RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:13-DEC-1999 16:24:06.00

SUBJECT: Re: IMPORTANT FOB -- Kate Britton

TO: John H. Corcoran III (CN=John H. Corcoran III/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

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

CREATION DATE/TIME:13-DEC-1999 16:19:03.00

SUBJECT: IMPORTANT FOB -- Kate Britton

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:
Devorah-- I spoke with the Alan Guttmacher Inst. and found out about #2 below. Do you know about #1? Specifically, do you have information (or can you point me toward info.) about the regulations for researchers who need to use fetal tissue from clinics? I have language from the recent 'stem cell' debate which is helpful and I think relates. Your suggestions/help is appreciated....

Thanks
John
---------- Forwarded by John H. Corcoran III/WHO/EOP on 12/13/99 04:17 PM ----------

John H. Corcoran III
12/10/99 03:13:04 PM
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: Debra D. Alexander/WHO/EOP
Subject: IMPORTANT FOB -- Kate Britton

Devorah --

We have a letter here from a woman who the POTUS and FLOTUS know from a prayer group in the early days of the Administration. He has corresponded multiple times with this woman about partial-birth abortion - - usually he writes long letters written by hand. This time, he's requested more information on some of Britton's arguments.

She makes two claims which the President has highlighted:

1.) Britton claims a 'dead baby body parts sub-industry' has grown up and is fueling the number of partial birth abortions each year. She claims 'fetal tissue wholesalers' solicit and advertise for body parts. The P. has written next to this section, "What about this?" Do you or Chris have information on this industry & how it's regulated?

2.) She claims 'the vast majority of partial-birth abortions are performed in the 5th and 6th months of normal pregnancies and are completely elective, that is, not associated with maternal or fetal risk. Most doctors in practice today did not learn this method of abortion in medical school.... " Do you have statistics -- do you know the number of late-term pregnancies that are elective vs. associated with some sort of health risk?

I'm faxing the incoming. Obviously, this is a top priority for us. We're also coordinating with Nicole Rabner, and spoken with the Alan Guttmacher Institute, and I'm waiting for statistics back from them. Please let me know if you have any ideas asap...

The P's note on pg. 1 reads: "What about her argument on p. 1 and 2 -- Does anyone really know how many of these procedures are done and when? I need to reply -- "

thank you.

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: Tim Leshan (Tim Leshan [UNKNOWN])

CREATION DATE/TIME:19-JAN-2000 11:23:51.00

SUBJECT: Stem Cell Meeting 1/21/00

TO: mstephens@vsadc.com (mstephens@vsadc.com [UNKNOWN])
READ:UNKNOWN

TO: harleyt@pva.org (harleyt@pva.org [UNKNOWN])
READ:UNKNOWN

TO: ndepaf@pinn.net (ndepaf@pinn.net [UNKNOWN])
READ:UNKNOWN

TO: info@parkinsonsaction.org (info@parkinsonsaction.org [UNKNOWN])
READ:UNKNOWN

TO: cdixon@nkca.org (cdixon@nkca.org [UNKNOWN])
READ:UNKNOWN

TO: Smedberg@nhcouncil.org (Smedberg@nhcouncil.org [UNKNOWN])
READ:UNKNOWN

TO: Jmelanson@modimes.org (Jmelanson@modimes.org [UNKNOWN])
READ:UNKNOWN

TO: tourette@ix.netcom.com (tourette@ix.netcom.com [UNKNOWN])
READ:UNKNOWN

TO: Jsalomon@genetics.faseb.org (Jsalomon@genetics.faseb.org [UNKNOWN])
READ:UNKNOWN

TO: ichow@faseb.org (ichow@faseb.org [UNKNOWN])
READ:UNKNOWN

TO: ipenn@cfl.org (ipenn@cfl.org [UNKNOWN])
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TO: md@capitolassociates.com (md@capitolassociates.com [UNKNOWN])
READ:UNKNOWN

TO: stipton@asrm.org (stipton@asrm.org [UNKNOWN])
READ:UNKNOWN

TO: EMARINCOLA@ascb.org (EMARINCOLA@ascb.org [UNKNOWN])
READ:UNKNOWN

TO: aarda@aol.com (aarda@aol.com [UNKNOWN])
READ:UNKNOWN

TO: Priscilla_Short@ama-assn.org (Priscilla_Short@ama-assn.org [UNKNOWN])
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TO: dperry@agingresearch.org (dperry@agingresearch.org [UNKNOWN])
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TO: Acshipp@aamc.org (Acshipp@aamc.org [UNKNOWN])
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TO: roberta@womens-health.org (roberta@womens-health.org [UNKNOWN])
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TO: rmerenstein@researchamerica.org (rmerenstein@researchamerica.org [UNKNOWN])
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TO: aeckerd@prodigy.net (aeckerd@prodigy.net [UNKNOWN])
READ:UNKNOWN

TO: wolpe@phrma.org (wolpe@phrma.org [UNKNOWN])
READ:UNKNOWN

TO: bente@nof.org (bente@nof.org [UNKNOWN])
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TO: weinberg@nhcouncil.org (weinberg@nhcouncil.org [OMB])
READ:UNKNOWN

TO: jkatz@natlbcc.org (jkatz@natlbcc.org [UNKNOWN])
READ:UNKNOWN

TO: lsoler@jdfcure.com (lsoler@jdfcure.com [UNKNOWN])
READ:UNKNOWN

TO: KDonahue@HillandKnowlton.com (KDonahue@HillandKnowlton.com [UNKNOWN])
READ:UNKNOWN

TO: egoss@fbt.com (egoss@fbt.com [UNKNOWN])
READ:UNKNOWN

TO: Skoppi@endo-society.org (Skoppi@endo-society.org [UNKNOWN])
READ:UNKNOWN

TO: etynes@ccmc.org (etynes@ccmc.org [UNKNOWN])
READ:UNKNOWN

TO: rlipner@basshowes.com (rlipner@basshowes.com [UNKNOWN])
READ:UNKNOWN

TO: Tim Leshan (Tim Leshan [UNKNOWN])
READ:UNKNOWN

TO: slrbc@aol.com (slrbc@aol.com [UNKNOWN])
READ:UNKNOWN

TO: amp@amprogress.org (amp@amprogress.org [UNKNOWN])
READ:UNKNOWN

TO: pcatterall@agingresearch.org (pcatterall@agingresearch.org [UNKNOWN])
READ:UNKNOWN

TO: KHendricks@aap.org (KHendricks@aap.org [UNKNOWN])
READ:UNKNOWN

TO: fpwhite@mail.faseb.org (fpwhite@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: nwells@vsadc.com (nwells@vsadc.com [UNKNOWN])
READ:UNKNOWN

CC: saem@saem.org (saem@saem.org [UNKNOWN])
READ:UNKNOWN

CC: nancys@psa.org (nancys@psa.org [UNKNOWN])
READ:UNKNOWN

CC: lrodrigz@mail.faseb.org (lrodrigz@mail.faseb.org [UNKNOWN])
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CC: crf@nordicgear.com (crf@nordicgear.com [UNKNOWN])
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CC: awexler@natlbcc.org (awexler@natlbcc.org [UNKNOWN])
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CC: tzemlo@mail.faseb.org (tzemlo@mail.faseb.org [UNKNOWN])
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CC: kenny@lan2wan.com (kenny@lan2wan.com [UNKNOWN])
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CC: mgilson@hadassah.org (mgilson@hadassah.org [UNKNOWN])
READ:UNKNOWN

CC: tlawless@faseb.org (tlawless@faseb.org [UNKNOWN])
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CC: Steve.gibson@cwix.com (Steve.gibson@cwix.com [UNKNOWN])
READ:UNKNOWN

CC: spattee@cff.org (spattee@cff.org [UNKNOWN])
READ:UNKNOWN

CC: tb@capitolassociates.com (tb@capitolassociates.com [UNKNOWN])
READ:UNKNOWN

CC: kwilson@cancer.org (kwilson@cancer.org [WHO])
READ:UNKNOWN

CC: mwerner@bio.org (mwerner@bio.org [UNKNOWN])
READ:UNKNOWN

CC: bernstei@aspetsrv.faseb.org (bernstei@aspetsrv.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: araanan@aps.faseb.org (araanan@aps.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: resolveadv@aol.com (resolveadv@aol.com [UNKNOWN])
READ:UNKNOWN

CC: Pam_Kurland@ama-assn.org (Pam_Kurland@ama-assn.org [UNKNOWN])
READ:UNKNOWN

CC: Jcerquone@agingresearch.org (Jcerquone@agingresearch.org [UNKNOWN])
READ:UNKNOWN

CC: sruhe@vsadc.com (sruhe@vsadc.com [UNKNOWN])
READ:UNKNOWN

CC: Jennifer.Poulakidas@ucop.edu (Jennifer.Poulakidas@ucop.edu [UNKNOWN])
READ:UNKNOWN

CC: pxe@pxe.org (pxe@pxe.org [UNKNOWN])
READ:UNKNOWN

CC: MGUARDUC@phrma.org (MGUARDUC@phrma.org [UNKNOWN])
READ:UNKNOWN

CC: hgarrison@mail.faseb.org (hgarrison@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: taylor@nhcouncil.org (taylor@nhcouncil.org [ONDCP])
READ:UNKNOWN

CC: jcrowley@MIT.EDU (jcrowley@MIT.EDU [UNKNOWN])
READ:UNKNOWN

CC: april@lewis-burke.org (april@lewis-burke.org [UNKNOWN])
READ:UNKNOWN

CC: JFriedma@HillandKnowlton.com (JFriedma@HillandKnowlton.com [OMB])
READ:UNKNOWN

CC: estrass@genetics.faseb.org (estrass@genetics.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: ASh@dc.sba.com (ASh@dc.sba.com [UNKNOWN])
READ:UNKNOWN

CC: Ess@columbia.edu (Ess@columbia.edu [UNKNOWN])
READ:UNKNOWN

CC: psparks@ccmc.org (psparks@ccmc.org [UNKNOWN])
READ:UNKNOWN

CC: estovall@cansearch.org (estovall@cansearch.org [UNKNOWN])
READ:UNKNOWN

CC: nbradish@bio.org (nbradish@bio.org [UNKNOWN])
READ:UNKNOWN

CC: sstewart@basshowes.com (sstewart@basshowes.com [OA])
READ:UNKNOWN

CC: Rebecca Wason (Rebecca Wason [UNKNOWN])
READ:UNKNOWN

CC: potoole@apa.org (potoole@apa.org [UNKNOWN])
READ:UNKNOWN

CC: apendleton@anatomy.org (apendleton@anatomy.org [UNKNOWN])
READ:UNKNOWN

CC: jennifer.zeitzer@alz.org (jennifer.zeitzer@alz.org [UNKNOWN])
READ:UNKNOWN

CC: Dbmoore@aamc.org (Dbmoore@aamc.org [UNKNOWN])
READ:UNKNOWN

TEXT:
Dear Stem Cell research advocates: Its been a while since we have all gotten together so I would like to invite you to a meeting to discuss this year's effort with regard to stem cell legislation. We will be meeting at the American Academy of Pediatrics, 601 13th St., NW, suite 400 north from 2:00-3:00 PM this Friday January 21. Please confirm your attendance.

We will be discussing:

1. A possible stem cell bill from Senators Specter & Harkin
2. A possible effort to block stem cell research in House
3. A possible effort to restrict fetal tissue research
3. The Draft NIH Stem Cell Guidelines

These issues will clearly be vigorously debated on Capitol Hill this year and I would like to use this opportunity to think about our strategy for the year. I have invited Hill staff to join us. Thank you.

****

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: "Katie M. O'Neill" ("Katie M. O'Neill" [UNKNOWN])

CREATION DATE/TIME:21-JAN-2000 13:26:01.00

SUBJECT: Important --Stem Cell Research

TO: Tucker Walton (Tucker Walton [UNKNOWN])
READ:UNKNOWN

TO: Straka Katherine Anne (Straka Katherine Anne [UNKNOWN])
READ:UNKNOWN

TO: Steph Ringler (Steph Ringler [UNKNOWN])
READ:UNKNOWN

TO: Natalie Elsener (Natalie Elsener [UNKNOWN])
READ:UNKNOWN

TO: Matt Fremont (Matt Fremont [UNKNOWN])
READ:UNKNOWN

TO: Lou Dickler (Lou Dickler [UNKNOWN])
READ:UNKNOWN

TO: Leigh Iacobucci (Leigh Iacobucci [UNKNOWN])
READ:UNKNOWN

TO: Lanie Pappas (Lanie Pappas [UNKNOWN])
READ:UNKNOWN

TO: Katherine McKeon (Katherine McKeon [UNKNOWN])
READ:UNKNOWN

TO: Jordan Fialkoff (Jordan Fialkoff [UNKNOWN])
READ:UNKNOWN

TO: Jennifer Miller (Jennifer Miller [UNKNOWN])
READ:UNKNOWN

TO: Jen Larrabee (Jen Larrabee [UNKNOWN])
READ:UNKNOWN

TO: Jason Newman (Jason Newman [UNKNOWN])
READ:UNKNOWN

TO: James P. Mulvehill (CN=James P. Mulvehill/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TO: Heidi Hammes (Heidi Hammes [UNKNOWN])
READ:UNKNOWN

TO: Harlan Weisman (Harlan Weisman [UNKNOWN])
READ:UNKNOWN

TO: Greg Kline (Greg Kline [UNKNOWN])
READ:UNKNOWN

TO: Emily Kwass (Emily Kwass [UNKNOWN])
READ:UNKNOWN

TO: Derick King (Derick King [UNKNOWN])
READ:UNKNOWN

TO: Cory Miller (Cory Miller [UNKNOWN])
READ:UNKNOWN

TO: Christine Kelly Leong (Christine Kelly Leong [UNKNOWN])
READ:UNKNOWN

TO: Beth Coale (Beth Coale [UNKNOWN])
READ:UNKNOWN

TO: Amy Douglas (Amy Douglas [UNKNOWN])
READ:UNKNOWN

TO: "Sally Weisman ("Sally Weisman/Towers Perrin" [UNKNOWN])
READ:UNKNOWN

TO: "Matthew G. Gorski" ("Matthew G. Gorski" [UNKNOWN])
READ:UNKNOWN

TO: "Kailian, Sonia" ("Kailian, Sonia" [UNKNOWN])
READ:UNKNOWN

TO: "Founds, Lindsay" ("Founds, Lindsay" [UNKNOWN])
READ:UNKNOWN

TO: Tim Pennise (Tim Pennise [UNKNOWN])
READ:UNKNOWN

TO: Steve Pritsios (Steve Pritsios [UNKNOWN])
READ:UNKNOWN

TO: Stacey Scullin (Stacey Scullin [UNKNOWN])
READ:UNKNOWN

TO: MEAGHAN MURPHY (MEAGHAN MURPHY [UNKNOWN])
READ:UNKNOWN

TO: Lucy Pollio (Lucy Pollio [UNKNOWN])
READ:UNKNOWN

TO: Levent Onar (Levent Onar [UNKNOWN])
READ:UNKNOWN

TO: Leigh Grieco (Leigh Grieco [UNKNOWN])
READ:UNKNOWN

TO: Kerry.A.Grevy@sb.com (Kerry.A.Grevy@sb.com [UNKNOWN])
READ:UNKNOWN

TO: Kadens Peter Albert (Kadens Peter Albert [UNKNOWN])
READ:UNKNOWN

TO: Jill Buchan (Jill Buchan [UNKNOWN])
READ:UNKNOWN

TO: Jen Schaeffer (Jen Schaeffer [UNKNOWN])
READ:UNKNOWN

TO: Jen Fox (Jen Fox [UNKNOWN])
READ:UNKNOWN

TO: Jamie McCarty (Jamie McCarty [UNKNOWN])
READ:UNKNOWN

TO: Heather Coghlan (Heather Coghlan [UNKNOWN])
READ:UNKNOWN

TO: Haley Futterknecht (Haley Futterknecht [UNKNOWN])
READ:UNKNOWN

TO: Genevieve Konz (Genevieve Konz [UNKNOWN])
READ:UNKNOWN

TO: Duncan Krebs (Duncan Krebs [UNKNOWN])
READ:UNKNOWN

TO: Dawn Dawson (Dawn Dawson [UNKNOWN])
READ:UNKNOWN

TO: Colette Rafferty (Colette Rafferty [UNKNOWN])
READ:UNKNOWN

TO: Christine Iacuzzo (Christine Iacuzzo [UNKNOWN])
READ:UNKNOWN

TO: Anne Demutis (Anne Demutis [UNKNOWN])
READ:UNKNOWN

TO: Amanda Donovan (Amanda Donovan [UNKNOWN])
READ:UNKNOWN

TO: "Nicholas Stone (GEIS)" ("Nicholas Stone (GEIS)" [UNKNOWN])
READ:UNKNOWN

TO: "Kathleen Fink (IB)" ("Kathleen Fink (IB)" [UNKNOWN])
READ:UNKNOWN

TO: "Kafaf, Jennifer" ("Kafaf, Jennifer" [UNKNOWN])
READ:UNKNOWN

TO: "Bryan C. Lang" ("Bryan C. Lang" [UNKNOWN])
READ:UNKNOWN

TEXT:
Hi Everyone:

PLEASE READ THIS THROUGH _ IT IS VERY IMPORTANT AND WILL ONLY TAKE 2 MINUTES!!!!! ALSO PASS IT ON IF YOU AGREE

I wanted to send you all an email as a request for you to send a very short email to the NIH (National Institutes of Health). This organization is a big part of all the national guidelines that are established as well as research performed in all areas of the health world(in the US)!! Anyway this past year there was a huge breakthrough in the research world - the discovery of the vast extent of uses for stem cells. Stem cells are cells that can differentiate themselves in to a multitude of other kinds of cells (such as liver cells, kidney, brain, nerve, epithileal, etc). The discovery
and use of these cells is a huge breakthrough for researchers studying anything ranging from things like diabetes to parkinson's to cancer to almost anything else. THey say this is definitely the biggest medical/research development in 1999. The possibility of finding cures to a
multitude of diseases has never been so in reach. The catch is that stem cells are often obtained from fetal tissue. The reason being from the very nature of the cell. Clearly this presents moral dilemnas to many people. As a result the NIH has developed a set of guidelines that monitor the use and source's of these stem cells. Still allowing research yet making sure that the used cells are derived from limited sources (such as frozen embryos
that have been donated to research or would otherwise be thrown away). If you want to see more about the stand of the NIH or all of the possibilities and potential these cells offer please go to the following site:

http://www.nih.gov/news/stemcell/index.htm

It should provide all of the information you need.

Well the reason why I am telling you all of this is because the NIH has been
taking a lot of heat from various groups about the use of these cells. They
desperately want to allow their usage under monitoring but if they continue to recieve heavy objection this huge discovery will go down the drain and in
a sense all of the potential will disappear. Many important studies will have to go back to square one. The thing is that there are a huge number of
supporters but many of them do not know about the need to tell the NIH of our support. We have documented letters from religous officials within Catholic, Jewish and other christian organizations. If you believe in this

cause and the need for stem cell research please send the NIH an email at
and if it is not too much of a hassle cc: it to
!!

The tide has been changing over the past couple of weeks and their are many more people emailing in support but we still need more and the NIH has requested our help in getting these. I am sorry for such a long email but this is our chance to make a difference because at this point every email means something. If you object to this research I am sorry to have bothered
you but I honestly believe that this is something that can greatly change all of ourt lives. Weather it makes a difference in the health of one of our loved ones or Maybe someday us!!! You email only has to say I support stem cell research. Short and Easy.

Again sorry for the lengthy email - thanks for your help.

Katie

Katie O'Neill
Executive Assistant
Alliance for Aging Research
2021 K Street, N.W., Suite 305
Washington, DC 20006
T: 202/293-2856 F: 202/785-8574
Email: koneill@agingresearch.org

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Tim Leshan (Tim Leshan [UNKNOWN])

CREATION DATE/TIME:21-JAN-2000 10:32:03.00

SUBJECT: Re: Stem Cell Meeting 1/21/00

TO: mstephens@vsadc.com (mstephens@vsadc.com [UNKNOWN])
READ:UNKNOWN

TO: harleyt@pva.org (harleyt@pva.org [UNKNOWN])
READ:UNKNOWN

TO: ndepaf@pinn.net (ndepaf@pinn.net [UNKNOWN])
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READ:UNKNOWN

TO: tourette@ix.netcom.com (tourette@ix.netcom.com [UNKNOWN])
READ:UNKNOWN

TO: Jsalomon@genetics.faseb.org (Jsalomon@genetics.faseb.org [UNKNOWN])
READ:UNKNOWN

TO: ichow@faseb.org (ichow@faseb.org [UNKNOWN])
READ:UNKNOWN

TO: ipenn@cfl.org (ipenn@cfl.org [UNKNOWN])
READ:UNKNOWN

TO: md@capitolassociates.com (md@capitolassociates.com [UNKNOWN])
READ:UNKNOWN

TO: stipton@asrm.org (stipton@asrm.org [UNKNOWN])
READ:UNKNOWN

TO: EMARINCOLA@ascb.org (EMARINCOLA@ascb.org [UNKNOWN])
READ:UNKNOWN

TO: aarda@aol.com (aarda@aol.com [UNKNOWN])
READ:UNKNOWN

TO: Priscilla_Short@ama-assn.org (Priscilla_Short@ama-assn.org [UNKNOWN])
READ:UNKNOWN

TO: dperry@agingresearch.org (dperry@agingresearch.org [UNKNOWN])
READ:UNKNOWN

TO: Acshipp@aamc.org (Acshipp@aamc.org [UNKNOWN])
READ:UNKNOWN

TO: roberta@womens-health.org (roberta@womens-health.org [UNKNOWN])
READ:UNKNOWN

TO: rmerenstein@researchamerica.org (rmerenstein@researchamerica.org [UNKNOWN])
READ:UNKNOWN

TO: aeckerd@prodigy.net (aeckerd@prodigy.net [UNKNOWN])
READ:UNKNOWN

TO: wolpe@phrma.org (wolpe@phrma.org [UNKNOWN])
READ:UNKNOWN

TO: bente@nof.org (bente@nof.org [UNKNOWN])
READ:UNKNOWN

TO: weinberg@nhcouncil.org (weinberg@nhcouncil.org [OMB])
READ:UNKNOWN

TO: jkatz@natlbcc.org (jkatz@natlbcc.org [UNKNOWN])
READ:UNKNOWN

TO: lsoler@jdfcure.com (lsoler@jdfcure.com [UNKNOWN])
READ:UNKNOWN

TO: KDonahue@HillandKnowlton.com (KDonahue@HillandKnowlton.com [UNKNOWN])
READ:UNKNOWN

TO: egoss@fbt.com (egoss@fbt.com [UNKNOWN])
READ:UNKNOWN

TO: Skoppi@endo-society.org (Skoppi@endo-society.org [UNKNOWN])
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TO: etynes@ccmc.org (etynes@ccmc.org [UNKNOWN])
READ:UNKNOWN

TO: rlipner@basshowes.com (rlipner@basshowes.com [UNKNOWN])
READ:UNKNOWN

TO: Tim Leshan (Tim Leshan [UNKNOWN])
READ:UNKNOWN

TO: slrbc@aol.com (slrbc@aol.com [UNKNOWN])
READ:UNKNOWN

TO: amp@amprogress.org (amp@amprogress.org [UNKNOWN])
READ:UNKNOWN

TO: pcatterall@agingresearch.org (pcatterall@agingresearch.org [UNKNOWN])
READ:UNKNOWN

TO: KHendricks@aap.org (KHendricks@aap.org [UNKNOWN])
READ:UNKNOWN

TO: fpwhite@mail.faseb.org (fpwhite@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: nwells@vsadc.com (nwells@vsadc.com [UNKNOWN])
READ:UNKNOWN

CC: saem@saem.org (saem@saem.org [UNKNOWN])
READ:UNKNOWN

CC: nancys@psa.org (nancys@psa.org [UNKNOWN])
READ:UNKNOWN

CC: lrodrigz@mail.faseb.org (lrodrigz@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: crf@nordicgear.com (crf@nordicgear.com [UNKNOWN])
READ:UNKNOWN

CC: awexler@natlbcc.org (awexler@natlbcc.org [UNKNOWN])
READ:UNKNOWN

CC: tzemlo@mail.faseb.org (tzemlo@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: kenny@lan2wan.com (kenny@lan2wan.com [UNKNOWN])
READ:UNKNOWN

CC: mgilson@hadassah.org (mgilson@hadassah.org [UNKNOWN])
READ:UNKNOWN

CC: tlawless@faseb.org (tlawless@faseb.org [UNKNOWN])
READ:UNKNOWN

CC: Steve.gibson@cwix.com (Steve.gibson@cwix.com [UNKNOWN])
READ:UNKNOWN

CC: spattee@cff.org (spattee@cff.org [UNKNOWN])
READ:UNKNOWN

CC: tb@capitolassociates.com (tb@capitolassociates.com [UNKNOWN])
READ:UNKNOWN

CC: kwilson@cancer.org (kwilson@cancer.org [WHO])
READ:UNKNOWN

CC: mwerner@bio.org (mwerner@bio.org [UNKNOWN])
READ:UNKNOWN

CC: bernstei@aspetsrv.faseb.org (bernstei@aspetsrv.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: araanan@aps.faseb.org (araanan@aps.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: resolveadv@aol.com (resolveadv@aol.com [UNKNOWN])
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CC: Pam_Kurland@ama-assn.org (Pam_Kurland@ama-assn.org [UNKNOWN])
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CC: Jcerquone@agingresearch.org (Jcerquone@agingresearch.org [UNKNOWN])
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CC: sruhe@vsadc.com (sruhe@vsadc.com [UNKNOWN])
READ:UNKNOWN

CC: Jennifer.Poulakidas@ucop.edu (Jennifer.Poulakidas@ucop.edu [UNKNOWN])
READ:UNKNOWN

CC: pxe@pxe.org (pxe@pxe.org [UNKNOWN])
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CC: MGUARDUC@phrma.org (MGUARDUC@phrma.org [UNKNOWN])
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CC: hgarrison@mail.faseb.org (hgarrison@mail.faseb.org [UNKNOWN])
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CC: taylor@nhcouncil.org (taylor@nhcouncil.org [ONDCP])
READ:UNKNOWN

CC: jcrowley@MIT.EDU (jcrowley@MIT.EDU [UNKNOWN])
READ:UNKNOWN

CC: april@lewis-burke.org (april@lewis-burke.org [UNKNOWN])
READ:UNKNOWN

CC: JFriedma@HillandKnowlton.com (JFriedma@HillandKnowlton.com [OMB])
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CC: estrass@genetics.faseb.org (estrass@genetics.faseb.org [UNKNOWN])
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CC: ASh@dc.sba.com (ASh@dc.sba.com [UNKNOWN])
READ:UNKNOWN

CC: Ess@columbia.edu (Ess@columbia.edu [UNKNOWN])
READ:UNKNOWN

CC: psparks@ccmc.org (psparks@ccmc.org [UNKNOWN])
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CC: estovall@cansearch.org (estovall@cansearch.org [UNKNOWN])
READ:UNKNOWN

CC: nbradish@bio.org (nbradish@bio.org [UNKNOWN])
READ:UNKNOWN

CC: sstewart@basshowes.com (sstewart@basshowes.com [OA])
READ:UNKNOWN

CC: Rebecca Wason (Rebecca Wason [UNKNOWN])
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CC: potoole@apa.org (potoole@apa.org [UNKNOWN])
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CC: apendleton@anatomy.org (apendleton@anatomy.org [UNKNOWN])
READ:UNKNOWN

CC: jennifer.zeitzer@alz.org (jennifer.zeitzer@alz.org [UNKNOWN])
READ:UNKNOWN

CC: Dbmoore@aamc.org (Dbmoore@aamc.org [UNKNOWN])
READ:UNKNOWN

TEXT:
This is a reminder that we will be having a stem cell meeting today at 2:00 PM at the American Academy of Pediatrics, 601 13th St., NW, suite 400 north. Congressional staff will be in attendance from the appropriation and authorizing committees. We look forward to seeing you there.

****

Tim Leshan
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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Tim Leshan (Tim Leshan [UNKNOWN])

CREATION DATE/TIME:24-JAN-2000 13:36:08.00

SUBJECT: Follow up from the Stem Cell meeting

TO: roberta@womens-health.org (roberta@womens-health.org [UNKNOWN])
READ:UNKNOWN

TO: rmerenstein@researchamerica.org (rmerenstein@researchamerica.org [UNKNOWN])
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TO: aeckerd@prodigy.net (aeckerd@prodigy.net [UNKNOWN])
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TO: wolpe@phrma.org (wolpe@phrma.org [UNKNOWN])
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TO: bente@nof.org (bente@nof.org [UNKNOWN])
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TO: weinberg@nhcouncil.org (weinberg@nhcouncil.org [OMB])
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TO: jkatz@natlbcc.org (jkatz@natlbcc.org [UNKNOWN])
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TO: rlipner@basshowes.com (rlipner@basshowes.com [UNKNOWN])
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TO: dperry@agingresearch.org (dperry@agingresearch.org [UNKNOWN])
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TO: Acshipp@aamc.org (Acshipp@aamc.org [UNKNOWN])
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TO: ndepaf@pinn.net (ndepaf@pinn.net [UNKNOWN])
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TO: info@parkinsonsaction.org (info@parkinsonsaction.org [UNKNOWN])
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TO: cdixon@nkca.org (cdixon@nkca.org [UNKNOWN])
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TO: Smedberg@nhcouncil.org (Smedberg@nhcouncil.org [UNKNOWN])
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TO: Jmelanson@modimes.org (Jmelanson@modimes.org [UNKNOWN])
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TO: tourette@ix.netcom.com (tourette@ix.netcom.com [UNKNOWN])
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CC: sruhe@vsadc.com (sruhe@vsadc.com [UNKNOWN])
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CC: pxe@pxe.org (pxe@pxe.org [UNKNOWN])
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CC: gpressberg@peacenow.org (gpressberg@peacenow.org [UNKNOWN])
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CC: hgarrison@mail.faseb.org (hgarrison@mail.faseb.org [UNKNOWN])
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READ:UNKNOWN

CC: Dbmoore@aamc.org (Dbmoore@aamc.org [UNKNOWN])
READ:UNKNOWN

TEXT:
On Friday afternoon, we had a very good meeting to discuss the upcoming year regarding stem cell and fetal tissue research legislation. Several patient groups and scientific societies were present as well as House Hill staff from the offices of Rep. Lowey, Rep. DeGette and the Commerce Committee. Thanks to all those who came. Below is a summary of what we discussed.

We began with a quick review of the draft NIH stem cell guidelines. The AAMC and the ASCB shared their letters to the NIH supporting the guidelines and urged others to be sure to get their comments in. Those who oppose stem cell research have been flooding the NIH with negative comments which outpace positive ones by almost 70/30.

The group then discussed the Specter/Harkin stem cell bill which they plan to introduce in the next week. Specter's staff has drafted the bill, but is still finalizing it. The bill would lift the ban on research involving human embryos, but only to allow federally funded scientists to derive stem cell lines for research. The bill would also change the Public Health Service Act: instead of a year long ban on embryo research being proposed in the Labor HHS Appropriations bill.

The groups were urged to endorse the bill once they see the final draft, but it was pointed out that by allowing federally funded scenists to derive stem cells, the bill goes further than most groups were willing to go last year in supporting research on stem cell lines. Some expressed concern about the timing of the bill and the fact that it would change the PHSA providing for a ban on embryo research. It was felt however that there will likely never be any good time to introduce such a bill and that there would have to be a change in the law if Specter was going to have any chance of moving the bill. It is not clear what will happen with the bill, but Specter hopes to have a hearing on February 23 to discuss it.

Then we reviewed the prospects for action in the House. It appears that the issues of stem cell research and fetal tissue research will be debated in the Commerce Committee this year. While we can't forget about the Appropriations Committee, there does appear to be a switch in emphasis from Appropriations to the Commerce Committee. Mary Booth of Rep. DeGette's office told the group that Rep. Bliley and his staff are preparing for hearings on the "sale of baby body parts," following the passage of the Tancredo amendment last fall. This will be an attempt to go after fetal tissue research because it has been alleged that suppliers are illegally profiting from the sale of fetal tissue. While Booth and Clare Coleman from Rep. Lowey's office are confident that these allegations are misrepresentations, they are sure the hearing this spring on the issue will be graphic and incriminating to commercial firms who prepare fetal tissue for use by researchers. They also believe the issue of stem cell research may be tied into the effort to attach fetal tissue research. Both Booth and Coleman feel that any effort to pass legislation on these issues can defeated in committee because there are allies on both committees. Coleman warned, however, that the support is 'soft.'

In order to successfully defeat an effort by those who would ban stem cell and or fetal tissue research our groups are going to have to work together again this year. We will have to work with Commence Committee members and staff and urge them to oppose any effort to move such legislation. On the Senate side we will have a different task. Those groups who can support the Specter/Harkin bill allowing federally funded scientists to derive stem cell lines will have to work to help pass the bill. As is said, often it is a lot easier to defeat legislation than pass it, so we will have our work cut out for us, but it is very important that we try to pass this bill while preventing an effort to amend it in some negative way.

Next steps - We will work with Hill staff to develop a one pager on fetal and stem cell research to be used in advocacy efforts. We will call the groups together on a regular basis to be sure our efforts are coordinated. We will meet with Members and staff on these issue. It will be important to involve as many groups as possible so please let me know what your group is willing to do and if there are others I should include. Please let me know if you have any questions. Thanks.

****

Tim Leshan
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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: NScoggan (NScoggan [UNKNOWN])

CREATION DATE/TIME:31-JAN-2000 10:04:01.00

SUBJECT: Fw: OCAP

TO: Mary Chris Krieger (Mary Chris Krieger [UNKNOWN])
READ:UNKNOWN

TO: BobN Carol Whitmore (BobN Carol Whitmore [UNKNOWN])
READ:UNKNOWN

TO: Linda L CNIN Scoggan (Linda L CNIN Scoggan [UNKNOWN])
READ:UNKNOWN

TO: Dorthy Powell (Dorthy Powell [UNKNOWN])
READ:UNKNOWN

TO: Christy Oliver (Christy Oliver [UNKNOWN])
READ:UNKNOWN

TO: Ronald Jackson (Ronald Jackson [UNKNOWN])
READ:UNKNOWN

TO: "Rev. Ramon McDonald" ("Rev. Ramon McDonald" [UNKNOWN])
READ:UNKNOWN

TO: BobbieNMike Gaines (BobbieNMike Gaines [UNKNOWN])
READ:UNKNOWN

TO: Vicki Phillips (Vicki Phillips [UNKNOWN])
READ:UNKNOWN

TO: "Glenne M. Ralls" ("Glenne M. Ralls" [UNKNOWN])
READ:UNKNOWN

TO: Lesley Murphy (Lesley Murphy [UNKNOWN])
READ:UNKNOWN

TO: Lynn A. Crable (CN=Lynn A. Crable/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TO: Michael Mulroney (Michael Mulroney [UNKNOWN])
READ:UNKNOWN

TO: Margaret Heiser (Margaret Heiser [UNKNOWN])
READ:UNKNOWN

TO: Suzanne King (Suzanne King [UNKNOWN])
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TO: Pauline Y Floyd (Pauline Y Floyd [UNKNOWN])
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TO: Ron Sybil Lee (Ron Sybil Lee [UNKNOWN])
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TO: John Shaffer (John Shaffer [UNKNOWN])
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TO: John Catale (John Catale [UNKNOWN])
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TO: Richard Davis (Richard Davis [UNKNOWN])
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TO: CarolynNVic Sundseth (CarolynNVic Sundseth [UNKNOWN])
READ:UNKNOWN

TO: Glen Fletcher (Glen Fletcher [UNKNOWN])
READ:UNKNOWN

TO: Gloria Putnam (Gloria Putnam [UNKNOWN])
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TO: Kay Witt (Kay Witt [UNKNOWN])
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TEXT:
-----Original Message-----
From: DBRoberts@aol.com
To: CAPHILPRAY@aol.com
Date: Saturday, January 29, 2000 9:01 PM
Subject: OCAP

>ON CAPITOL HILL THIS WEEK: Vol VII, No. 3: January 31-February 4, 2000
>The Lord thy God in the midst of thee is mighty (Zeph. 3:17a).
>
>TOPICS FOR THIS WEEK:
>1. ABORTION: THE DEFINING ISSUE
>2. WHITE HOUSE SUED OVER PRO-LIFE DATA BASE
>3. EX-RUSSIAN SPY SPEAKS BEFORE HOUSE COMMITTEE: FEARS SNEAK ATTACK
>4. ALBRIGHT DISAVOWS SENATOR HELMS' STATEMENT AT THE U.N.
>5. PRESIDENT CLINTON'S EXECUTIVE ORDER NO. 13139
>6. PUBLIC COMMENT ON HUMAN EMBRYONIC STEM CELL RESEARCH
>7. CONGRESSIONAL TRENDS IN THE DEVELOPMENT OF A NATIONAL ID CARD
>8. FEDERAL BUDGET SURPLUS?
>9. SNOW . . . SNOW . . . SNOW!
>LATE BREAKING: FCC RULE RESCINDED
>
>1. ABORTION: THE DEFINING ISSUE
>
>In the United States, the only domestic issue that really counts is
abortion:

> the legalized murder of 1.3 million unborn babies each year. This week,
we
>rejoiced again as 100,000 people poured into Washington for the 37th
Annual
>March for Life. They were protesting the Supreme Court decision, Roe v
Wade,
>which legalized abortion in 1973, and set the stage for the murder of
>39,000,000 unborn babies since then. On the same day, President Clinton
>reaffirmed his full support for that decision. Elsewhere, on the same day,
>the first of the presidential primaries was held in Iowa, where legalized
>abortion has been debated by all the candidates. Here, too, there is a
vast
>dividing line. The Democratic candidates (Al Gore and Bill Bradley) are
both
>publicly pro-choice [read "pro-abortion"], while the Republican candidates
>(George W. Bush, Steve Forbes, Alan Keyes, John Mc Cain, and Gary Bauer)
are
>verbally pro-life, some more convincing than others.
>PRAYER FOCUS: Pray that our nation would repent of the blood on our hands
>from the slaying of innocents. Pray that millions of Americans would wake
up
>to the devastating consequences of Roe v Wade and that they would vote in
>support of life when the time comes.
>SCRIPTURE: Wherefore he saith, Awake thou that sleepest, and arise from
the
>dead, and Christ shall give thee light (Eph 5:14). I call heaven and
earth
>to record this day against you, that I have set before you life and death,
>blessing and cursing: therefore choose life, that both thou and thy seed
may
>live (Deut 30:19).
>
>2. WHITE HOUSE SUED OVER PRO-LIFE DATA BASE
>
>Rev. Jerry Falwell and Judicial Watch have filed a Privacy Act lawsuit
>against the White House and the Department of Justice in an attempt to
>uncover the contents of a secret database allegedly being kept by
>administration officials on pro-life advocates. The database, dubbed
>"VAAPCON," is thought to contain secret information on pro-life advocates
in
>violation of the Privacy Act. The lawsuit has been filed because the White
>House has denied a request, filed last August by Judicial Watch under the
>Freedom of Information Act, to have the contents of those files revealed.
>Though he isn't sure what might be contained in such a file, Rev. Falwell
>stated, "When I consider that my Christian friend and colleague, Chuck
>Colson, went to prison for violating ONE file, it is appalling to me that
>this president has violated at least 900 files with no repercussions
>whatever."
>PRAYER FOCUS: Ask the Lord to bring forth justice speedily in this case,
so
>that our rights to freedom of speech as American citizens would be
preserved.
>SCRIPTURE: And shall not God avenge his own elect, which cry day and
night

>unto him, though he bear long with them? I tell you that he will avenge
them
>speedily. Nevertheless when the Son of man cometh, shall he find faith on
the
>earth? (Luke 18:7-8).
>
>3. EX-RUSSIAN SPY SPEAKS BEFORE HOUSE COMMITTEE: FEARS SNEAK ATTACK
>
>In an interesting set of circumstances on Tuesday, January 25, while the
>federal government was shut down by a blizzard, at least one Congressional
>committee was still functioning. The House Committee on Government Reform,
>headed by Rep. Dan Burton, held an off-site hearing in Los Angeles, in
order
>to hear the testimony of a former Russian spy, Stanislav Lunev, who has
now
>defected to the United States. Because he is in the witness protection
>program, Lunev was escorted into the hearing room with a black bag over
his
>head.
>
>The information he presented to the Committee was truly alarming: Russian
>generals have designed a special plan for a future war against America and
>its allies. In this scenario, Russian special-operations forces would
enter
>the nation days or hours before the start of the conflict, and would
utilize
>weapons they have already stockpiled in the U.S. Those hidden stockpiles
>include portable nuclear devices, chemical and biological weapons,
>conventional weapons and incendiary devices.
>
>Lunev also indicated the possibility that the Russians are using Chechnya
as
>a test battlefield for a future, real war that may be against the U.S. and
>its allies. The meeting was held in California, because "there is a high
>likelihood of positioning weapons in [this state]" said Rep. Tom Campbell,
a
>committee member from California.
> PRAYER FOCUS: Only the grace of God stands between us and disaster. We
>continue to ask for mercy in the midst of judgment.
>SCRIPTURE: O LORD, I have heard thy speech, and was afraid: O LORD,
revive
>thy work in the midst of the years, in the midst of the years make known;
in
>wrath remember mercy (Hab 3:2).
>
>4. ALBRIGHT DISAVOWS SENATOR HELMS' STATEMENT AT THE U.N.
>
>Last week, we reported that the head of the Senate Armed Services
Committee,
>Jesse Helms, had visited the United Nations Security Council. He delivered
a
>scathing attack upon its performance and a threat that the United States
>might withdraw its membership from that body if it continues to challenge
our

>sovereignty in international policy. This week Secretary of State,
Madeleine
>K. Albright, addressing the same body, distanced herself and the President
>from those statements. "Let me be clear. Only the President and the
executive
>branch can speak for the United States. Today, . . . let me say that the
>Clinton administration . . . sees our relationship to this organization
quite
>differently than does Senator Helms." Meanwhile, others on the Senate
Foreign
>Relations Committee, including Senator Rod Gram and Senator Joseph Biden,
>continued to support Mr. Helms' remarks particularly concerning the need
to
>see the U.N. restructured and better managed.
>PRAYER FOCUS: Pray for clarity regarding our involvement in and national
>policy toward the United Nations. Pray for strength for those who must
>endure the battle in standing for righteousness, integrity and honesty
within
>that international body.
>SCRIPTURE: Again I say unto you, That if two of you shall agree on earth
as
>touching any thing that they shall ask, it shall be done for them of my
>Father which is in heaven (Matt 18:19).
>
>5. PRESIDENT CLINTON'S EXECUTIVE ORDER NO. 13139
>
>On September 30, 1999, President Clinton signed into law Executive Order
No.
>13139, titled "Improving Health Protection of Military Personnel
>Participating in Particular Military Operations." This executive order
>requires U.S. military personnel to receive "experimental" vaccines not
>approved by the Food and Drug Administration. In his order, Mr. Clinton
>refers to these vaccines as "investigational new drugs," and then
authorizes
>the military to force both men and women to receive them. For further
>information on this Executive Order, see the website for Eagle Forum:
>.
>PRAYER FOCUS: Pray for the protection of those who protect us.
>SCRIPTURE: No weapon that is formed against thee shall prosper; and every
>tongue that shall rise against thee in judgment thou shalt condemn. This
is
>the heritage of the servants of the LORD, and their righteousness is of
me,
>saith the LORD (Isa 54:17).
>
>6. PUBLIC COMMENT ON HUMAN EMBRYONIC STEM CELL RESEARCH
>
>The National Institutes of Health (NIH) recently issued guidelines for the
>federal funding of human embryonic stem cell research, outlining how
>researchers may obtain and destroy live human embryos from fertility
clinics
>for taxpayer-funded experimentation. Stem cells, which in the future may
be
>used to cure such diseases as Parkinson's and diabetes, can be found in

adult
>tissues, placentas, and umbilical cords. To use and destroy human embryos
for
>their stem cells is entirely unnecessary, and treats the child as a mere
blob
>of tissue a science experiment. The NIH is requesting public comment on
its
>new draft guidelines the deadline is Feb. 14.
>PRAYER FOCUS: Ask the Lord to energize the necessary response to this
>violation of the principle of life. [Please contact our office
(703-709-5473
>or) for further information about how to respond to the
>NIH proposal.]
>SCRIPTURE: Then he answered and spake unto me, saying, This is the word
of
>the LORD unto Zerubbabel, saying, Not by might, nor by power, but by my
>spirit, saith the LORD of hosts (Zech 4:6).
>
>7. CONGRESSIONAL TRENDS IN THE DEVELOPMENT OF A NATIONAL ID CARD
>
>As watchmen on the wall here in Congress, we are noting a developing trend
>that is causing great division on Capitol Hill even among members of the
same
>political persuasion. That trend is the tendency to combat illegal
>immigration by creating either an actual national identification (ID) card
or
>its equivalent through a series of measures. For example, last October the
>federal government was proposing a law that would require every driver's
>license to include a national ID number. In response, Sen. Richard Shelby,
>Rep. Frank Wolf, and others worked to be sure that this proposal would not
be
>included in the appropriations package for the Department of
Transportation.
>Their efforts were successful, and this requirement was not a part of the
>final funding bill.
>
>Now, two other bills are being introduced in the House which, on the
surface,
>may seem to be justified, but which both MAY contain loopholes leading to
the
>national ID system. One of these is H.R. 3429: The Legal Employment
>Authentication Program (LEAP), sponsored by Rep. Bob Barrett. Its intent
is
>to authorize the Social Security Administration to check its own existing
>database to ensure that a person using a social security number (SSN) is
the
>actual owner of that number. The other, H.R. 191, sponsored by Rep. Bill
>McCollum, seeks to secure the SSN against counterfeits by requiring a
photo
>ID to be placed on the card. There are some who assert that this very
>modification would be one more step in establishing the social security
card
>as a national ID card.
>PRAYER FOCUS: Pray for wisdom for those in authority regarding the issue

of
>establishing a national ID card. Pray that our right to privacy would be
>secured and protected through federal law. Finally, ask the Lord to
quicken
>the "watchmen" on the Hill, i.e., congressional staffers, to be alert to
>these changing needs.
>SCRIPTURE: Thy watchmen shall lift up the voice (Isa 52:8a).
>
>8. FEDERAL BUDGET SURPLUS?
>
>Considerable rhetoric is being expended on monetary subjects in this
>presidential election year. High tax rates appear to be producing a
federal
>surplus, which is likely to produce an "itchy-pocket syndrome" among our
>elected leaders, that is, "if we've got money in our pocket, we need to
spend
>it." The concept of a federal surplus while carrying a $5.7 trillion
national
>debt escapes us. Alan Greenspan, Chairman of the Federal Reserve, spoke
>before a Senate confirmation hearing last week. He is reported to have
said
>that the surplus has possibly developed through the payment of capital
gains
>taxes by American investors on their substantial gains in the stock
market.
>He wisely observed that those gains could disappear were the stock market
to
>change which to us seems inevitable. House Speaker Dennis Hastert is
>promoting the elimination of our national debt over 15 years. This appears
to
>be a desirable objective, but it will require fiscal restraint and a
>political will which our elected officials have been reluctant to impose
on
>themselves, as demonstrated by recent budgets which have exceeded spending
>caps established in 1997.
>PRAYER FOCUS: Pray that our leaders would restrict themselves to funding
>what our country needs, not what they and the various interest groups
want.
>SCRIPTURE: Boast not thyself of tomorrow; for thou knowest not what a day
>may bring forth (Prov 27:1).
>
>9. SNOW . . . SNOW . . . SNOW!
>
>Why are we highlighting snow on an OCAP? Because last week we had two
reports
>about "special" snow in the world: one here in Washington and one in
Israel.
>First, Washington: as you recall from last week's OCAP, we had prayed
that
>the plumb line of God would be established in the hearts of our leaders,
so
>they would govern in TRUTH. In other words, we asked that His government
>would prevail over that of man. Well, we prayed those verses on Monday,
>January 24 the first day that Congress met this year. On Tuesday, the Lord

>sent 9 inches of snow, in blizzard conditions, thereby CLOSING DOWN THE
>FEDERAL GOVERNMENT'S OFFICES! We were, admittedly, rather stunned at this
>turn of events. Locally, we then asked the Lord to visit all those who
found
>themselves suddenly "stuck at home," and nudge them to consider His
>Government the One who has the power to shut down the governments of man.
>
>The same day, we learned that a major snowstorm was being forecast for
>Jerusalem later in the week. This snow has indeed come to the city in an
>historic proportion. We understand that it has been snowing not only in
>Jerusalem, but also throughout the nation of Israel for almost two days,
with
>accumulations of up to 20 inches. At the very least, this event is, again,
an
>answer to our intercession for precipitation in the land; but we feel,
too,
>that just as in Washington, the Lord is speaking of His Sovereignty over
the
>nations. There is nothing like a good "snow day" to cause one to stop,
take
>stock, enjoy his family, and ponder the deeper and bigger issues of life.
>PRAYER FOCUS: Thank the Lord for His wondrous works, which He is doing in
>our midst!
>SCRIPTURE: God thundereth marvellously with his voice; great things doeth
>he, which we cannot comprehend. For he saith to the snow, Be thou on the
>earth; likewise to the small rain, and to the great rain of his strength.
He
>sealeth up the hand of every man; that all men may know his work (Job
>37:5-7).
>
>LATE BREAKING: We have just been notified that the FCC has now REVERSED
its
>ruling regarding the restriction of religious broadcasting rights on
>noncommercial stations. Thank you all for praying, and Praise the Lord!
>
>Thought for the Week: In righteousness shalt thou be established: thou
shalt>be far from oppression; for thou shalt not fear: and from terror; for it
>shall not come near thee (Isa 54:14).
>
>[Note: All scriptures are quoted from the King James Version of the Bible,
>unless otherwise cited.]
>
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>We are a 501(c)(3), tax-exempt, ministry, dedicated to praying for our
>leaders (1 Tim 2:1,2).

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TEXT:
I have heard that the deadline for responding to the Draft NIH Stem
Cell Guidelines will likely be extended in the next few days, until

February 22. I hope this will give us all some more time to get in many more comments in support of the guidelines. Those opposed continue to flood the NIH with many more comments than those in support.

We are also hearing that there may be three hearings on these issues in February. On February 10 the House Science Committee will have a hearing on Cloning. On the same day the Commerce Committee will likely have a hearing on the "sale of baby body parts" in other words fetal tissue. That hearing date has not been confirmed. Senator Specter's hearing on his new stem cell bill may now be switched to February 22 from the 23rd, but that has not been finalized either.

Sunday's New York Times magazine story on stem cells is worth a read.

Please let me know if you have any questions. Thanks.

****

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TEXT:
Below is a copy of the Specter/Harkin stem cell bill that was
introduced yesterday - S. 2015 or the "Stem Cell Research Act of 2000"

It was referred to the Committee on Health, Education, Labor, and Pensions and is up on Thomas. The Labor HHS subcommittee does plan to have their next stem cell hearing on Tuesday, February 22.

To amend the Public Health Service Act to provide for research with respect to human embryonic stem cells.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Stem Cell Research Act of 2000'.

SEC. 2. RESEARCH ON HUMAN EMBRYONIC STEM CELLS.

Part G of the Title IV of the Public Health Service Act (42 U.S.C. 288 et seq.) is amended by inserting after section 498B the following:

`SEC. 498C. RESEARCH ON HUMAN EMBRYONIC STEM CELLS.

`(a) IN GENERAL- Notwithstanding any other provision of law, the Secretary may only conduct, support, or fund research on, or utilizing, human embryos for the purpose of generating embryonic stem cells in accordance with this section.

`(b) SOURCES OF EMBRYONIC CELLS- For purposes of carrying out research under paragraph (1), the human embryonic stem cells involved shall be derived only from embryos that otherwise would be discarded that have been donated from in-vitro fertilization clinics with the written informed consent of the progenitors.

`(c) RESTRICTIONS-

`(1) IN GENERAL- The following restriction shall apply with respect to human embryonic stem cell research conducted or supported under subsection (a):

`(A) The research involved shall not result in the creation of human embryos.

`(B) The research involved shall not result in the reproductive cloning of a human being.

`(2) PROHIBITION-

`(A) IN GENERAL- It shall be unlawful for any person receiving Federal funds to knowingly acquire, receive, or otherwise transfer any human gametes or human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce.

`(B) DEFINITION- In subparagraph (A), the term `valuable consideration' does not include reasonable payments associated with transportation, transplantation, processing, preservation, quality control, or storage.

`(d) GUIDELINES-

`(1) IN GENERAL- The Secretary, in conjunction with the Director of the National Institutes of Health, shall issue guidelines governing human embryonic stem cell research under this section, including the definitions and terms used for purposes of such research.

`(2) REQUIREMENTS- The guidelines issued under paragraph (1) shall ensure that--

`(A) all Federal research protocols and consent forms involving human embryonic stem cell research must be reviewed and approved by an institutional review board; and

`(B) the institutional review board is empowered to make a determination as to whether or not the proposed research is in accordance with National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells.

`(e) REPORTING REQUIREMENTS.- Not later than January 1, 2001, and each January 1 thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the preceding fiscal year, and including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.'.

****

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: 1-FEB-2000 14:05:15.00

SUBJECT: Specter/Harkin Bill

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

TEXT:
I think you are on tim's bcc list but want to make sure that you get this. Hearing on Feb. 22. They want to know if we are doing anything or if we want them to do anything. I think they have done a great job carrying our water and should continue to do so.

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/01/2000 02:03 PM ----------

Tim Leshan <TLESHAN@ascb.org>
02/01/2000 09:14:27 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: Specter/Harkin Bill

Below is a copy of the Specter/Harkin stem cell bill that was introduced yesterday - S. 2015 or the "Stem Cell Research Act of 2000" It was referred to the Committee on Health, Education, Labor, and Pensions and is up on Thomas. The Labor HHS subcommittee does plan to have their next stem cell hearing on Tuesday, February 22.

To amend the Public Health Service Act to provide for research with respect to human embryonic stem cells.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Stem Cell Research Act of 2000'.

SEC. 2. RESEARCH ON HUMAN EMBRYONIC STEM CELLS.

Part G of the Title IV of the Public Health Service Act (42 U.S.C. 288 et seq.) is amended by inserting after section 498B the following:

`SEC. 498C. RESEARCH ON HUMAN EMBRYONIC STEM CELLS.

`(a) IN GENERAL- Notwithstanding any other provision of law, the Secretary may only conduct, support, or fund research on, or utilizing, human embryos for the purpose of generating embryonic stem cells in accordance with this section.

`(b) SOURCES OF EMBRYONIC CELLS- For purposes of carrying out research under paragraph (1), the human embryonic stem cells involved shall be derived only from embryos that otherwise would be discarded that have been donated from in-vitro fertilization clinics with the written informed consent of the progenitors.

`(c) RESTRICTIONS-

`(1) IN GENERAL- The following restriction shall apply with respect to human embryonic stem cell research conducted or supported under subsection (a):

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`(A) IN GENERAL- It shall be unlawful for any person receiving Federal funds to knowingly acquire, receive, or otherwise transfer any human gametes or human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce.

`(B) DEFINITION- In subparagraph (A), the term `valuable consideration' does not include reasonable payments associated with transportation, transplantation, processing, preservation, quality control, or storage.

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`(1) IN GENERAL- The Secretary, in conjunction with the Director of the National Institutes of Health, shall issue guidelines governing human embryonic stem cell research under this section, including the definitions and terms used for purposes of such research.

`(2) REQUIREMENTS- The guidelines issued under paragraph (1) shall ensure that--

`(A) all Federal research protocols and consent forms involving human embryonic stem cell research must be reviewed and approved by an institutional review board; and

`(B) the institutional review board is empowered to make a determination as to whether or not the proposed research is in accordance with National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells.

`(e) REPORTING REQUIREMENTS.- Not later than January 1, 2001, and each January 1 thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the preceding fiscal year, and including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.'.

****

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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: 2-FEB-2000 17:35:46.00

SUBJECT: Re: stem cell

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

TEXT:
sounds perfect - I am happy to make myself available

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 2-FEB-2000 17:55:35.00

SUBJECT: Re: stem cell

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

TEXT:
Absolutely, I'll keep you posted.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 2-FEB-2000 16:50:36.00

SUBJECT: stem cell

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

TEXT:
what do you think about doing an internal meeting with chris to figure out what we want to do, then follow up with a call to tim and dan on our strategy.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Emily Tynes <etynes@ccmc.org> (Emily Tynes <etynes@ccmc.org> [UNKNOWN])

CREATION DATE/TIME: 3-FEB-2000 13:28:09.00

SUBJECT: Stem Cell.

TO: Ann F. Lewis (CN=Ann F. Lewis/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TEXT:
Hi Ann,

It was nice to have you join us for dinner last night. The Labor/HHS Subcommitte plans to hold a hearing on the Specter/Harkin Bill on February 22.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Tim Leshan <TLESHAN@ascb.org> (Tim Leshan <TLESHAN@ascb.org> [UNKNOWN])

CREATION DATE/TIME: 7-FEB-2000 10:50:14.00

SUBJECT: Stem Cell Hearings

TO: roberta@womens-health.org (roberta@womens-health.org [UNKNOWN])
READ:UNKNOWN

TO: rmerenstein@researchamerica.org (rmerenstein@researchamerica.org [UNKNOWN])
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TO: aeckerd@prodigy.net (aeckerd@prodigy.net [UNKNOWN])
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TO: wolpe@phrma.org (wolpe@phrma.org [UNKNOWN])
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TO: bente@nof.org (bente@nof.org [UNKNOWN])
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TO: weinberg@nhcouncil.org (weinberg@nhcouncil.org [OMB])
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TO: jkatz@natlbcc.org (jkatz@natlbcc.org [UNKNOWN])
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TO: lsoler@jdfcure.org (lsoler@jdfcure.org [UNKNOWN])
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TO: KDonahue@HillandKnowlton.com (KDonahue@HillandKnowlton.com [UNKNOWN])
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TO: ichow@faseb.org (ichow@faseb.org [UNKNOWN])
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TO: ipenn@cfl.org (ipenn@cfl.org [UNKNOWN])
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TO: md@capitolassociates.com (md@capitolassociates.com [UNKNOWN])
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TO: rlipner@basshowes.com (rlipner@basshowes.com [UNKNOWN])
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TO: Tim Leshan <TLESHAN@ascb.org> (Tim Leshan <TLESHAN@ascb.org> [UNKNOWN])
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TO: slrbc@aol.com (slrbc@aol.com [UNKNOWN])
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TO: amp@amprogress.org (amp@amprogress.org [UNKNOWN])
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TO: dperry@AGINGRESEARCH.ORG (dperry@AGINGRESEARCH.ORG [UNKNOWN])
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TO: Acshipp@aamc.org (Acshipp@aamc.org [UNKNOWN])
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TO: mstephens@vsadc.com (mstephens@vsadc.com [UNKNOWN])
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TO: harleyt@pva.org (harleyt@pva.org [UNKNOWN])
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TO: ndepaf@pinn.net (ndepaf@pinn.net [UNKNOWN])
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TO: info@parkinsonsaction.org (info@parkinsonsaction.org [UNKNOWN])
READ:UNKNOWN

TO: cdixon@nkca.org (cdixon@nkca.org [UNKNOWN])
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TO: Smedberg@nhcouncil.org (Smedberg@nhcouncil.org [UNKNOWN])
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TO: Jmelanson@modimes.org (Jmelanson@modimes.org [UNKNOWN])
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TO: Skoppi@endo-society.org (Skoppi@endo-society.org [UNKNOWN])
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TO: etynes@ccmc.org (etynes@ccmc.org [UNKNOWN])
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TO: egoss@btclaw.com (egoss@btclaw.com [UNKNOWN])
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TO: stipton@asrm.org (stipton@asrm.org [UNKNOWN])
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TO: EMARINCOLA@ascb.org (EMARINCOLA@ascb.org [UNKNOWN])
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TO: aarda@aol.com (aarda@aol.com [UNKNOWN])
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TO: Priscilla_Short@ama-assn.org (Priscilla_Short@ama-assn.org [UNKNOWN])
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TO: KHendricks@aap.org (KHendricks@aap.org [UNKNOWN])
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TO: fpwhite@mail.faseb.org (fpwhite@mail.faseb.org [UNKNOWN])
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CC: sruhe@vsadc.com (sruhe@vsadc.com [UNKNOWN])
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CC: Jennifer.Poulakidas@ucop.edu (Jennifer.Poulakidas@ucop.edu [UNKNOWN])
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CC: pxe@pxe.org (pxe@pxe.org [UNKNOWN])
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CC: gpressberg@peacenow.org (gpressberg@peacenow.org [UNKNOWN])
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CC: hgarrison@mail.faseb.org (hgarrison@mail.faseb.org [UNKNOWN])
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CC: taylor@nhcouncil.org (taylor@nhcouncil.org [ONDCP])
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CC: kenny@lan2wan.com (kenny@lan2wan.com [UNKNOWN])
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CC: Ehalpern@hhlaw.com (Ehalpern@hhlaw.com [UNKNOWN])
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CC: estrass@genetics.faseb.org (estrass@genetics.faseb.org [UNKNOWN])
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CC: ASh@dc.sba.com (ASh@dc.sba.com [UNKNOWN])
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CC: Ess@columbia.edu (Ess@columbia.edu [UNKNOWN])
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CC: spattee@cff.org (spattee@cff.org [UNKNOWN])
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CC: tb@capitolassociates.com (tb@capitolassociates.com [UNKNOWN])
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CC: kwilson@cancer.org (kwilson@cancer.org [WHO])
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CC: nbradish@bio.org (nbradish@bio.org [UNKNOWN])
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CC: sstewart@basshowes.com (sstewart@basshowes.com [OA])
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CC: Rebecca Wason <RWASON@ascb.org> (Rebecca Wason <RWASON@ascb.org> [UNKNOWN])
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CC: resolveadv@aol.com (resolveadv@aol.com [UNKNOWN])
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CC: Timothy_leeth@ama-assn.org (Timothy_leeth@ama-assn.org [UNKNOWN])
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CC: jennifer.zeitzer@alz.org (jennifer.zeitzer@alz.org [UNKNOWN])
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CC: msimon@acog.org (msimon@acog.org [UNKNOWN])
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CC: jfishburn@aamc.org (jfishburn@aamc.org [UNKNOWN])
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CC: nwells@vsadc.com (nwells@vsadc.com [UNKNOWN])
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CC: saem@saem.org (saem@saem.org [UNKNOWN])
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CC: nancys@psa.org (nancys@psa.org [UNKNOWN])
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CC: MGUARDUC@phrma.org (MGUARDUC@phrma.org [UNKNOWN])
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CC: lrodrigz@mail.faseb.org (lrodrigz@mail.faseb.org [UNKNOWN])
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CC: crf@nordicgear.com (crf@nordicgear.com [UNKNOWN])
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CC: awexler@natlbcc.org (awexler@natlbcc.org [UNKNOWN])
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CC: Judith.benkendorf@mail.house.gov (Judith.benkendorf@mail.house.gov [UNKNOWN])
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CC: april@lewis-burke.org (april@lewis-burke.org [UNKNOWN])
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CC: JFriedma@HillandKnowlton.com (JFriedma@HillandKnowlton.com [OMB])
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CC: mgilson@hadassah.org (mgilson@hadassah.org [UNKNOWN])
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CC: tlawless@faseb.org (tlawless@faseb.org [UNKNOWN])
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CC: Steve.gibson@cwix.com (Steve.gibson@cwix.com [UNKNOWN])
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CC: pberg@cmgm.stanford.edu (pberg@cmgm.stanford.edu [UNKNOWN])
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CC: psparks@ccmc.org (psparks@ccmc.org [UNKNOWN])
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CC: estovall@cansearch.org (estovall@cansearch.org [UNKNOWN])
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CC: pfnandes@btclaw.com (pfnandes@btclaw.com [UNKNOWN])
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CC: mwerner@bio.org (mwerner@bio.org [UNKNOWN])
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CC: apendleton@anatomy.org (apendleton@anatomy.org [UNKNOWN])
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CC: Pam_Kurland@ama-assn.org (Pam_Kurland@ama-assn.org [UNKNOWN])
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CC: Dbmoore@aamc.org (Dbmoore@aamc.org [UNKNOWN])
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TEXT:
Last week I told you about three possible hearings relating to stem cell research. I am now hearing that two of those hearings will be postponed.

The House Science Committee Cloning hearing scheduled for Feb 10, has been postponed indefinitely.

The Commerce Committee hearing on the "sale of baby body parts" has not been scheduled yet and will not occur this week. ABC's 20/20 is planing on doing a story on this issue to air on Feb. 23.

As you know the Labor HHS stem cell hearing has been changed to Feb. 22. We have heard that Christopher Reeve will be testifying. Dr. Paul Berg will testify as well. Other possible witnesses include Sen. Thurmond and Rep. Henry Hyde.

Ida Chow from the Society for Developmental Biology has alerted me to a new resolution introduce on February 2 by Rep. Maloney (D-NY) and Morella (R-MD) H.RES.414 "supporting Federal funding directed toward human pluripotent stem cell research to further research into Parkinson's disease and other medical conditions."

****

Tim Leshan
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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Tim Leshan <TLESHAN@ascb.org> (Tim Leshan <TLESHAN@ascb.org> [UNKNOWN])

CREATION DATE/TIME: 9-FEB-2000 18:20:49.00

SUBJECT: Stem Cell Meeting 2/17/00

TO: roberta@womens-health.org (roberta@womens-health.org [UNKNOWN])
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TO: rmerenstein@researchamerica.org (rmerenstein@researchamerica.org [UNKNOWN])
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TO: aeckerd@prodigy.net (aeckerd@prodigy.net [UNKNOWN])
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CC: gpressberg@peacenow.org (gpressberg@peacenow.org [UNKNOWN])
READ:UNKNOWN

CC: hgarrison@mail.faseb.org (hgarrison@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: taylor@nhcouncil.org (taylor@nhcouncil.org [ONDCP])
READ:UNKNOWN

CC: jcrowley@MIT.EDU (jcrowley@MIT.EDU [UNKNOWN])
READ:UNKNOWN

CC: tzemlo@mail.faseb.org (tzemlo@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: kenny@lan2wan.com (kenny@lan2wan.com [UNKNOWN])
READ:UNKNOWN

CC: JFriedma@HillandKnowlton.com (JFriedma@HillandKnowlton.com [OMB])
READ:UNKNOWN

CC: mgilson@hadassah.org (mgilson@hadassah.org [UNKNOWN])
READ:UNKNOWN

CC: tlawless@faseb.org (tlawless@faseb.org [UNKNOWN])
READ:UNKNOWN

CC: Steve.gibson@cwix.com (Steve.gibson@cwix.com [UNKNOWN])
READ:UNKNOWN

CC: spattee@cff.org (spattee@cff.org [UNKNOWN])
READ:UNKNOWN

CC: tb@capitolassociates.com (tb@capitolassociates.com [UNKNOWN])
READ:UNKNOWN

CC: kwilson@cancer.org (kwilson@cancer.org [WHO])
READ:UNKNOWN

CC: nbradish@bio.org (nbradish@bio.org [UNKNOWN])
READ:UNKNOWN

CC: sstewart@basshowes.com (sstewart@basshowes.com [OA])
READ:UNKNOWN

CC: Rebecca Wason <RWASON@ascb.org> (Rebecca Wason <RWASON@ascb.org> [UNKNOWN])
READ:UNKNOWN

CC: Donna.crane@apha.org (Donna.crane@apha.org [UNKNOWN])
READ:UNKNOWN

CC: resolveadv@aol.com (resolveadv@aol.com [UNKNOWN])
READ:UNKNOWN

CC: Timothy_leeth@ama-assn.org (Timothy_leeth@ama-assn.org [UNKNOWN])
READ:UNKNOWN

CC: jennifer.zeitzer@alz.org (jennifer.zeitzer@alz.org [UNKNOWN])
READ:UNKNOWN

CC: msimon@acog.org (msimon@acog.org [UNKNOWN])
READ:UNKNOWN

CC: jfishburn@aamc.org (jfishburn@aamc.org [UNKNOWN])
READ:UNKNOWN

CC: sruhe@vsadc.com (sruhe@vsadc.com [UNKNOWN])
READ:UNKNOWN

CC: Jennifer.Poulakidas@ucop.edu (Jennifer.Poulakidas@ucop.edu [UNKNOWN])
READ:UNKNOWN

CC: pxe@pxe.org (pxe@pxe.org [UNKNOWN])
READ:UNKNOWN

CC: MGUARDUC@phrma.org (MGUARDUC@phrma.org [UNKNOWN])
READ:UNKNOWN

CC: lrodrigz@mail.faseb.org (lrodrigz@mail.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: crf@nordicgear.com (crf@nordicgear.com [UNKNOWN])
READ:UNKNOWN

CC: awexler@natlbcc.org (awexler@natlbcc.org [UNKNOWN])
READ:UNKNOWN

CC: Judith.benkendorf@mail.house.gov (Judith.benkendorf@mail.house.gov [UNKNOWN])
READ:UNKNOWN

CC: april@lewis-burke.org (april@lewis-burke.org [UNKNOWN])
READ:UNKNOWN

CC: claeysmichael@hotmail.com (claeysmichael@hotmail.com [UNKNOWN])
READ:UNKNOWN

CC: Ehalpern@hhlaw.com (Ehalpern@hhlaw.com [UNKNOWN])
READ:UNKNOWN

CC: estrass@genetics.faseb.org (estrass@genetics.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: ASh@dc.sba.com (ASh@dc.sba.com [UNKNOWN])
READ:UNKNOWN

CC: Ess@columbia.edu (Ess@columbia.edu [UNKNOWN])
READ:UNKNOWN

CC: psparks@ccmc.org (psparks@ccmc.org [UNKNOWN])
READ:UNKNOWN

CC: estovall@cansearch.org (estovall@cansearch.org [UNKNOWN])
READ:UNKNOWN

CC: pfernandes@btclaw.com (pfernandes@btclaw.com [UNKNOWN])
READ:UNKNOWN

CC: mwerner@bio.org (mwerner@bio.org [UNKNOWN])
READ:UNKNOWN

CC: bernstei@aspetsrv.faseb.org (bernstei@aspetsrv.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: araanan@aps.faseb.org (araanan@aps.faseb.org [UNKNOWN])
READ:UNKNOWN

CC: potoole@apa.org (potoole@apa.org [UNKNOWN])
READ:UNKNOWN

CC: apendleton@anatomy.org (apendleton@anatomy.org [UNKNOWN])
READ:UNKNOWN

CC: Pam_Kurland@ama-assn.org (Pam_Kurland@ama-assn.org [UNKNOWN])
READ:UNKNOWN

CC: Jcerquone@AGINGRESEARCH.ORG (Jcerquone@AGINGRESEARCH.ORG [UNKNOWN])
READ:UNKNOWN

CC: jscott@acog.org (jscott@acog.org [UNKNOWN])
READ:UNKNOWN

CC: Dbmoore@aamc.org (Dbmoore@aamc.org [UNKNOWN])
READ:UNKNOWN

TEXT:
The American Society for Cell Biology and the National Health Council will hold a briefing on legislation and regulation governing the use of stem cells on Thursday, February 17, at 2:00 PM at the Carnegie Institution of Washington, 1530 P Street, NW. Interested patient-based groups and scientific organizations are invited to attend.

The stem cell debate is at a critical juncture. Senators Specter and Harkin have introduced S. 2015, "The Stem Cell Research Act of 2000", to allow federally funded scientists to use and derive stem cells. Senator Specter has scheduled a hearing on this issue for February 22; witnesses include Christopher Reeve and Dr. Paul Berg.

Senator Brownback has just released a letter from 20 Senators asking that the draft NIH stem cell guidelines be withdrawn. In the meantime, the House and Senate Commerce Committees are considering hearings on fetal tissue research later this month.

There is clearly a great deal happening surrounding the stem cell issue, and it is important that biomedical research advocates come together to be sure we are up-to-date on these matters.

Whether or not your organization has taken a position on stem cell research, you are urged to attend this meeting to be informed about the state of play on Capitol Hill.

Please direct questions to Tim Leshan at the ASCB or Paul Smedberg at the NHC; RSVP to Tim Leshan at tleshan@ascb.org or 301-530-7153.

Tim Leshan and Paul Smedberg

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Neal Lane (CN=Neal Lane/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:17-FEB-2000 18:04:14.00

SUBJECT: your question

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

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

TEXT:
Maria: Sorry for the delay in answering your question.

Human Stem Cells
The University of Wisconsin announced this week that it has established a non-profit research institute (WiCell) that will distribute human stem cells derived from embryos using a technology developed with private funds from Geron Corp. WiCell will derive the cells in a manner that is compliant with the yet-to-be issued NIH guidelines. NIH will accept comments on its draft guidelines until Feb. 22. NIH-funded researchers may obtain the cells for research purposes only for a one-time fee of $5000. Industrial licensees will pay a "significant up-front fee and a yearly maintenance fee." Geron owns the commercial rights to therapeutics and diagnostics developed from Univ. of Wisconsin,s and Johns Hopkins, stem cells. Hopkins, stem cells are derived from fetuses using a process that is permissible under current law.

Senators Specter and Harkin introduced S. 2015, a bill to permit broader NIH funding of stem cell research. A hearing had been scheduled for Feb. 22, but has been postponed. Christopher Reeve was a confirmed witness. (Reeve,s optimistic Superbowl commercial was based on his hope that stem cell research might lead to a treatment for spinal cord injury.) Senator Brownback sent a letter to NIH signed by 19 others asking that the draft guidelines be withdrawn. In yesterday,s House Appropriations Subcommittee hearing, Rep. Jay Dickey told NIH that he would continue to try to restrict NIH,s authority to fund research on stem cells derived from human embryos.

"Sale of Baby Body Parts"

Federally-funded research on human fetal tissue is legal when conducted in compliance with DHHS regulations. However, sale of human fetuses (or embryos or organs) is not permissible. Tissue used in research, or eggs

or embryos used to overcome infertility, must be donated. Donors maybe compensated for their inconvenience, medical expenses and any risk they might encounter. Unconfirmed reports of trafficking in human fetal tissue stimulated interest in both the House and Senate Commerce Committees but no hearings have been scheduled. "20/20" is scheduled to run a story on this topic on Feb. 25. This topic is not directly related to stem cells but both tend to get drawn into the current abortion rhetoric.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Marjorie Tarmey (CN=Marjorie Tarmey/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:29-FEB-2000 08:41:45.00

SUBJECT: Morning mtg/notes

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

TEXT:
NSC:
Cuba spy - still in Canada
4 US teenagers were arrested in Germany for throwing rocks off a bridge - one death (?)

DPC
the Philip Morris position reported in the newspaper is different from ours
ESEA being circulated

NEC
Vacine meeting is going well - expect deliverables from Am. Health Products
Expect a Medicare Financing hearing this week
Asbestos will come up today - Interagency process decision unsure of response
Section 125/WTO will not be ready today. (JP can it be leaked?)

OSTP
Gene patenting - critical article in LA Times
Stem cell - continued good news

Staff Secretary
Drug decision

ONDCP
Hearing on Colombia -BMcC will testify today at 3:00

One America
2 demonstrations scheduled for Thursday and 1 on Saturday

Legislative Affairs
Expect activity onSenate Education Bills - a lot of amendments and possible cloture vote

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:31-MAR-2000 13:15:33.00

SUBJECT: LHHS NIH Hearing & Stem Cells

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

TEXT:
FYI
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 03/31/2000 01:15 PM ----------

Tim Leshan <TLESHAN@ascb.org>
03/30/2000 04:49:15 PM
Record Type: Record

To: Rachel E. Levinson/OSTP/EOP, Kenneth C. Whang/OSTP/EOP
cc:
Subject: LHHS NIH Hearing & Stem Cells

Today the Senate Labor HHS Appropriations Subcommittee held its annual NIH budget hearing which was exciting but daunting. It was exciting because the subcommittee reiterated its commitment to doubling the NIH budget. It was daunting because Chairman Specter and ranking member Tom Harkin asked NIH institute directors to justify the need for research with embryonic stem cells. Senator Specter said that stem cells would be the subject of a major floor debate in the near future. He commented that those who are opposed to stem cell research are misguided in their belief that stem cells are human life, but that at the same time it will be difficult to convince them otherwise. Clearly both senators want to push forward with their stem cell bill S. 2015 the "The Stem Cell Research Act of 2000" that supports the use and derivation of these cells by federally-funded researchers, probably in the next month.

Senator Harkin asked Acting Director Ruth Kirschstein about the NIH stem cell guidelines and when they would be completed. She explained that they hoped to finalize the guidelines by early summer and at the same time put in place the Human Pluripotent Stem Cell Review Group (HPSCRG) to review the grant proposals. When pressed on how the draft guidelines might be altered as a result of the comments Dr. Kirschstein said they would substantially remain the same, but their would be some further explanatory language added. Senator Harkin was also able to make the point with the help of the NIDDK director that in terms of juvenile diabetes that adult stem cells would not be

sufficient that we would need an additional supply of islet cells which would likely come from embryos. Each institute director was asked to provide further justification as to why embryonic cells were needed.

Senator Specter is still planning to conduct another stem cell hearing on April 26 at which he hopes Christopher Reeve will testify. The AAAS is also working to organize a briefing on their stem cell report for Congressional staff before that hearing.

Given how serious Senators Specter and Harkin sounded today about moving forward on the stem cell issue our groups are going to have to work with the Senate to show our support for this research. Although some are concerned about the approach if our champions want to press forward I feel we must back them up. We will look for a time to get togther soon to discuss all this. Please let me know if you have any questions. 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: Heather F. Hurlburt (CN=Heather F. Hurlburt/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:20-APR-2000 12:27:40.00

SUBJECT: commencement next week?

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

TEXT:
Together again, it seems. And rumor has it you may have a stem cell

deliverable for us?

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Lauren M. Supina (CN=Lauren M. Supina/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:27-APR-2000 09:04:47.00

SUBJECT: Sr. Staff

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

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

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

TO: Christine A. Stanek (CN=Christine A. Stanek/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Daniel E. OBrien (CN=Daniel E. O'Brien/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Deborah B. Mohile (CN=Deborah B. Mohile/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

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

TO: Jackson T. Dunn (CN=Jackson T. Dunn/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Jena V. Roscoe (CN=Jena V. Roscoe/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

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

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

TO: Julie K. Anderson (CN=Julie K. Anderson/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Kendee A. Yamaguchi (CN=Kendee A. Yamaguchi/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

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

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

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

TO: Mary E. Cahill (CN=Mary E. Cahill/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: maureen t. shea (CN=Maureen T. Shea/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: Sondra L. Seba (CN=Sondra L. Seba/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TO: kevin.hanretta (Kevin.hanretta@mail.va.gov @ inet [UNKNOWN])
READ:UNKNOWN

TEXT:
SCH -- Little Rock remarks at memorial service/ law school dedication; AR

ARts Center; returns to WH 6:45

LEG -- Sen vote cloture on marriage penalty; will move on VRA

DPC -- VRA; gun buyback event

OSTP -- no shuttle lift off yet; it will go up in early May; stem cell

research reports out

OMB --MLK plaque issue at Lincoln Memorial

VP -- in Pittsburgh and Philadelphia today

Comm -- radio address on prescription drugs

CEA -- price index up 2.7%; employment cost index 5.9%

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Justin G. Cooper (CN=Justin G. Cooper/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:15-MAY-2000 10:16:37.00

SUBJECT: Phone Call

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

TEXT:
Date Caller Message Contact # Status

05-15-00 Cathy Berlin Mrs. Berlin sent a note to POTUS and wanted to find

out when she could meet with POTUS for 15 min. Re: Stem Cell Research.

She is available any time. (Recently met with Ann Lewis on this topic)

212-496-6305

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: AHERWITT (AHERWITT@naral.org [UNKNOWN])

CREATION DATE/TIME:22-MAY-2000 15:00:11.00

SUBJECT: UpComing Action on Reproductive Rights This Week

TO: Heather H. Howard (CN=Heather H. Howard/OU=OPD/O=EOP [OPD])
READ:UNKNOWN

TO: Lauren M. Supina (CN=Lauren M. Supina/OU=WHO/O=EOP [WHO])
READ:UNKNOWN

TEXT:
FYI -- Here's the quick rundown of what's on tap for the week...

1) Agriculture Appropriations in House - The House expects that the bill will be on the floor by Tuesday afternoon. There's no Rule yet, but Coburn is expected to do his RU-486 amendment, which has been "narrowed" from year's past to prohibit FDA approval of drugs intended **solely** for the inducement of abortion. We're expecting a close vote, but we probably will lose again.

2) Bankruptcy - Final deals are being cut and Lott hopes to have a conference report on the floor by the end of the week. We're weighing in heavily with Senate offices asking them to preserve the Schumer clinic-violence amendment.

3) Roe v. Wade - The National Right to Life Committee is circulating an alert saying that on Thursday, the House will vote on a motion to instruct PBA conferees on the Roe v. Wade resolution. As you'll recall, the Senate PBA bill includes the Harkin-Boxer resolution in support of Roe, while the House bill does not. In order to reconcile this difference, conferees will

have to be named, and this provides an opportunity for pro-choice House Members to move to instruct their conferees to preserve the Roe language. This would be the first time the House has ever taken a direct vote on Roe.

4) Labor-HHS-Education Appropriations - The House Appropriations Committee is tentatively scheduled to mark-up the Labor-HHS spending bill Wednesday morning. Right now, we're not specifically expecting bad amendments, but we're keeping our ears and eyes peeled, and will let you know if that changes. This is the bill the funds Title X, abstinence education, and stem cell research, so obviously, there are plenty of opportunities for the anti's.

We'll pass along anything new or revised as it comes. Thanks.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:31-MAY-2000 15:49:09.00

SUBJECT: stem cell bill

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

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

TEXT:
I don't know a whole lot more than what I put in my earlier e-mail but I can answer a couple of your questions. Last winter, Lott cut a deal with Specter to take a Specter stem cell carve-out off the L/HHS approps bill but allow a free-standing bill later. That's how we got S. 2015. Specter held a hearing on the bill in April, at which he said that he would ask that it be brought to floor asap, but no one believed him. I know that Nickles wants to kill the bill and that Brownback (who testified against the bill in April) wants to offer an amendment in the form of a substitute to prevent NIH from issuing guidelines for stem cell research. NIH won't fund the research without the guidelines.

I don't know how Lott feels about the bill but assume that he wants to kill it. Lott got badly burned on cloning and I really don't think he will bring this to the floor if he is not certain that he has the votes, but I've heard the same rumor from different sources. He might want Frist to lead the charge and it's not clear where Frist is on this. As a transplant surgeon, he ought to be in favor of stem cell research but he was anti-cloning, so who knows.

Patient advocacy groups are on the Hill today talking to Specter and Harkin staff to try to get them working on votes but that is not Specter's way.

I am trying to be careful not to talk to anyone who might think we are doing anything on this. If the bill passes, it would be good for science, but it is not essential, right now. If it goes down and leaves an opening for a Brownback or Nickles bid to disrupt the status quo, then we are in worse shape than if the bill never came up. I think we should learn what we can, but lay low unless it looks like Brownback is going to do something.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:31-MAY-2000 14:30:39.00

SUBJECT: possible Senate activity -- stem cells

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

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

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

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

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

TEXT:
Kay -- pasted below is a note from Rachel Levinson (6-6137), who is Neal's

biotech expert. This stem cell issue is an important one for us, and for

the S&T community. Would you be good enough to look into this report, at

the very least put this issue on your and Chuck's radar? If we could get

some solid intelligence, then perhaps constituent groups could weigh in

effectively. Thanks.

---------- Forwarded by Jeffrey M. Smith/OSTP/EOP on

05/31/2000 02:24 PM ----------

Rachel E. Levinson 05/31/2000 10:49:56 AM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP@EOP, Arthur Bienenstock/OSTP/EOP@EOP, Clifford J. Gabriel/OSTP/EOP@EOP

cc:

Subject: Re: WSJ -Gore interview

Thanks - it's the "Send" button.

I have new news that Lott and Nickles will try to bring the Specter-Harkin stem cell bill (S.2015) to the floor ASAP. This is the stem cell carve-out of the embryo research prohibition in NIH Approps. Vote count looks close: 27 Yes, 20 No, 26 Likely Yes, 16 Likely No and 11 unknown. There is some concern that Specter doesn't seem to have a floor strategy. Patients' CURe would like a call to Daschle to get him motivated to do something. My own view is that we are not pressing for the bill, but would be happy if it passed. The bigger problem would be anything that disrupts the status quo, for example, a Brownback substitution to prohibit NIH from going ahead with the stem cell guidelines. This would mean no Fed support at all for stem cell research from embryos, even if the cells are derived in the private sector.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:31-MAY-2000 09:00:52.00

SUBJECT: video message for the Geoffrey Lance Foundation

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

CC: Neal Lane (CN=Neal Lane/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: thurgood marshall jr (CN=Thurgood Marshall Jr/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

TEXT:
Anne -- I'm forward to you our response to your recent inguiry about the

possibility of the President taping a video message for the Lance

Foundation. Rachel Levinson (6-6137) did all the legwork on this. She'd

be your best source to go to should you require additional information if

this video request progresses.

If our office can be helpful to you or Goody on this or any other matter,

just give a yell.

---------- Forwarded by Jeffrey M. Smith/OSTP/EOP on

05/31/2000 08:53 AM ----------

Rachel E. Levinson 05/30/2000 05:50:48 PM

Record Type: Record

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

cc:

Subject: possible video message for the Geoffrey Lance Foundation

The word I get is that this would be a good thing to do.

First, disability community activists have not heard of this group, but that's OK if they get a good crowd.

Second - you asked about views in the disability community regarding Reeve's strong support for research on cures, without acknowledging the possibility of accepting and learning to live with his disability. It's true that his efforts have attracted controversy, highlighting the schism between those who have lived with a disability for some time and argue for services to improve quality of life and attain/retain as close to normal lifestyles as possible. Then there are those who push for cures, largely those like Reeve who have suffered traumatic injury in the past few years and see potential in stem cells, for example, to restore normal function.

The organized research community appreciate's Reeve's attitude, which is

to push for a broad neuroscience research agenda, not only for avenues that might result in restoring his mobility. He does not belittle those who are concerned about services or less dramatic measures. He does offer hope and he has been an extremely effective and tireless advocate for neuroscience and biotechnology research. He is not afraid to go after the most controversial aspects of opposition to stem cell research.

In sum, a short video that recognizes the courage and determination of all of those living with disability would not alienate those who are working to accept and improve their condition. Talking points should also recognize the need for care, services and jobs for the disabled, in addition to research, would be well-received.

Attached is some background information that might be useful in preparing remarks.

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

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D68]ARMSZY000GR31.000 to ASCII,
The following is a HEX DUMP:

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

Geoffrey Lance Foundation for Spinal Cord Injury Research and Support
June 13, 2000
Background Material

Scope of Problem

About 200,000 Americans now use a wheelchair because of spinal cord injury. Each year, about 10,000 more people suffer permanent spinal cord injury from traffic accidents, falls, sports injuries, gunshot wounds, and other trauma, resulting in paralysis, loss of sensation, and a host of problems associated with living with chronic injury. About two-thirds of these people are under the age of 30. Spinal cord injury costs our nation as much as $10 billion per year.

Federal Efforts

In the current fiscal year, the National Institutes of Health (NIH) expects to spend approximately $68.7 million on spinal cord injury research. **[Additional DHHS/Federal funding for services and benefits could be cited, if available.]** The effort is led by the National Institute of Neurological Disorders and Stroke (NINDS) and includes participation by several other NIH components such as the National Center for Medical Rehabilitation Research. NIH supports a broad-based research program, ranging from cutting edge technologies such as cell replacement and the application of nerve growth factors to the development of improved prosthetics and measures to improve the daily quality of life for persons living with spinal cord injury.

Progress to Date

In 1990 an NINDS- supported clinical trial, the National Acute Spinal Cord Injury Study (NASCIS), demonstrated that a very high dose of the steroid methylprednisolone, given within eight hours of injury, significantly improves the extent of recovery following spinal cord injury. This discovery, developed through research on animal models, established the principle that spinal cord injury can be treated and set a new standard of treatment for acute spinal cord injury. A subsequent trial showed that prolonging the duration of administration from 24 to 48 hours resulted in improved function, provided treatment began within three to eight hours following injury. If treatment is begun within three hours after injury, 24 hours of methylprednisolone treatment is still recommended. This means that physicians can now customize treatment for acute spinal cord injury according to the time passed from injury.

The field of bioengineering has made significant contributions to the well-being of people with spinal cord injury, much of it supported through the NINDS Neural Prosthesis Program. Neural prostheses are implanted devices that restore function by making connections with the nervous system, in effect bypassing circuits that no longer function because of injury or disease. In August 1997 the FDA approved a surgically implantable medical device, developed with NINDS funding, to restore partial hand movement in

certain quadriplegics. This is the first such approved device anywhere in the world. The device, called the Freehand System, is a neural prosthesis that allows hand grasp under control of the patient's shoulder muscles, allowing individuals to perform such activities as picking up a cup of water, a telephone, or a video cassette without assistance. In January 1999, FDA approved the first commercially available implanted device that restores bladder function to spinal cord-injured patients. Work is underway to develop other devices to assist with standing and walking and to control bladder, bowel, and sexual function through direct stimulation of the spinal cord.

Research Opportunities

People with spinal cord injury stand to benefit greatly from the explosion of knowledge about the central nervous system. Improved treatments for spinal cord injury are expected to emerge on several fronts: minimizing the effects of the initial injury; promoting more effective repair of injured cells and circuits; replacing injured cells and circuits; and more effective rehabilitation strategies. Recognizing these opportunities, the NINDS has identified the topic of nervous system repair and plasticity, or capacity for change, as a central theme of its strategic research plan.

We now know, for example, that the initial damage is not the only challenge to the injured spinal cord. A cascade of secondary cellular and biochemical events in response to injury destroys neural tissue and prevents the recovery of neural function. There is significant opportunity to intervene and limit this destructive process both acutely and over a period of weeks following injury. Understanding these processes is critical not only to restoring function after spinal cord injury but also to preventing cell death resulting from traumatic brain injury, stroke, and neurodegenerative disorders such as Parkinson's disease.

Providing a hospitable environment within the spinal cord for regeneration and functional recovery is critical as well. Much is being learned about growth factors and other agents that support the healthy nervous system, and efforts are underway to apply this knowledge to healing it.

The discovery that the adult central nervous system includes progenitor, or stem cells, has revolutionized our approach to spinal cord injury and a host of neurological disorders. Before this discovery, most scientists thought that the adult central nervous system could not create new cells after very early life. Research has also shown that embryonic stem cell transplants can facilitate functional recovery in rats. We need to learn how to harness the innate capacity of the nervous system for recovery and to apply emerging technologies for cell replacement and repair to help solve the problems of recovery and rehabilitation for persons with spinal cord injury.

Prompt and continuing rehabilitation is critical in spinal cord injury and requires a team effort involving neurologists, neurosurgeons, bioengineers, rehabilitation and nursing specialists, and others who can help patients deal with the daily challenges of living with injury.

Finally, it is incumbent on all of us to ensure that adequate funding for research and equitable health care benefits are available to allow persons with spinal cord injuries to fulfill their potential as productive members of society.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Kay Casstevens (CN=Kay Casstevens/OU=WHO/O=EOP [WHO])

CREATION DATE/TIME:31-MAY-2000 14:39:50.00

SUBJECT: Re: possible Senate activity -- stem cells

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

TEXT:
I'll definitely talk to Chuck about this this afternoon, but I'm a little

hazy on the details. Do you think Rachel can flesh out some of the

rumors? Does Lott favor this carve-out? Is he bringing the entire LHHS

bill to the floor and then allowing this amendment? Or is he bringing the

bill up as a stand alone? (hard to imagine) Is there a break-out of the

yeses and nos (and the likelys too)? If not, we can try to find that out

from here -- but if Rachel or someone has more info, that would be

helpful.

Jeffrey M. Smith

05/31/2000 02:30:39 PM

Record Type: Record

To: Kay Casstevens/WHO/EOP@EOP

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

Subject: possible Senate activity -- stem cells

Kay -- pasted below is a note from Rachel Levinson (6-6137), who is Neal's biotech expert. This stem cell issue is an important one for us, and for the S&T community. Would you be good enough to look into this report, at the very least put this issue on your and Chuck's radar? If we could get some solid intelligence, then perhaps constituent groups could weigh in effectively. Thanks.

---------- Forwarded by Jeffrey M. Smith/OSTP/EOP on 05/31/2000 02:24 PM ----------

Rachel E. Levinson 05/31/2000 10:49:56 AM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP@EOP, Arthur Bienenstock/OSTP/EOP@EOP, Clifford J. Gabriel/OSTP/EOP@EOP

cc:

Subject: Re: WSJ -Gore interview

Thanks - it's the "Send" button.

I have new news that Lott and Nickles will try to bring the Specter-Harkin stem cell bill (S.2015) to the floor ASAP. This is the stem cell carve-out of the embryo research prohibition in NIH Approps. Vote count looks close: 27 Yes, 20 No, 26 Likely Yes, 16 Likely No and 11 unknown. There is some concern that Specter doesn't seem to have a floor strategy. Patients' CURe would like a call to Daschle to get him motivated to do something. My own view is that we are not pressing for the bill, but would be happy if it passed. The bigger problem would be anything that disrupts the status quo, for example, a Brownback substitution to prohibit NIH from going ahead with the stem cell guidelines. This would mean no Fed support at all for stem cell research from embryos, even if the cells are derived in the private sector.

Message Copied

To:_____

Neal Lane/OSTP/EOP@EOP

Anthony J. Gibson/OSTP/EOP@EOP

Arthur Bienenstock/OSTP/EOP@EOP

Clifford J. Gabriel/OSTP/EOP@EOP

Richard A. Kostro/OSTP/EOP@EOP

Holly L. Gwin/OSTP/EOP@EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 2-JUN-2000 16:47:27.00

SUBJECT: S.2015 - stem cell bill

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

TEXT:
Kay... what was that that "Rosanne Roseannadanna" used to say....
"nevermind!" ...sorry to give you a bum steer, but it looks as though
you can stand down on this issue...

---------- Forwarded by Jeffrey M. Smith/OSTP/EOP on
06/02/2000 04:45 PM ----------

Rachel E. Levinson 06/02/2000 04:12:36 PM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP@EOP
cc:
Subject: S.2015 - stem cell bill

Just heard that it won't come up next week and maybe this month. I think
Lott felt that he didn't have the votes locked in.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 5-JUN-2000 16:39:17.00

SUBJECT: follow-up -- Neal Lane interview & John Podesta interview

TO: nmunro@nationaljournal.com (nmunro@nationaljournal.com [UNKNOWN])
READ:UNKNOWN

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

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

CC: Michele Ballantyne (CN=Michele Ballantyne/OU=WHO/O=EOP@EOP [WHO])
READ:UNKNOWN

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

TEXT:
Neil -- according to my notes, we owe you a few pieces of information that you requested. They will be sent to you tomorrow. John Podesta has indicated to us that he would visit with you and/or Alexis Simendinger on S&T policy. He returns with the President late Monday night from Moscow. If you'll advise me of your time frame, I'll work with John's office to nail down a mutually convenient time. Thanks.

-- Jeff Smith (456-6047)

Being sent on 6/6

1) the President's statement on stem cell derivation.
2) the dollar amount of the vaccine R&D package.
3) date - recombinant DNA.
4) date of first nanotech memo.

If there are others, please let me know.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:27-JUN-2000 10:59:53.00

SUBJECT: Re: Senate Fetal Tissue Amendment

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

TEXT:
did you see in the wash post today where the american heart ass finally
supports stem cell!!

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:28-JUN-2000 13:27:01.00

SUBJECT: Whew re: Smith Amendment

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

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

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

TEXT:
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 06/28/2000 12:01 PM ----------

Tim Leshan <TLESHAN@ascb.org>
06/28/2000 09:25:55 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: Re: Smith Amendment

Below is the note we just sent to the groups working on the fetal tissue and stem cell issues. Thank you very much to Senate staff for all your wonderful hard work in opposition to the Smith amendment. I have to say I hate that Smith got anything out of it, but we are fine with what he got. We at the ASCB are prepared to help again as these issues continue to play out. Thanks again.

Tim

As you may have heard, we successfully dodged another bullet on the fetal tissue research issue last night. Instead of bringing the amendment you all saw yesterday up for a vote, Senator Smith was convinced to change his amendment to simply call for a GAO study into
"the Federal involvement in the use of fetal tissue." The amendment was
agreed to by voice vote. While we would have preferred that no version
of Senator Smith's amendment had passed, this is a much better outcome

than expected. Another study into the allegations of illegal fetal tissue trafficking is not likely to harm this research, given that the House Commerce Committee has been unable to find any evidence of wrongdoing in this area and the FBI, which has been investigating this issue, has reported no violations of the law to date. Smith's original amendment would have wreaked much more damage.

Thanks to all those who made calls, sent letters and responded to the ASCB emails over the past couple of days. We can consider this a successful practice run for the stem cell issue, should that arise. We need to be prepared in the event that something on that front begins to move. We also want to thank the Senators and their staff who helped us on the Smith amendment. They include, but are not limited to, Specter, Harkin, Kennedy and Daschle.

Tim Leshan & Penny Catterall
American Society for Cell Biology

****

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)

Message Sent
To:_____
BETTILOU_TAYLOR@appro.senate.gov
ELLEN_MURRAY@appro.senate.gov
Shelly_Ten_Napel@daschle.senate.gov
Peter_reinecke@harkin.senate.gov
david_bowen@labor.senate.gov
Mark_Rasenick@labor.senate.gov
Sabrina_Corlette@labor.senate.gov

Message Copied
To:_____
Bruce.Lesley@mail.house.gov
Clare.Coleman@mail.house.gov
John.Ford@mail.house.gov
Judith.Benkendorf@mail.house.gov

Mary.Booth@mail.house.gov
Paul.Kim@mail.house.gov
FlamberG@OD.NIH.GOV
GadboisE@OD.NIH.GOV
Smolonsm@OD.NIH.GOV
Rachel E. Levinson/OSTP/EOP

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME:28-JUL-2000 17:11:21.00

SUBJECT: stem cell guidelines

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

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

TEXT:
HHS is putting the finishing touches on the stem cell research guidelines. They plan to send OMB a "courtesy copy" as early as next week. I will get you copies as soon they arrive.

Various patient groups have been calling to learn when the guidelines will be released and offering to serve as validators.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 3-AUG-2000 14:33:54.00

SUBJECT: NIH Stem Cell Research Guidelines

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

TEXT:
sorry - just realized that I left you off. I'M SORRY!!

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on
08/03/2000 02:33 PM ----------

Rachel E. Levinson 08/02/2000 06:49:47 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
Subject: NIH Stem Cell Research Guidelines

- stem cell final 8-2-00.wpd

Message Sent
To:
Neal Lane/OSTP/EOP@EOP
Jeffrey M. Smith/OSTP/EOP@EOP
David W. Beier/OVP/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Devorah R. Adler/OPD/EOP@EOP
Melissa M. Goldstein/OVP/EOP@EOP

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

TEXT:
Unable to convert NTNFS203:[ATTACH.D67]ARMS22000VBKX.001 to ASCII,
The following is a HEX DUMP:

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

(Billing Code 4140-01-P)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells

SUMMARY: The National Institutes of Health (NIH) is hereby publishing final "National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells." The Guidelines establish procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner.

EFFECTIVE DATE: These Guidelines are effective on [insert date of publication in the Federal Register]. The moratorium on research using human pluripotent stem cells derived from human embryos and fetal tissue put in place by the Director, NIH, in January 1999, will be lifted on [insert date of publication in the Federal Register].

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On December 2, 1999, the NIH published Draft Guidelines for research involving human pluripotent stem cells (hPSCs) in the *Federal Register* for public comment. The comment period ended on February 22, 2000.

The NIH received approximately 50,000 comments from members of Congress, patient advocacy

groups, scientific societies, religious organizations, and private citizens. This Notice presents the final Guidelines together with NIH's response to the substantive public comments that addressed provisions of the Guidelines.

Scope of Guidelines and General Issues

Respondents asked for clarification of terminology used in the Guidelines and some commented that the language, particularly the informed consent sections, was too technical for the general public. The NIH agrees that these Guidelines should be clear and understandable. Editorial changes, including some reorganization of the sections, were made to this end. The Guidelines are written primarily for the purpose of informing investigators of the conditions that must be met in order to receive NIH funding for research using hPSCs and, therefore, some technical language is required. The Guidelines do not define the precise language that should appear in informed consent documents because these should be developed by the investigator/clinician specifically for a particular study protocol or procedure for which the consent is being sought. Existing regulatory provisions require (45 CFR 46.116) that the language in informed consent documents be understandable to prospective participants in the study.

Respondents suggested that NIH funding for research using hPSCs would be in violation of the DHHS appropriations law and that derivation of hPSC cannot be distinguished from their use. For this reason, a number of respondents asked that the NIH withdraw the draft Guidelines. The NIH sought the opinion of the DHHS General Counsel, who determined that "federally funded research that utilizes hPSCs would not be prohibited by the HHS appropriations law

prohibiting human embryo research, because such cells are not human embryos." Comments questioning this conclusion did not present information or arguments that justify reconsideration of the conclusion.

Respondents commented that the Guidelines are too restrictive or that there is no need for federal Guidelines for this arena of research. Comments asserted that federally funded research using hPSCs should go forward without formal requirements, in the same manner as in the private sector. In order to help ensure that the NIH-funded research using hPSCs is conducted in an ethical and legal manner, the NIH Director convened a Working Group of the Advisory Committee to the Director, NIH (ACD) to advise the ACD on the development of guidelines and an oversight process for research involving hPSCs. The NIH Director charged the Working Group with developing appropriate guidelines governing research involving the derivation and use of hPSCs from fetal tissue and research involving the use of hPSCs derived from early human embryos in excess of clinical need.

Respondents commented regarding the sources of stem cells. Some respondents stated that research on hPSCs was unnecessary because stem cells from adults, umbilical cords, and placentas could be used instead. Other respondents asked the NIH to restrict Federal funding for hPSC research to those cells derived from fetal and adult tissue but not embryos. Other respondents asked that the Guidelines encompass research using stem cells from adult tissues. As stated under Section I. Scope of Guidelines, the Guidelines apply to the use of NIH funds for research using hPSCs derived from human embryos or human fetal tissue. The Guidelines do not

impose requirements on federal funding for research involving stem cells from human adults, umbilical cords, or placentas.

Given the enormous potential of stem cells to the development of new therapies for the most devastating diseases, it is important to simultaneously pursue all lines of promising research. It is possible that no single source of stem cells is best or even suitable/usable for all therapies. Different types or sources of stem cells may be optimal for treatment of specific conditions. In order to determine the very best source of many of the specialized cells and tissues of the body for new treatments and even cures, it is vitally important to study the potential of adult stem cells for comparison to that of hPSCs derived from embryos and fetuses. Unless all stem cell types are studied, the differences between adult stem cells and embryo and fetal-derived hPSCs will not be known.

Moreover, there is evidence that adult stem cells may have more limited potential than hPSCs. First, stem cells for all cell and tissue types have not yet been found in the adult human. Significantly, cardiac stem cells or pancreatic islet stem cells have not been identified in adult humans. Second, stem cells in adults are often present in only minute quantities, are difficult to isolate and purify, and their numbers may decrease with age. For example, brain cells from adults that may be neural stem cells have been obtained only by removing a portion of the brain of an adult with epilepsy, a complex and invasive procedure that carries the added risk of further neurological damage. Any attempt to use stem cells from a patient's own body for treatment would require that stem cells would first have to be isolated from the patient and then grown in

culture in sufficient numbers to obtain adequate quantities for treatment. This would mean that for some rapidly progressing disorders, there may not be sufficient time to grow enough cells to use for treatment. Third, in disorders that are caused by a genetic defect, the genetic error likely would be present in the patient's stem cells, making cells from such a patient inappropriate for transplantation. In addition, adult stem cells may contain more DNA abnormalities caused by exposure to daily living, including sunlight, toxins, and errors made during DNA replication than will be found in fetal or embryonic hPSCs. Fourth, there is evidence that stem cells from adults may not have the same capacity to multiply as do younger cells. These potential weaknesses may limit the usefulness of adult stem cells.

Respondents were concerned that these are guidelines and not requirements or regulations. Although these are guidelines and not regulations, they prescribe the documentation and assurances that must accompany requests for NIH funding for research utilizing hPSCs. If the funding requests do not contain the prescribed information, funding for hPSC research will not be provided. Compliance with the Guidelines will be imposed as a condition of grant award.

Respondents commented that there had not been enough widespread public disclosure/discussion of this research or the Guidelines. Prior to the development of draft Guidelines, there were two Congressional hearings on hPSCs. In a further effort to ensure substantial discussion and comment, the NIH convened a Working Group of the Advisory Committee to the Director (ACD), NIH to advise the ACD on the development of these Guidelines. The Working Group was composed of scientists, patients and patient advocates, ethicists, clinicians, and lawyers.

The Working Group met in public session on April 8, 1999, and heard from members of the public, as well as professional associations and Congress. In developing the draft Guidelines, the NIH also considered advice from the National Bioethics Advisory Commission (NBAC). Draft Guidelines were published for public comment in the *Federal Register* on December 2, 1999, for 60 days, and, in response to public interest, the comment period was extended an additional 28 days. Approximately 50,000 comments were received. NIH issued a national press release announcing the Federal Register Notice and many of the Nation's newspapers carried articles on this area of research and on the Guidelines. Patient groups, scientific societies, and religious organizations convened meetings and discussion groups and disseminated materials about this area of research and about the Guidelines.

Comment was received about whether the Guidelines apply to hPSC lines developed outside of the United States. The Guidelines make no distinction based upon the country in which a hPSC line is developed. All lines to be used in hPSC cell research funded by NIH must meet the same requirements.

Derivation and Use of hPSCs From Fetal Tissue

Respondents made the point that the NIH has specified certain requirements for the use of human fetal tissue to derive hPSCs in addition to those imposed on other areas of human fetal tissue research. These respondents suggested that the section of the Guidelines pertaining to fetal tissue sources be omitted. In order to ensure uniformity in NIH's oversight of research using

hPSCs, the Guidelines were extended to govern hPSCs derived from both human embryos and fetal tissue.

Use of hPSCs Derived From Human Embryos

Respondents suggested that the Guidelines refer to "fertility treatment," rather than to "infertility treatment" in order to clarify that they allow the use of human embryos from treatments that employ assisted reproductive technologies to facilitate reproduction in fertile, as well as, infertile individuals. The Guidelines have been changed accordingly.

Respondents suggested dropping the word "early" throughout the document or more clearly defining "early." The word "early" in reference to human embryos has been deleted; the Guidelines make it clear that NIH funding of research using hPSCs derived in the private sector from human embryos can involve only embryos that have not reached the stage at which the mesoderm is formed.

Some respondents were concerned that embryos might be created for research purposes. Other respondents stated there should be no distinction between embryos created for research purposes and those created for fertility treatment. Investigators seeking NIH funds for research using hPSCs are required to provide documentation, prior to the award of any NIH funds, that embryos were created for the purposes of fertility treatment. President Clinton, many members of

Congress, the NIH Human Embryo Research Panel, and the NBAC have all embraced the distinction between embryos created for research purposes and those created for reproductive purposes.

Respondents were concerned about the creation of a "black market" for human embryos, and expressed concerns that individuals will be coerced into donating embryos. The Guidelines state that there can be no incentives for donation and that a decision to donate must be made free of coercion. In addition, the Guidelines set forth conditions that will help ensure all donations are voluntary. For example, with regard to hPSCs derived from embryos, research using federal funds may only be conducted if the cells were derived from frozen embryos that were created for the purpose of fertility treatment and that were in excess of clinical need.

Respondents commented on the requirement that human embryos be frozen in order to qualify for derivation of hPSCs to be used in NIH-funded research. Respondents suggested that the freezing requirement would preclude the use of hPSCs derived from embryos that are genetically and chromosomally abnormal, since such embryos are usually not frozen for reproductive purposes. While the NIH acknowledges that research on hPSCs derived from such embryos could yield important scientific information, limiting research to hPSCs derived from frozen human embryos will help ensure that the decision to donate the embryo for hPSC research is distinct and separate from the fertility treatment.

Financial Issues

Respondents expressed concern regarding the sale of fetal tissue for profit and whether hPSC research would encourage such activity. Respondents also were concerned about whether clinics or doctors would profit from the derivation of hPSCs and/or their sale. Section 498B of the Public Health Service Act prohibits any individual from knowingly acquiring or selling human fetal tissue for "valuable consideration." In addition, the Guidelines prohibit any inducement for the donation of human embryos for research purposes. The Guidelines also call for an assurance that the hPSCs to be used in NIH-funded research were obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the hPSCs. All grantees must sign an assurance that they are in compliance with all applicable Federal, State, and local laws. Each funded research institution is responsible for monitoring compliance by individual investigators with any such applicable laws.

Respondents questioned the prohibition against embryo donors benefitting financially from their donation. This clause was retained in the final Guidelines to help ensure that the donating individuals are offered no inducements to donate and that all donations are voluntary.

Respondents suggested that the Guidelines be strengthened to include a waiver of intellectual property rights. This proposed change would be inconsistent with 45 CFR 46.116 of the regulation for the protection of human subjects of research, which provides that no informed

consent may include language through which the subject waives or appears to waive any of the subject's legal rights.

Respondents questioned the reference in the requirements for informed consent related to the commercial potential of donated material. The paragraphs providing for disclosure in the informed consent of the possibility that the donated material may have commercial potential were modified. The reference in these paragraphs to "donated material" did not accurately reflect the intent of the provision. The Guidelines now make clear that the "results of research on the human pluripotent stem cells may have commercial potential."

Ineligible Research

Respondents objected to the areas of research that the NIH has deemed ineligible, particularly research that is not restricted by statute or regulation, such as research utilizing hPSCs that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human egg. The NIH determined that, at this time, research using hPSCs derived from such sources has not received adequate discussion and consideration by the public and is, therefore, ineligible for NIH funding.

Separation of Fertility Treatment and Abortion From Research

Respondents were concerned that hPSC research would encourage abortion. The law and the

Guidelines guard against encouraging abortion by requiring that the decision to have an abortion be made apart from and prior to the decision to donate tissue.

Respondents objected to the condition in the Guidelines that the fertility physician could not be the same person as the researcher deriving stem cells. Some respondents stated that the IRB or an independent physician would be able to guard against this conflict of interest. The restriction was designed so that the person treating the individuals seeking fertility treatment, who is involved in decisions such as how many embryos to produce, is not the person seeking to derive hPSCs. This separation will help ensure that embryos will not be created in numbers greater than necessary for fertility treatment.

Respondents suggested that the clauses regarding donation of fetal tissue or human embryos for derivation of stem cells for eventual use in transplantation be changed explicitly to prevent directed donation. This change has been made.

Identifiers

Respondents were concerned about removing identifiers. There was concern that the investigator would not be able to document compliance with the Guideline requirements without identifiers, or that the removal of identifiers would make it impossible to conduct certain genetic studies or develop therapeutic materials. The Guidelines have been modified to clarify that the term "identifier" refers to any information from which the donor(s) can be identified, directly or

through identifiers linked to the donors. However, since information identifying the donor(s) may be necessary if the tissue or cells are to be used in transplantation, the Guidelines have also been modified to state that the informed consent should notify donor(s) whether or not identifiers will be retained.

Respondents commented that DNA is an identifier and that all donors of human embryos or fetal tissue should be told that identifiers such as DNA will be retained with the samples. Although DNA can be used to determine the individual from whom a tissue sample was taken, this can be done only when one has a sample from both the tissue in question and the putative donor; it cannot be used to identify an individual out of a population. Moreover, it is difficult to identify a donor using tissue derived from a fetus or embryo, since the tissue is not genetically identical to the donor.

Informed Consent and IRB Review

Respondents asked why investigators were expected to provide documentation of IRB review of derivation from human embryos, but IRB review "...,if any,..." for derivation from fetal tissue. Respondents suggested that the requirements be changed so that protocols for both sources of hPSCs must be approved by an IRB. The Guidelines have been changed to make clear that the IRB review requirements regarding the derivation of cells from fetal tissue and human embryos are the same.

Comment was received expressing concern that the informed consent explicitly state that the donor will have no dispositional authority over derived pluripotent stem cells. The Guidelines state that donation of human embryos should have been made without any restriction regarding the individual(s) who may be the recipient of the cells derived from the hPSCs for transplantation. Such a statement is consistent with the statutory provision applicable to the donor informed consent for the use of fetal tissue for transplantation. The Guidelines now provide for the inclusion of a statement to this effect in the informed consent.

Respondents urged that the Guidelines be revised to remove the prohibition on potential donors receiving information regarding subsequent testing of donated tissue in the situation when physicians deem disclosure to be in the donors' best interest. This change has been made.

Respondents requested clarification regarding the persons from whom consent for donation of embryos for research must be obtained. The Guidelines call for informed consent from individual(s) who have sought fertility treatment. Only the individual(s) who were part of the decision to create the embryo for reproductive purposes should have been part of the decision to donate for the derivation of hPSCs.

Respondents urged that fertility clinics should be able to discuss with patients the option of donating embryos for research at the beginning of the IVF process. The Guidelines do not delineate the timeframe during which the general option of donating embryos for research can be discussed. However, according to the Guidelines, obtaining consent for donation of embryos for

the purpose of deriving hPSCs should not occur until after the embryos are determined to be in "excess of clinical need."

Oversight

Respondents stated that the NIH's oversight in this area of research was very important to the legal and ethical conduct of this research, and asked for more information regarding the oversight process. Information about the operations of the HPSCRG can be found in the final Guidelines and on the NIH webpage.

Respondents were concerned about whether and how NIH would monitor research after a researcher receives NIH funds. Compliance with the Guidelines will be largely determined prior to the award of funds. Follow-up to ensure continued compliance with the Guidelines will be conducted in the same manner as for all other conditions of all other NIH grant awards. It is the responsibility of the investigator to file progress reports, and it is the responsibility of the funded institution to ensure compliance with the NIH Guidelines. NIH staff will also monitor the progress of these investigators as part of their regular duties.

Respondents asked about penalties for not following the Guidelines. The following actions may be taken by the NIH when there is a failure to comply with the terms and conditions of any award: 1) Under 45 CFR 74.14, the NIH can impose special conditions on an award, including increased oversight/monitoring/reporting requirements for an institution, project or investigator;

2) Under 45 CFR 74.62, if a grantee materially fails to comply with the terms and conditions of the award, the NIH may withhold funds pending correction of the problem or pending more severe enforcement action, disallow all or part of the costs of the activity that was not in compliance, withhold further awards for the project, or suspend or terminate all or part of the funding for the project. Individuals and institutions may be debarred from eligibility for all Federal financial assistance and contracts under 45 CFR Part 76 and 48 CFR Subpart 9.4, respectively. Because these sanctions pertain to all conditions of grant award, the NIH did not reiterate them in the Guidelines.

Respondents suggested that the HPSCRG hold periodic Stem Cell Policy Conferences (similar to the Gene Therapy Policy Conferences conducted by the Recombinant DNA Advisory Committee ("RAC")) in order to solicit and consider public comment from interested parties on the scientific, medical, legal, and ethical issues arising from stem cell research. The HPSCRG will serve as a resource for recommending to the NIH any need for Human Pluripotent Stem Cell Policy Conferences.

Other Changes

We have added a sentence requiring the principal investigator's written consent to the disclosure of all material submitted to carry out public review and other oversight procedures.

The draft Guidelines required HPSCRG review of proposals from investigators planning to derive hPSCs from fetal tissue. Because the Guidelines address proposals for NIH funding for the use hPSCs, this requirement has been removed from the Guidelines.

The text of the final Guidelines follows.

National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). For purposes of these Guidelines, "human pluripotent stem cells" are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos. NIH research funded under these Guidelines will involve human pluripotent stem cells derived 1) from human fetal tissue; or 2) from human embryos that are the result of *in vitro* fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed.

In accordance with 42 Code of Federal Regulations (CFR) § 52.4, these Guidelines prescribe the documentation and assurances that must accompany requests for NIH funding for research utilizing human pluripotent stem cells from: (1) awardees who want to use existing funds; (2) awardees requesting an administrative or competing supplement; and 3) applicants or intramural

researchers submitting applications or proposals. NIH funds may be used to derive human pluripotent stem cells from fetal tissue. NIH funds may not be used to derive human pluripotent stem cells from human embryos. These Guidelines also designate certain areas of human pluripotent stem cell research as ineligible for NIH funding.

II. Guidelines for Research Using Human Pluripotent Stem Cells That Is Eligible for NIH Funding

A. Utilization of Human Pluripotent Stem Cells Derived from Human Embryos

1. Submission to NIH

Intramural or extramural investigators who are intending to use existing funds, are requesting an administrative supplement, or are applying for new NIH funding for research using human pluripotent stem cells derived from human embryos must submit to NIH the following:

a. An assurance signed by the responsible institutional official that the pluripotent stem cells were derived from human embryos in accordance with the conditions set forth in Section II.A.2 of these Guidelines and that the institution will maintain documentation in support of the assurance.

b. A sample informed consent document (with patient identifier information

removed) and a description of the informed consent process, which meet the criteria for informed consent set forth in Section II.A.2.e of these Guidelines.

c. An abstract of the scientific protocol used to derive human pluripotent stem cells from an embryo;

d. Documentation of IRB approval of the derivation protocol.

e. An assurance that the stem cells to be used in the research were or will be obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the stem cells.

f. A short paragraph describing the nature of the research to be conducted with the human pluripotent stem cells.

g. An assurance that the proposed research using human pluripotent stem cells is not a class of research that is ineligible for NIH funding as set forth in Section III of these Guidelines.

h. The Principal Investigator's written consent to the disclosure of all

material submitted under Paragraph A.1 of this Section, as necessary to carry out the public review and other oversight procedures set forth in Section IV of these Guidelines.

2. Conditions for the Utilization of Human Pluripotent Stem Cells Derived From Human Embryos

Studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.

a. To ensure that the donation of human embryos in excess of the clinical need is voluntary, no inducements, monetary or otherwise, should have been offered for the donation of human embryos for research purposes. Fertility clinics and/or their affiliated laboratories should have implemented specific written policies and practices to ensure that no such inducements are made available.

a. There should have been a clear separation between the decision to create embryos

for fertility treatment and the decision to donate human embryos in excess of clinical need for research purposes to derive pluripotent stem cells. Decisions related to the creation of embryos for fertility treatment should have been made free from the influence of researchers or investigators proposing to derive or utilize human pluripotent stem cells in research. To this end, the attending physician responsible for the fertility treatment and the researcher or investigator deriving and/or proposing to utilize human pluripotent stem cells should not have been one and the same person.

c. To ensure that human embryos donated for research were in excess of the clinical need of the individuals seeking fertility treatment and to allow potential donors time between the creation of the embryos for fertility treatment and the decision to donate for research purposes, only frozen human embryos should have been used to derive human pluripotent stem cells. In addition, individuals undergoing fertility treatment should have been approached about consent for donation of human embryos to derive pluripotent stem cells only at the time of deciding the disposition of embryos in excess of the clinical need.

d. Donation of human embryos should have been made without any restriction or direction regarding the individual(s) who may be the recipients of transplantation of the cells derived from the human pluripotent stem cells.

e. Informed Consent

Informed consent should have been obtained from individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes. The informed consent process should have included discussion of the following information with potential donors, pertinent to making the decision whether to donate their embryos for research purposes.

Informed consent should have included:

(i) A statement that the embryos will be used to derive human pluripotent stem cells for research, that may include human transplantation research.

(ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo.

(iii) A statement whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells.

(iv) A statement that derived cells and/or cell lines may be kept for many

years.

(v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development.

(vi) A statement that the research is not intended to provide direct medical benefit to the donor.

(vii) A statement that embryos donated will not be transferred to a woman's uterus and will not survive the human pluripotent stem cell derivation process.

f. Derivation protocols should have been approved by an Institutional Review Board (IRB) established in accord with 45 CFR §46.107 and §46.108 or FDA regulations at 21 CFR §56.107 and §56.108.

B. Utilization of Human Pluripotent Stem Cells Derived From Human Fetal Tissue

1. Submission to NIH

Intramural or extramural investigators who are intending to use existing funds, are requesting an administrative supplement, or are applying for new NIH funding for research using human pluripotent stem cells derived from fetal tissue must submit to NIH the following:

a. An assurance signed by the responsible institutional official that the pluripotent stem cells were derived from human fetal tissue in accordance with the conditions set forth in Section II.A.2 of these Guidelines and that the institution will maintain documentation in support of the assurance.

b. A sample informed consent document (with patient identifier information removed) and a description of the informed consent process, which meet the criteria for informed consent set forth in Section II.B.2.b of these Guidelines.

c. An abstract of the scientific protocol used to derive human pluripotent stem cells from fetal tissue;

d. Documentation of IRB approval of the derivation protocol.

e. An assurance that the stem cells to be used in the research were or will be obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the stem cells.

f. A short paragraph describing the nature of the research to be conducted with the human pluripotent stem cells.

g. An assurance that the proposed research using human pluripotent stem cells is not a class of research that is ineligible for NIH funding as set forth in Section III of these Guidelines.

h. The Principal Investigator's written consent to the disclosure of all material submitted under Paragraph B.1 of this Section, as necessary to carry out the public review and other oversight procedures set forth in Section IV of these Guidelines.

2. Conditions for Utilization of Human Pluripotent Stem Cells Derived From Fetal Tissue.

a. Unlike pluripotent stem cells derived from human embryos, DHHS funds may be used to support research to derive pluripotent stem cells from fetal tissue, as well as for research utilizing such cells. Such research is governed by Federal statutory restrictions regarding fetal tissue research at 42 U.S.C. 289g-2(a) and the Federal regulations at 45 CFR § 46.210. In addition, because cells derived from fetal tissue at the early stages of investigation may, at a later date, be used in human fetal tissue transplantation research, it is the policy of NIH to require that all NIH-funded research involving the derivation or utilization of pluripotent stem cells from human fetal tissue also comply with the fetal tissue transplantation research statute at 42 U.S.C. 289g-1.

b. Informed Consent

As a policy matter, NIH funded research deriving or utilizing human pluripotent stem cells from fetal tissue should comply with the informed consent law applicable to fetal tissue transplantation research (42 U.S.C. 289g-1) and the following conditions. The informed consent process should have included discussion of the following information with potential donors, pertinent to making the decision whether to donate fetal tissue for research purposes.

Informed consent should have included:

(i) A statement that fetal tissue will be used to derive human pluripotent stem cells for research that may include human transplantation research.

(ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the fetal tissue.

(iii) A statement whether or not information that could identify the donors of the fetal tissue, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells.

(iv) A statement that derived cells and/or cell lines may be kept for many years.

(v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development.

(vi) A statement that the research is not intended to provide direct medical benefit to the donor.

c. Derivation protocols should have been approved by an Institutional Review Board

(IRB) established in accord with 45 CFR §46.107 and §46.108 or FDA regulations at 21 CFR §56.107 and §56.108.

III. Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding

Areas of research ineligible for NIH funding include:

A. The derivation of pluripotent stem cells from human embryos;

B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo;

C. Research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, rather than for fertility treatment;

D. Research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

E. Research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

F. Research in which human pluripotent stem cells are combined with an animal embryo; and

G. Research in which human pluripotent stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human.

IV. Oversight

A. The NIH will establish a Human Pluripotent Stem Cell Review Group (HPSCRG). This group will review documentation of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells, and may, when warranted, seek further information in support of an application. The HPSCRG will review all funding requests that propose the use of human pluripotent stem cells. The group will hold public review meetings when a funding request proposes the use of a line of human pluripotent stem cells that has not been previously reviewed and approved by the HPSCRG.

B. In the case of new or competing continuation (renewal) or competing supplement applications, all applications shall be reviewed by HPSCRG and for scientific merit by a Scientific Review Group. In the case of requests to use existing funds or applications for an administrative supplement or in the case of intramural proposals, Institute or Center staff should forward material to the HPSCRG for review and determination of compliance with the

Guidelines prior to allowing the research to proceed.

C. The NIH will compile a yearly report that will include the number of applications and proposals reviewed and the titles of all awarded applications, supplements or administrative approvals for the use of existing funds, and intramural projects.

D. The HPSCRG will also serve as a resource for recommending to the NIH any revisions to the NIH Guidelines for Research Using Human Pluripotent Stem Cells and any need for human pluripotent stem cell policy conferences.

Dated:

_____

Ruth Kirschstein, M.D.

Acting Director, NIH

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 3-AUG-2000 15:19:36.00

SUBJECT: Re: NIH stem cell guidance

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

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

TO: David W. Beier (CN=David W. Beier/OU=OVP/O=EOP@EOP [OVP])
READ:UNKNOWN

CC: andrew f. schneider (CN=andrew f. schneider/OU=ovp/O=eop@eop [ovp])
READ:UNKNOWN

CC: julia doan (CN=julia doan/OU=opd/O=eop@eop [opd])
READ:UNKNOWN

CC: barbara d. woolley (CN=barbara d. woolley/OU=who/O=eop@eop [who])
READ:UNKNOWN

TEXT:
Now that the guidelines are here, we should go ahead and set that meeting up quickly so as not to hold them up. We also need to think about alerting the patient advocacy groups so that they are ready with their response when the guidelines go on display. Not so sure about other validators as they (industry and scientific societies) are perceived to have a vested interest.

DHHS has press release and Qs and As in the works. We should review and tailor as needed.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 4-AUG-2000 18:01:58.00

SUBJECT: stem cell

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

TEXT:
tim leshen is calling. whats the latest on stem cell.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 7-AUG-2000 13:16:43.00

SUBJECT: Stem cell conference call

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

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

TO: Andrew F. Schneider (CN=Andrew F. Schneider/OU=OVP/O=EOP@EOP [OVP])
READ:UNKNOWN

TO: Betty J. Fountain (CN=Betty J. Fountain/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: David W. Beier (CN=David W. Beier/OU=OVP/O=EOP@EOP [OVP])
READ:UNKNOWN

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

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

TEXT:
Tomorrow's 3:30 stem cell conference call can be reached at:
1-800-545-4387, code# 24717

Please let me know how many people are calling in to make sure that HHS
has enough lines. Thanks

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

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

CREATION DATE/TIME: 7-AUG-2000 10:03:09.00

SUBJECT: Re: stem cell

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

TEXT:
I sent you guidelines last week but attach in case. We will have a conference call with HHS tomorrow at 3:00 to talk rollout. I think Rich Tarplin sugggested that Tim call you. Rich has asked Tim to poll patient groups for their views. They all say that we (WH) should keep a low profile on the rollout to avoid scaring away moderate GOP who won't make a stink if we don't. So, I think that's how we should go. Maybe just a short paragraph in support of the guidelines for day they go on display in FR. What do you think?

I will send you the contact info for the call.

- stem cell final 8-2-00.wpd

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

TEXT:
Unable to convert NTNFS304:[ATTACH.D38]ARMS350017HLX.001 to ASCII,
The following is a HEX DUMP:

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

(Billing Code 4140-01-P)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells

SUMMARY: The National Institutes of Health (NIH) is hereby publishing final "National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells." The Guidelines establish procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner.

EFFECTIVE DATE: These Guidelines are effective on [insert date of publication in the Federal Register]. The moratorium on research using human pluripotent stem cells derived from human embryos and fetal tissue put in place by the Director, NIH, in January 1999, will be lifted on [insert date of publication in the Federal Register].

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On December 2, 1999, the NIH published Draft Guidelines for research involving human pluripotent stem cells (hPSCs) in the *Federal Register* for public comment. The comment period ended on February 22, 2000.

The NIH received approximately 50,000 comments from members of Congress, patient advocacy

groups, scientific societies, religious organizations, and private citizens. This Notice presents the final Guidelines together with NIH's response to the substantive public comments that addressed provisions of the Guidelines.

Scope of Guidelines and General Issues

Respondents asked for clarification of terminology used in the Guidelines and some commented that the language, particularly the informed consent sections, was too technical for the general public. The NIH agrees that these Guidelines should be clear and understandable. Editorial changes, including some reorganization of the sections, were made to this end. The Guidelines are written primarily for the purpose of informing investigators of the conditions that must be met in order to receive NIH funding for research using hPSCs and, therefore, some technical language is required. The Guidelines do not define the precise language that should appear in informed consent documents because these should be developed by the investigator/clinician specifically for a particular study protocol or procedure for which the consent is being sought. Existing regulatory provisions require (45 CFR 46.116) that the language in informed consent documents be understandable to prospective participants in the study.

Respondents suggested that NIH funding for research using hPSCs would be in violation of the DHHS appropriations law and that derivation of hPSC cannot be distinguished from their use. For this reason, a number of respondents asked that the NIH withdraw the draft Guidelines. The NIH sought the opinion of the DHHS General Counsel, who determined that "federally funded research that utilizes hPSCs would not be prohibited by the HHS appropriations law

prohibiting human embryo research, because such cells are not human embryos." Comments questioning this conclusion did not present information or arguments that justify reconsideration of the conclusion.

Respondents commented that the Guidelines are too restrictive or that there is no need for federal Guidelines for this arena of research. Comments asserted that federally funded research using hPSCs should go forward without formal requirements, in the same manner as in the private sector. In order to help ensure that the NIH-funded research using hPSCs is conducted in an ethical and legal manner, the NIH Director convened a Working Group of the Advisory Committee to the Director, NIH (ACD) to advise the ACD on the development of guidelines and an oversight process for research involving hPSCs. The NIH Director charged the Working Group with developing appropriate guidelines governing research involving the derivation and use of hPSCs from fetal tissue and research involving the use of hPSCs derived from early human embryos in excess of clinical need.

Respondents commented regarding the sources of stem cells. Some respondents stated that research on hPSCs was unnecessary because stem cells from adults, umbilical cords, and placentas could be used instead. Other respondents asked the NIH to restrict Federal funding for hPSC research to those cells derived from fetal and adult tissue but not embryos. Other respondents asked that the Guidelines encompass research using stem cells from adult tissues. As stated under Section I. Scope of Guidelines, the Guidelines apply to the use of NIH funds for research using hPSCs derived from human embryos or human fetal tissue. The Guidelines do not

impose requirements on federal funding for research involving stem cells from human adults, umbilical cords, or placentas.

Given the enormous potential of stem cells to the development of new therapies for the most devastating diseases, it is important to simultaneously pursue all lines of promising research. It is possible that no single source of stem cells is best or even suitable/usable for all therapies. Different types or sources of stem cells may be optimal for treatment of specific conditions. In order to determine the very best source of many of the specialized cells and tissues of the body for new treatments and even cures, it is vitally important to study the potential of adult stem cells for comparison to that of hPSCs derived from embryos and fetuses. Unless all stem cell types are studied, the differences between adult stem cells and embryo and fetal-derived hPSCs will not be known.

Moreover, there is evidence that adult stem cells may have more limited potential than hPSCs. First, stem cells for all cell and tissue types have not yet been found in the adult human. Significantly, cardiac stem cells or pancreatic islet stem cells have not been identified in adult humans. Second, stem cells in adults are often present in only minute quantities, are difficult to isolate and purify, and their numbers may decrease with age. For example, brain cells from adults that may be neural stem cells have been obtained only by removing a portion of the brain of an adult with epilepsy, a complex and invasive procedure that carries the added risk of further neurological damage. Any attempt to use stem cells from a patient's own body for treatment would require that stem cells would first have to be isolated from the patient and then grown in

culture in sufficient numbers to obtain adequate quantities for treatment. This would mean that for some rapidly progressing disorders, there may not be sufficient time to grow enough cells to use for treatment. Third, in disorders that are caused by a genetic defect, the genetic error likely would be present in the patient's stem cells, making cells from such a patient inappropriate for transplantation. In addition, adult stem cells may contain more DNA abnormalities caused by exposure to daily living, including sunlight, toxins, and errors made during DNA replication than will be found in fetal or embryonic hPSCs. Fourth, there is evidence that stem cells from adults may not have the same capacity to multiply as do younger cells. These potential weaknesses may limit the usefulness of adult stem cells.

Respondents were concerned that these are guidelines and not requirements or regulations. Although these are guidelines and not regulations, they prescribe the documentation and assurances that must accompany requests for NIH funding for research utilizing hPSCs. If the funding requests do not contain the prescribed information, funding for hPSC research will not be provided. Compliance with the Guidelines will be imposed as a condition of grant award.

Respondents commented that there had not been enough widespread public disclosure/discussion of this research or the Guidelines. Prior to the development of draft Guidelines, there were two Congressional hearings on hPSCs. In a further effort to ensure substantial discussion and comment, the NIH convened a Working Group of the Advisory Committee to the Director (ACD), NIH to advise the ACD on the development of these Guidelines. The Working Group was composed of scientists, patients and patient advocates, ethicists, clinicians, and lawyers.

The Working Group met in public session on April 8, 1999, and heard from members of the public, as well as professional associations and Congress. In developing the draft Guidelines, the NIH also considered advice from the National Bioethics Advisory Commission (NBAC). Draft Guidelines were published for public comment in the *Federal Register* on December 2, 1999, for 60 days, and, in response to public interest, the comment period was extended an additional 28 days. Approximately 50,000 comments were received. NIH issued a national press release announcing the Federal Register Notice and many of the Nation's newspapers carried articles on this area of research and on the Guidelines. Patient groups, scientific societies, and religious organizations convened meetings and discussion groups and disseminated materials about this area of research and about the Guidelines.

Comment was received about whether the Guidelines apply to hPSC lines developed outside of the United States. The Guidelines make no distinction based upon the country in which a hPSC line is developed. All lines to be used in hPSC cell research funded by NIH must meet the same requirements.

Derivation and Use of hPSCs From Fetal Tissue

Respondents made the point that the NIH has specified certain requirements for the use of human fetal tissue to derive hPSCs in addition to those imposed on other areas of human fetal tissue research. These respondents suggested that the section of the Guidelines pertaining to fetal tissue sources be omitted. In order to ensure uniformity in NIH's oversight of research using

hPSCs, the Guidelines were extended to govern hPSCs derived from both human embryos and fetal tissue.

Use of hPSCs Derived From Human Embryos

Respondents suggested that the Guidelines refer to "fertility treatment," rather than to "infertility treatment" in order to clarify that they allow the use of human embryos from treatments that employ assisted reproductive technologies to facilitate reproduction in fertile, as well as, infertile individuals. The Guidelines have been changed accordingly.

Respondents suggested dropping the word "early" throughout the document or more clearly defining "early." The word "early" in reference to human embryos has been deleted; the Guidelines make it clear that NIH funding of research using hPSCs derived in the private sector from human embryos can involve only embryos that have not reached the stage at which the mesoderm is formed.

Some respondents were concerned that embryos might be created for research purposes. Other respondents stated there should be no distinction between embryos created for research purposes and those created for fertility treatment. Investigators seeking NIH funds for research using hPSCs are required to provide documentation, prior to the award of any NIH funds, that embryos were created for the purposes of fertility treatment. President Clinton, many members of

Congress, the NIH Human Embryo Research Panel, and the NBAC have all embraced the distinction between embryos created for research purposes and those created for reproductive purposes.

Respondents were concerned about the creation of a "black market" for human embryos, and expressed concerns that individuals will be coerced into donating embryos. The Guidelines state that there can be no incentives for donation and that a decision to donate must be made free of coercion. In addition, the Guidelines set forth conditions that will help ensure all donations are voluntary. For example, with regard to hPSCs derived from embryos, research using federal funds may only be conducted if the cells were derived from frozen embryos that were created for the purpose of fertility treatment and that were in excess of clinical need.

Respondents commented on the requirement that human embryos be frozen in order to qualify for derivation of hPSCs to be used in NIH-funded research. Respondents suggested that the freezing requirement would preclude the use of hPSCs derived from embryos that are genetically and chromosomally abnormal, since such embryos are usually not frozen for reproductive purposes. While the NIH acknowledges that research on hPSCs derived from such embryos could yield important scientific information, limiting research to hPSCs derived from frozen human embryos will help ensure that the decision to donate the embryo for hPSC research is distinct and separate from the fertility treatment.

Financial Issues

Respondents expressed concern regarding the sale of fetal tissue for profit and whether hPSC research would encourage such activity. Respondents also were concerned about whether clinics or doctors would profit from the derivation of hPSCs and/or their sale. Section 498B of the Public Health Service Act prohibits any individual from knowingly acquiring or selling human fetal tissue for "valuable consideration." In addition, the Guidelines prohibit any inducement for the donation of human embryos for research purposes. The Guidelines also call for an assurance that the hPSCs to be used in NIH-funded research were obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the hPSCs. All grantees must sign an assurance that they are in compliance with all applicable Federal, State, and local laws. Each funded research institution is responsible for monitoring compliance by individual investigators with any such applicable laws.

Respondents questioned the prohibition against embryo donors benefitting financially from their donation. This clause was retained in the final Guidelines to help ensure that the donating individuals are offered no inducements to donate and that all donations are voluntary.

Respondents suggested that the Guidelines be strengthened to include a waiver of intellectual property rights. This proposed change would be inconsistent with 45 CFR 46.116 of the regulation for the protection of human subjects of research, which provides that no informed

consent may include language through which the subject waives or appears to waive any of the subject's legal rights.

Respondents questioned the reference in the requirements for informed consent related to the commercial potential of donated material. The paragraphs providing for disclosure in the informed consent of the possibility that the donated material may have commercial potential were modified. The reference in these paragraphs to "donated material" did not accurately reflect the intent of the provision. The Guidelines now make clear that the "results of research on the human pluripotent stem cells may have commercial potential."

Ineligible Research

Respondents objected to the areas of research that the NIH has deemed ineligible, particularly research that is not restricted by statute or regulation, such as research utilizing hPSCs that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human egg. The NIH determined that, at this time, research using hPSCs derived from such sources has not received adequate discussion and consideration by the public and is, therefore, ineligible for NIH funding.

Separation of Fertility Treatment and Abortion From Research

Respondents were concerned that hPSC research would encourage abortion. The law and the

Guidelines guard against encouraging abortion by requiring that the decision to have an abortion be made apart from and prior to the decision to donate tissue.

Respondents objected to the condition in the Guidelines that the fertility physician could not be the same person as the researcher deriving stem cells. Some respondents stated that the IRB or an independent physician would be able to guard against this conflict of interest. The restriction was designed so that the person treating the individuals seeking fertility treatment, who is involved in decisions such as how many embryos to produce, is not the person seeking to derive hPSCs. This separation will help ensure that embryos will not be created in numbers greater than necessary for fertility treatment.

Respondents suggested that the clauses regarding donation of fetal tissue or human embryos for derivation of stem cells for eventual use in transplantation be changed explicitly to prevent directed donation. This change has been made.

Identifiers

Respondents were concerned about removing identifiers. There was concern that the investigator would not be able to document compliance with the Guideline requirements without identifiers, or that the removal of identifiers would make it impossible to conduct certain genetic studies or develop therapeutic materials. The Guidelines have been modified to clarify that the term "identifier" refers to any information from which the donor(s) can be identified, directly or

through identifiers linked to the donors. However, since information identifying the donor(s) may be necessary if the tissue or cells are to be used in transplantation, the Guidelines have also been modified to state that the informed consent should notify donor(s) whether or not identifiers will be retained.

Respondents commented that DNA is an identifier and that all donors of human embryos or fetal tissue should be told that identifiers such as DNA will be retained with the samples. Although DNA can be used to determine the individual from whom a tissue sample was taken, this can be done only when one has a sample from both the tissue in question and the putative donor; it cannot be used to identify an individual out of a population. Moreover, it is difficult to identify a donor using tissue derived from a fetus or embryo, since the tissue is not genetically identical to the donor.

Informed Consent and IRB Review

Respondents asked why investigators were expected to provide documentation of IRB review of derivation from human embryos, but IRB review "...,if any,..." for derivation from fetal tissue. Respondents suggested that the requirements be changed so that protocols for both sources of hPSCs must be approved by an IRB. The Guidelines have been changed to make clear that the IRB review requirements regarding the derivation of cells from fetal tissue and human embryos are the same.

Comment was received expressing concern that the informed consent explicitly state that the donor will have no dispositional authority over derived pluripotent stem cells. The Guidelines state that donation of human embryos should have been made without any restriction regarding the individual(s) who may be the recipient of the cells derived from the hPSCs for transplantation. Such a statement is consistent with the statutory provision applicable to the donor informed consent for the use of fetal tissue for transplantation. The Guidelines now provide for the inclusion of a statement to this effect in the informed consent.

Respondents urged that the Guidelines be revised to remove the prohibition on potential donors receiving information regarding subsequent testing of donated tissue in the situation when physicians deem disclosure to be in the donors' best interest. This change has been made.

Respondents requested clarification regarding the persons from whom consent for donation of embryos for research must be obtained. The Guidelines call for informed consent from individual(s) who have sought fertility treatment. Only the individual(s) who were part of the decision to create the embryo for reproductive purposes should have been part of the decision to donate for the derivation of hPSCs.

Respondents urged that fertility clinics should be able to discuss with patients the option of donating embryos for research at the beginning of the IVF process. The Guidelines do not delineate the timeframe during which the general option of donating embryos for research can be discussed. However, according to the Guidelines, obtaining consent for donation of embryos for

the purpose of deriving hPSCs should not occur until after the embryos are determined to be in "excess of clinical need."

Oversight

Respondents stated that the NIH's oversight in this area of research was very important to the legal and ethical conduct of this research, and asked for more information regarding the oversight process. Information about the operations of the HPSCRG can be found in the final Guidelines and on the NIH webpage.

Respondents were concerned about whether and how NIH would monitor research after a researcher receives NIH funds. Compliance with the Guidelines will be largely determined prior to the award of funds. Follow-up to ensure continued compliance with the Guidelines will be conducted in the same manner as for all other conditions of all other NIH grant awards. It is the responsibility of the investigator to file progress reports, and it is the responsibility of the funded institution to ensure compliance with the NIH Guidelines. NIH staff will also monitor the progress of these investigators as part of their regular duties.

Respondents asked about penalties for not following the Guidelines. The following actions may be taken by the NIH when there is a failure to comply with the terms and conditions of any award: 1) Under 45 CFR 74.14, the NIH can impose special conditions on an award, including increased oversight/monitoring/reporting requirements for an institution, project or investigator;

2) Under 45 CFR 74.62, if a grantee materially fails to comply with the terms and conditions of the award, the NIH may withhold funds pending correction of the problem or pending more severe enforcement action, disallow all or part of the costs of the activity that was not in compliance, withhold further awards for the project, or suspend or terminate all or part of the funding for the project. Individuals and institutions may be debarred from eligibility for all Federal financial assistance and contracts under 45 CFR Part 76 and 48 CFR Subpart 9.4, respectively. Because these sanctions pertain to all conditions of grant award, the NIH did not reiterate them in the Guidelines.

Respondents suggested that the HPSCRG hold periodic Stem Cell Policy Conferences (similar to the Gene Therapy Policy Conferences conducted by the Recombinant DNA Advisory Committee ("RAC")) in order to solicit and consider public comment from interested parties on the scientific, medical, legal, and ethical issues arising from stem cell research. The HPSCRG will serve as a resource for recommending to the NIH any need for Human Pluripotent Stem Cell Policy Conferences.

Other Changes

We have added a sentence requiring the principal investigator's written consent to the disclosure of all material submitted to carry out public review and other oversight procedures.

The draft Guidelines required HPSCRG review of proposals from investigators planning to derive hPSCs from fetal tissue. Because the Guidelines address proposals for NIH funding for the use hPSCs, this requirement has been removed from the Guidelines.

The text of the final Guidelines follows.

National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). For purposes of these Guidelines, "human pluripotent stem cells" are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos. NIH research funded under these Guidelines will involve human pluripotent stem cells derived 1) from human fetal tissue; or 2) from human embryos that are the result of *in vitro* fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed.

In accordance with 42 Code of Federal Regulations (CFR) § 52.4, these Guidelines prescribe the documentation and assurances that must accompany requests for NIH funding for research utilizing human pluripotent stem cells from: (1) awardees who want to use existing funds; (2) awardees requesting an administrative or competing supplement; and 3) applicants or intramural

researchers submitting applications or proposals. NIH funds may be used to derive human pluripotent stem cells from fetal tissue. NIH funds may not be used to derive human pluripotent stem cells from human embryos. These Guidelines also designate certain areas of human pluripotent stem cell research as ineligible for NIH funding.

II. Guidelines for Research Using Human Pluripotent Stem Cells That Is Eligible for NIH Funding

A. Utilization of Human Pluripotent Stem Cells Derived from Human Embryos

1. Submission to NIH

Intramural or extramural investigators who are intending to use existing funds, are requesting an administrative supplement, or are applying for new NIH funding for research using human pluripotent stem cells derived from human embryos must submit to NIH the following:

a. An assurance signed by the responsible institutional official that the pluripotent stem cells were derived from human embryos in accordance with the conditions set forth in Section II.A.2 of these Guidelines and that the institution will maintain documentation in support of the assurance.

b. A sample informed consent document (with patient identifier information

removed) and a description of the informed consent process, which meet the criteria for informed consent set forth in Section II.A.2.e of these Guidelines.

c. An abstract of the scientific protocol used to derive human pluripotent stem cells from an embryo;

d. Documentation of IRB approval of the derivation protocol.

e. An assurance that the stem cells to be used in the research were or will be obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the stem cells.

f. A short paragraph describing the nature of the research to be conducted with the human pluripotent stem cells.

g. An assurance that the proposed research using human pluripotent stem cells is not a class of research that is ineligible for NIH funding as set forth in Section III of these Guidelines.

h. The Principal Investigator's written consent to the disclosure of all

material submitted under Paragraph A.1 of this Section, as necessary to carry out the public review and other oversight procedures set forth in Section IV of these Guidelines.

2. Conditions for the Utilization of Human Pluripotent Stem Cells Derived From Human Embryos

Studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.

a. To ensure that the donation of human embryos in excess of the clinical need is voluntary, no inducements, monetary or otherwise, should have been offered for the donation of human embryos for research purposes. Fertility clinics and/or their affiliated laboratories should have implemented specific written policies and practices to ensure that no such inducements are made available.

a. There should have been a clear separation between the decision to create embryos

for fertility treatment and the decision to donate human embryos in excess of clinical need for research purposes to derive pluripotent stem cells. Decisions related to the creation of embryos for fertility treatment should have been made free from the influence of researchers or investigators proposing to derive or utilize human pluripotent stem cells in research. To this end, the attending physician responsible for the fertility treatment and the researcher or investigator deriving and/or proposing to utilize human pluripotent stem cells should not have been one and the same person.

c. To ensure that human embryos donated for research were in excess of the clinical need of the individuals seeking fertility treatment and to allow potential donors time between the creation of the embryos for fertility treatment and the decision to donate for research purposes, only frozen human embryos should have been used to derive human pluripotent stem cells. In addition, individuals undergoing fertility treatment should have been approached about consent for donation of human embryos to derive pluripotent stem cells only at the time of deciding the disposition of embryos in excess of the clinical need.

d. Donation of human embryos should have been made without any restriction or direction regarding the individual(s) who may be the recipients of transplantation of the cells derived from the human pluripotent stem cells.

e. Informed Consent

Informed consent should have been obtained from individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes. The informed consent process should have included discussion of the following information with potential donors, pertinent to making the decision whether to donate their embryos for research purposes.

Informed consent should have included:

(i) A statement that the embryos will be used to derive human pluripotent stem cells for research, that may include human transplantation research.

(ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo.

(iii) A statement whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells.

(iv) A statement that derived cells and/or cell lines may be kept for many

years.

(v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development.

(vi) A statement that the research is not intended to provide direct medical benefit to the donor.

(vii) A statement that embryos donated will not be transferred to a woman's uterus and will not survive the human pluripotent stem cell derivation process.

f. Derivation protocols should have been approved by an Institutional Review Board (IRB) established in accord with 45 CFR §46.107 and §46.108 or FDA regulations at 21 CFR §56.107 and §56.108.

B. Utilization of Human Pluripotent Stem Cells Derived From Human Fetal Tissue

1. Submission to NIH

Intramural or extramural investigators who are intending to use existing funds, are requesting an administrative supplement, or are applying for new NIH funding for research using human pluripotent stem cells derived from fetal tissue must submit to NIH the following:

a. An assurance signed by the responsible institutional official that the pluripotent stem cells were derived from human fetal tissue in accordance with the conditions set forth in Section II.A.2 of these Guidelines and that the institution will maintain documentation in support of the assurance.

b. A sample informed consent document (with patient identifier information removed) and a description of the informed consent process, which meet the criteria for informed consent set forth in Section II.B.2.b of these Guidelines.

c. An abstract of the scientific protocol used to derive human pluripotent stem cells from fetal tissue;

d. Documentation of IRB approval of the derivation protocol.

e. An assurance that the stem cells to be used in the research were or will be obtained through a donation or through a payment that does not exceed the reasonable costs associated with the transportation, processing, preservation, quality control and storage of the stem cells.

f. A short paragraph describing the nature of the research to be conducted with the human pluripotent stem cells.

g. An assurance that the proposed research using human pluripotent stem cells is not a class of research that is ineligible for NIH funding as set forth in Section III of these Guidelines.

h. The Principal Investigator's written consent to the disclosure of all material submitted under Paragraph B.1 of this Section, as necessary to carry out the public review and other oversight procedures set forth in Section IV of these Guidelines.

2. Conditions for Utilization of Human Pluripotent Stem Cells Derived From Fetal Tissue.

a. Unlike pluripotent stem cells derived from human embryos, DHHS funds may be used to support research to derive pluripotent stem cells from fetal tissue, as well as for research utilizing such cells. Such research is governed by Federal statutory restrictions regarding fetal tissue research at 42 U.S.C. 289g-2(a) and the Federal regulations at 45 CFR § 46.210. In addition, because cells derived from fetal tissue at the early stages of investigation may, at a later date, be used in human fetal tissue transplantation research, it is the policy of NIH to require that all NIH-funded research involving the derivation or utilization of pluripotent stem cells from human fetal tissue also comply with the fetal tissue transplantation research statute at 42 U.S.C. 289g-1.

b. Informed Consent

As a policy matter, NIH funded research deriving or utilizing human pluripotent stem cells from fetal tissue should comply with the informed consent law applicable to fetal tissue transplantation research (42 U.S.C. 289g-1) and the following conditions. The informed consent process should have included discussion of the following information with potential donors, pertinent to making the decision whether to donate fetal tissue for research purposes.

Informed consent should have included:

(i) A statement that fetal tissue will be used to derive human pluripotent stem cells for research that may include human transplantation research.

(ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the fetal tissue.

(iii) A statement whether or not information that could identify the donors of the fetal tissue, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells.

(iv) A statement that derived cells and/or cell lines may be kept for many years.

(v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development.

(vi) A statement that the research is not intended to provide direct medical benefit to the donor.

c. Derivation protocols should have been approved by an Institutional Review Board

(IRB) established in accord with 45 CFR §46.107 and §46.108 or FDA regulations at 21 CFR §56.107 and §56.108.

III. Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding

Areas of research ineligible for NIH funding include:

A. The derivation of pluripotent stem cells from human embryos;

B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo;

C. Research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, rather than for fertility treatment;

D. Research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

E. Research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

F. Research in which human pluripotent stem cells are combined with an animal embryo; and

G. Research in which human pluripotent stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human.

IV. Oversight

A. The NIH will establish a Human Pluripotent Stem Cell Review Group (HPSCRG). This group will review documentation of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells, and may, when warranted, seek further information in support of an application. The HPSCRG will review all funding requests that propose the use of human pluripotent stem cells. The group will hold public review meetings when a funding request proposes the use of a line of human pluripotent stem cells that has not been previously reviewed and approved by the HPSCRG.

B. In the case of new or competing continuation (renewal) or competing supplement applications, all applications shall be reviewed by HPSCRG and for scientific merit by a Scientific Review Group. In the case of requests to use existing funds or applications for an administrative supplement or in the case of intramural proposals, Institute or Center staff should forward material to the HPSCRG for review and determination of compliance with the

Guidelines prior to allowing the research to proceed.

C. The NIH will compile a yearly report that will include the number of applications and proposals reviewed and the titles of all awarded applications, supplements or administrative approvals for the use of existing funds, and intramural projects.

D. The HPSCRG will also serve as a resource for recommending to the NIH any revisions to the NIH Guidelines for Research Using Human Pluripotent Stem Cells and any need for human pluripotent stem cell policy conferences.

Dated:

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Ruth Kirschstein, M.D.

Acting Director, NIH