

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Mary L. Smith (CN=Mary L. Smith/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 17:13:38.00

SUBJECT: Re: Finally... A Message Schedule Update!

TO: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Thomas L. Freedman (CN=Thomas L. Freedman/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

We could do this in LA on Oct 4:

Hate Crimes -- Community Mobilization Event (this fall): In November 1997, the President announced the creation of hate crime working groups led by U.S. Attorneys across the country. The President could host a roundtable to highlight what these working groups are doing. He could also demonstrate the Anti-Defamation League's & HateFilter8 which protects children by blocking access to hate sites on the Internet.

Also this is a possibility for the Oct 14 opening in DC
Domestic Violence Screening (October): The Family Violence Prevention Fund is holding events around the country, including in Washington, D.C., to further educate and encourage health care providers to routinely screen for domestic violence. We could take this as an opportunity for the President to speak about our efforts on this issue.

Karin Kullman

09/09/99 03:54:35 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Finally... A Message Schedule Update!

Please note the possible opportunity in Los Angeles on Oct. 4. If we do meet with people from the JCC people were very interested in doing either a guns or a hate crimes event. Is there something specific we would want to push to do there?

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:52 PM -----

Karin Kullman
09/09/99 03:45:58 PM
Record Type: Record

To: See the distribution list at the bottom of this message
cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP
Subject: Finally... A Message Schedule Update!

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Lady)

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Location: DC Convention Center or White

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:52:38.00

SUBJECT: Finally... A Message Schedule Update!

TO: Eric P. Liu (CN=Eric P. Liu/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Andy Rotherham (CN=Andy Rotherham/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Bruce N. Reed (CN=Bruce N. Reed/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Palisades Update.... This event was raised at this afternoon's message meeting. I confirmed that it is NOT possible for the President to attend the Palisades event. HOWEVER, the First Lady will be in NY on that day and her office was interested in knowing more.

I raised the issue of making a Charlottesville anniversary education speech in the fall. I think we have a lot more selling to do, but at least it's on the radar screen.

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:50 PM -----

Karin Kullman

09/09/99 03:45:58 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:50:11.00

SUBJECT: Finally... A Message Schedule Update!

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Things to note for our healthcare team:

We no longer have Sept. 23 as a healthcare/Rx event

Still looking to do the health reporters on Oct. 7

Oct. 12 -- 10,000 pediatricians will be in DC at the Convention Center for the American Academy of Pediatricians Conference. Two options were discussed:

1. address the whole group at the Convention Center
 2. bring a subset to the WH for an event or meeting, and give the pediatricians an opportunity to do press on the North Lawn.
- People were interested in what announcements we could make. Do you think this would be a good venue for our CHIP event?

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:46 PM -----

Karin Kullman

09/09/99 03:45:58 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:56:25.00

SUBJECT: Finally... A Message Schedule Update!

TO: Eric P. Liu (CN=Eric P. Liu/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Bruce N. Reed (CN=Bruce N. Reed/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Last thing to note: I believe scheduling/communications is tentatively holding Oct. 19 to do something around the Hill Youth Violence Summit.
----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:55 PM -----

Karin Kullman

09/09/99 03:45:58 PM

Record Type: Record

To: See the distribution list at the bottom of this message

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Irene Bueno (CN=Irene Bueno/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 19:15:22.00

SUBJECT: Re: Please note error --Finally... A Message Schedule Update!

TO: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Leanne A. Shimabukuro (CN=Leanne A. Shimabukuro/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Mary L. Smith (CN=Mary L. Smith/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Thomas L. Freedman (CN=Thomas L. Freedman/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Thanks for the update. An October 4th guns/ hate crime event should include the participation of a family member of Joseph Ileto, the mailcarrier who was killed after the JCC shootings. Please let me know if you need more info.

Karin Kullman

09/09/99 04:37:00 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Please note error --Finally... A Message Schedule Update!

See my change of dates in red below. It should be message schedule may change on Sept. 16 or 17 due to Hill activity (not the 12 and 13).

Thanks.

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
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09/09/99 03:45:58 PM

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Anna Richter/OPD/EOP@EOP
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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME: 9-SEP-1999 12:30:38.00

SUBJECT: Re: Anderson Letter & FAX

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Debra D. Alexander (CN=Debra D. Alexander/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TEXT:

I rewrote this to address the two statements from the WH website (7/14/99 and 11/21/98)... I hope this is more what you were looking for. Thanks.

Thank you for your letter in regards to human pluripotent embryonic stem cell research funding and the National Institutes of Health. I appreciate your thoughts and input on this important matter.

Last November, I asked my National Bioethics Advisory Commission to undertake a thorough review of all the ethical and medical considerations associated with human stem cell research. After much thought and deliberation, we determined that human stem cell technology's potential medical benefits are compelling and worthy of pursuit, as long as the research is conducted according to the highest ethical standards. As you know, stem cell research has potential application for treating people with diabetes, heart disease, Parkinson's disease, cancer, and spinal cord injury. As we proceed on this complex and sensitive issue, the NIH will be putting together guidelines to ensure that the cells are obtained in an ethically sound manner.

As we work to keep our commitment to combating disease through biomedical research, I am grateful for your consultation. Thank you again for sharing your thoughts and concerns.

Devorah R. Adler
09/08/99 05:57:21 PM
Record Type: Record

To: John H. Corcoran III/WHO/EOP@EOP
cc: Debra D. Alexander/WHO/EOP@EOP
Subject: Re: Anderson Letter & FAX

We've issued several statements on stem cell -- you might want to check those out and see if they work and can be incorporated into this letter.

Congressional Black Caucus Dinner, DC

Monday, Sept. 20 No Message Opportunity (also could change)

Tuesday, Sept. 21 Address to UN General Session, NY

Wednesday, Sept. 22 Y2K Message Event (T)
NOTE: This marks 100 days until the millenium

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Possible Surplus Event (or on 9/29)

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Location: White House

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Topic: TBD

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Thursday, Sept. 30 Message Opportunity, DC

Friday, Oct. 1 Departure Statement Opportunity

Travel to Las Vegas, NV and Silicon Valley, CA

Saturday, Oct. 2 Radio Address (taped 10/1)
Topic: TBD

Saturday, Oct. 2 - Travel to Los Angeles, CA
Monday, Oct. 4

Monday, Oct. 4 Message Opportunity, Los Angeles, CA
NOTE: There was interest in doing a possible hate crimes or guns event in coordination with victims/heroes of the JCC shooting.

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Wednesday, Oct. 6 Comp. Test Ban Treaty Event (T)

Thursday, Oct. 7 Healthcare Event (T)

Location: White House

NOTE: We are looking to invite health reporters from across the country to the White House on this day. Possible topics are Medicare State-by-State Report or Patients' Bill or Rights event.

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Saturday, Oct. 9 Radio Address
Topic: TBD

Monday, Oct. 11 No Message Opportunity

Tuesday, Oct. 12 Possible Event with American Academy of Pediatricians
Location: DC Convention Center or White House

Wednesday, Oct. 13 Message Opportunity, DC

Thursday, Oct. 14 Message Opportunity, DC

Friday, Oct. 15 Possible Stem Cell Event

Saturday, Oct. 16 Radio Address
Topic: TBD

Message Sent

To: _____
Sarah A. Bianchi/OVP@OVP
Thomas L. Freedman/OPD/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Jeanne Lambrew/OPD/EOP@EOP
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Ann O'Leary/OPD/EOP@EOP
Andy Rotherham/OPD/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:54:47.00

SUBJECT: Finally... A Message Schedule Update!

TO: Thomas L. Freedman (CN=Thomas L. Freedman/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Eric P. Liu (CN=Eric P. Liu/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Mary L. Smith (CN=Mary L. Smith/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Leanne A. Shimabukuro (CN=Leanne A. Shimabukuro/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Bruce N. Reed (CN=Bruce N. Reed/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:

Please note the possible opportunity in Los Angeles on Oct. 4. If we do meet with people from the JCC people were very interested in doing either a guns or a hate crimes event. Is there something specific we would want to push to do there?

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:52 PM -----

Karin Kullman
09/09/99 03:45:58 PM
Record Type: Record

To: See the distribution list at the bottom of this message
cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP
Subject: Finally... A Message Schedule Update!

The following is an update on the President's message schedule for the remainder of September and early October. DPC events are in italics and open message slots are in bold. Please call me with any questions.

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PLEASE NOTE: The message schedule for Sept. 12 and 13 may change pending events during the President's foreign travel (ie, Hill activity).

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Topic: TBD

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Location: DC Convention Center or White House

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Thursday, Oct. 14 Message Opportunity, DC

Friday, Oct. 15 Possible Stem Cell Event

Saturday, Oct. 16 Radio Address
Topic: TBD

Message Sent

To: _____
Sarah A. Bianchi/OVP@OVP
Thomas L. Freedman/OPD/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Jeanne Lambrew/OPD/EOP@EOP
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Ann O'Leary/OPD/EOP@EOP
Andy Rotherham/OPD/EOP@EOP
Anna Richter/OPD/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 16:37:07.00

SUBJECT: Please note error --Finally... A Message Schedule Update!

TO: Bruce N. Reed (CN=Bruce N. Reed/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Andy Rotherham (CN=Andy Rotherham/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Eric P. Liu (CN=Eric P. Liu/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Eugenia Chough (CN=Eugenia Chough/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Irene Bueno (CN=Irene Bueno/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Andrea Kane (CN=Andrea Kane/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Mary L. Smith (CN=Mary L. Smith/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Leanne A. Shimabukuro (CN=Leanne A. Shimabukuro/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Nicole R. Rabner (CN=Nicole R. Rabner/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Jeanne Lambrew (CN=Jeanne Lambrew/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Thomas L. Freedman (CN=Thomas L. Freedman/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Anna Richter (CN=Anna Richter/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Ann O'Leary (CN=Ann O'Leary/OU=OPD/O=EOP@EOP [OPD])
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TO: Ruby Shamir (CN=Ruby Shamir/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Bethany Little (CN=Bethany Little/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: J. Eric Gould (CN=J. Eric Gould/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Teresa M. Jones (CN=Teresa M. Jones/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Essence P. Washington (CN=Essence P. Washington/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Paul J. Weinstein Jr. (CN=Paul J. Weinstein Jr./OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Cynthia A. Rice (CN=Cynthia A. Rice/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Cathy R. Mays (CN=Cathy R. Mays/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Sarah A. Bianchi (CN=Sarah A. Bianchi/O=OVP@OVP [UNKNOWN])
READ:UNKNOWN

TEXT:
See my change of dates in red below. It should be message schedule may
change on Sept. 16 or 17 due to Hill activity (not the 12 and 13).
Thanks.

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
04:35 PM -----

Karin Kullman
09/09/99 03:45:58 PM
Record Type: Record

To: See the distribution list at the bottom of this message
cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP
Subject: Finally... A Message Schedule Update!

The following is an update on the President's message schedule for the
remainder of September and early October. DPC events are in italics and
open message slots are in bold. Please call me with any questions.

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Friday, Sept. 10 - New Zealand Visit
Wednesday, Sept. 15

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Topic: Safe Schools, Healthy Students/COPS
grants

Wednesday, Sept. 15 Hawaii

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No Message Opportunity

Friday, Sept. 17 No Message Opportunity

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 Topic: TBD

Saturday, Oct. 2 - Travel to Los Angeles, CA
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Monday, Oct. 4 Message Opportunity, Los Angeles, CA
 NOTE: There was interest in doing a
 possible hate crimes or guns event in
 coordination with
 victims/heroes of the JCC shooting.

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 Pediatricians
 Location: DC Convention Center or White
 House

Wednesday, Oct. 13 Message Opportunity, DC

Thursday, Oct. 14 Message Opportunity, DC

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Message Sent

To: _____
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Andy Rotherham/OPD/EOP@EOP
Anna Richter/OPD/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:55:43.00

SUBJECT: Finally... A Message Schedule Update!

TO: Bethany Little (CN=Bethany Little/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Andy Rotherham (CN=Andy Rotherham/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

One more thing to note: Cabinet Affairs has submitted a scheduling proposal for the President to do an event with the Blue Ribbon Schools when they're in town October 28-29.

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:55 PM -----

Karin Kullman

09/09/99 03:45:58 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP

Subject: Finally... A Message Schedule Update!

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Lady)
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victims/heroes of the JCC shooting.

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Anna Richter/OPD/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Karin Kullman (CN=Karin Kullman/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 9-SEP-1999 15:46:06.00

SUBJECT: Finally... A Message Schedule Update!

TO: Andy Rotherham (CN=Andy Rotherham/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Eric P. Liu (CN=Eric P. Liu/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Eugenia Chough (CN=Eugenia Chough/OU=OPD/O=EOP@EOP [OPD])
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TO: Irene Bueno (CN=Irene Bueno/OU=OPD/O=EOP@EOP [OPD])
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READ:UNKNOWN

TO: Teresa M. Jones (CN=Teresa M. Jones/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Essence P. Washington (CN=Essence P. Washington/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Paul J. Weinstein Jr. (CN=Paul J. Weinstein Jr./OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Cynthia A. Rice (CN=Cynthia A. Rice/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Cathy R. Mays (CN=Cathy R. Mays/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Sarah A. Bianchi (CN=Sarah A. Bianchi/O=OVP@OVP [UNKNOWN])
READ:UNKNOWN

CC: Cathy R. Mays (CN=Cathy R. Mays/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Bruce N. Reed (CN=Bruce N. Reed/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:

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Topic: TBD

Saturday, Oct. 2 - Travel to Los Angeles, CA
Monday, Oct. 4

Monday, Oct. 4 Message Opportunity, Los Angeles, CA
NOTE: There was interest in doing a
possible hate crimes or guns event in
coordination with
victims/heroes of the JCC shooting.

Tuesday, Oct. 5 Message Opportunity, DC

Wednesday, Oct. 6 Comp. Test Ban Treaty Event (T)

Thursday, Oct. 7 Healthcare Event (T)

Location: White House

NOTE: We are looking to invite health reporters from across the country to the White House on this day. Possible topics are Medicare State-by-State Report or Patients' Bill or Rights event.

Friday, Oct. 8 Travel to Ottawa, Canada

Saturday, Oct. 9 Radio Address

Topic: TBD

Monday, Oct. 11 No Message Opportunity

Tuesday, Oct. 12 Possible Event with American Academy of Pediatricians

Location: DC Convention Center or White House

Wednesday, Oct. 13 Message Opportunity, DC

Thursday, Oct. 14 Message Opportunity, DC

Friday, Oct. 15 Possible Stem Cell Event

Saturday, Oct. 16 Radio Address

Topic: TBD

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:10-SEP-1999 14:45:58.00

SUBJECT: Re: ?

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

Here's the final q&a on stem cell -- Chris and Varmus talked and this is what they decided on. Also, Podesta has expressed an interest in waiting until Monday to put this out.

Devorah

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we are not now requesting a change in current law to permit Federal support for derivation of stem cells from human embryos. The President's 1994 ban will remain in effect.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical) to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. We believe that there is a fundamental difference between the derivation of a stem cell, which involves the destruction of an embryo, and the use of a stem cells in research. Stem cells are not embryos and do not have the potential to form a child.

However, because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation. However, we do not answer hypothetical veto questions, particularly over legislation that is unlikely to pass the Congress. Because of the broad-based bipartisan support for current research activities (such as Senators Spector, Harkin, and Thurmond, as well as Representative Bilbray), we do not believe that Congress would pass such ill advised legislation.

DRAFT STATEMENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's report are complex and difficult, and the national dialogue addressed a range of opinions that must be respected. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:10-SEP-1999 11:31:12.00

SUBJECT: Finally... A Message Schedule Update!

TEXT:

----- Forwarded by Christopher C. Jennings/OPD/EOP on
09/10/99 10:49 AM -----

Karin Kullman
09/09/99 03:50:04 PM
Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Devorah R.
Adler/OPD/EOP@EOP
cc:
Subject: Finally... A Message Schedule Update!

Things to note for our healthcare team:

We no longer have Sept. 23 as a healthcare/Rx event
Still looking to do the health reporters on Oct. 7
Oct. 12 -- 10,000 pediatricians will be in DC at the Convention Center for
the American Academy of Pediatrics Conference. Two options were
discussed:

1. address the whole group at the Convention Center
 2. bring a subset to the WH for an event or meeting, and give the
pediatricians an opportunity to do press on the North Lawn.
- People were interested in what announcements we could make. Do you
think
this would be a good venue for our CHIP event?

----- Forwarded by Karin Kullman/OPD/EOP on 09/09/99
03:46 PM -----

Karin Kullman
09/09/99 03:45:58 PM
Record Type: Record

To: See the distribution list at the bottom of this message
cc: Bruce N. Reed/OPD/EOP@EOP, Cathy R. Mays/OPD/EOP@EOP
Subject: Finally... A Message Schedule Update!

The following is an update on the President's message schedule for the
remainder of September and early October. DPC events are in italics and
open message slots are in bold. Please call me with any questions.

Thursday, Sept. 9 Depart for New Zealand

Friday, Sept. 10 - New Zealand Visit
Wednesday, Sept. 15

Saturday, Sept. 11 Radio Address (taped at WH Thursday 9/9)
Topic: Safe Schools, Healthy Students/COPS
grants

Wednesday, Sept. 15 Hawaii

Thursday, Sept. 16 Arrive WH -- 8:30am
No Message Opportunity

Friday, Sept. 17 No Message Opportunity

PLEASE NOTE: The message schedule for Sept. 12 and 13 may change pending events during the President's foreign travel (ie, Hill activity).

Saturday, Sept. 18 Radio Address (Live)
Topic: TBD

Congressional Black Caucus Dinner, DC

Monday, Sept. 20 No Message Opportunity (also could
change)

Tuesday, Sept. 21 Address to UN General Session, NY

Wednesday, Sept. 22 Y2K Message Event (T)
NOTE: This marks 100 days until the
millenium

Thursday, Sept. 23 Meeting with Chairman Arafat (T)

Possible Surplus Event (or on 9/29)

Friday, Sept. 24 Adoption Event (with the First
Lady)

Location: White House

Saturday, Sept. 25 Radio Address (taped 9/24)
Topic: TBD

Monday, Sept. 27 Message Opportunity, New Orleans, LA

Tuesday, Sept. 28 WH Religious Leaders Breakfast

Wednesday, Sept. 29 Possible Surplus Event (if not 9/23)

Arts and Humanities Awards Ceremony

Thursday, Sept. 30 Message Opportunity, DC

Friday, Oct. 1	Departure Statement Opportunity
Valley, CA	Travel to Las Vegas, NV and Silicon
Saturday, Oct. 2	Radio Address (taped 10/1)
	Topic: TBD
Saturday, Oct. 2 - Monday, Oct. 4	Travel to Los Angeles, CA
Monday, Oct. 4	Message Opportunity, Los Angeles, CA
possible hate coordination with victims/heroes of the JCC shooting.	NOTE: There was interest in doing a crimes or guns event in
Tuesday, Oct. 5	Message Opportunity, DC
Wednesday, Oct. 6	Comp. Test Ban Treaty Event (T)
Thursday, Oct. 7	Healthcare Event (T)
	Location: White House
reporters from across the White House on this day. Possible topics are	NOTE: We are looking to invite health country to the Medicare State-by-State Report or Patients' Bill or Rights event.
Friday, Oct. 8	Travel to Ottawa, Canada
Saturday, Oct. 9	Radio Address
	Topic: TBD
Monday, Oct. 11	No Message Opportunity
Tuesday, Oct. 12	Possible Event with American Academy of Pediatricians
House	Location: DC Convention Center or White
Wednesday, Oct. 13	Message Opportunity, DC
Thursday, Oct. 14	Message Opportunity, DC
Friday, Oct. 15	Possible Stem Cell Event
Saturday, Oct. 16	Radio Address
	Topic: TBD

Message Sent

To:

Sarah A. Bianchi/OVP@OVP
Thomas L. Freedman/OPD/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Jeanne Lambrew/OPD/EOP@EOP
Cathy R. Mays/OPD/EOP@EOP
Nicole R. Rabner/WHO/EOP@EOP
Cynthia A. Rice/OPD/EOP@EOP
Leanne A. Shimabukuro/OPD/EOP@EOP
Paul J. Weinstein Jr./OPD/EOP@EOP
Mary L. Smith/OPD/EOP@EOP
Essence P. Washington/OPD/EOP@EOP
Andrea Kane/OPD/EOP@EOP
Teresa M. Jones/OPD/EOP@EOP
Devorah R. Adler/OPD/EOP@EOP
J. Eric Gould/OPD/EOP@EOP
Irene Bueno/OPD/EOP@EOP
Bethany Little/OPD/EOP@EOP
Eugenia Chough/OPD/EOP@EOP
Ruby Shamir/OPD/EOP@EOP
Eric P. Liu/OPD/EOP@EOP
Ann O'Leary/OPD/EOP@EOP
Andy Rotherham/OPD/EOP@EOP
Anna Richter/OPD/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:10-SEP-1999 11:35:48.00

SUBJECT: here you go

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

TEXT:

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we see no immediate need to alter current law to permit Federal support for derivation of stem cells from human embryos.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical) to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. We believe that there is a fundamental difference between the derivation of a stem cell, which involves the destruction of an embryo, and the use of a stem cells in research. Stem cells are not embryos and do not have the potential to form a child.

However, because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation. However, we do not answer hypothetical veto questions, particularly over legislation that is unlikely to pass the Congress. Because of the broad-based bipartisan

support for current research activities (such as Senators Spector, Harkin, and Thurmond, as well as Representative Bilbray), we do not believe that Congress would pass such ill advised legislation.

DRAFT STATEMENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's report are complex and difficult, and the national dialogue addressed a range of opinions that must be respected. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:10-SEP-1999 11:29:57.00

SUBJECT: Re: where are we?

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

Since we went soft in the statement, here are the q&a we would like to add to the list. Let's talk about this -- call me or I'll call you.

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of stem cells, and because this important research can be conducted through other avenues, we see no immediate need to alter current law to permit Federal support for derivation of stem cells from human embryos.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical) to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. We believe that there is a fundamental difference between the derivation of a stem cell, which involves the destruction of an embryo, and the use of a stem cells in research. Stem cells are not considered to be embryos because they do not have the potential to form a child.

However, because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding

for stem cell research?

A: Clearly, we would not support such legislation. However, we do not answer hypothetical veto questions, particularly over legislation that is unlikely to pass the Congress. Because of the broad-based bipartisan support for current research activities (members such as) I need to fill in the blanks here), we do not believe that Congress would pass such ill advised legislation.

Devorah

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Lorrie McHugh-Wytkind <lmchugh-@os.dhhs.gov> (Lorrie McHugh-Wytkind <lmchugh-@os.dhhs.gov> [UNKNOWN])

CREATION DATE/TIME:13-SEP-1999 10:02:37.00

SUBJECT: re: stem cell

TO: Deborah R. Adler (CN=Deborah R. Adler/OU=OPD/O=EOP [OPD])

READ:UNKNOWN

CC: Robert Jasak <rjasak@os.dhhs.gov> (Robert Jasak <rjasak@os.dhhs.gov> [UNKNOWN])

READ:UNKNOWN

TEXT:

Thanks. We'll take a look at it. Is the statement going to be released today?

Original Text

From: <Deborah_R._Adler@opd.eop.gov>, on 9/13/99 9:26 AM:

Hello --

Here is what we sent over to OSTP as our final comments on the stem cell package -- q&a and statement.

This was negotiated in hideous, excruciating detail with Varmus, so it should be okay.

This is not final paper, since technically OSTP is the lead, but I don't expect them to change it and wanted to make sure that you guys had a copy.

Please call with questions.

Deborah

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we are not now requesting a change in current law to permit Federal support for derivation of stem cells from human embryos. The President's 1994 ban on the use of Federal funds for the creation of human embryos for

research purposes will remain in effect.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical ? to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. However, we believe that the law is clear. It permits the use of Federal funds to conduct stem cell research, and prohibits the use of Federal funds to derive stem cells.

Because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation, and because of the enormous potential for health breakthroughs, we believe that it would not pass the Congress. There is broad-based, bipartisan support for current research activities, from members such as Senators Specter, Harkin, Thurmond, and Representatives Porter and Bilbray.

DRAFT STATEMENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:13-SEP-1999 09:27:28.00

SUBJECT: final edits on stem cell

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

TEXT:

hey -- wanted to make sure that you realized there were some changes in the q&a as well, even though I forgot to bold them. I will resend with bolded edits if you feel the need.

Devorah

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:13-SEP-1999 11:30:58.00

SUBJECT: NBAC stem cell report -- press guidance and POTUS statement

TO: Jennifer M. Palmieri (CN=Jennifer M. Palmieri/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Erica S. Lepping (CN=Erica S. Lepping/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Nanda Chitre (CN=Nanda Chitre/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Barry J. Toiv (CN=Barry J. Toiv/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

CC: Sean P. Maloney (CN=Sean P. Maloney/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

CC: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP.])
READ:UNKNOWN

CC: Neal Lane (CN=Neal Lane/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: Holly L. Gwin (CN=Holly L. Gwin/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: Anthony J. Gibson (CN=Anthony J. Gibson/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

Barry -- The President's National Bioethics Advisory Commission has completed its report on stem cells, and has delivered it to the White House.

Attached for your consideration are press guidance and Qs & As, as well as

a statement from the President that acknowledges the receipt of the report and thanks the members of NBAC.

The carefully chosen wording of both these draft documents has been approved and coordinated between OSTP (Rachel Levinson, 6-6137) and DPC (Chris Jennings and Devorah Adler, 6-5560), as well as between HHS and NIH. Any changes should be cleared with the above offices.

We would appreciate it if you would consider issuing this statement as soon as is practical. NBAC is holding off posting the stem cell report on their website until they hear that the White House has released the President's statement. Thanks.

-- Jeff Smith (6-6047)

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D87]ARMS28238655Y.236 to ASCII,
The following is a HEX DUMP:

===== END ATTACHMENT 2 =====

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release
September 13, 1999

Contact: 202/456-6047

STATEMENT BY THE PRESIDENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

###

Human Embryonic Stem Cells September 13, 1999

Context: *In November, 1998, the President asked his National Bioethics Advisory Commission (NBAC) to undertake a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations. In a report released today, the Commission recommends that the use of human embryonic stem cells for research, as well as their derivation from embryos donated by individuals being treated for infertility, be eligible for Federal funding. Because the Congressional ban prohibits Federal funding of research using human embryos, NBAC recommends that an exception be made to the ban to permit the derivation of these cells from human embryos. On July 14, the White House issued a statement responding to release of NBAC's draft recommendations that endorsed the Commission's view of the importance of stem cell research and the need for Federal funding of research using such cells. However, the White House statement suggested that there was no immediate need to alter legislation to permit Federal support for derivation of human stem cells from human embryos.*

Background: Human embryonic stem cells, which were first isolated in November 1998 by privately funded researchers, are cells that have the capacity to specialize into virtually all the types of cells of the human body. The range of potential biomedical applications for these cells is enormous—any disease or injury that is caused by or results in damaged or dead cells, such as Parkinson's disease, heart disease, diabetes, and burn and spinal cord injuries, could be treated, or even cured, by transplantation of freshly differentiated stem cells.

The controversy that has surrounded this scientific breakthrough originates from the fact that some of these stem cells were isolated from donated human embryos. Since FY1996, HHS appropriations laws have barred Federally-funded scientists from conducting research in which human embryos are subjected to more than minimal risk. This proscription goes considerably further than the President's 1994 ban on the use of Federal funds to create embryos for research purposes. In January 1999, the HHS General Counsel determined that because stem cells are not human embryos, Federally-funded research using human embryonic stem cells is not prohibited under the ban. The House Pro-Life Caucus sharply criticized this decision, and promised legislative action this year to prevent the use of Federal funds to support human embryonic stem cell research.

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we are not now requesting a change in current law to permit Federal support for derivation of stem cells from human embryos. The President's 1994 ban on the use of Federal funds for the creation of human embryos for research purposes will remain in effect.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical – to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. However, we believe that the law is clear. It permits the use of Federal funds to conduct stem cell research, and prohibits the use of Federal funds to derive stem cells from embryos.

Because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation, and because of the enormous potential for health breakthroughs, we believe that it would not pass the Congress. There is broad-based, bipartisan support for current research activities, from members such as Senators Specter, Harkin, Thurmond, and Representative Bilbray.

Q: Is the NIH currently funding research using human embryonic stem cells?

A: No. After the HHS General Counsel issued her opinion that Federal funding of research using human embryonic stem cells is not prohibited, NIH announced that this research would go forward *only* after NIH guidelines and an oversight process are put into place. The NIH Director established a Working Group of his Advisory Committee to develop guidelines and an oversight procedure to ensure that public sector research using human embryonic stem cells is done ethically. NIH's draft guidelines are expected to be published in the Federal Register for public comment in early September.

Q. Some research has shown that adult stem cells can produce many of the same cells and tissues of the body that could be developed using pluripotent stem cells (stem cells that can specialize into many cell types) derived from human embryos. Why wouldn't NIH just fund research using adult stem cells?

A. There is, in fact, very intriguing research being done to assess the utility and versatility of human stem cells obtained from adults. For instance, the critical role of blood stem cells in replenishing our lifetime supply of red and white blood cells and platelets has been known for some time. Recently, it was shown that stem cells taken from bone marrow could be induced to develop into fat and bone cells. There would be significant advantages to being able to use a patient's own stem cells for repair of missing or worn out tissues because there would be no threat of rejection by the patient's immune system.

However, biological differences between stem cells obtained from adults and those from embryos point to serious scientific and technical limitations to the adult stem cell approach. For example, there are no known adult stem cells for many tissues and organs, including heart and pancreatic islet cells, and others are difficult to locate or to remove without causing serious harm to the patient, such as brain stem cells. Experience with animal research has provided insights into methods for inducing stem cells obtained from early embryos and fetuses to develop into a variety of cell types that may be useful in treating Parkinson's disease, damaged heart muscle following heart attacks, and spinal cord injury.

Although it may be possible to develop cell and tissue therapies using adult stem cells, human pluripotent stem cells still hold enormous promise. Given the remarkable potential of this line of research, it is vital that all approaches be explored simultaneously. In this manner, researchers can rapidly determine which sources of stem cells are the best for the development of therapies to treat human disease.

Q: How do you think this issue will play out on Capitol Hill?

A: It is possible that Congress will attempt to ban Federal funding for human embryonic stem cell research. Congressman Dickey, Senator Brownback and others have publicly stated their opposition to this research. However, Senators Specter and Harkin and Congressman Porter, the leaders of the Senate and House Appropriations Labor/HHS Subcommittees, have expressed support for Federal funding of stem cell research, citing both the potential biomedical benefits that could be reaped, and the value of ensuring government oversight of this research. Most recently, on July 29, Senator Thurmond and Congressman Bilbray, two conservative Pro-Life Republicans, voiced their support for NIH funding for human embryonic stem cell research.

Q: Where does the public stand on this issue?

A: There is substantial support for using Federal funds for human embryonic stem cell research. Because of the extraordinary promise of this research, patient groups have formed a coalition called Patients' Coalition for Urgent Research (or Patients' CURE) to urge Federal funding of this research. A public opinion survey commissioned by the coalition showed that 74% of the public favored the funding of stem cell research by the NIH. There is also substantial opposition to this research, mostly from so-called "Pro-Life" groups.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:13-SEP-1999 09:51:56.00

SUBJECT: Re: final edits on stem cell

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

TEXT:

I think the edits are fine and I have forwarded them to Neal with that view. The only question I have is with respect to the metnion of Porter. I believe he has said privately that he supports NIH doing stem cell research but that he won't say this publicly. If you have other word, that would be great to include him.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:13-SEP-1999 09:26:24.00

SUBJECT: stem cell

TO: lmchugh-@os.dhhs.gov (lmchugh-@os.dhhs.gov @ inet [UNKNOWN])
READ:UNKNOWN

CC: rjasak@os.dhhs.gov (rjasak@os.dhhs.gov @ inet [UNKNOWN])
READ:UNKNOWN

TEXT:
Hello --

Here is what we sent over to OSTP as our final comments on the stem cell package -- q&a and statement.

This was negotiated in hideous, excruciating detail with Varmus, so it should be okay.

This is not final paper, since technically OSTP is the lead, but I don't expect them to change it and wanted to make sure that you guys had a copy.

Please call with questions.

Devorah

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we are not now requesting a change in current law to permit Federal support for derivation of stem cells from human embryos. The President's 1994 ban on the use of Federal funds for the creation of human embryos for research purposes will remain in effect.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical) to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. However, we believe that the law is clear. It permits the use of Federal funds to conduct stem cell research, and prohibits the use of Federal funds to derive stem cells.

Because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation, and because of the enormous potential for health breakthroughs, we believe that it would not pass the Congress. There is broad-based, bipartisan support for current research activities, from members such as Senators Specter, Harkin, Thurmond, and Representatives Porter and Bilbray.

DRAFT STATEMENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:13-SEP-1999 10:16:03.00

SUBJECT: re: stem cell

TO: lmchugh-@os.dhhs.gov (lmchugh-@os.dhhs.gov [UNKNOWN])

READ:UNKNOWN

TEXT:

yes, we are releasing the statement sometime today.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Barry J. Toiv (CN=Barry J. Toiv/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:13-SEP-1999 13:24:53.00

SUBJECT: Re: NBAC stem cell report -- press guidance and POTUS statement

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: holly l. gwin (CN=holly l. gwin/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: devorah r. adler (CN=devorah r. adler/OU=opd/O=eop@eop [OPD])
READ:UNKNOWN

CC: clifford j. gabriel (CN=clifford j. gabriel/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: anthony j. gibson (CN=anthony j. gibson/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: rachel e. levinson (CN=rachel e. levinson/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: nanda chitre (CN=nanda chitre/OU=who/O=eop@eop [WHO])
READ:UNKNOWN

CC: sean p. maloney (CN=sean p. maloney/OU=who/O=eop@eop [WHO])
READ:UNKNOWN

CC: christopher c. jennings (CN=christopher c. jennings/OU=opd/O=eop@eop [OPD])
READ:UNKNOWN

CC: arthur bienenstock (CN=arthur bienenstock/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: neal lane (CN=neal lane/OU=ostp/O=eop@eop [OSTP])
READ:UNKNOWN

CC: jennifer m. palmieri (CN=jennifer m. palmieri/OU=who/O=eop@eop [WHO])
READ:UNKNOWN

CC: erica s. lepping (CN=erica s. lepping/OU=who/O=eop@eop [WHO])
READ:UNKNOWN

TEXT:

Based on the statement, I assume we're seeking to say nothing. Will there be stories, and if so, do we want to be in them in any way?

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:13-SEP-1999 09:14:45.00

SUBJECT: final edits on stem cell

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

TEXT:

Chris looked at the paper again last night and here are his final edits. I think that this should be fine, but if Neal or anyone else has questions, they should call or page -- if you can't find Chris easily, call me and I will track him down.

Edits are attached.

Thanks a lot.

Devorah

QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

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I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:13-SEP-1999 15:15:58.00

SUBJECT: List of Priority

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Debra D. Alexander (CN=Debra D. Alexander/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TEXT:
Here's a list of priority for letters you have. Thanks for all your help
last week

Tomorrow:
Glendening (ASAP, please) - - you wanted to get Chris's input on this

Anderson ("Stem cell" issue) - - does the draft still fit after the NBAC
report which was issued today? If not, how can I get my hands on that
report? thx.

Wednesday:
American Academy of Physical Therapy - - I sent a revised draft last week

Patricia Curry (draft included below; I'll FAX the incoming)

To: Patricia Curry

Thank you for your letter regarding H.R. 19, the resolution dedicated to
the formation of a House Mental Health Advisory Committee. As you know,
my Administration is fully committed to ensuring quality health care for
all Americans suffering from mental illness.

My Administration has been focused on mental health initiatives in an
effort to help prevent youth violence. With the vision and leadership of
Tipper Gore, we launched the first-ever White House Conference on Mental
Health and unveiled new initiatives to address the mental health concerns
of Americans. Among the programs we introduced was a national school
safety training initiative for teachers, school personnel, and community
members.

As we continue our efforts to make improvements in mental health care, I
applaud your dedication to this important issue and extend my deepest
thanks for your contributions.

You have my best wishes.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:13-SEP-1999 13:41:44.00

SUBJECT: stem cell report -- POTUS statement

TO: Barry J. Toiv (CN=Barry J. Toiv/OU=WHO/O=EOP@EOP [WHO])

READ:UNKNOWN

CC: holly l. gwin (CN=holly l. gwin/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: devorah r. adler (CN=devorah r. adler/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

CC: clifford j. gabriel (CN=clifford j. gabriel/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: anthony j. gibson (CN=anthony j. gibson/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: rachel e. levinson (CN=rachel e. levinson/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: nanda chitre (CN=nanda chitre/OU=who/O=eop@eop [WHO])

READ:UNKNOWN

CC: sean p. maloney (CN=sean p. maloney/OU=who/O=eop@eop [WHO])

READ:UNKNOWN

CC: christopher c. jennings (CN=christopher c. jennings/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

CC: arthur bienenstock (CN=arthur bienenstock/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: neal lane (CN=neal lane/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: jennifer m. palmieri (CN=jennifer m. palmieri/OU=who/O=eop@eop [WHO])

READ:UNKNOWN

CC: erica s. lepping (CN=erica s. lepping/OU=who/O=eop@eop [WHO])

READ:UNKNOWN

TEXT:

Barry -- Your assumption is correct. We'd like to low key this because we hope not to make a large splash because of the sensitivity in the Labor-HHS appropriations process where this stem cell issue is expected to be a hot button issue. Because there were already stories on this very same stem cell issue triggered by the White House's July 14th

statement -- you'll note in today's statement and in the accompanying Q&A that we are deemphasizing the no-immediate-need- for-change-in-legislation aspect because of Varmus/HHS wishes -- there's very little that is really new here. We expect there will be short stories in the NYT (Wade), the WP (Weiss), and perhaps the Boston Globe (Saltus)... but everything else will likely be in the trade press.

Barry J. Toiv

09/13/99 01:24:51 PM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP@EOP

cc: See the distribution list at the bottom of this message

Subject: Re: NBAC stem cell report -- press guidance and POTUS statement

Based on the statement, I assume we're seeking to say nothing. Will there be stories, and if so, do we want to be in them in any way?

Message Copied

To:

erica s. lepping/who/eop@eop

nanda chitre/who/eop@eop

jennifer m. palmieri/who/eop@eop

rachel e. levinson/ostp/eop@eop

neal lane/ostp/eop@eop

anthony j. gibson/ostp/eop@eop

arthur bienenstock/ostp/eop@eop

clifford j. gabriel/ostp/eop@eop

christopher c. jennings/opd/eop@eop

devorah r. adler/opd/eop@eop

sean p. maloney/who/eop@eop

holly l. gwin/ostp/eop@eop

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Barbara D. Woolley (CN=Barbara D. Woolley/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:16-SEP-1999 18:37:47.00

SUBJECT: Stem Cell Event - Need to talk to Karen T.

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Chris, can you talk to either Karen T or John P. regarding the stem cell event. As you may recall, in August we (OSTP) were pushing for a big message event with groups and POTUS. Currently, in talking to the groups, they would like a non-press meeting with John Podesta. Low profile, no press, no message event with the President announcing the federal guidelines on stem cell research. Timing for this meeting needs to occur prior to the release of the federal guidelines and before appropriation mark up, probably within the next week to 10 days. The purpose of the meeting should be to say now is the time, we all need everyone working on this, get the group pumped up. Show the Administration is behind them. Have the Administration give them a heads up on the federal guidelines prior to their release.

John P. thinks we want a message event and we need to let him know that is not the case. However, timing is such that we will need to move quickly on the meeting. If John P doesn't want to do the meeting we need to get other folks to do it. Thanks.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:17-SEP-1999 12:11:31.00

SUBJECT: fyi

TO: Barbara D. Woolley (CN=Barbara D. Woolley/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TEXT:

----- Forwarded by Devorah R. Adler/OPD/EOP on 09/17/99
12:11 PM -----

Eric P. Liu
09/17/99 12:10:37 PM
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc:
Subject: fyi

At Senior Staff mtg, Neal Lane said to Podesta that he'd like to get a group of folks from the science community to do a private mtg with him on stem cell research. Neal said this after noting that HHS is wary of doing anything public. No commitment from Podesta at the time.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:20-SEP-1999 15:36:11.00

SUBJECT: List of Priority

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Debra D. Alexander (CN=Debra D. Alexander/OU=WHO/O=EOP [WHO])

READ:UNKNOWN

TEXT:

Reminder...

----- Forwarded by John H. Corcoran III/WHO/EOP on
09/20/99 03:36 PM -----

John H. Corcoran III
09/16/99 11:18:19 AM
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: Debra D. Alexander/WHO/EOP
Subject: List of Priority

Reminder... thanks.
----- Forwarded by John H. Corcoran III/WHO/EOP on
09/16/99 11:18 AM -----

John H. Corcoran III
09/13/99 03:15:55 PM
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: Debra D. Alexander/WHO/EOP
Subject: List of Priority

Here's a list of priority for letters you have. Thanks for all your help
last week

Tomorrow:
Glendening (ASAP, please) - - you wanted to get Chris's input on this

Anderson ("Stem cell" issue) - - does the draft still fit after the NBAC
report which was issued today? If not, how can I get my hands on that
report? thx.

Wednesday:

American Academy of Physical Therapy - - I sent a revised draft last week

Patricia Curry (draft included below; I'll FAX the incoming)

To: Patricia Curry

Thank you for your letter regarding H.R. 19, the resolution dedicated to the formation of a House Mental Health Advisory Committee. As you know, my Administration is fully committed to ensuring quality health care for all Americans suffering from mental illness.

My Administration has been focused on mental health initiatives in an effort to help prevent youth violence. With the vision and leadership of Tipper Gore, we launched the first-ever White House Conference on Mental Health and unveiled new initiatives to address the mental health concerns of Americans. Among the programs we introduced was a national school safety training initiative for teachers, school personnel, and community members.

As we continue our efforts to make improvements in mental health care, I applaud your dedication to this important issue and extend my deepest thanks for your contributions.

You have my best wishes.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:20-SEP-1999 17:46:58.00

SUBJECT: NIH Stem cell guidelines

TO: Richard J. Turman (CN=Richard J. Turman/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

CC: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

You should have received a faxed copy of the NIH guidelines by now. If not, please let me know. I have conveyed a few non-showstopper comments to DHHS/NIH, namely: FDA needs to look at the references to use of stem cells for possible future transplantation purposes (page 11) to make sure that appropriate cites are included, and a few other editorial things. For the most part, I think they are OK and should go out as soon as possible. Keep in mind that these are going out for public comment and that although they are meant to be a good first approximation of what HHS wants them to look like, there is room for change based on comments. It may help to know that to the extent possible, procedures for stem cells derived from embryos track regs already in place for fetal tissue transplantation research.

Specter has tentatively scheduled a hearing for Sept. 28 and NIH wants to have the guidelines out before then. It would also be good for NIH to put them out before the end of the fiscal year so that in the event of a CR, they are not counted as a new initiative.

So - please let me know if you have questions or any problems that may hold this up so we can get them resolved as quickly as possible.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:21-SEP-1999 17:34:26.00

SUBJECT: stem cell guidelines

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

Sorry to bother you yet again but I would like to know (1) if you got the NIH guidelines, and (2) are you OK with them going out for public comment?

If you haven't received copies, I will have them sent right away.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP [OMB])

CREATION DATE/TIME:21-SEP-1999 09:38:59.00

SUBJECT: Re: NIH Stem cell guidelines

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

CC: jeffrey m. smith (CN=jeffrey m. smith/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: devorah r. adler (CN=devorah r. adler/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

CC: richard j. turman (CN=richard j. turman/OU=omb/O=eop@eop [OMB])

READ:UNKNOWN

CC: christopher c. jennings (CN=christopher c. jennings/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

TEXT:

I think the guidelines are helpful and should be released as soon as possible. Appropriations staff (both minority and majority) agree with this.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:21-SEP-1999 11:50:17.00

SUBJECT: Re: NIH Stem cell guidelines

TO: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

CC: jeffrey m. smith (CN=jeffrey m. smith/OU=ostp/O=eop@eop [OSTP])

READ:UNKNOWN

CC: devorah r. adler (CN=devorah r. adler/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

CC: richard j. turman (CN=richard j. turman/OU=omb/O=eop@eop [OMB])

READ:UNKNOWN

CC: christopher c. jennings (CN=christopher c. jennings/OU=opd/O=eop@eop [OPD])

READ:UNKNOWN

TEXT:

Thanks Dan. Any views from DPC? I have a call pending from HHS asking when this is a go.

Daniel N. Mendelson

09/21/99 09:38:42 AM

Record Type: Record

To: Rachel E. Levinson/OSTP/EOP@EOP

cc: christopher c. jennings/opd/eop@eop, devorah r. adler/opd/eop@eop, richard j. turman/omb/eop@eop, jeffrey m. smith/ostp/eop@eop

Subject: Re: NIH Stem cell guidelines

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CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:23-SEP-1999 15:40:38.00

SUBJECT: NIH stem cell guidelines

TO: ls25d@nih.gov (ls25d@nih.gov [UNKNOWN])

READ:UNKNOWN

TO: lfishbac@os.dhhs.gov (lfishbac@os.dhhs.gov [UNKNOWN])

READ:UNKNOWN

CC: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

CC: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

CC: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Holly L. Gwin (CN=Holly L. Gwin/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

CC: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

CC: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TEXT:

This is to let you know that OSTP, OMB (Budget/Health), and DPC have reviewed and cleared the Sept. 13 draft of the NIH Guidelines for Research Involving Human Pluripotent Stem Cells and encourage you to publish them for public comment as soon as possible. It would be helpful if you could forward your current version and let me know if there are any further points under discussion.

Thanks
Rachel

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:23-SEP-1999 17:22:02.00

SUBJECT: Re: Anderson Letter & FAX

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Debra D. Alexander (CN=Debra D. Alexander/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TEXT:
PRETTY PLEASE...

----- Forwarded by John H. Corcoran III/WHO/EOP on
09/23/99 05:22 PM -----

John H. Corcoran III
09/09/99 12:30:28 PM
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: Debra D. Alexander/WHO/EOP
bcc: Records Management@EOP
Subject: Re: Anderson Letter & FAX

I rewrote this to address the two statements from the WH website (7/14/99 and 11/21/98)... I hope this is more what you were looking for. Thanks.

Thank you for your letter in regards to human pluripotent embryonic stem cell research funding and the National Institutes of Health. I appreciate your thoughts and input on this important matter.

Last November, I asked my National Bioethics Advisory Commission to undertake a thorough review of all the ethical and medical considerations associated with human stem cell research. After much thought and deliberation, we determined that human stem cell technology's potential medical benefits are compelling and worthy of pursuit, as long as the research is conducted according to the highest ethical standards. As you know, stem cell research has potential application for treating people with diabetes, heart disease, Parkinson's disease, cancer, and spinal cord injury. As we proceed on this complex and sensitive issue, the NIH will be putting together guidelines to ensure that the cells are obtained in an ethically sound manner.

As we work to keep our commitment to combating disease through

biomedical research, I am grateful for your consultation. Thank you again for sharing your thoughts and concerns.

Devorah R. Adler

09/08/99 05:57:21 PM

Record Type: Record

To: John H. Corcoran III/WHO/EOP@EOP

cc: Debra D. Alexander/WHO/EOP@EOP

Subject: Re: Anderson Letter & FAX

We've issued several statements on stem cell -- you might want to check those out and see if they work and can be incorporated into this letter.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:28-SEP-1999 10:45:51.00

SUBJECT: Senate Markup

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Holly L. Gwin (CN=Holly L. Gwin/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: Barbara D. Woolley (CN=Barbara D. Woolley/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Anthony J. Gibson (CN=Anthony J. Gibson/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Neal Lane (CN=Neal Lane/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

Not sure from this note if Lott's deal with Specter precludes anyone else (Craig) from offering related amendments that would prohibit NIH from using stem cells. That's the hope - but I guess we'll see later today or tomorrow after floor action.

----- Forwarded by Rachel E. Levinson/OSTP/EOP on
09/28/99 10:41 AM -----

Tim Leshan <TLESHAN@ascb.org>
09/28/99 07:35:26 AM

Record Type: Record

To: See the distribution list at the bottom of this message
cc: See the distribution list at the bottom of this message

Subject: Senate Markup

Last night's Senate Labor/HHS Subcommittee Appropriation markup was highlighted by the discussion of stem cell research. After describing the funding in the bill, including a \$2 billion increase for the NIH, Senator Specter said the one other item he wanted to discuss was stem cell research. As we suspected he included language in his bill that "carves out an exception to the human embryo ban to permit Federal researchers to derive human embryonic stem cells from embryos obtained from in vitro fertilization clinics." But Specter went on to explain that Majority Leader Lott had ask him to strike the language which Specter agreed to do on the floor, but not before getting assurances that he could bring this issue before the Senate next year. This means the derivation language will remain in the bill when the full Appropriations Committee marks up the bill today, but Specter will move to strike it when the bill comes to the Senate floor on Wednesday. I assume this means that there will not be an attempt to amend the bill with regard to stem cells by others on the committee. Ultimately, I believe we will return to the status quo in the Senate which would allow the NIH to move forward to with use of stem cells, but not their derivation.

This leaves us with the full Appropriations Committee markup in the House on Thursday. It is still not clear what kind of an amendment Rep. Jay Dickey (R-AR) will offer, but if he does the vote will be very close. I think the ad coming out today in the Congressional Monitor will help, but we need to keep the pressure on to be sure Members know we oppose a ban. Thanks.

Tim Leshan
Director of Public Policy
American Society for Cell Biology
tleshan@ascb.org
www.jscpp.org/jscpp
301-530-7153 (p)
301-530-7139 (f)

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:28-SEP-1999 14:20:56.00

SUBJECT: stem cell guidelines

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Barbara D. Woolley (CN=Barbara D. Woolley/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Holly L. Gwin (CN=Holly L. Gwin/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Neal Lane (CN=Neal Lane/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

Just got off a conference call with HHS (Rich Tarplin, Harriet Rabb, Marcie Wilder, Lana Skirboll, Lorraine Fishback, and others), OMB (Dan Mendelson, Richard Turman) re: timing of release of NIH stem cell guidelines. Rather than releasing them tomorrow, HHS proposes to wait until at least after Senate floor action, expected tomorrow morning. The view is that Specter's acquiescence to Lott's request that he strike his amendment allowing NIH to fund derivation of stem cells might also preclude anyone else from offering an amendment that would tighten the current ban. If this assumption holds up (no guarantees), that would preserve the status quo and allow NIH to fund use of stem cells. There is concern that releasing the guidelines tomorrow might upset the assumed balance and ought to be delayed, perhaps only until Thursday, depending on the result of the floor action.

Opinion on a meeting between Podesta or other WH rep and patient groups is that such a meeting should wait until the guidelines are released and then an assessment made as to the value of such a meeting. Right now, Patients' CURE is doing a great job on the Hill and we wouldn't want to distract them.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:30-SEP-1999 14:53:38.00

SUBJECT: Dickey stem cell amendment withdrawn

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Barbara D. Woolley (CN=Barbara D. Woolley/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TEXT:

An amendment scheduled to be offered today at the full House Appropriations Committee mark up of the FY 2000 Labor, Health and Human Services, Education, and Related Agencies (L/HHS) spending bill that would have prevented the National Institutes of Health (NIH) from funding research with embryonic stem cells was withdrawn late last night at the request of the House leadership. (see Washington Fax 9/30/99)

Rep. Jay Dickey, R-AR, the amendment's sponsor withdrew his rider to meet the broad request of House Majority Whip Thomas DeLay, R-TX, that no controversial amendments be tacked on to this spending bill. Dickey has indicated that he has no plans to offer the amendment when the bill reaches the House floor.

Advocates of stem cell research say they believe they have "dodged a bullet" and that for the time being the tide of politics has switched to a more favorable flow for them by eliminating worry of an amendment to the existing spending bill.

The Senate at this hour has set aside floor debate of its L/HHS bill and turned to other matters.

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME: 8-OCT-1999 16:07:37.00

SUBJECT: W. Post piece on stem cells

TO: Arthur Bienenstock (CN=Arthur Bienenstock/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Clifford J. Gabriel (CN=Clifford J. Gabriel/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Holly L. Gwin (CN=Holly L. Gwin/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Neal Lane (CN=Neal Lane/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

CC: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

CC: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:

It is likely that the Washington Post will run an article on A1 on Sunday or Monday marking one year from the first announcement of the isolation and culture of human stem cells. The focus will be on what we have learned about stem cells in the past year. I sent the reporter the piece from October 1 Science called "Ethical Loophole Closing Up for Stem Cell Researchers." The gist of it is that stem cells derived from fetuses may not have the same therapeutic potential as stem cells derived from embryos. Note that this was a news article and not peer-reviewed experimental results. These results, however, may be important in the congressional debate on stem cells. Jay Dickey's amendment would have allowed NIH funding for research involving stem cells from fetuses, but not from embryos. He has not ruled reintroducing it if the Labor/HHS approps bill is vetoed and a new bill is considered.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Ed Furtek <furtek@sio.ucsd.edu> (Ed Furtek <furtek@sio.ucsd.edu> [UNKNOWN])

CREATION DATE/TIME:26-OCT-1999 00:42:26.00

SUBJECT: Biomedical Engineering Challenges

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

TEXT:

Tom,

I don't know what your time frame was on this, so I did a quick and limited survey. I'm sure I can develop something more substantial with time, but realize that is not a resource always in abundance. Let me know your thoughts. (Where appropriate I have included my second thoughts in parens.)

Ed

A.) NEUROSCIENCES:

- 1) tissue engineering and regeneration including stem cell research to develop cellular therapies for diabetes, heart failure and neurodegenerative diseases among others;
- 2) neuroscience research to combat neurodegenerative diseases (if we knew how to control inappropriate nerve cell firing or neural networks, or even if we knew why people developed neurodegenerative diseases, then we might be able to fix them. at present we don't);
- 3) neuroscience research to fight neuropathic illnesses (if we knew the nature of the neuropathic disease cure that neuroscience research would discover, we could implement it right now; that's the problem;
- 4) research on control of vascular growth to fight heart disease.

B.) BIOENGINEERING:

The grand challenge in Bioengineering is to synthesize accurate computer models based on genomic and biochemical data of cellular processes. Or in silico biology--a new revolution in the field. Bioengineering seems likely to lead this change. (Clear interagency possibilities here with NSF - informatics, DOE & genomics, and NIH & NCI's bioinformatics initiatives.)

Now politically the question will be, what are the short term benefits? I feel that they will be in new anti-microbials and in cancer. In silico models (that already exist for many bacteria) can guide the development of optimal killing strategies and thus focus the search for new effective antibiotics.

Cancer, where progress has been very disappointing in the past 10 years, may follow suit. Unlike heart disease and diabetes, where real progress has been made, cancer has pretty much the same mortality rates as it has had historically.

This is somewhat ironic since cancer is now arguably the best understood human disease in molecular and genetic terms. The cellular pathways that malfunction in cancer are becoming known. There is a growing sense that there will be real progress in the treatment of cancer over the coming years. Interestingly, as with antimicrobials, in silico models of the malfunctioning cellular pathways may be one of the keys to developing optimal 'killing strategies'.

C.) Examples of Recent UCSD Discoveries in Related Areas:

1/2 Age-related memory loss might be reversible, according to neuroscientists, who have identified the process of brain degeneration that can occur with aging and have found that it can be reversed with gene therapy. While normal aging often results in some memory loss, up until now, scientists have been unable to pinpoint changes in specific areas of the brain associated with degeneration. The researchers have found that in primates, the degeneration occurs in the cells of the system that activates brain function in the hippocampus and cortex, and appears to be almost completely reversible with the implantation of tissue grafts of genetically modified cells.

1/2 The poisonous jack-o-lantern mushroom - it glows yellowish-orange in the dark- is the source of a promising new cancer drug developed by university researchers. The drug, which selectively destroys cancer cells without harming surrounding tissue, is being viewed by the National Cancer Institute as a drug of choice in fighting some of the most intractable cancers. Clinical trials at NCI sites around the country have shown the drug to be effective in shrinking or eliminating tumors of the breast, prostate, pancreas, ovaries, and other hard to manage cancers.

1/2 A potential cure for one of the most deadly forms of leukemia. UCSD oncologists have disarmed human leukemia cells and genetically modified them in a way that induces a powerful, killing response from the immune system. In the laboratory, researchers have shown that the immune response prompted by the modified cells destroys not only the harmless modified cells, but also the active leukemia cells lurking nearby. In the first FDA-approved gene therapy trial for cancer in San Diego, 11 patients with chronic lymphocytic leukemia were each injected with their own modified leukemia cells and all but one had a significant drop in the number of leukemia cells found in their blood.

Associate Vice Chancellor for Science and Technology Policy and Projects
U.C. San Diego
9500 Gilman Drive
La Jolla, California 92093-0993

phone: 858-534-0888

fax: 858-534-6404

email: efurtek@ucsd.edu

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jason H. Schechter (CN=Jason H. Schechter/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:29-NOV-1999 08:56:44.00

SUBJECT: press guidance request

TO: Elliot J. Diringer (CN=Elliot J. Diringer/OU=CEQ/O=EOP@EOP [CEQ])
READ:UNKNOWN

TO: Richard A. Kostro (CN=Richard A. Kostro/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: James R. Fallin (CN=James R. Fallin/OU=NSC/O=EOP@EOP [NSC])
READ:UNKNOWN

TO: David C. Leavy (CN=David C. Leavy/OU=NSC/O=EOP@EOP [NSC])
READ:UNKNOWN

TO: Anne W. Bovaird (CN=Anne W. Bovaird/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Robert S. Weiner (CN=Robert S. Weiner/OU=ONDCP/O=EOP@EOP [ONDCP])
READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Anna Richter (CN=Anna Richter/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Kymberly M. Escobar (CN=Kymberly M. Escobar/OU=CEQ/O=EOP@EOP [CEQ])
READ:UNKNOWN

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP@EOP [OSTP])
READ:UNKNOWN

TO: Michael A. Hammer (CN=Michael A. Hammer/OU=NSC/O=EOP@EOP [NSC])
READ:UNKNOWN

TO: Natalie S. Wozniak (CN=Natalie S. Wozniak/OU=NSC/O=EOP@EOP [NSC])
READ:UNKNOWN

TO: Sean P. O'Shea (CN=Sean P. O'Shea/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Steven W. Panton (CN=Steven W. Panton/OU=ONDCP/O=EOP@EOP [ONDCP])
READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Patrick M. Dorton (CN=Patrick M. Dorton/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

CC: Barry J. Toiv (CN=Barry J. Toiv/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

CC: Richard L. Siewert (CN=Richard L. Siewert/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

CC: Jennifer M. Palmieri (CN=Jennifer M. Palmieri/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TEXT:
welcome back - for 11:15 am please:

nec
bush income-tax cut (wsj) - reducing existing marginal rates, cutting
estate taxes, etc. - our views
wto - does final guidance packet answer:
 wp a1 article on lack of agenda? -
 venezuela gasoline dispute in wp as example of wto favoring free
trade at expense of environment (also ceq)
 business wto lobbying (wsj) - will businesses have their say in
seattle?

dpc
national center for women and aging (wp) - why are caregivers for elderly
losing out at work? are we doing anything?
drug dispensing on internet (wsj a1) - dispensing drugs without an
in-person diagnosis by a physician - our views
national school board report (usa today) - threats facing children - what
are we doing? (fyi, there will be a national press club press
conference on this today)

ondcp
border drug seizures on rise (wp a1) - are we alarmed at larger
trafficking? what are we doing to stop it?

cabinet affairs
fbi working with militia leaders (usa today a1) - does this send a bad
signal?

nsc
food assistance to Sudanese rebels (nyt a1) - why are we involving
ourselves in another country's civil war?
trump, us military first strike against north korea (wp) - our views?
mexico charging american cars a fee for entering (la times) - people have
appealed to administration - what's our response?
cuban custody battle/coast guard (usa today) - is u.s. at fault?

ostp
stem cell guidance
space launch failure - per michelle i should be receiving these soon?
thanks

southern baptist plan (nyt) - potus views on converting jews, hindus to christianity

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:29-NOV-1999 08:58:45.00

SUBJECT: Re: press guidance request

TO: Jason H. Schechter (CN=Jason H. Schechter/OU=WHO/O=EOP@EOP [WHO])

READ:UNKNOWN

TEXT:

Jason --

Since sometimes we have a difference of opinion with OSTP on the right message on stem cell issues, we'd like to review that guidance quickly if you don't mind -- was there an article today that I missed?

Devorah

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jason H. Schechter (CN=Jason H. Schechter/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:29-NOV-1999 09:03:09.00

SUBJECT: press guidance request

TO: Melissa G. Green (CN=Melissa G. Green/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

hey, just saw that patrick isn't here - i haven't really looked at final
wto guidance packet yet (i'll review this morning), just wanted to make
sure it answered questions below - also see bush request - thanks
----- Forwarded by Jason H. Schechter/WHO/EOP on 11/29/99
09:01 AM -----

Jason H. Schechter
11/29/99 08:56:38 AM
Record Type: Record

To: See the distribution list at the bottom of this message
cc: Jennifer M. Palmieri/WHO/EOP@EOP, Barry J. Toiv/WHO/EOP@EOP,
Richard L. Siewert/WHO/EOP@EOP
Subject: press guidance request

welcome back - for 11:15 am please:

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estate taxes, etc. - our views
wto - does final guidance packet answer:
 wp a1 article on lack of agenda? -
 venezuela gasoline dispute in wp as example of wto favoring free
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 business wto lobbying (wsj) - will businesses have their say in
seattle?

dpc

national center for women and aging (wp) - why are caregivers for elderly
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ostp

stem cell guidance

space launch failure - per michelle i should be receiving these soon?

thanks

southern baptist plan (nyt) - potus views on converting jews, hindus to christianity

Message Sent

To:

Patrick M. Dorton/OPD/EOP@EOP

Anna Richter/OPD/EOP@EOP

Christopher C. Jennings/OPD/EOP@EOP

Devorah R. Adler/OPD/EOP@EOP

Steven W. Panton/ONDCP/EOP@EOP

Robert S. Weiner/ONDCP/EOP@EOP

Sean P. O'Shea/WHO/EOP@EOP

Anne W. Bovaird/WHO/EOP@EOP

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David C. Leavy/NSC/EOP@EOP

Michael A. Hammer/NSC/EOP@EOP

James R. Fallin/NSC/EOP@EOP

Jeffrey M. Smith/OSTP/EOP@EOP

Richard A. Kostro/OSTP/EOP@EOP

Kymberly M. Escobar/CEQ/EOP@EOP

Elliot J. Diringer/CEQ/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jason H. Schechter (CN=Jason H. Schechter/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:29-NOV-1999 09:00:52.00

SUBJECT: Re: press guidance request

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

i didnt see any articles but apparently this is something that we expect to come up today (per michelle ballantyne) - i'll make sure you see it first.

Devorah R. Adler
11/29/99 08:58:40 AM
Record Type: Record

To: Jason H. Schechter/WHO/EOP@EOP

cc:

Subject: Re: press guidance request

Jason --

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Devorah

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Robert J. Pellicci (CN=Robert J. Pellicci/OU=OMB/O=EOP [OMB])

CREATION DATE/TIME: 7-DEC-1999 08:45:22.00

SUBJECT: Medical Errors Hearing

TO: Richard J. Turman (CN=Richard J. Turman/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: Barry T. Clendenin (CN=Barry T. Clendenin/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: JENNINGS_C@A1@CD@LNGTWY (JENNINGS_C@A1@CD@LNGTWY [UNKNOWN]) (WHO)
READ:UNKNOWN

TO: Mark E. Miller (CN=Mark E. Miller/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TO: Daniel N. Mendelson (CN=Daniel N. Mendelson/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

CC: Janet R. Forsgren (CN=Janet R. Forsgren/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

CC: James J. Jukes (CN=James J. Jukes/OU=OMB/O=EOP@EOP [OMB])
READ:UNKNOWN

TEXT:
HEADS UP--

Sen. Specter has scheduled a hearing for Monday, December 13th, on IOM's recent report on medical mistakes. HHS will testify. The Department is currently drafting testimony - likely witnesses: Eisenberg or Raub.

A hearing on stem cell research also likely within next couple of weeks.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Robert J. Pellicci@EOP@LNGTWY@LNGTWY (Robert J. Pellicci@EOP@LNGTWY@LNGTWY [OMB])

CREATION DATE/TIME: 7-DEC-1999 08:50:58.00

SUBJECT: Medical Errors Hearing

TO: Christopher C. Jennings@eop (Christopher C. Jennings@eop [OPD])
READ:UNKNOWN

TEXT:
Message Creation Date was at 7-DEC-1999 08:45:00

HEADS UP--

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A hearing on stem cell research also likely within next couple of weeks.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Sarah A. Bianchi (CN=Sarah A. Bianchi/O=OVP [UNKNOWN])

CREATION DATE/TIME:10-DEC-1999 11:35:12.00

SUBJECT: Stem Cell Guidance

TO: Elizabeth Baylor (CN=Elizabeth Baylor/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:

----- Forwarded by Sarah A. Bianchi/OVP on 12/10/99 11:35
AM -----

Barry J. Toiv @ EOP

05/24/99 12:44:36 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Sarah A. Bianchi/OVP@OVP, Devorah
R. Adler/OPD/EOP@EOP

cc:

Subject: Stem Cell Guidance

haven't we been ok in the past on embryo research if only "spare" embryos
are used and not those created for research purposes?

----- Forwarded by Barry J. Toiv/WHO/EOP on 05/24/99
12:43 PM -----

Laura Emmett

05/24/99 11:17:14 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Devorah R. Adler/OPD/EOP@EOP, Christopher C. Jennings/OPD/EOP@EOP,
Sarah A. Bianchi/OVP@OVP, Jeanne Lambrew/OPD/EOP@EOP

Subject: Stem Cell Guidance

Stem Cell Q&A

May 24, 1999

Q: What is your response to reports that the National Bioethics Advisory
Commission is considering recommending that Federal funding should be made

available for research on embryos made by invitro fertilization?

A: The Commission has not submitted or even written their report on this issue, so it would be premature and unwarranted to comment on it at this time. However, the Administration,s position on stem cell research has been clearly articulated by Secretary Shalala, NIH Director Harold Varmus, and other Administration officials. Current law prohibits Federal funding the production of stem cells from embryos. The Administration has supported this prohibition. However, HHS,s Office of the General Counsel has determined that the statute permits the funding of research using stem cells that have previously been created. This is because stem cells cannot become embryos and such research does not involve the destruction or use of embryos. Stem cell research of this kind could lead to treatment for Parkinson,s disease, heart disease, diabetes, stroke, burns, arthritis, and other serious medical conditions.

Message Sent

To: _____
Barry J. Toiv/WHO/EOP@EOP
Joseph P. Lockhart/WHO/EOP@EOP
Jennifer M. Palmieri/WHO/EOP@EOP
Nanda Chitre/WHO/EOP@EOP
Elizabeth R. Newman/WHO/EOP@EOP
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Karin Kullman/OPD/EOP@EOP
Mark D. Neschis/WHO/EOP@EOP
Erica S. Lepping/WHO/EOP@EOP
Alejandro G. Cabrera/OVP@OVP
Melissa B. Ratcliff/OVP@OVP
Deborah Akel/WHO/EOP@EOP
David Vandivier/OMB/EOP@EOP

TEXT:

Unable to convert ARMS_EXT:[ATTACH.D1]ARMS242804067.336 to ASCII,

The following is a HEX DUMP:

===== END ATTACHMENT 1 =====

Stem Cell Q&A
May 24, 1999

Q: What is your response to reports that the National Bioethics Advisory Commission is considering recommending that Federal funding should be made available for research on embryos made by invitro fertilization?

A: The Commission has not submitted or even written their report on this issue, so it would be premature and unwarranted to comment on it at this time. However, the Administration's position on stem cell research has been clearly articulated by Secretary Shalala, NIH Director Harold Varmus, and other Administration officials. Current law prohibits Federal funding the production of stem cells from embryos. The Administration has supported this prohibition. However, HHS's Office of the General Counsel has determined that the statute permits the funding of research using stem cells that have previously been created. This is because stem cells cannot become embryos and such research does not involve the destruction or use of embryos. Stem cell research of this kind could lead to treatment for Parkinson's disease, heart disease, diabetes, stroke, burns, arthritis, and other serious medical conditions.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Sarah A. Bianchi (CN=Sarah A. Bianchi/O=OVP [UNKNOWN])

CREATION DATE/TIME:10-DEC-1999 12:05:02.00

SUBJECT: NBAC stem cell report will arrive on Sept. 7

TO: Elizabeth Baylor (CN=Elizabeth Baylor/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:

----- Forwarded by Sarah A. Bianchi/OVP on 12/10/99 12:04
PM -----

David W. Beier
09/03/99 04:02:25 PM
Record Type: Record

To: Sarah A. Bianchi/OVP@OVP
cc:
Subject: NBAC stem cell report will arrive on Sept. 7

----- Forwarded by David W. Beier/OVP on 09/03/99 04:02
PM -----

Rachel E. Levinson @ EOP 09/03/99 03:36:59 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Barbara D.
Woolley/WHO/EOP@EOP, David W. Beier/OVP@OVP, Devorah R. Adler/OPD/EOP@EOP
cc:
Subject: NBAC stem cell report will arrive on Sept. 7

the attached materials are provided for your comment in advance of the
NBAC stem cell report, which we expect will be delivered next Tuesday.
NBAC will put it up on the Web as soon as we tell them it has been
received. Both documents went through HHS and have Varmus' comments
incorporated.

Please note the proposal for a POTUS briefing from NBAC chair Harold
Shapiro and Harold Varmus, which would also be next week. Also note that
we are NOT suggesting that there be a public event for the NBAC report
release or the NIH guidelines publication due to potential negative impact
on the HHS appropriations process. Rep. Dickey has drafted approps
amendment language restricting funding of implementation of the NIH
guidelines.

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D72]ARMS21096606N.336 to ASCII,
The following is a HEX DUMP:

===== END ATTACHMENT 2 =====

Human Embryonic Stem Cells September X, 1999

Context: *In November, 1998, the President asked his National Bioethics Advisory Commission (NBAC) to undertake a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations. In a report that will be released tomorrow, the Commission recommends that the use of human embryonic stem cells for research, as well as their derivation from embryos donated by individuals being treated for infertility, be eligible for Federal funding. Because the Congressional ban prohibits Federal funding of research using human embryos, NBAC recommends that an exception be made to the ban to permit the derivation of these cells from human embryos. On July 14, the WH issued a statement responding to release of NBAC's draft recommendations endorsing the Commission's view of the importance of stem cell research and the need for Federal funding of research using such cells, and suggesting that there is no immediate need to alter legislation to permit Federal support for derivation of human stem cells from human embryos.*

Background: Human embryonic stem cells, which were first isolated in November 1998 by privately funded researchers, are cells that have the capacity to specialize into virtually all the types of cells of the human body. The range of potential biomedical applications for these cells is enormous—any disease or injury that is caused by or results in damaged or dead cells, such as Parkinson's disease, heart disease, diabetes, and burn and spinal cord injuries, could be treated, or even cured, by transplantation of freshly differentiated stem cells.

The controversy that has surrounded this scientific breakthrough originates from the fact that some of these stem cells were isolated from donated human embryos. Federally funded scientists have been barred from research using human embryos since FY1996 in HHS Appropriations law. This proscription goes considerably further than the President's 1994 ban on the use of Federal funds to create embryos for research purposes. In January 1999, the HHS General Counsel rendered an opinion that federally funded research using human embryonic stem cells is not prohibited under the ban, because stem are not human embryos. The House Pro-Life Caucus sharply criticized this decision, and promised legislative action this year to prevent the use of federal funds to support human embryonic stem cell research.

Q: What is the Administration position on the use of human embryonic stem cells in research?

A: Clinton Administration, recognizing that the potential medical benefits of human stem cell technology are compelling and worthy of pursuit, believes that this arena of research should be supported with Federal funding in accordance with the highest ethical standards. Such research promises new treatments and possibly cures for many debilitating diseases and injuries, including Parkinson's, diabetes, heart disease, multiple sclerosis, burns, and spinal cord injury. NIH is drafting guidelines and an oversight process for public comment to ensure that human embryonic stem cells used in Federally funded research are obtained in an ethically sound manner.

Q: What is the Administration position on NBAC's recommendation to modify the Congressional funding ban on human embryo research?

A: The President agrees with the Commission's conclusions that the potential medical benefits of human stem cells are compelling and that the research using these cells should go forward under strict ethical standards. The President clearly stated his position on human embryo research in December 1994 when he issued an executive directive prohibiting the use of NIH funds to create human embryos for research purposes, a position which is also consistent NBAC's recommendations. The President's ban does not prohibit NIH from supporting important stem cell research, under the confines of current law.

Q: Is the NIH currently funding research using human embryonic stem cells?

A: No. After the HHS General Counsel issued her opinion that Federal funding of research using human embryonic stem cells is not prohibited, NIH announced that this research would go forward only after NIH guidelines and an oversight process are put into place. The NIH Director established a Working Group of the Advisory Committee to the Director, NIH to develop guidelines and an oversight procedure to ensure that public sector research using human embryonic stem cells is done ethically. NIH's draft guidelines should be published in the Federal Register for public comment in early September.

Q: How do you think this issue will play out on Capitol Hill?

A: It is possible that Congress will attempt to ban federal funding for human embryonic stem cell research. Congressman Dickey, Senator Brownback and others have publicly stated their opposition to this research. However, Senators Specter and Harkin and Congressman Porter, the leadership of the Senate and House Appropriations Labor/HHS Subcommittees, have expressed support for federal funding of stem cell research, citing both the potential biomedical benefits that could be reaped, and the value of ensuring government oversight of this research. Most recently, on July 29 Senator Thurmond and Congressman Bilbray, two conservative Pro-Life Republicans, voiced their support for NIH funding for human embryonic stem cell research.

Q: Where does the public stand on this issue?

A: There is substantial support for using Federal funds for human embryonic stem cell research. Because of the extraordinary promise of this research, patient groups have formed a coalition called Patients' Coalition for Urgent Research (or Patients' CURE) to advocate for Federal funding of this research. A public opinion survey commissioned by the coalition showed that 74% of the public favored the funding of stem cell research by the NIH. There is also substantial opposition to this research, mostly from so-called "Pro-Life" groups.

Possible scenario for response to NBAC report and publication of NIH guidelines:

[PLEASE COMMENT]

NBAC plans to deliver their report to the President on Sept. 7. NIH plans to publish its draft guidelines for public comment in the Federal Register shortly after Congress returns. The gap between these two events could be used to our advantage in a White House response to the NBAC report. One possible scenario would be to have a private meeting between the President and the NBAC Chairman and the NIH Director, and release a statement that the White House has received the report and charged NIH to use the NBAC recommendations in drafting its guidelines for the ethical research use of human embryonic stem cells, within the confines of current law. In September, the White House could meet with the patient advocacy groups and indicate support for their efforts. These White House actions would serve to signal our position to Congress, prior to the markup of Labor/HHS appropriations bills in the House and Senate.

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

I also understand that human embryonic stem cell research raises ethical concerns that need to be addressed, and the national dialogue facilitated by NBAC addressed a range of opinions that must be respected. The NBAC Commissioners are to be commended for the thoroughness with which they engaged in this discussion, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the National Bioethics Advisory Commission, and other Commissioners for a thoughtful report that will significantly contribute to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:13-DEC-1999 17:20:07.00

SUBJECT: Re: IMPORTANT FOB -- Kate Britton

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TEXT:

True. Well, I meant that the 'language' (in the press releases, fact sheets, etc.) which the Admin. uses when it refers to the stem cell issue is similar to the kind of language we might be able to use when talking about the handling of "fetal tissue" which comes from the so-called partial birth abortion procedure and which is later used for medical research. These are similar realms of medical research which have the potential for great medical breakthroughs but which also raise profound ethical dilemmas for many people.

Although the 7/14/99 Statement says "it appears that human embryonic stem cells will be available from the private sector," I assumed this to mean that stem cells would be retrieved from PB abortion.

I realize the stem cell issue isn't exactly the same as the 'dead baby subpart' industry, but seeing as we don't have any previous POTUS language (either in speeches or previous letters) talking about handling of fetal tissue from partial birth abortion, I hoped we could base the language of this letter upon the stem cell statements/fact sheets, etc. Our goal, of course, is write the letter as accurately to what he would say about the issue -- which can be difficult if he's never commented on that issue before! Does that make sense?

Thanks,
John

Devorah R. Adler
12/13/99 04:24:02 PM
Record Type: Record

To: John H. Corcoran III/WHO/EOP@EOP

cc:

Subject: Re: IMPORTANT FOB -- Kate Britton

The stem cell issue is totally different than a "dead baby subpart" industry. Stem cells are individual cells that will never develop into humans.

Are you sure that stem cells apply here?

Devorah

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Jennie Kim <JKim@basshowes.com> (Jennie Kim <JKim@basshowes.com> [UNKNOWN])

CREATION DATE/TIME:28-DEC-1999 14:35:08.00

SUBJECT: work question

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

READ:UNKNOWN

TEXT:

Hey D:

quick question: is a directive different from an executive order? I'm still

working on the stem cell paper I told you about and I'm looking at a statement Varmus made about a President's directive (that no NIH funds should be used for the creation of human embryos for research purposes). I thought this was an Executive Order - can you help clarify? Thanks!!!!

Jennie Kim
Senior Program Associate
BASS and HOWES, Inc.
Tel 202-530-2900
Fax 202-530-2901
jkim@basshowes.com

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME:11-FEB-2000 15:19:02.00

SUBJECT: stem cell

TO: Sarah A. Bianchi (CN=Sarah A. Bianchi/OU=OPD/O=EOP@EOP [OPD])
READ:UNKNOWN

TEXT:
QUESTIONS AND ANSWERS ON STEM CELL RESEARCH

Q: Does the Administration support the use of Federal funding to derive stem cells from human embryos, as NBAC recommends?

A: The potential medical benefits of using stem cells in research are compelling, holding great promise for treatments for Parkinson's disease, heart disease, diabetes, stroke, and arthritis, and the Administration believes that the research using these cells should go forward under strict ethical standards. Funding Federal research on these cells is legally permissible and within the confines of the ban.

However, because of the sensitive ethical issues and social considerations raised by the derivation of human stem cells, we are not now requesting a change in current law to permit Federal support for derivation of stem cells from human embryos. The President's 1994 ban on the use of Federal funds for the creation of human embryos for research purposes will remain in effect.

Q: The Administration does believe that research on the stem cells themselves can be funded. Isn't that hypocritical) to fund research on the product of a destroyed embryo, as long as someone else actually destroys the embryo?

A: We maintain great respect for the full range of viewpoints surrounding these issues. However, we believe that the law is clear. It permits the use of Federal funds to conduct stem cell research, and prohibits the use of Federal funds to derive stem cells.

Because of the serious ethical and social considerations raised by this research, NIH research conducted on stem cells will proceed with great care. Currently, NIH is setting up a special oversight committee, developing guidelines, and consulting with outside authorities and experts as the process continues. We expect these guidelines to be released sometime this fall.

Q: Would you veto any legislation that would ban Federal funding for stem cell research?

A: Clearly, we would not support such legislation, and because of the enormous potential for health breakthroughs, we believe that it would

not pass the Congress. There is broad-based, bipartisan support for current research activities, from members such as Senators Specter, Harkin, Thurmond, and Representatives Porter and Bilbray.

DRAFT STATEMENT

Today, my National Bioethics Advisory Commission (NBAC) delivered its report on "The Ethical Use of Human Stem Cells in Research." Back in November, when I asked NBAC to look at the ethical and medical issues surrounding human stem cell research, I recognized the enormous medical potential of such research. The scientific results that have come out in just the past few months already strengthen my basis for hope that one day, stem cells will be used to replace cardiac muscle cells for people with heart disease, nerve cells for hundreds of thousands of Parkinson's patients, or insulin-producing cells for children who suffer from diabetes.

The issues addressed by NBAC's recommendations are complex and difficult. The Commissioners are to be commended for the thoroughness with which they engaged in this discussion and the national dialogue that they facilitated, seeking the views and opinions of virtually every segment of our society, including scientists, patients, scholars from most of the major religions in the United States, lawyers, philosophers, ethicists and the public.

I want to thank Dr. Harold Shapiro, Chairman of the NBAC, and other Commissioners for a thoughtful report that will contribute significantly to the efforts of my Administration as we establish the highest ethical standards for the conduct of human stem cell research.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Marshall J. Rodgers (CN=Marshall J. Rodgers/OU=OMB/O=EOP [OMB])

CREATION DATE/TIME:21-APR-2000 12:14:47.00

SUBJECT: LRM MJR37 - - HEALTH & HUMAN SERVICES Testimony on Stem Cell Research

TO: Allison H. Eydt (CN=Allison H. Eydt/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Amandeep K. Matharu (CN=Amandeep K. Matharu/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: barry t. clendenin (CN=Barry T. Clendenin/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Caroline B. Davis (CN=Caroline B. Davis/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Christopher C. Jennings (CN=Christopher C. Jennings/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Devorah R. Adler (CN=Devorah R. Adler/OU=OPD/O=EOP@EOP [OPD])

READ:UNKNOWN

TO: Ingrid M. Schroeder (CN=Ingrid M. Schroeder/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Jeanne Lambrew (CN=Jeanne Lambrew/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Judy C. Lin (CN=Judy C. Lin/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Mark E. Miller (CN=Mark E. Miller/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Melany Nakagiri (CN=Melany Nakagiri/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP@EOP [OSTP])

READ:UNKNOWN

TO: robert donnelly (CN=Robert Donnelly/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TO: Robert J. Pellicci (CN=Robert J. Pellicci/OU=OMB/O=EOP@EOP [OMB])

READ:UNKNOWN

TEXT:

Attached is HHS testimony on stem cell research. The hearing is April

26th before the Senate Appropriations Subcommittee.

----- Forwarded by Marshall J. Rodgers/OMB/EOP on

04/21/2000 12:11 PM -----

LRM ID: MJR37

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF MANAGEMENT AND BUDGET

Washington, D.C. 20503-0001

Friday, April 21, 2000

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution
below

FROM: Ingrid M. Schroeder (for) Assistant Director for
Legislative Reference

OMB CONTACT: Marshall J. Rodgers

PHONE: (202)395-7813 FAX: (202)395-6148

SUBJECT: HEALTH & HUMAN SERVICES Testimony on Stem Cell Research

DEADLINE: 12:00 PM Monday, April 24, 2000

In accordance with OMB Circular A-19, OMB requests the views of your
agency on the above subject before advising on its relationship to the
program of the President. Please advise us if this item will affect
direct spending or receipts for purposes of the "Pay-As-You-Go" provisions

of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Dr. Allen Spiegel and Dr. Gerald Fischbach will testify April 26th before the Senate Appropriations Subcommittee on stem cell research.

DISTRIBUTION LIST

AGENCIES:

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456-6047

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Jeanne Lambrew

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Judy C. Lin

Caroline B. Davis

Melany Nakagiri

Amandeep K. Matharu

Allison H. Eydt

Rachel E. Levinson

Robert Donnelly

Robert J. Pellicci

Ingrid M. Schroeder

LRM ID: MJR37 SUBJECT: HEALTH & HUMAN SERVICES Testimony on Stem

Cell Research

RESPONSE TO

LEGISLATIVE REFERRAL

MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or

(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Marshall J. Rodgers Phone: 395-7813 Fax: 395-6148

Office of Management and Budget

Branch-Wide Line (to reach legislative assistant):

395-3925

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

The following is the response of our agency to your request for views on
the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet=====

ATTACHMENT 1 =====

ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

Unable to convert ARMS_EXT:[ATTACH.D47]ARMSZY00028IU.000 to ASCII,
The following is a HEX DUMP:

===== END ATTACHMENT 1 =====

STATEMENT OF

ALLEN M. SPIEGEL, M. D.

DIRECTOR

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY

DISEASES

AND

GERALD D. FISCHBACH, M.D.

DIRECTOR

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND

STROKE

BEFORE THE

SENATE APPROPRIATIONS SUBCOMMITTEE

ON

LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

APRIL 26, 2000

Mr. Chairman and Members of the Subcommittee, we are pleased to appear before you to discuss the promise of human pluripotent stem cell research. Recent published reports on the isolation and successful culturing of the first human pluripotent stem cell lines have generated great excitement among scientists, patients and their families. Research using human pluripotent stem cells holds enormous promise for advances in the prevention, treatment, and diagnosis of a vast array of diseases. Virtually every realm of medicine might be touched by this innovation. Because of this enormous promise, NIH believes that this research must proceed, as long as it is conducted safely, ethically, and legally.

What are stem cells?

Stem cells are self-renewing and can give rise to the more specialized cells of the human body, such as muscle cells, blood cells and brain cells. They are best described in the context of normal human development. When a sperm fertilizes an egg, the product is a single cell that has the potential to form an entire organism. This fertilized egg is a totipotent stem cell, which has the potential to develop into a complete organism. In the first hours and days after fertilization, this cell begins to divide into identical totipotent stem cells. Then, approximately four days after fertilization, these totipotent stem cells begin to specialize, forming a hollow sphere of cells called a blastocyst. One part of the blastocyst is a cluster of cells called the inner cell mass, which are the stem cells that will go on to form most of the cells and tissues of the human body. These are pluripotent stem cells, which are different than totipotent stem cells — pluripotent stem cells cannot develop into a complete organism.

Recently, human pluripotent stem cells have been isolated from two sources: the inner cell mass of human embryos at the blastocyst stage and from fetal tissue obtained from terminated pregnancies. Because these cells are capable of limitless division and self-renewal, they can be maintained indefinitely in tissue culture, making them a vital resource for research.

Why are human pluripotent stem cells important?

There are several reasons why the isolation of human pluripotent stem cells might lead to better treatment, even cures, of many diseases. At the most fundamental level, pluripotent stem cells could help us to understand the complex events that occur during normal human development. Identifying the mechanisms underlying routine cell differentiation will improve the understanding of abnormal differentiation that characterizes many diseases. Another goal of this research would be the identification of the factors involved in the cellular decision-making process that results in cell specialization -- why do some cells become heart cells, for example, while other cells become liver cells? We know that turning genes on and off is central to this process, but we do not know much about these "decision-making" genes or what turns them on or off. Some of our most serious medical conditions, such as cancer and birth defects, are due to abnormal cell differentiation and cell division. A better understanding of normal cell processes will allow us to further delineate the fundamental errors that cause these often deadly illnesses.

Human pluripotent stem cell research could also dramatically change the way we develop drugs and test them for safety. While a limited number of cultivated cell lines are currently available and provide invaluable tools for drug development and testing, pluripotent stem cells would allow expansion of this testing to more varied cell types. For example, drugs could be tested first on particular cell lines to determine toxicity, before they are tested in either animals or humans. Although this would not replace testing in animals and in human beings, it would streamline the process of drug development, and reduce potential for harm in humans and animals. Only the drugs that are both safe and appear to have a beneficial effect in cell line testing would graduate to further testing in laboratory animals and human subjects.

Perhaps the most far-reaching potential application of human pluripotent stem cells is the generation of cells and tissue that could be used for "cell transplantation therapies," which are aimed at diseases and disorders resulting from the destruction or dysfunction of specific cells and tissue. Although donated organs and tissues can sometimes be used to replace diseased or destroyed tissue, the number of people suffering from such disorders far outstrips the number of organs and tissues available for transplantation. Pluripotent stem cells, stimulated to develop into specialized cells and tissue, offer real hope for the possibility of a renewable source of replacement cells and tissue to treat a myriad of diseases, conditions, and disabilities for which replacement tissue is in short supply. Examples of these include neurological disorders, burns, heart disease, osteoarthritis and rheumatoid arthritis.

Human Pluripotent Stem Cells and Diabetes Research

One of the best examples of the promise of this line of research is in the treatment of Type 1 diabetes. Research on islet cell transplantation and stem-cell biology offers compelling opportunities for the development of new, innovative approaches for treating and ultimately curing this disease.

Type 1 diabetes, often referred to as Juvenile Diabetes, is characterized by the inability of the body to produce insulin, a hormone necessary for glucose metabolism. This form of diabetes occurs when the body's immune system attacks and destroys its own insulin-producing beta cells in the islets of the pancreas. As a result of inadequate insulin production, glucose is unable to enter cells and the blood glucose level becomes elevated. The standard treatment is to control the glucose level with insulin injections, but good control is difficult to achieve. Moreover, although treatment with insulin sustains the patient's life, it does not prevent the devastating complications of type I diabetes, which include kidney failure, blindness, amputation, heart attack and stroke. Clinical trials have shown that these complications can be prevented or significantly delayed by maintaining blood

glucose levels as close to normal as possible. However, precise blood glucose control is difficult to achieve and requires multiple daily injections of insulin or use of an insulin pump. These regimens are extremely challenging to follow, especially for children and teenagers. In addition, one risk of such precise blood glucose control is the development of dangerously low blood sugars which could cause loss of consciousness, seizures or other complications.

To address these problems, researchers are investigating alternative approaches to restoring insulin-producing capacity, including attempts to develop an artificial pancreas, whole pancreas transplantation, and islet cell transplantation. Formidable bioengineering problems attend development of an artificial pancreas, and while researchers are working diligently to overcome them, a time frame for success cannot be predicted. Whole pancreas transplantation, while successful in some patients, is an extremely difficult surgical procedure and it requires lifelong treatment with immunosuppressive drugs that can have toxic side effects. This surgery is typically performed only in adults, often in conjunction with a needed kidney transplant for which immunosuppressive drugs would already be required. But, the success rate for the survival of the transplanted pancreas is much lower than the survival rate for the transplanted kidney.

Islet cell transplantation is a much simpler procedure than whole pancreatic transplantation and has several potential advantages. Until very recently, serious technical problems have been a major impediment to rapid progress in islet transplantation research. These key challenges have been: (1) to keep the body's immune defense system from rejecting the transplanted islets; and (2) to ensure that there is a sufficient supply of islet cells for transplantation. To date, only about five percent of people with diabetes who have received transplanted islets along with immunosuppressive drugs have been able to stay off insulin longer than one year. Stem cell research offers the potential to overcome these obstacles.

The renewed promise of islet cell transplantation derives from two complementary research opportunities. The first is the development of new methods for adjusting the immune system to keep the body from rejecting transplanted islet cells. The second is the prospect that stem cell research could ensure the needed supply of islet cells for transplantation. Human pluripotent stem cells offer the greatest promise of providing a limitless source of islet cells for treating and curing type 1 diabetes. Together, these opportunities offer unprecedented hope for curing type 1 diabetes, especially for children and young adults whose disease has not yet progressed to the point of debilitating complications.

Human Pluripotent Stem Cell Research and the Nervous System

As significant as the promise of stem cells is for the treatment of diabetes, the potential of stem cells for treating diseases of the nervous system is equally impressive. It is startling to consider the range of neurological disorders for which scientists are actively investigating stem cell therapies in animal models. A partial list would include classic neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease and amyotrophic lateral sclerosis (ALS); acute insults of stroke, brain trauma and spinal cord injury; multiple sclerosis and other demyelinating disorders; and inherited disorders such as Tay-Sachs disease and Duchenne muscular dystrophy. It might be possible to use stem cells to treat epilepsy and brain tumors. We have only begun to understand the extraordinary range of possibilities that stem cells present for treatment of these maladies.

The most obvious and exciting use of stem cells in neurological disorders is to replace lost nerve cells. Many diseases destroy particular types of nerve cells, and mature nerve cells cannot produce new cells to replace those that are lost. Animal experiments have demonstrated that the potential

exists for coaxing stem cells to specialize and replace the dopamine cells that are lost in the brain in Parkinson's disease. A similar approach might apply to several other neurological disorders. Stem cells, given appropriate control signals, might specialize to replace the lost acetylcholine producing nerve cells in Alzheimer's disease, to restore lost motor neurons in ALS, or to produce inhibitory cells to help restrain electrical activity in epilepsy.

Replacing lost nerve cells is only the beginning of the list of possible therapeutic applications for stem cells. For some disorders, such as multiple sclerosis, stem cells might replace supporting cells -- the glial cells that wrap essential electrical insulation around nerve cells. Because of the plasticity of the developing brain, stem cell strategies might be useful for correcting inherited defects. For example, in disorders that devastate children's brains because a single enzyme is missing, such as Tay-Sachs disease, we might rely on the ability of stem cells to migrate widely in the brain and supply the needed enzyme. In brain trauma and stroke, stem cells might regenerate complex brain tissue, with many integrated types of cells. Stem cells might also supply natural growth and survival chemicals to pave the way for regeneration following spinal cord injury. Recent findings suggest that stem cells might be harnessed to seek out and deliver therapies to brain tumor cells that evade surgery or radiotherapy. The list of possible applications of stem cells continues to grow as we learn more about these cells.

Future Challenges

There is much to be done before these discoveries can be incorporated into clinical practice. First, we must do the basic research to understand the process by which human cells become specialized, so that we can direct pluripotent stem cells to

become the type(s) of tissue needed for transplantation. For example, applying basic knowledge obtained from research in developmental and stem cell biology will enable the production of progenitor stem cells and the rational design of cellular therapies for human diseases such as diabetes. It is essential to underscore that studies of stem cells and the genes that regulate their development could be important for the development of ways to intervene in type 1 diabetes, and various neurological conditions, even beyond their use in transplantation.

Second, before these cells can be used for transplantation, the well-known problem of immune rejection must be overcome. Because human pluripotent stem cells derived from embryos or fetal tissue would be genetically different from the recipient, future research would need to focus on modifying human pluripotent stem cells to minimize tissue incompatibility or to create tissue banks with the most common tissue-type profiles. In addition, just delivering cells to the appropriate sites within the human body is an extremely difficult task. All of these factors argue for intensified efforts to understand the basic biology of pluripotent stem cells and, with due caution, to apply what is learned towards the treatment of disease.

What are the limitations of adult stem cells?

Recent findings have shown that even the adult human brain harbors neural stem cells, and that these adult stem cells can respond to a wide range of external and internal influences, such as learning, stress, exercise, seizures, and trauma. In addition, if pancreatic stem cells are ever isolated from adult tissue, it might be possible to direct these cells to differentiate into islet cells. In addition, the identification of adult pancreatic stem cells would open entirely new prospects, beyond transplantation strategies, for encouraging the body's own stem cells to help repair damage.

It is important to note that scientists who are leading the way in studying adult stem cells present compelling arguments why we must pursue research on both pluripotent and adult stem cells.

While some stem cells are present in adults, there may not be an adult stem cell for every type of cell in the body, and they may be present in only minute numbers. In addition, they may be very difficult to isolate; for example, in the case of adult neural stem cells, they may be confined to certain regions of the brain that are not easily accessible. More importantly, pluripotent and adult stem cells are not qualitatively alike. Pluripotent stem cells have truly amazing abilities to self-renew and to form many different cell types, even complex tissues, but in contrast the full potential of adult stem cells is uncertain, and, in fact, there is evidence to suggest they may be more limited. Unlike pluripotent stem cells, the adult stem cells may be able to divide only a limited number of times, which would limit their usefulness in the production of adequate numbers of well characterized cells for reliable therapies. Another issue is the question of how robust transplanted adult cells may be or how vulnerable to disease processes. In light of these limitations, it is important that we pursue research on both pluripotent and adult stem cells simultaneously.

Conclusion

Mr. Chairman, we appreciate the opportunity to discuss this promising and extraordinary science and are pleased to respond to any questions you may have.