

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
--------------------------	---------------	------	-------------

001. letter	[Personally Identifiable Information] [partial] (1 page)	06/01/1997	b(6)
-------------	--	------------	------

COLLECTION:

Clinton Presidential Records
Staff Secretary
Todd Stern
OA/Box Number: 9359

FOLDER TITLE:

Chron Files: Thursday, June 19, 1997

2019-0774-S

rs3361

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE PRESIDENT HAS SEEN
6/19/97

June 18, 1997

Stanley

MEMORANDUM

To: The President

From: Nancy Hernreich
Ana Lee Sanchez

Re: Memo from Stanley Sheinbaum on American Jewish attitudes toward Israel

Stanley Sheinbaum and Marge Tabankin write about the fact that American Jews are revising their attitudes toward Israel and drastically cutting back on their support for Israel. The two main reasons are: 1) Orthodox Jewish leadership- mainly in Israel- no longer recognize those who are not Orthodox but merely Reform or Conservative as Jewish and 2) Bibi Netanyahu is dragging his feet on the peace process which has caused many to lose hope and trust.

Fewer and fewer Jewish Federations across the country are interested in supporting Israel. This is due in part because Jews have begun to worry about the American Jewish community and at the same time have seen Israel become more economically sound. There has been an increasing disappointment in the peace process which has intensified the feeling that Israel should no longer be supported unconditionally.

Marge Tabankin senses that many American Jews think that you are not getting more involved in the Middle East because you think the Jewish community still wants the United States to support Israel unconditionally. The increasing schism over how Israel should exist and the cynicism needs to stop.

Stanley suggests you meet with Marge Tabankin if you don't already know her personally - you can check with Sandy Berger since he has worked with her before.

*Copied
Berger
eos*

Chyon



Stanley K. Sheinbaum

FAX TRANSMITTAL

DATE: JUNE 17, 1997

TO: NANCY HERNREICH

FIRM: THE WHITE HOUSE

FROM: STANLEY K. SHEINBAUM

COMMENTS: NANCY,

PLEASE FORWARD THIS TO THE PRESIDENT. I CONSIDER

IT IMPORTANT. THANK YOU.

OF PAGES (including cover sheet) 6

DESTINATION FAX #

*If you experience any problems with this transmittal
please call us at 310-472-9541*

Fax: # 310-476-9853

e-mail: SKS345@aol.com

345 North Rockingham Avenue Los Angeles California 90049-2635 Telephone (310) 472-9541 FAX (310) 476-9853



Stanley K. Sheinbaum

CONFIDENTIAL

MEMO TO: President Bill Clinton

DATE: June 17, 1997

SUBJECT: American Jewish attitudes toward Israel--something dramatic is happening.

Marge Tabankin--whom I think you know or at least know of--has just brought something to my attention that I feel is critically important for you. I have known Marge for about thirty years and for perhaps the last ten years she has handled Barbra Streisand's political and philanthropic affairs and for the last two years the same also for Steven Spielberg. Especially in the latter category she has been the recipient of what sounded like an infinity of approaches from the leaders of the major Jewish Federations around the country. Each city has a Federation which briefly described is something of an umbrella organization for most Jewish community activities.

What Marge has discerned comes down to this: For them something of an emergency situation is developing as American Jews are revising their attitudes toward Israel and, worse, are cutting back drastically on their support for Israel. Obviously, Spielberg, being a billionaire with a manifest (*Schindler's List*) and deep interest in Jewish affairs is among the few to whom they could turn at a time when a large number of American Jews are starting to fall away. Thus the calls to Marge.

She called me last week here in Italy, and in a long and very substantive discussion filled me in on what she had been experiencing in her conversations with the Federation types. It was both startling and dramatic, and seems to reflect something new in the American political scene. She then wrote me the attached memo, which very briefly but powerfully articulates what it is that she learned. Better you should read her memo, not mine.

I will not attempt to repeat all that, other than to say there are two major concerns about Israel among American Jews. First, the Orthodox Jewish leadership--especially in Israel--has been taking a strong stand that those of us who are not Orthodox but "merely" Reform or Conservative cannot purport ourselves to be Jewish. This has long been an issue within Israel itself, but to have thrown it at American Jews is no less than scary and insulting--profoundly so, and is fast becoming an intense concern for American Jews.

The second issue, of course, is how Bibi Netanyahu has been foot dragging on the peace process. Many are convinced that he is determined to bring it to an end, even though he keeps protesting that he supports Oslo. Without the very right wing religious part of his coalition pounding the table he could possibly be less rigid, but also without them his coalition would not exist.

DETERMINED TO BE AN ADMINISTRATIVE

MARKING INITIALS: OB DATE: 07/29/97
2019-0774-S

Over this past year there has been increasing public comment that you and therefore your colleagues have been reluctant because of the American Jewish vote to apply pressure on Netanyahu to move more aggressively on the peace process. If there is any validity to that at all then we cannot make the claim to being the *honest brokers* in the mediation and thus we seriously weaken our ability to work with the two sides.

The point, of course--to repeat Marge--is that if American Jewish attitudes are turning away from concerns about Israel in these two regards then the tactic--if indeed such really exists--of keeping pressure off Netanyahu is a wasted exercise. In fact, except for the relatively few elite Jewish country club types you will always have the support of the greater number of American Jews.

Over the three decades I have known and worked with Marge Tabankin she is clearly one of the sanest and soundest political activists I have ever been involved with. In fact, she and I and Sandy Berger were on the Board of Mark Green's Democracy Project for a number of years. (You should have been there too.) So you might want to check with Sandy on my judgment about her. In fact, if you don't know Marge personally I strongly suggest that you ask her to come visit. She's worth the time.

While her conclusions are clearly not the result of a scientific poll, the comments she got had a clear consistency. In any event, given the policy recommendation herein, it all should be checked out.

Going back to the matter of the peace process, Netanyahu's inertia--a mild term--is suddenly compounded by the clumsiness--an even milder term--of Arafat what with jailings and murders without due process, and the misuse--again putting it mildly--of hundreds of millions of dollars of donor country funds by Arafat's own people. It is hard to be critical of Netanyahu to anybody and certainly to him directly when the response that so readily comes back with some seeming evidence is that Arafat is worse.

The damage to the peace process no doubt has been further exacerbated by Arafat. Recently, however, there does seem to be some signs of contrition (mild again) by him of these failures of democracy and corruption. That does not a clean slate make, but he is beginning to call for due process and now is actively cooperating with the Swedes to take a close look at the matter of the funds. After the fact, that sort of thing only helps a little. Whatever Arafat's failings, they should not take Netanyahu off the hook. They are both at fault, but keep in mind that Netanyahu's provocations mainly hurt Palestinians. Arafat's don't hurt the Israelis, only his own people.

President Clinton

June 17, 1997

Page 3

The focus of all these comments obviously falls heaviest on Netanyahu--by a long shot. He's the one who is working aggressively against the peace process itself. Arafat is just being dumb--thereby getting in the way of everyone who needs or wants peace--especially the Palestinians, himself included.

I urge you to consider the implications of this very carefully.

With continued respect and warmest wishes.

P.S. From the news shots your leg looks better. I hope so. However, the cane does add dignity.

P.P.S. Marge Tabankin's number is 310-395-3599

P.P.S. I am Italy, but moving around. If anyone needs me, I can be reached through my office in Los Angeles at 310-472-9541.

**RIGHTEOUS
PERSONS
FOUNDATION**

MEMORANDUM

TO: Stanley Sheinbaum
FROM: Margery Tabankin 
DATE: June 10, 1997

CHAIRMAN
Steven Spielberg

BOARD OF DIRECTORS
Gerald Breslauer, President
Bruce Ramer
Michael Rutman

EXECUTIVE DIRECTOR
Margery Tabankin

PROGRAM OFFICER
Rachel Levin

It was good talking to you this morning.

After our conversation, I thought that it might be useful to put into writing a few of the things that we discussed. As I mentioned when we spoke, my recent work heading up Steven Spielberg's Righteous Persons Foundation has led me to see that the Jewish community is no longer the monolith that many people still assume.

I have found this disparity most striking in the area of Israel. While only a few years ago Jewish Federations across the country were able to raise hundreds of support Israel, now they are finding that their donors are less interested in Israel (and in some cases even resent their money going abroad).

This trend has existed for the past few years as Jews have begun to worry about the American Jewish community and at the same time seen Israel become more economically viable. However, the recent outrage over the issue of religious pluralism in Israel and increasing disappointment in the peace process has rapidly intensified the feeling that Israel should no longer be supported unconditionally.

I know you are aware of how upset many in the community were when they were told by a group of Orthodox rabbis (hoping to influence Israeli policy) that those who practice Conservative and Reform Judaism are no longer Jews. While the repercussions of this are just beginning to play out on the domestic front, it has had an incredible impact on the way many Jews view their relationship to Israel. There is a strong perception and increasing sense of anger that Netanyahu has allowed extreme Orthodox factions in Israel to have a stronghold on the religious (and even civic) nature of the country. The ultra Orthodox are now in the position of being able to determine in essence who is a Jew (a definition which many American Jews do not fit).

This sense of anger and betrayal around the issue of religious pluralism is matched by incredible disillusionment with the way Netanyahu has dealt with the peace process. In the past, whether or not people agreed with Rabin's strategy, they were willing to wait and see where he was leading the country. With Netanyahu, the feeling of trust and even hope no longer exists. In my travels I have found a tremendous sense of despair about Netanyahu's policies and judgments. Many people (even those who supported him in the beginning) do not feel like he is taking Israel on the right path and thus have become more estranged from the country.

1460 Fourth Street
Suite 212
Santa Monica, CA 90401
310.395.3599
310.395.9676 Fax

While American Jews have disagreed with Israel's policies in the past, I have never seen such a profound sense of disappointment and increasing detachment. Clearly, if Israel were in true jeopardy, I believe people would come to its rescue. But until that moment, I think people will increasingly feel removed and cynical.

My sense is that many American Jews think the President is not getting more involved in the Middle East because he thinks that the Jewish community still wants the United States to support Israel unconditionally. While I believe there is a consensus on Israel's *right* to exist, there is an increasing schism over *how* Israel should exist - over the character and nature of the country which binds Jews from all over the world.

As I said when we spoke, these are my views. I am not speaking for Steven or the Foundation. However, I thought it important to reflect on what I have been seeing.

Hope all is well with you and I will talk to you soon.

CENTENNIAL SCHOOL DISTRICT**Office of the Superintendent**

Administration Building
433 Centennial Road
Warminster, PA 18974-5455
(215) 441-6225

June 10, 1997

Ms. Betty W. Currie
Personal Secretary to the President of the United States
1st Floor West Wing
The White House
1600 Pennsylvania Avenue, North Wing
Washington, DC 20500

Dear Ms. Currie:

'97 JUN 18 AM 11:54

The Centennial School Board in Warminster, Pa. will be meeting with Senator Arlen Specter on Tuesday, June 17 at 1:30 p.m. in his Washington office, 711 Hart Senate Office Building.

The purpose of the meeting is to resolve the financial condition created by the military housing installation located within the Centennial School District.

At present, the Centennial School District is educating some 300 students residing in housing under the jurisdiction of the Willow Grove Naval Air Station, which is located in a neighboring school district. The annual cost to Centennial is in excess of \$2,000,000.

We would like to invite President Clinton, or his representative, to attend our meeting with Senator Specter so that he may become more fully acquainted with this financial condition and of our difficulty in resolving this problem despite communications with the Department of the Navy, the U. S. Department of Education, the Willow Grove Naval Air Station, as well as the Pennsylvania Department of Education.

I would appreciate your responding to this invitation by contacting me at 441-2665 as to President Clinton's availability to attend this meeting.

Sincerely,

Nancy A. Reid

Nancy A. Reid, Ed.D.
Superintendent

/rmd

To Scheduling for
reply.

6-18-97

~~Did this go
to Scheduling?
I don't need!~~

[Signature]

CENTENNIAL SCHOOL DISTRICT



Office of the Superintendent

Administration Building
433 Centennial Road
Warminster, PA 18974-5455
(215) 441-6225

*Handled
file*

June 10, 1997

Ms. Betty W. Currie
Personal Secretary to the President of the United States
1st Floor West Wing
The White House
1600 Pennsylvania Avenue, North Wing
Washington, DC 20500

Dear Ms. Currie:

The Centennial School Board in Warminster, Pa. will be meeting with Senator Arlen Specter on Tuesday, June 17 at 1:30 p.m. in his Washington office, 711 Hart Senate Office Building.

The purpose of the meeting is to resolve the financial condition created by the military housing installation located within the Centennial School District.

At present, the Centennial School District is educating some 300 students residing in housing under the jurisdiction of the Willow Grove Naval Air Station, which is located in a neighboring school district. The annual cost to Centennial is in excess of \$2,000,000.

We would like to invite President Clinton, or his representative, to attend our meeting with Senator Specter so that he may become more fully acquainted with this financial condition and of our difficulty in resolving this problem despite communications with the Department of the Navy, the U. S. Department of Education, the Willow Grove Naval Air Station, as well as the Pennsylvania Department of Education.

I would appreciate your responding to this invitation by contacting me at 441-2665 as to President Clinton's availability to attend this meeting.

Sincerely,

Nancy A. Reid, Ed.D.
Superintendent

/rmd

CENTENNIAL SCHOOL DISTRICT • DEDICATED TO OUR STUDENTS AND THEIR FUTURE

Our mission is to provide educational programs, and experiences which will enable students to become confident, responsible, and productive citizens

PHILIP M. CRANE, ILLINOIS
BILL THOMAS, CALIFORNIA
E. CLAY SHAW, JR., FLORIDA
NANCY L. JOHNSON, CONNECTICUT
JIM BUNNING, KENTUCKY
AMO HOUGHTON, NEW YORK
WALLY HERGER, CALIFORNIA
JIM McCRERY, LOUISIANA
DAVE CAMP, MICHIGAN
JIM RAMSTAD, MINNESOTA
JIM NUSSLE, IOWA
SAM JOHNSON, TEXAS
JENNIFER DUNN, WASHINGTON
MAC COLLINS, GEORGIA
ROB PORTMAN, OHIO
PHILIP S. ENGLISH, PENNSYLVANIA
JOHN ENSIGN, NEVADA
JON CHRISTENSEN, NEBRASKA
WES WATKINS, OKLAHOMA
J.D. HAYWORTH, ARIZONA
JERRY WELLER, ILLINOIS
KENNY HULSHOF, MISSOURI

CHARLES B. RANGEL, NEW YORK
FORTNEY PETE STARK, CALIFORNIA
ROBERT T. MATSUI, CALIFORNIA
BARBARA B. KENNELLY, CONNECTICUT
WILLIAM J. COYNE, PENNSYLVANIA
SANDER M. LEVIN, MICHIGAN
BENJAMIN L. CARDIN, MARYLAND
JIM McDERMOTT, WASHINGTON
GERALD D. KLECKA, WISCONSIN
JOHN LEWIS, GEORGIA
RICHARD E. NEAL, MASSACHUSETTS
MICHAEL R. McNULTY, NEW YORK
WILLIAM J. JEFFERSON, LOUISIANA
JOHN S. TANNER, TENNESSEE
XAVIER BECERRA, CALIFORNIA
KAREN L. THURMAN, FLORIDA

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6348

June 12, 1997

A.L. SINGLETON, CHIEF OF STAFF

JANICE MAYS, MINORITY CHIEF COUNSEL

The President
The White House
Washington, D.C. 20500

'97 JUN 18 AM 9:16

Dear Mr. President:

The Democratic tax bill we have put together in the House is the first step in a long process — that can culminate with a Democratic majority in the House. Please keep us at the table. We are the best downfield blockers you have.

Sincerely,

Charles B. Rangel
Ranking Democrat

CBR/dcc

See Rubin and his staff
have really been great in helping
in keeping on track in support
of your proposals.

6/18/97
to Chris
Walker for
Reply?
yes ☒
no ☐

THE PRESIDENT HAS SEEN
6/18/97

Meghan Alvey
Malcolm
they got copies
of speech after
the event
BX

Mrs. Coretta Scott King.....404/524-1956

*In memory and honor of Dr. King's legacy, placing a call to Mrs. King
will be important when she receives press call.

Andy Young.....404/753-4402

*Validator for the National media

He also has very interesting ideals on how racism is rooted in poverty

Kweisi Mfume.....410/486-9100

(PRESIDENT, NAACP)

*Validator for the National media.

Mignon Moore
make sure they
get copies of
speech after
I edit.
BX

Father Theodore Hessburg.....219/631-6882

Former President of Notre Dame

Chancellor Chang Tien.....510/642-7464.

(UNIV. OF BERKELEY)

It would be helpful to hear the Chancellor's views about how prop 209 is playing out in the CA
school community and what impact it will have on your speech.

Antonia Hernandez.....213/692-2512.

(MALDEF)

Although this call does cover the breath of the Latino community, it will be an important call
since the speech is CA based.

copied
Moore
Ann Walker

CC:
Ann Walker
too

Please note: We will have the Vice-President make additional calls to insure the President's
initiative is well received in the broader community.

FYI:

At some point he will need to speak with John Hope Franklin to make sure he shares the
President's vision and direction.

Handy
Dorothy

THE PRESIDENT HAS SEEN
6-17-97

June 17, 1997

Dear Mr. President,

As I prepare to leave the area, I just wanted to thank you for ALL your support. You have been a true inspiration and leader to thousands of individuals, including one young lady from Bettendorf, pleasure to work with you and the entire White House staff.

To Doris kind for reply?

Yes ☒

No ☐

Coordinate with NCC?

Yes ☐

No ☒

Mr.
Office

ing two years of my life with hundreds of events and trips burned
farewell ceremony I mentioned, "As a native of Bettendorf, Iowa,
Wizard of Oz. The White House is a truly spectacular place!
home" to the Coast Guard and to Tim, where hopefully God will
ays wanted. I will miss this truly magical place with its very

ank you" on behalf of my entire family. We sincerely
appreciated you taking time out of your busy schedule to meet each of them on the road! My
parents, brothers and sisters, nieces and nephews still talk about it as if it were yesterday!

I know you, your family, and the White House staff will have a great time with my relief, LCDR
Graham Stowe. He's a super individual.

Best of luck in the future. My thoughts and prayers are always with you.

A world of thanks!

I Sincerely,

June Ryan

June Ryan

Lieutenant Commander, U.S. Coast Guard

Former Military Aide to the President

Handy
to my

THE PRESIDENT HAS SEEN
6-17-97

Dear Mr. President,

June 17, 1997

As I prepare to leave the area, I just wanted to thank you for ALL your support. You have been a true inspiration and leader to thousands of individuals, including one young lady from Bettendorf, Iowa. It has been an honor and a pleasure to work with you and the entire White House staff.

These have been the most rewarding two years of my life with hundreds of events and trips burned into my memory forever. In my farewell ceremony I mentioned, "As a native of Bettendorf, Iowa, I feel a little like Dorothy from the Wizard of Oz. The White House is a truly spectacular place! But I look forward to returning "home" to the Coast Guard and to Tim, where hopefully God will bless us with the family we've always wanted. I will miss this truly magical place with its very special people!..."

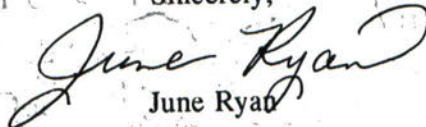
I wanted to express a heartfelt "thank you" on behalf of my entire family. We sincerely appreciated you taking time out of your busy schedule to meet each of them on the road! My parents, brothers and sisters, nieces and nephews still talk about it as if it were yesterday!

I know you, your family, and the White House staff will have a great time with my relief, LCDR Graham Stowe. He's a super individual.

Best of luck in the future. My thoughts and prayers are always with you.

A world of thanks!

Sincerely,


June Ryan

Lieutenant Commander, U.S. Coast Guard
Former Military Aide to the President

THE WHITE HOUSE
WASHINGTON

Date 6/19

To: Chris Walker

From: The Staff Secretary

Can you make sure Todd's
edits are substantively OK?

If so, put on cover.

Phil
by fax

MESSAGE CONFIRMATION

JUN-19-97 18:00

FAX NUMBER : 2024562215

NAME :

FAX NUMBER : 66221

PAGE : 06

ELAPSED TIME : 02'08"

MODE : G3 STD

RESULTS : O.K

'97 JUN 17 PM2:34

THE WHITE HOUSE

OFFICE OF LEGISLATIVE AFFAIRS

FAX COVER SHEET

NOTE: THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS
CONFIDENTIAL AND INTENDED FOR THE RECIPIENT ONLY.

DATE: 6/17

TO:

PHIL

FAX:

FROM:

CHRISTOPHER WALKER

456-7500 (TEL)

456-6221 (FAX)

RE:

Pl. Review

PAGE 1 OF 4

If there are any problems with this transmission, please call
(202) 456-7500.

DRAFT

Phil - need to
check that my
exits are
substantively
OK.
T-

Dear Joe:

ing
Thank you for writing regarding children's health. I am glad that you share my commitment to expand health coverage for millions of uninsured children. As you know, I fought very hard to ensure that \$16 billion for children's health care was included in the Budget Agreement.

One task now is that
~~I am strongly committed to working to ensure that the \$16 billion for children's health in the Budget Agreement covers as many uninsured children as possible and believe that we must develop policies that do not undermine the efforts that Massachusetts and other states have undertaken to cover children. In order to recognize the accomplishments and the special needs of states like Massachusetts, we are considering options that allow states that have already taken steps to expand children's health to use some of their existing state funding to leverage additional federal dollars to build and broaden their programs.~~

✓
In doing this,

I commend you and your Massachusetts colleagues for the outstanding work you have done to expand health coverage for uninsured children in your state and hope that our efforts to invest in children's health in this Congress meet with similar success. In addition, I appreciate your support and look forward to continuing our work together to expand health coverage for millions of uninsured children.

Sincerely,

The Honorable Joseph P. Kennedy II
House of Representatives
Washington, D.C. 20515

Phil,
Ph. Review
Approved by
Chris Jennings
Susan

JOSEPH P. KENNEDY II
8TH DISTRICT, MASSACHUSETTS

COMMITTEE ON BANKING AND
FINANCIAL SERVICES

SUBCOMMITTEES
HOUSING AND COMMUNITY OPPORTUNITY,
RANKING MINORITY MEMBER
DOMESTIC AND INTERNATIONAL
MONEY AND POLICY

COMMITTEE ON VETERANS' AFFAIRS

SUBCOMMITTEES
HOSPITALS AND HEALTH CARE
COMPENSATION, PENSION, INSURANCE
AND MEMORIAL AFFAIRS



Congress of the United States

House of Representatives

2242 RAYBURN BUILDING
WASHINGTON, DC 20515-2108
(202) 225-6111

SUITE 805, THE SCHRAFFY CENTER
529 MAIN STREET
CHARLESTOWN, MA 02129
(617) 242-0200

801(A) TREMONT STREET
ROXBURY, MA 02119
(617) 445-1261

May 21, 1997

The Honorable William J. Clinton,
President of the United States of America
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

MAY 22 PM4:30

Dear Mr. President:

We are writing to commend your Administration's efforts to extend health coverage to some of the estimated 10 million children who are currently uninsured, through your fiscal year 1998 budget proposal and your resolve to negotiate the inclusion of these provisions in the Congressional budget for this fiscal year.

We support your proposal to provide \$3.8 billion in annual grants to states in order to create partnerships between insurers, providers, employers, schools, and others to develop innovative ways to provide health insurance coverage to children.

However, we wish to underscore concerns that when such funding is distributed, it not be allocated in a way that discriminates against states like Massachusetts which have already committed significant state resources to provide health insurance for uninsured children.

Assuming this particular proposal will, in some manner, be included in the final budget passed by Congress later this year, our questions for you are twofold: (1) Is the Administration committed to ensuring that states like Massachusetts will not be penalized with smaller grant amounts simply because they have already covered most, if not all, of the state's uninsured children? (2) Would such states be able to redirect state funds freed up by new federal funding for other important health care needs in the state, such as improving the Massachusetts children's health care package to provide coverage for services offered under the Medicaid plan of Early and Periodic Screening, Diagnosis, and Treatment, for example?

We share your Administration's conviction that our nation should adopt policies which promote the health of all children. Accordingly, we pledge to work with you to do all we can to enact such proposals in the United States Congress.

We appreciate your consideration of our concerns and urge your Administration to protect those states which have already committed significant resources to expand children's health care.

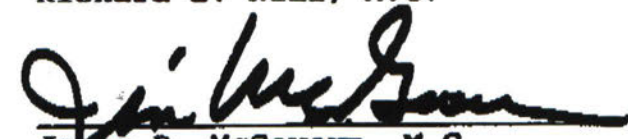
Sincerely,


Joseph P. Kennedy II, M.C.


John Joseph Moakley, M.C.

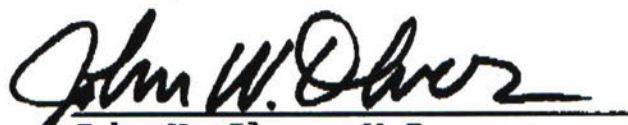

Martin T. Meehan, M.C.

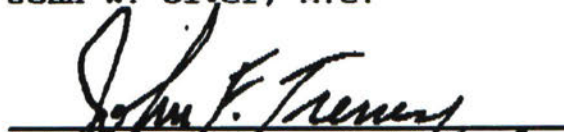

Richard E. Neal, M.C.

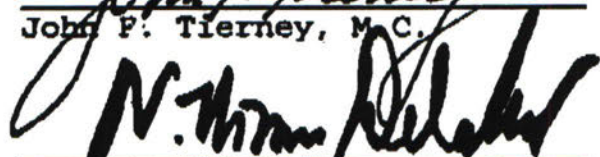

James P. McGovern, M.C.


Edward J. Markey, M.C.


Barney Frank, M.C.


John W. Olver, M.C.


John F. Tierney, M.C.


William D. Delahunt, M.C.

cc: The Honorable Donna Shalala
Secretary, Department of Health and Human Services

THE WHITE HOUSE
WASHINGTON

Date 6/19

To: Don Kermick

From: The Staff Secretary

This came from Nancy
Abernethy. Can you forward
to State for appropriate action.

Marks,
Phil Caplan

'97 JUN 19 AM 11:08

Gravity Sports Concepts, Inc.

June 11th, 1997

*Known -
Sec
Mrs
July 4
we con*

Ms. Nancy Hernreich
The White House
Washington, D.C., 20500

Dear Nancy,

It was a pleasure to speak with you on the phone a couple of weeks ago. I really appreciate that you called me back so promptly.

We spoke concerning a gentleman from South Africa named Hugh Marshall who is currently working for me at our new golf teaching center in Hot Springs, Arkansas. Hugh is without question one of the finest individuals whom I have ever had the privilege of knowing. As you will see from his enclosed letter, he is very concerned about the safety of his children and is very anxious to have them join him in our country.

If there is anything you can do to aid or expedite the process, both Hugh and I would be deeply appreciative.

Please give my regards to the president and tell him I will be writing him soon about what we are doing here.

My deepest thanks,


David Lee

625 Ragweed Valley Rd., Royal, AR 71968 (501) - 991-3635

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
--------------------------	---------------	------	-------------

001. letter	[Personally Identifiable Information] [partial] (1 page)	06/01/1997	b(6)
-------------	--	------------	------

COLLECTION:

Clinton Presidential Records
Staff Secretary
Todd Stern
OA/Box Number: 9359

FOLDER TITLE:

Chron Files: Thursday, June 19, 1997

2019-0774-S

rs3361

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Hugh Marshall
125 Pinehill Rd.
Hot Springs, AR 71913
(501)525-4885
(501)991-3635

June 1, 1997

RE: Phone call from David Lee.

Dear Nancy

David spoke with you a week ago regarding a visa for my children to come to the United States. I am married to a U.S. citizen. My wife and I have filled all I.N.S. papers to legalize my residency. My current status is I am a conditional permanent resident with a work permit, (working for David Lee). I have applied for my permanent residency which will eventually entitle my unmarried children residing in South Africa to receive the same permanent residency in the United States, if they so desire.

The problem is I would like to bring over two of my three children, as I have not seen them in almost 2 years. Not only would I love to see my children but I would love for them to meet my new family. I would love to show them the United States before they get much older and tied down to a job and/or career. Charlene, my younger daughter is 20, has expressed an interest in going to college in the states. Matthew, my son, is 19 and does not have any direction in life as of yet. Prior to my getting married last year, Matthew applied for a Visa to join me here on holiday, but the U.S. Embassy in South Africa denied his visa and he lost his airfare. The U. S. Embassy grounds for denial were he had no real property and would have no reason to return.

The crime rate in Johannesburg is terrible and I worry constantly about the safety of all my children. I would greatly appreciate anything you can do to get my children visas. I really need to see them! Thanking you in advance for your assistance in this matter. I realize you have many other pressing matters to attend too.

Sincerely



Hugh Charles James Marshall

P.S. I believe the contact person at the U.S. Embassy in S.A. is David Chang. The names of my children are Samantha Marshall, D.O.B. [redacted]; Charelene Marshall, D.O.B. [redacted] Matthew Marshall, D.O.B. [redacted] (b)(6)

TRW Inc.

Executive Offices
1900 Richmond Road
Cleveland, OH 44124

Joseph T. Gorman
Chairman of the Board &
Chief Executive Officer

97 JUN 19 PM 5:47

June 19, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

On behalf of TRW Inc., I commend you for your recent initiative to increase seat belt usage rates across the country. By achieving your stated goals of 85% seat belt usage by the year 2000, and 90% by 2005, we can save over 4,000 lives and prevent more than 100,000 serious injuries every year. As you know, proper seat belt usage is the key to airbag safety for the overwhelming majority of vehicle occupants.

As the world's leading manufacturer of occupant restraint systems - seat belts and airbags - we at TRW are keenly aware of the lifesaving benefits our products provide to properly belted occupants. Conversely, we share your concern about the small number of airbag-induced injuries involving unbelted or improperly restrained occupants. However, I must register my strong objection to the National Highway Traffic Safety Administration's (NHTSA) proposed rulemaking that would permit any vehicle owner to have his or her driver or passenger-side airbag deactivated, on-demand, without cause or prior approval from the agency. Although I understand NHTSA's desire to quell public concern over airbag safety, I believe that the agency's deactivation proposal is unsound, unsafe, and contrary to its statutory mandate. Therefore, it should be rejected by your administration.

Experience has shown that airbags save lives. In fact, according to NHTSA's own estimates, airbags have saved more than 1,900 lives to date. Airbags are expected to save over 3,000 lives a year when all vehicles on the road are equipped with driver and passenger-side airbags. A public policy allowing for widespread, on-demand deactivation will send consumers the wrong message about occupant safety, will reduce the acceptance of future smart restraints technology, and will lead to increased highway fatalities and injuries whereas a fully functioning occupant restraint system would save lives and reduce injuries.

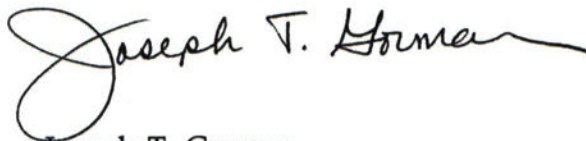
Is Doriskind for reply?
Yes ☒
No ☐

NHTSA has confirmed that instances where airbags pose a legitimate safety risk are few, and that nearly all the airbag deployment fatalities have involved unrestrained or improperly restrained occupants. I believe that NHTSA is fully capable of evaluating and approving deactivation in those rare cases where it may be warranted. Consistent with its mission, this is a proper role for NHTSA and should not be delegated to individual consumers, auto dealers, or repair facilities.

As increased seat belt usage is the key to airbag safety, TRW has joined with others in the private sector to fund the Air Bag Safety Campaign. In addition to educating the public about the benefits of "buckling up," the Campaign has a goal of working with the states to enact and enforce strong seat belt use laws. It is the active enforcement of mandatory seat belt laws that will enable your administration to realize the enhanced safety benefits it seeks with a 90% seat belt usage rate.

Mr. President, the combination of seat belts and airbags provides the best crash protection available. Additionally, the implementation of smart restraints technology will eliminate airbag-induced injuries altogether. Now is not the time to turn back the clock on automotive safety. As four former NHTSA Administrators recently stated in their joint letter opposing the deactivation rule, "The decision the agency makes in this proceeding must be carefully crafted to preserve this lifesaving technology, reduce the potential dangers to certain at-risk persons or groups, and to preserve the public's confidence in government safety policies." I hope you share these views and will formally request that NHTSA reconsider its proposed rulemaking.

Sincerely,

A handwritten signature in black ink, reading "Joseph T. Gorman". The signature is fluid and cursive, with a large loop at the beginning of the first name.

Joseph T. Gorman
Chairman & Chief Executive Officer
TRW Inc.

/cor

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

June 18, 1997

MEMORANDUM FOR DEBBIE BIRD

FROM: SUE BACHTEL, Ext. 6-7116

*Debbie/Barbara
in case you
get this
letter
Jys*

Debbie:

Attached is a fax to our new Chief of Staff, Holly Gwin,
from William V. Corr, Chief of Staff to Secretary Shalala.

Corr received a copy of a letter to the President dated
June 11, 1997, from Public Citizen (Ralph Nader, founder) signed
by Sidney M. Wolfe and Peter Lurie, and has asked our help in
responding.

Holly Gwin requests that when the letter is received that
it be assigned to OSTP for action/response. Assuming that will
be the case, would someone please send us the notice % John H. Gibbons,
Room 424 OEOB.

Many thanks.

6-19-97

Paul

for you to see

see
Dec

send to Jim
for reply prior 6/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

FACSIMILE**PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION
TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:**

Name: Holly Gwin, Chief of Staff

OSTP

Address:

Message: For your information.

Telephone: Office: 456-6014 FAX: 456-6021

Number Of Pages Being Transmitted (Including This One) 12

FROM: William V. Corr

FAX NUMBER:
OFFICE NUMBER: 690-7431

JUN 11 '97 15:54 FR

TO 96906247

P.02/11

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

June 11, 1997

President William J. Clinton
1600 Pennsylvania Avenue
Washington, DC

Dear President Clinton:

The United States government is sponsoring biomedical research on mother-to-infant HIV transmission in developing countries that could not be carried out in the U.S. Many people believe it is therefore unethical to conduct these studies in Africa, Asia, and the Caribbean, as is currently planned. This is because thousands of HIV+ pregnant women in these studies are being denied access to AZT, a treatment that has been proven to be dramatically effective in reducing the rate of HIV transmission from pregnant women to their babies. Experts in HIV/AIDS and research methodology attest that these studies could be redesigned to be ethical while still answering the relevant research questions.

On April 22 of this year we wrote to HHS Secretary Shalala strongly urging that nine developing country experiments involving HIV+ pregnant women, funded by the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC) be changed so that all subjects receive an active treatment rather than consigning several thousand women to get a placebo or other unproven treatments. While we support the goal of these studies, namely to find a less expensive, shorter and less-complicated treatment regimen to reduce maternal-infant transmission of HIV than that proven effective in the study known as ACTG 076, we stated that it was highly unethical to achieve that goal by exposing large numbers of women to no treatment (a placebo) or treatments not proven effective. We suggested that all women should get some arguably effective treatment and that, for example, these shorter courses of treatment could be compared to the full 076 regimen. Such a study design could have resulted in the prevention of up to 1,000 unnecessary HIV infections in the U.S.-funded studies.

Since April 22, we have obtained government documents and other information which further strengthen the case for immediately redesigning these studies to prevent further loss of life in infants whose mothers do not receive AZT. At the very least, if you are unwilling to order these experiments to be changed to equivalency studies (see below) now, this matter is clearly

Ralph Nader, Founder

1600 20th Street NW • Washington, DC 20009-1001 • (202) 388-1000

Printed on Recycled Paper

JUN 11 '97 11:55

PAGE.02

JUN 11 '97 15:54 FR

TO 96905247

P.03/11

urgent and controversial enough to be promptly reviewed by the newly constituted Presidential National Bioethics Advisory Commission (NBAC) when it meets again next month. A recommendation for a referral to NBAC has been endorsed by Dr. Philip Lee, former Assistant Secretary for Health of HHS,¹ Dr. Thomas Murray, a member of the NBAC² and Director of the Center for Biomedical Ethics, Case Western Reserve University School of Medicine, Dr. Richard Humphrey,³ a Johns Hopkins University Medical School and School of Public Health faculty member (despite the fact that his institution is involved in six of the studies) and Dr. Arthur Caplan, Director of the Center for Bioethics, University of Pennsylvania.⁴

The new findings which further undermine the ethical basis for the current studies are:

- Despite American researchers' emphasis on how widely these studies have been endorsed by developing country scientists, Cote d'Ivoire researchers actually involved in the CDC study there raised ethical questions about conducting placebo-controlled trials in that country. An internal CDC memo dated January 27, 1995, in a section on ethical issues stated that "Despite detailed discussions (both verbal and in the protocol) justifying the use of placebo, it has become evident that some of the Ivoirian physicians working at project RETRO-CI [the CDC research base in Cote d'Ivoire=CI], several of our important Ivoirian collaborators, and a number of international researchers involved in MTEHC [mother to child HIV transmission], do not feel comfortable with the use of placebo." (emphasis supplied) CDC described the views of these dissenters as: "since all children infected with HIV during the trial would likely die, it is argued that it would not be ethical to subject these families to the risk of placebo within the context of a clinical trial."⁵ Their concerns appear to have been overpowered by CDC's and others' arguments supporting the use of placebos.

Similarly, in an NIH-funded study in Ethiopia which involves Johns Hopkins University, the local ethical review committee voted by a narrow and controversial 6 to 5 vote to approve of that study, the first time the committee had taken a formal vote. In addition, 135 physicians from Brazil have written to Secretary Shalala criticizing the U.S.-funded studies.

- In Thailand, the CDC is also conducting a placebo-controlled study involving AZT, claiming that, since the standard of care in Thailand is not to give AZT to HIV+ pregnant women, it is necessary to have one group of women in the study get a placebo. In sharp contrast, the investigators of a study funded by NIH (also an HHS agency) in the same country does not use a placebo. Instead it compares the shorter, simpler treatments to the full 076 regimen in an equivalency study (see below). Asked about the contradiction between these two kinds of studies in Thailand when he was testifying before Rep. Christopher Shays' Subcommittee on Human Resources on May 8, 1997, NIH Director Harold Varmus conceded that placebo-controlled studies are "not the only way to achieve results." If placebo-controlled trials are not the only acceptable research design, why is NIH funding a placebo-controlled trial?

JUN 11 '97 15:55 FR

TO 96906247

P.04/11

- The researchers, in the equivalency study from Harvard and Thailand, had to overcome efforts by an NIH study section which tried to force them to change the design of their study to placebo-controlled. Indeed, officials at NIH supported the Harvard researchers in their efforts to conduct the equivalency study instead of a placebo-controlled trial. Responding to the study section's pressure in December 1994, long before CDC's placebo-controlled trial had begun in Thailand, the Director of Harvard's Human Subjects Committee wrote NIH that "Our Committee members believe that once an active therapy for particular diseases is identified, use of placebo-control trials of different agents and different modes of administration may be unethical. The conduct of a placebo-controlled trial for ZDV [AZT] in pregnant women in Thailand would be unethical and unacceptable since an active-controlled trial is feasible...." (emphasis supplied)⁶

(Actually, there was a third maternal-infant HIV transmission study in Thailand at one point, a placebo-controlled study conducted by a Thai university. However, during the trial, AZT became more available in Thailand. It is manufactured locally by the Government Pharmaceutical Organization and costs \$0.36 per 100 mg capsule. The Ministry of Public Health provides AZT free to about 2,000 poor patients and others receive the drug free through the Thai Red Cross Society. With this increased availability, the Thai researchers terminated their study so that no one would receive placebo. However, the CDC researchers continue to enroll patients in their placebo-controlled study.)

- In June 1994, a WHO meeting recommended that "placebo-controlled trials offer the best option for rapid and scientifically valid assessment of alternative [to the 076 regimen] antiretroviral drug regimens to prevent MTI [maternal to infant] transmission of HIV," and this dictum has been widely cited as justification for doing placebo-controlled trials. For example, the CDC states in its response to our April 22nd letter that a study comparing short-course AZT treatment with the regimen proved effective in Protocol 076 "would require an extremely large study that would take a long time to complete." In a May 1995 memo reviewing possible maternal-infant transmission study designs, the Division of HIV/AIDS Prevention at CDC considers seven different clinical trial designs and endorses placebo-controlled trials, but fails to even mention the alternative that we suggest and which has been adopted in the NIH-funded study being conducted by Harvard University and local researchers in Thailand: an equivalency study.

Equivalency studies are typically conducted when a regimen has been proved effective and one is interested in determining whether a second regimen is about as effective, but less toxic or less expensive. (By contrast, a placebo-controlled trial asks whether a given intervention is better than nothing.) The current state of knowledge in maternal-infant transmission studies of antiretrovirals mandates such an approach,

JUN 11 '97 15:56 FR

TO 95906247

P.05/11

and would prevent the unnecessary loss of life.

Despite WHO/CDC (some NIH) insistence on the superiority of placebo-controlled trials, a recent review by a statistician consultant demonstrates that an equivalency study can be conducted using approximately the same number of subjects as placebo-controlled trial (See attachment). In a placebo-controlled trial, assuming that the HIV transmission rate in the placebo group would be 25% and that in the short-course AZT group it would be 15%, 500 subjects would be needed to reach statistical significance. In an equivalence study, assuming that HIV transmission in the 076-regimen group was 10% and setting a "tolerance" for a 6% difference between the groups (this means that one would be willing to accept up to a 6% difference between the groups; 6% was the tolerance used in the NIH-funded equivalency study in Thailand), 620 subjects would be needed. If the tolerance were further increased to 7%, only 454 subjects would be needed.

Further emphasizing that placebo-controlled trials are not necessarily speedy, the December 12, 1996 minutes of the Data Safety Monitoring Board of the CDC-funded study in Cote d'Ivoire stated that "in [the] first 28 weeks of study only 6% of the total number of women who need to be entered have been recruited" and that "rate of accrual is much slower than the anticipated rate...." The speed of the trial is, therefore, more likely to depend on actual conditions in the field than on minor differences in sample size.

- The studies are duplicative and poorly coordinated as demonstrated by 1/ the conflict between the two studies in Thailand (see above), 2/ the fact that one NIH-funded vitamin A vs placebo study in Tanzania was designed without AZT in either part of the study because the investigators had been told that AZT was not a possibility in that country while the UN AIDS study in the same country uses AZT and two other antiviral drugs vs a placebo in its design and 3/ even among the AZT placebo-controlled trials, there are large differences in experimental design, making ultimate policy judgments difficult.

A recent letter to HHS Secretary Shalala from Dr. Curt Furberg, formerly the Director of Clinical Trials for the National Heart, Lung and Blood Institute of NIH, former President of the Society of Clinical Trials and currently Chairman of the Department of Public Health Sciences at Bowman Gray School of Medicine stated that "My first major concern relates to the coordination of these programs. Based on my review of the design of the 15 international randomized clinical trials that are evaluating treatments for mother-to-infant HIV transmission, it appears that the program coordination for these trials has been less than optimal. There is a real risk that this could lead to 1/ unnecessary delays in getting important scientific answers and 2/ duplication in effort, leading to waste of research resources and possibly to conflicting results from underpowered experiments. Fewer, but larger trials would have the advantage of providing faster and more reliable answers."

JUN 11 '97 15:56 FR

TO 96906247

P.06/11

Dr. Furberg also criticized the placebo-controlled mantra of the WHO because it "fails to recognize that there are other and better design options." He referred to the Harvard equivalency study in Thailand as such a study. He concluded by stating that "These concerns—inadequate study coordination, suboptimal design, and ethically inappropriate care....reflect poorly on the scientists and institutions conducting these studies and on the funding agencies and, ultimately, the U.S. government. I urge you to consider immediately convening a meeting that would include the involved parties as well as a number of 'outside' qualified scientists and ethicists. This urgent public health problem needs to be addressed in a balanced fashion, in hopes of reaching reasonable and expeditious solutions."⁴

- Even though they are to be faulted for charging as much as they have for these and other drugs, at least two pharmaceutical companies have raised serious ethical questions about conducting placebo-controlled studies involving AZT after ACTG 076. Hoffmann-La Roche senior medical advisor Peter King, whose company makes DDC, a rival drug to AZT, said "We know AZT works. It cuts transmission by two-thirds. So any trial with a complete placebo arm is completely unethical."⁹ Jennifer McMillan, an official with Glaxo-Wellcome (the manufacturer of AZT), has stated that the company has expressed serious reservations about placebo-controlled trials because such a design entails denying patients treatment known to benefit them.¹⁰
- Finally, Congresswoman Patsy Mink, a victim of unethical human experimentation with diethylstilbestrol (DES) in the 1950s, has written to Secretary Shalala about these experiments: Referring to these studies, she wrote: "There is no justification for our country to fund these experiments in developing countries without the same standard of care and concern for the children. Before another scandal exposes our indefensible disregard for life, I urge you to amend the protocol for these overseas experiments to conform to international, moral and ethical standards. We should be more meticulous in our insistence that in dealing with developing countries we follow the most stringent and highest standards that we insist for ourselves. We should never be the funders of overseas experiments that do not have the same safeguards as we would have if they were being conducted in this country."¹¹

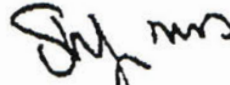
JUN 11 '97 15:57 FR

TO 96906247

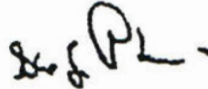
P.07/11
P.07

In sum, we believe this new information adds significantly to that in our April 22 letter, and further undermines the ethical basis for these US-funded studies. The reputation of the United States as a world leader in ethical medical research is at stake. We hope that you will respond rapidly to this urgent request.

Sincerely,



Sidney M. Wolfe, M.D.
Director



Peter Lurie, M.D., MPH
Research Associate
Public Citizen's Health Research Group

1. Personal communication with Sidney Wolfe, June 8, 1997.
2. Personal communication with Sidney Wolfe, June 6, 1997.
3. Letter from Dr. Richard Humphrey, Associate Professor of Medicine, Pathology and Oncology, Johns Hopkins University School of Medicine and School of Public Health, to HHS Secretary Donna Shalala, June 5, 1997. The letter also said that "Having talked with several of my colleagues here at Hopkins, it is only honest to tell you that there has been a lot of discussion about this issue and that a unanimity of opinion about these issues does not exist."
4. Personal communication with Sidney Wolfe, June 8, 1997
5. CDC memo dated January 27, 1995 from Tim Dondero, Phil Neiberg and Martha Rogers to Alan E. Greenberg and Stefan Z. Wiktor.
6. Letter from Troyan Brennan, M.D., Chairperson of Human Subjects Committee, Harvard School of Public Health, to Dr. Gilbert Meier, Division of Research Ethics, NIH, December 28, 1994.
7. Analysis done by William McCarthy, PhD, a biostatistician, for Public Citizen's Health Research Group.
8. Letter from Curt Furberg, M.D., PhD, to HHS Secretary Shalala, June 5, 1997.

JUN 11 '97 15:57 FR

TO 96905247

P.08/11

9. Michael Day. *How the West Gets Well*. New Scientist. May 17, 1997.

10. Personal communication with Sidney Wolfe, June 5, 1997.

11. Letter from Congresswoman Patsy Mink, (D-Hawaii), to HHS Secretary Shalala, May 21, 1997.

JUN 11 '97 15:57 FR

TO 96906247

P.09/11

ATTACHMENT

Placebo-controlled trial (Short-course AZT vs. placebo)

Assumptions:

HIV transmission rate in placebo group = 25%

Beta = 0.2

Alpha = 0.05 (two-sided)

Equal numbers of subjects in each study arm

HIV transmission rate in short-course group	13%	15%	16%	19%	20%	21%	24%
Required sample size	334	500	630	1494	2188	3472	58072

Equivalency trial (Protocol 076 vs. short-course AZT)

Assumptions:

HIV transmission rate in Protocol 076 rate: 10%

Beta = 0.2

Alpha = 0.05 (one-sided)

Equal numbers of subjects in each arm

Tolerance	5%	6%	7%	10%
Required sample size	948	658	484	238

HARVARD SCHOOL
OF
PUBLIC HEALTH



HARVARD
MEDICAL SCHOOL

THOMAS A. BROWN, M.D., J.D., M.P.H.

Professor of Law and Public Health

June 10, 1997

Professor of Medicine

Donna Shalala, Secretary
Department of Health and Human Services
2003 Independence Ave
Room 6006
Washington, D.C.

Dear Ms Shalala:

I have been following with interest the recent debate over the ethics of placebo/control trials for pregnant women in developing countries who may be at risk of transmitting HIV to their offspring. Our Human Subjects Committee at the Harvard School of Public Health approved two of these studies. As the Chairperson, I was involved in and take responsibility for our decisions.

One study involved treating women prophylactically with AZT to avoid transmission in Thailand. Although some international organizations had advocated use of placebo to evaluate the efficacy of the AZT, given the existing data and the commitment of the Thai government to use of AZT in pregnancy, our investigator successfully advocated with NIH for an active control arm; ethically it seemed to us anything else would have been unacceptable.

The other study concerned use of Vitamin A in pregnancy to prevent transmission in sub-Saharan Africa. The study was designed before information on the efficacy of AZT was known. Once this information came available, we thought that the key issue would be the availability of AZT in the study country. We were assured that during the trial AZT would not be available and so testing this lower cost strategy seemed appropriate. With the possibility that AZT might now be more widely available, this decision will have to be carefully re-considered.

We continue to believe that we made the right decisions. Nonetheless, I think it is necessary to scrutinize and re-scrutinize decisions in this very sensitive area. Therefore,

JUN 11 '97 15:58 FR

TO 96906247

P.11/11

Donna Shalala, Secretary

Page 2

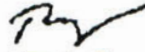
June 10, 1997

I personally believe that Public Citizen has discharged an important civic duty in bringing these issues to light. We must continue to be concerned about using double standards when we do research in developing countries. Therefore I am surprised by the academic attacks on Dr. Wolfe and Public Citizen. We should be welcoming this oversight and attention to the issues.

Nor do I believe that Public Citizen's concerns represent cultural imperialism. I think that there are some basic human rights that we must all uphold, and I believe that Public Citizen's penetrating questions serve that purpose.

As contexts change in developing countries, so must our views about what research is acceptable. In my view, and it is my personal view (I am not speaking on behalf of Harvard University), it is unethical to do placebo/control trials of AZT in the perinatal setting in Thailand today; and it may be becoming unethical to do so in some areas of Sub-Saharan Africa. Moreover, as a researcher and human subjects committee member I believe we should encourage others to question our decisions and engender debate.

Sincerely yours,


Troyen A. Brennan

TOTAL P.03

TOTAL P.11

PAGE.11

JUN 11 '97 11:59