology

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voice 202.387.8030, fax 202.234.5176

RECORD TYPE: PRESIDENTIAL (TRP NOTES MAIL)

CREATOR: Richard Sorian (Richard Sorian <SORIANR@gunet.georgetown.edu> [UNKNOWN]

CREATION DATE/TIME: 1-OCT-1998 15:59:07.00

SUBJECT: fyi

TO: Daniel C. Montoya (CN=Daniel C. Montoya/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

TEXT:

WHO: New Director Addresses Global AIDS Issues

Dr. Gro Harlem Brundtland, the new director-general of the World Health Organization, spoke yesterday about her agency's commitment to curb infectious diseases during an interview with PBS NewsHour's Susan Dentzer. Brundtland, like Jonathan Mann, the former head of WHO's global AIDS effort, said she recognizes the importance of eliminating the disparity in AIDS care and services between people in affluent and impoverished countries. She said she will work toward providing pregnant women worldwide with access to anti-AIDS drug regimens, in an effort to curb vertical HIV transmission. Furthermore, she asserted that an emphasis on research will lead to less expensive drugs, "so that we can make ... a major effort" to provide similar care to all economic groups worldwide. In conclusion, Brundtland said that all nations have a responsibility to address global health

issues. "Presidents, prime ministers and finance ministers are, indeed, health ministers" and influence policies impacting global health, she said (9/29). (Back to Contents)

RECORD TYPE: PRESIDENTIAL (TRP NOTES MAIL)

CREATOR: JWright (JWright@osophs.dhhs.gov (Jason Wright) [UNKNOWN])

CREATION DATE/TIME:14-MAY-1999 21:30:06.00

SUBJECT: Sign-on letter to Vice President Gore regarding his oppositi

TO: Daniel C. Montoya (CN=Daniel C. Montoya/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

TO: montoya_dc (montoya_dc@al.eop.gov [UNKNOWN])
READ:UNKNOWN

TEXT:
Daniel,

FYI.

Jason

_____ Forward Header

_____

Subject: Sign-on letter to Vice President Gore regarding his oppositi

Author: love@cptech.org at INTERNET

Date: 5/14/99 5:15 PM

****

Sign-on letter to Vice President Gore regarding his

opposition to African access to essential medicines

****

** Over the past three years public health groups have repeatedly petitioned Vice President Gore (co-chair of the US/South Africa Binational Commission) and US trade organizations to stop pressuring South Africa and other developing countries over to access to medicines.

** The disputes involve complex intellectual property and trade matters. In essence, the US government is demanding that South Africa, India, Thailand and many other countries not enact provisions in WTO/TRIPS rules on intellectual property that would lower drug prices. The US position is that WTO rules regarding protection of patent rights are not high enough.

** Africa is suffering from a mind boggling public health emergency. According to the US Surgeon General, in nine south African nations, 20% to 26% of people between the ages of 15 and 49 are infected with HIV/AIDS. The disease is also widespread and growing in Thailand, India and other parts of the world, and is associated also with new epidemics in tuberculous, meningitis and other diseases. Public health authorities believe this is creating new treatment resistance strains of infectious illnesses.

** So far all efforts to change US policy have failed. On April 30, 1999, Vice President Gore authorized the USTR to issue a sweeping new review of South Africa policies on compulsory licensing, parallel imports and approval of generic drugs such as Taxol. Among other things, the US government is officially punishing South African for permitting its public health officials to speak out on trade and intellectual property issues in the World Health Organization.

** Public health groups now are trying to reach a broader

audience. We are asking for signatures on the following letter to the Vice President. We hope we can raise enough public awareness in this issue that the Vice President will be forced to change US policy. Please help circulate this important letter.

James Love <love@cptech.org> 202.387.8030
http://www.cptech.org

If you are willing to sign, please send the following information to James Love by mail <love@cptech.org> or by fax 202.234.5176.

Yes, include my name:
Name:
Title (optional):
Affiliation (optional):
City, State, Country:

(For more info, see http://www.cptech.org/ip/health/sa
signatures will be accepted through June 30, 1999)

<-----the sign-on letter to Vice President Gore------>

Dear Vice President Gore,

We are writing to express opposition to trade pressures you are bringing against the people of South Africa over their struggle to obtain access to essential medicines.

The White House dispute with South Africa concerns three

basic points.

1. The South Africa government has indicated it wants to use compulsory licensing of medical patents to produce cheaper copies of HIV drugs and other essential medicines. This is of course legal under the WTO/TRIPS agreement, subject to Article 31 safeguards.

2. The South Africa government wants to authorize "parallel imports" of pharmaceuticals, so that it can buy drugs in the United States, Europe or elsewhere, in order to get the best world price. As you know, parallel importing of pharmaceuticals is legal under Article 6 of the WTO/TRIPS agreement, and is a common practice in Europe.

3. The South African government has approved generic versions of Taxol, a US government invention for treating cancer.

As co-chairman of the US/South Africa Binational Commission (BNC) you have authorized a wide range of trade pressures against South Africa, much of which is documented in a February 5, 1999 report to the Congress by the US Department of State. (See:http://www.cptech.org/ip/health/sa/stdept-feb51999.html).

Despite increasing criticism of the US bilateral pressures on South Africa, here and internationally, your office has authorized new trade pressures against South Africa on April 30, 1999. (http://www.cptech.org/ip/health/sa/sa301-ap99.html)

The April 3 "in many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected." 0, 1999 announcement of a Special 301 out-of-cycle review of trade pressures against South Africa ignored every shred of information that has been provided to your office by public health groups. Indeed, this most recent announcement is basically a recycled version of the February 16, 1999 submissions by the Pharmaceutical Research and Manufactures Association (PhRMA), the trade association that represents giant drug companies like Bristol-Myers Squibb, Glaxo, Pfizer, and Johnson and Johnson that are trying to stop South Africa from implementing policies to cut costs for pharmaceuticals in South Africa.

It is shocking that the US government is adapting such an aggressive trade policy on behalf of US pharmaceutical companies, when all of sub-Saharan Africa is confronted with a public health crisis of historical dimensions. The US Surgeon General, Dr. David Satcher, recently wrote in the Journal of the America Medical Association that "HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century." Dr. Satcher says that "in many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected."

This is a here-and-now emergency. It is not a hypothetical or potential emergency. These people will die without access to pharmaceutical drugs.

Your response to this emergency should be to find ways to

save lives. But look what you are doing.

** You are aggressively seeking the repeal of legislation in South Africa that would permit that country to do what nations in Europe do, use parallel imports to buy drugs at the best world price. South Africa wants to use market forces to cut drug costs. You are pushing to protect pharmaceutical companies from global competition, thereby forcing the South Africa people to pay premiums to buy drugs.

** You are punishing South Africa for even speaking out in favor of compulsory licensing of HIV/AIDS and other essential medicines. The April 30, 1999 report on South Africa complains that:

> During the past year, South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS.

In fact, everything South Africa is seeking to do is legal under the WTO/TRIPS agreement, so this and countless other statements by US government officials are bald lies. But regardless, the exercise of free speech in international forums is an astonishing basis for trade sanctions. As an elected official, indeed, as a human, how would you act if 20 percent of all sexually active young people in the United

States were infected with a fatal disease, and a foreign country was trying to prevent you from purchasing drugs on the global market to save money, and was preventing you from licensing firms to manufacture life saving medicines? Would you simply show up at the World Health Assembly and docilely applaud the actions of that country? Even if that foreign country was engaged in a relentless public relations campaign to label every legal action as a form of piracy or lawlessness? At what point would you have the guts to tell the world the truth, and to speak out on behalf of millions of infected young men and women?

** You are punishing South Africa for giving approval to generic versions of Taxol, a cancer drug that was invented by the US government. There are aspects of the US government complaint about Taxol that are absurd, on technical grounds, such as the insistence that South Africa extend longer periods of data exclusivity than are required in the United States. But the larger issue is more basic. Why on earth should Vice President Al Gore or any other US government employee seek to prevent global competition for Taxol, a life saving cancer drug that was invented and developed by the US National Institutes of Health? Taxol was in NIH sponsored Phase III trials before the Bush Administration gave BMS exclusive rights to use NIH research for drug approvals. What is the moral basis for extending the BMS monopoly on Taxol in a country that is so poor?

As the Vice President of the United States you are in a

position to do much good or much harm in the world. US voters will soon be asked to determine if you should be the next President of the United States. Please explain why they should choose you.

Sincerely,

James Love
Director
Consumer Project on Technology

Dr. Bernard P?coul
Project Director
Access to Essential Drugs
M?decins Sans Fronti?res

Joelle Tanguy
Executive Director
Doctors Without Borders/Medecins Sans Frontieres USA

Eric Sawyer
Executive Director
HIV/AIDS Human Rights Project

Kim Nichols
Development Director
African Services Committee, Inc.

Bas van der Heide

Director

Health Action International Europe

Beryl Leach

Africa Program Coordinator

Health Action International

Lori Wallach

Director

Global Trade Watch

Professor Richard Laing

Boston University

Robert Weissman

Co-Director

Essential Action

David Scondras

President

Search for a Cure

Bob Lederer

Senior Editor

POZ Magazine

Steve Suppan, PhD

Director of Research

Institute for Agriculture and Trade

Axel Delmotte

Act Up - Paris

Professor Patrick Bond

University of the Witwatersrand

Graduate School of Public and Development Management

Johannesburg, South Africa

Clarence Mini, MD

Treatment Action Campaign

Johannesburg, Gauteng Province, South Africa

Ellen 't Hoen

International Drug Policy Consultant

Amsterdam, The Netherlands

--

James Love, Director, Consumer Project on Technology

I can be reached at love@cptech.org, by telephone 202.387.8030,

by fax at 202.234.5176. CPT web page is http://www.cptech.org

RECORD TYPE: PRESIDENTIAL (TRP NOTES MAIL)

CREATOR: JWright (JWright@osophs.dhhs.gov (Jason Wright) [UNKNOWN])

CREATION DATE/TIME:25-MAY-1999 19:28:55.00

SUBJECT: Re: AIDS and South Africa

TO: Thomas_M._Rosshirt (Thomas_M._Rosshirt@ovp.eop.gov [ovp])
READ:UNKNOWN

CC: Daniel C. Montoya (CN=Daniel C. Montoya/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

CC: montoya_dc (montoya_dc@a1.eop.gov [UNKNOWN])
READ:UNKNOWN

TEXT:

Tom,

Since you have not had the opportunity to respond to my voice mail, I thought that I would send you a copy of the draft letter.

The letter originates from the Consumer Project on Technology, which is directed by James (Jamie) Love and is under the Center for Study of Responsive Law started by Ralph Nader in 1968.

An initial list of signatures appears at the bottom of the letter. Signatures are to be accepted through June 30.

I continue to update Daniel Montoya on the issue. Since it is an extremely complicated issue, please feel free to contact me if you would like more background.

Jason Taylor Wright, MSFS, MA
International Health Officer
Office of International and Refugee Health
Department of Health and Human Services
(301) 443-7246 phone

(301) 443-6288 fax

jwright@osophs.dhhs.gov

_____ Reply Separator

_____

Subject: AIDS and South Africa

Author: Thomas_M._Rosshirt@ovp.eop.gov at INTERNET

Date: 5/19/99 4:22 PM

Jason:

I've heard you're on top of the issue of AIDS, Africa, and the cost of pharmaceuticals. Do you know anything about the group releasing the petition, and whether the petition has been released yet? thanks.

Tom

****

Sign-on letter to Vice President Gore regarding his opposition to African access to essential medicines

****

** Over the past three years public health groups have repeatedly petitioned Vice President Gore (co-chair of the US/South Africa Binational Commission) and US trade organizations to stop pressuring South Africa and other developing countries over to access to medicines.

** The disputes involve complex intellectual property and trade matters. In essence, the US government is demanding that South Africa, India, Thailand and many other countries not enact provisions in WTO/TRIPS rules on intellectual property that would lower drug prices. The US position is that WTO rules regarding protection of patent rights are not high enough.

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http://www.cptech.org

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Yes, include my name:

Name:

Title (optional):

Affiliation (optional): City, State, Country:

(For more info, see http://www.cptech.org/ip/health/sa signatures will be accepted through June 30, 1999)

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We are writing to express opposition to trade pressures you are bringing against the people of South Africa over their struggle to obtain access to essential medicines.

The White House dispute with South Africa concerns three basic points.

1. The South Africa government has indicated it wants to use compulsory licensing of medical patents to produce cheaper copies of HIV drugs and other essential medicines. This is of course legal under the WTO/TRIPS agreement, subject to Article 31 safeguards.

2. The South Africa government wants to authorize "parallel imports"

of pharmaceuticals, so that it can buy drugs in the United States, Europe or elsewhere, in order to get the best world price. As you know, parallel importing of pharmaceuticals is legal under Article 6 of the WTO/TRIPS agreement, and is a common practice in Europe.

3. The South African government has approved generic versions of Taxol, a US government invention for treating cancer.

As co-chairman of the US/South Africa Binational Commission (BNC) you have authorized a wide range of trade pressures against South Africa, much of which is documented in a February 5, 1999 report to the Congress by the US Department of State. (See http://www.cptech.org/ip/health/sa/stdept-feb51999.html.)

Despite increasing criticism of the US bilateral pressures on South Africa, here and internationally, your office has authorized new trade pressures against South Africa on April 30, 1999. (See: http://www.cptech.org/ip/health/sa/sa301-ap99.html.)

The April 30, 1999 announcement of a Special 301 out-of-cycle review of trade pressures against South Africa ignored every shred of information that has been provided to your office by public health groups. Indeed, this most recent announcement is basically a recycled version of the February 16, 1999 submissions by the Pharmaceutical Research and Manufactures Association (PhRMA), the trade association that represents giant drug companies like Bristol-Myers Squibb, Glaxo, Pfizer, and Johnson and Johnson that are trying to stop South Africa from implementing policies to cut costs for pharmaceuticals in South Africa.

It is shocking that the US government is adapting such an aggressive trade policy on behalf of US pharmaceutical companies, when all of sub-Saharan Africa is confronted with a public health crisis of historical dimensions. The US Surgeon General, Dr. David Satcher, recently wrote in the Journal of the America Medical Association that "HIV/AIDS can be likened to the plague that decimated the population of Europe in the 14th century." Dr. Satcher says that "in many southern African countries, HIV/AIDS has become an unprecedented emergency, with 20% to 26% of people between the ages of 15 and 49 infected."

This is a here-and-now emergency. It is not a hypothetical or potential emergency. These people will die without access to pharmaceutical drugs.

Your response to this emergency should be to find ways to save lives. But look what you are doing.

** You are aggressively seeking the repeal of legislation in South Africa that would permit that country to do what nations in Europe do, use parallel imports to buy drugs at the best world price. South Africa wants to use market forces to cut drug costs. You are pushing to protect pharmaceutical companies from global competition, thereby forcing the South Africa people to pay premiums to buy drugs.

** You are punishing South Africa for even speaking out in favor of compulsory licensing of HIV/AIDS and other essential medicines. The April 30, 1999 report on South Africa complains that:

During the past year, South African representatives have led a faction

of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS.

In fact, everything South Africa is seeking to do is legal under the WTO/TRIPS agreement, so this and countless other statements by US government officials are bald lies. But regardless, the exercise of free speech in international forums is an astonishing basis for trade sanctions. As an elected official, indeed, as a human, how would you act if 20 percent of all sexually active young people in the United States were infected with a fatal disease, and a foreign country was trying to prevent you from purchasing drugs on the global market to save money, and was preventing you from licensing firms to manufacture life saving medicines? Would you simply show up at the World Health Assembly and docilely applaud the actions of that country? Even if that foreign country was engaged in a relentless public relations campaign to label every legal action as a form of piracy or lawlessness? At what point would you have the guts to tell the world the truth, and to speak out on behalf of millions of infected young men and women?

** You are punishing South Africa for giving approval to generic versions of Taxol, a cancer drug that was invented by the US government. There are aspects of the US government complaint about Taxol that are absurd, on technical grounds, such as the insistence that South Africa extend longer periods of data exclusivity than are required in the United States. But the larger issue is more basic. Why on earth should Vice President Al Gore or any other US government employee seek to prevent global competition for Taxol, a life saving cancer drug that was invented and developed by the US National

Institutes of Health? Taxol was in NIH sponsored Phase III trials before the Bush Administration gave BMS exclusive rights to use NIH research for drug approvals. What is the moral basis for extending the BMS monopoly on Taxol in a country that is so poor?

As the Vice President of the United States you are in a position to do much good or much harm in the world. US voters will soon be asked to determine if you should be the next President of the United States. Please explain why they should choose you.

Sincerely,

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Consumer Project on Technology

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