

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: TRISH@NH1.NH.PDX.EDU (TRISH@NH1.NH.PDX.EDU [UNKNOWN])

CREATION DATE/TIME: 3-AUG-1999 13:39:50.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

As I see it we use Dena's informal and "straight ahead" remarks to respond to Meilander's important concern (this concern, I suspect reflects accurately some elements of public opinion that regards us as a tool being used to promote certain interests). Her words make clear that we have no intention of playing footsie and obfuscating the ethical connections between use and derivation of stem cells. Even though the first sentence of the paragraph in question (p. 22, lines 6- 24) states what our intentions are, perhaps it would be wise to follow Dena's remarks with some kind of succinct agreement with her.

Trish

> Date sent: Tue, 3 Aug 1999 13:06:27 -0400
> Send reply to: nbac-members@lists.Princeton.EDU
> From: "Meslin, Eric (OD)" <MeslinE@od.nih.gov>
> To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>
> Subject: RE: stem cell report
> Originally to: "nbac-members@lists.Princeton.EDU"
> <nbac-members@lists.Princeton.EDU>

> Trish, could you say why you disagree with Tom regarding the Davis comments (so

> others will have a chance to understand what is at issue here).

>

> Eric M. Meslin, Ph.D

> Executive Director

> National Bioethics Advisory Commission

> 6100 Executive Blvd. Suite 5B01

> Rockville, Maryland 20892-7508

> Tel: (301) 402-4242

> Fax: (301) 480-6900

> Email: MeslinE@OD.NIH.GOV

> <http://www.bioethics.gov>

>

> -----Original Message-----

> From: TRISH@NH1.NH.PDX.EDU [SMTP:TRISH@NH1.NH.PDX.EDU]

> Sent: Tuesday, August 03, 1999 2:02 PM

> To: NBAC Members E-list

> Subject: Re: stem cell report
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> Kathi, Eric, and staff, what I have seen of the report really
> looks good. My few 'me too' remarks are: I agree with Larry and
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> > Date sent: Tue, 3 Aug 1999 06:56:35 -0700 (PDT)
> > Send reply to: nbac-members@lists.Princeton.EDU
> > From: Alex Capron <acapron@law.usc.edu>
> > To: NBAC Members E-list
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> > Subject: Re: stem cell report
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> Patricia Backlar
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> Department of Philosophy
> Portland State University
> POB 751
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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME: 3-AUG-1999 16:03:51.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Trish,

Now I am confused. It seems to me that Dena's remarks are an echo of Gil Meilander's concerns, not a response to them.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of
TRISH@NH1.NH.PDX.EDU
Sent: Tuesday, August 03, 1999 2:38 PM
To: NBAC Members E-list
Subject: RE: stem cell report

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> > Subject: Re: stem cell report

> > Originally to: NBAC Members E-list

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 3-AUG-1999 11:05:20.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Thanks to Alex for this.
Commissioners will have received chapter 4 (ethics) by now, and hopefully have found that both of Alex's points are attended to. We intend to send chapter 3 (legal issues) later today and chapter 5 (conclusions and recommendations) tomorrow. Our timetable for completion would benefit greatly if commissioners can get comments on both back to staff by Friday August 6. This timetable will result in the full report (edited once, but thoroughly) back in commissioners' hands by about August 18. This is an approximate date, it may be a little earlier or a little later. We'll give commissioners a heads up on this, since we we'd like to be able to give you the whole report with a 24 hour-turnaround.

p.s. to Alex, if you need materials faxed/fedexed to a particular location for tomorrow's arrival, please let us know.

Eric

Eric M. Meslin, Ph.D
Executive Director
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6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Alex Capron [SMTP:acapron@law.usc.edu]
Sent: Tuesday, August 03, 1999 9:57 AM

To: NBAC Members E-list
Subject: Re: stem cell report

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alex

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Bernard Lo, M.D." <bernie@itsa.ucsf.edu> ("Bernard Lo, M.D." <bernie@itsa.ucsf.edu> [UNKNOWN])

CREATION DATE/TIME: 3-AUG-1999 13:02:20.00

SUBJECT: Comments on Chapter 4

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

I think Chap 4 is very good and agree with the detailed comments of Jim and Tom. I have some suggestions regarding the arguments for federal funding on pages 30-31, where we do not really spell out how federal funding could be beneficial or synergistic. There are several important issues that we can address more fully:

1. Federal research will encourage basic research on the biology of stem cells, in addition to the product-oriented research typically supported by biotechnology firms. Biotechnology firms are understandably focused on developing products that can be brought to market. However, in the long run, advances in the basic biology of stem cells - what are the conditions and signals which lead stem cells to differentiate and what are detailed mechanisms of differentiation - are essential for therapeutic advances. Such basic research will require long-term efforts, which traditionally have been supported by NIH funding.

2. Federal funding would attract top-rank scientists who are currently not working in the field. The availability of long-term research grants through NIH is likely to attract distinguished scientists who are not now working in the field of stem cell research and who would not be attracted by the short-term support for product-oriented research that is typically available through industry. [Is this argument valid? Is there evidence to support it from other fields of biomedical research?]

3. Research findings and materials derived on federal grants may be more likely to be shared with other researchers. Surveys suggest that researchers funded by industry may be less willing to share their findings and ideas candidly. Such reluctance may be caused by concerns about disclosing proprietary information about products under development. Furthermore, sharing of biological materials derived from industry funding may be less widespread because industry-supported researchers may attach conditions to the sharing of materials, such as ownership claims on future inventions related to the materials [IOM report Resource Sharing in Biomedical Research, page 81]. Thus federal funding may lead to more widespread dissemination of findings and sharing of materials, which ultimately may enhance scientific discoveries.

Bernard Lo, M.D.

Professor of Medicine

Room C-126

521 Parnassus Ave.

University of California San Francisco

San Francisco, CA 94143-0903

Ph: 415-476-5370

Fax: 415-476-5020

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 4-AUG-1999 10:49:20.00

SUBJECT: HBM and the media

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Dear Commissioners--

With the posting on the web and distribution of the HBM report, there may be inquiries from the media. As in the past, commissioners are of course welcome to comment on the report, its recommendations, etc. Harold will likely give some media interviews on this at his discretion. I have two requests:

1. If you give an interview, please let staff know (you could simply mention this on the NBAC e-list, or email directly to me and Pat Norris). It is easier for staff to follow up if necessary when we know you've given an interview, and to avoid being caught off-guard when a story appears that we were unaware of. You don't have to "clear" the interview with staff before you give it, so long as you are not speaking on behalf of the commission. You can say anything you want as a commissioner...well, almost anything.

2. It is very likely that some reporters will either confuse the HBM with the stem cell report (e.g., "I read through this whole report and NBAC hasn't said anything about stem cells, what's going on???"), or will try to elicit comments from you about the stem cell report (e.g., "so, how do these recommendations match up with your recommendations in the stem cell report?"). As noted in a previous email from me, it would be preferable if you didn't comment on the stem cell report until it has been sent to the President. This will avoid confusing stories coming out.

The posting of the HBM report yesterday was simply a result of it having been received by the white house and available as of yesterday. It was not a substitute for the stem cell report. Our schedule for completing the stem cell report -- as you can all attest by the flurry of getting chapters to you -- is around the end of August.

Thanks for your understanding...

Eric

Eric M. Meslin, Ph.D
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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Arturo Brito <abrito@peds.med.miami.edu> (Arturo Brito <abrito@peds.med.miami.edu> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 15:09:39.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

I agree with Trish on this point about Dena's comments. I do not agree that it is disrespectful to those who do not agree with her comments. But, we do need to follow the quoted comments with a statement clarifying our position.
-Artutro

At 03:25 PM 8/3/99 -0400, you wrote:

>Dear Trish,

>

>I would want to see what we propose to add before I agree to it. I still
>think we should lose the sentence about disrespect as it is in its own way
>disrespectful of those who don't agree with Dena's take on this matter.

>

>Tom

>

>-----Original Message-----

>From: owner-nbac-members@lists.Princeton.EDU
>[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of
>TRISH@NH1.NH.PDX.EDU
>Sent: Tuesday, August 03, 1999 4:09 PM
>To: NBAC Members E-list
>Subject: RE: stem cell report

>

>

>Yes, Dena does echo Meilaender's concern but as I read this paragraph
>she also eloquently responds to him by laying out precisely what those
>"concerns" may be. The paragraph refers only to Meilaender's concern
>that the "Commission...avoid misleading and even deceptive
>language...." Dena makes explicit what only is implicit in the way
>Meilaender's concerns are presented. That is why I suggest that we
>follow her quoted remarks, with something that indicates we are in
>accord with her argument

>

>> Date sent: Tue, 3 Aug 1999 14:44:23 -0400
>> Send reply to: nbac-members@lists.Princeton.EDU
>> From: "Thomas Murray" <murrayt@thehastingscenter.org>
>> To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>
>> Subject: RE: stem cell report

>> Originally to: <nbac-members@lists.Princeton.EDU>
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>> TRISH@NH1.NH.PDX.EDU
>> Sent: Tuesday, August 03, 1999 2:38 PM
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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Bernard Lo, M.D." <bernie@itsa.ucsf.edu> ("Bernard Lo, M.D." <bernie@itsa.ucsf.edu> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 16:08:30.00

SUBJECT: Comments on Chap 5

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Eric, this may miss the deadline, but our e-mail has been on the blink today.

Generally, I think this reads well. I have a number of suggestions:

Page 3, line 18. Substitute people for elements.

Page 5. Lines 14-23. We talk about diversity of opinion and our intense deliberations at several places in this chapter. It would be best to say it just once. I would suggest reworking this paragraph as follows: First two sentences as is. Then insert material from page 6, lines 2-5. "Some people are eager to see this area of research go forward as rapidly as possible, while others oppose such research if it is built on any activity connected to abortion of the destruction of human embryos." Then insert a revision of the (current) last sentence. "The Commission listened closely to testimony from members of the public holding a wide range of position. Our deliberations have been informed by testimony from ?" Then return to what is currently the 3rd sentence.

Page 6, lines 1-14. Much of this material can be condensed. I would omit lines 1-2, move material from lines 3-5 as above. Then insert material from lines 6-10 directly after line 29 of page 5. The material on lines 10-14 doesn't really fit the flow of the argument; also I'm not sure we want to encourage a patchwork of policies in different states.

Page 7, lines 8-10. Would omit; we've said it before in the chapter.

Page 8, line 23. Omit however. Line 26. Split the long sentence. Period after area. Then "However, because important biologic differences exist?"

Page 9, line 23. Insert "stem cell" before research.

Page 11, lines 21-22. After the comma in line 21, "which encourage the relief of human suffering."

Page 11, line 26. Delete embryo research. We are talking about changing the policy of embryo research, so don't cite it as an example.

Page 11, line 29. Delete "the traditions of."

Page 12, line 3. Delete infertility, which is not an example that everyone will agree on.

Page 12, lines 13-14. Simply say, "respecting human embryos."

Page 18, lines 13-22. Repeated from the previous page.

Page 21, lines 7-10. Doesn't fit the flow of commentary on Recommendation 6 and should be deleted or moved elsewhere.

Page 23, lines 15-20. This material on directed donation should be placed with the commentary to Rec 6.

Page 28, lines 5-13. Simplify this long sentence as follows: "preventing

ethically problematic research, assuring the public that research is scientifically meritorious and ethically acceptable; providing public oversight of controversial research practices, assuring consistency in the review of protocols, evaluating this type of research, and educating the public." The thought that some people don't like this research but would rather have it done in public doesn't really fit the flow of the sentence. Eric, this may miss the deadline, but our e-mail has been on the blink today.

Generally, I think this reads well. I have a number of suggestions:

Page 3, line 18. Substitute people for elements.

Page 5. Lines 14-23. We talk about diversity of opinion and our intense deliberations at several places in this chapter. It would be best to say it just once. I would suggest reworking this paragraph as follows: First two sentences as is. Then insert material from page 6, lines 2-5. "Some people are eager to see this area of research go forward as rapidly as possible, while others oppose such research if it is built on any activity connected to abortion of the destruction of human embryos." Then insert a revision of the (current) last sentence. "The Commission listened closely to testimony from members of the public holding a wide range of position. Our deliberations have been informed by testimony from ?" Then return to what is currently the 3rd sentence.

Page 6, lines 1-14. Much of this material can be condensed. I would omit lines 1-2, move material from lines 3-5 as above. Then insert material from lines 6-10 directly after line 29 of page 5. The material on lines 10-14 doesn't really fit the flow of the argument; also I'm not sure we want to encourage a patchwork of policies in different states.

Page 7, lines 8-10. Would omit; we've said it before in the chapter.

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Arturo Brito <abrito@peds.med.miami.edu> (Arturo Brito <abrito@peds.med.miami.edu> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 15:06:09.00

SUBJECT:

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Regarding Bernie's specific comments on pages 30-13 in Chapter 4, I agree in concept, but favor rephrasing a few of the sentences. The use of the term "understandably focused" sounds apologetic and unfairly implies that private industry is unique in having secondary gains. Those that work for the federal government are not immune to secondary gain from research, which can include financial incentives as well as personal status gains. Bernie's third point, that industry will be less willing to share findings, is speculative at best. It is not uncommon for public agencies to also hold off disclosure of information garnered from reserach studies for the purpose of prestige and institutional financial gains. I think that a better approach would be to emphasize that by allowing for both private and public funding of stem cell reserach, there is a greater chance of yielding broader and more widely applicable results and, hence, increase the likelihood of more equitable distribution of this resource.

-Arturo

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 19:29:23.00

SUBJECT: RE: Points to Consider

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Larry--

The original purpose of the Points to Consider document was to (a) provide
a
list of those considerations felt to be useful by both reviewers (local or
national) of stem cell protocols, and also for investigators intending to
design
protocols and submit them; and (b) as a summary of many of the ethical
issues
the report had addressed.

Since the main focus of the report is on federal funding, and the
recommendations address requirements for local and national review, your
comments seems right, i.e., the P/C should be clear about that it is
intended
for those who review and conduct federally sponsored stem cell research.
However, since there is the expectation that the private sector may choose
to
voluntarily comply with NBAC'S recommendations, the P/C could certainly be
used
by the private sector. Perhaps the easiest thing is to slightly edit the
opening
paragraph of the document to ensure that this is clear.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Larry Miiike [SMTP:lhmiike@aloha.com]
Sent: Thursday, August 05, 1999 5:59 PM
To: NBAC Members E-list
Subject: Re: Points to Consider

I have a problem with section II: it can be read as being primarily directed at donors who are being recruited to produce embryos specifically for research, and not providers of aborted fetuses or excess embryos.

Who are we directing these "Points..." to? Reviewers of projects submitted for federal funding, or also to include the private sector? If the latter, I

think we should limit it to federal funding projects only.

larry

-----Original Message-----

From: Hanna, Kathi (OD) <HannaK@od.nih.gov>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Tuesday, August 03, 1999 10:09 AM

Subject: Points to Consider

>For your review and comment.

>

>Thanks, Kathi

>

> <<Points to Consider 8-3.doc>>

>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 19:29:22.00

SUBJECT: RE: stem cell update

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Thanks Arturo.

Eric

p.s. As a reminder to any who haven't already commented, we'd also like comments on Chp 5 by the end of the day today (it's now 5:22pm EDT)

p.p.s. As a further reminder about the timetable for the stem cell report: once staff has received all comments from commissioners and incorporated them into each chapter we'll be sending the entire report to our editor (actually we've sent chps 1,2 already).

Over the next 10-14 days, the editor will be...editing.... all chapters, appendices, references, tables of contents--the works. This is a very time consuming and detailed task. Commissioners will receive a clean, complete copy of the full report some time around August 23; again, it may take more or less time, as we get closer we'll confirm delivery dates. Commissioners will then have another 2 days to read through the entire document. As with HBM and Capacity, we'll want you to let us know of any final editing concerns and, if you feel the need, any personal statements you want to submit. Once this is complete, the text will be copy edited again and made available to the white house--the schedule for which has not been determined but very likely during the last week of August.

p.p.s. With all of the editing going on next week, both Kathi and I will be on leave (she to North Carolina, me to the Sierra Nevadas). I will be in the office on Monday the 9th, then gone from the Aug 10-18th, Kathi from Aug 7-21.

The NBAC
office will know how to reach us, respectively, if needed.

Eric

Eric M. Meslin, Ph.D
Executive Director
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6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Arturo Brito [SMTP:abrito@peds.med.miami.edu]
Sent: Friday, August 06, 1999 6:15 AM
To: NBAC Members E-list
Subject:

Regarding Bernie's specific comments on pages 30-13 in Chapter 4, I
agree
in concept, but favor rephrasing a few of the sentences. The use
of the
term "understandably focused" sounds apologetic and unfairly
implies
that
private industry is unique in having secondary gains. Those that
work
for
the federal government are not immune to secondary gain from
research,
which can include financial incentives as well as personal status
gains.
Bernie's third point, that industry will be less willing to share
findings,
is speculative at best. It is not uncommon for public agencies to
also
hold
off disclosure of information garnered from reserach studies for
the
purpose of prestige and institutional financial gains. I think
that a
better approach would be to emphasize that by allowing for both
private
and
public funding of stem cell reserach, there is a greater chance of
yielding
broader and more widely applicable results and, hence, increase the
likelihood of more equitable distribution of this resource.
-Arturo

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 15:11:37.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
thanks again.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Arturo Brito [SMTP:abrito@peds.med.miami.edu]
Sent: Wednesday, August 04, 1999 2:41 PM
To: NBAC Members E-list
Subject: RE: stem cell report

I agree with Trish on this point about Dena's comments. I do not agree

that it is disrespectful to those who do not agree with her comments.

But,

we do need to follow the quoted comments with a statement clarifying our position.

-Artutro

At 03:25 PM 8/3/99 -0400, you wrote:

>Dear Trish,

>

>I would want to see what we propose to add before I agree to it.

I
still

>think we should lose the sentence about disrespect as it is in its own way

>disrespectful of those who don't agree with Dena's take on this

matter.

>

>Tom

>

>-----Original Message-----

>From: owner-nbac-members@lists.Princeton.EDU

>[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of

>TRISH@NH1.NH.PDX.EDU

>Sent: Tuesday, August 03, 1999 4:09 PM

>To: NBAC Members E-list

>Subject: RE: stem cell report

>

>

>Yes, Dena does echo Meilaender's concern but as I read this paragraph

>she also eloquently responds to him by laying out precisely what those

>"concerns" may be. The paragraph refers only to Meilaender's concern

>that the "Commission...avoid misleading and even deceptive

>language...." Dena makes explicit what only is implicit in the way

>Meilaender's concerns are presented. That is why I suggest that we

>follow her quoted remarks, with something that indicates we are in

>accord with her argument

>

>> Date sent: Tue, 3 Aug 1999 14:44:23 -0400

>> Send reply to: nbac-members@lists.Princeton.EDU

>> From: "Thomas Murray" <murrayt@thehastingscenter.org>

>> To: NBAC Members E-list

<nbac-members@lists.Princeton.EDU>

>> Subject: RE: stem cell report

>> Originally to: <nbac-members@lists.Princeton.EDU>

>

>> Trish,

>>

>> Now I am confused. It seems to me that Dena's remarks are an echo of Gil

>> Meilander's concerns, not a response to them.

>>

>> Tom

>>

>> -----Original Message-----

>> From: owner-nbac-members@lists.Princeton.EDU

>> [mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of

>> TRISH@NH1.NH.PDX.EDU

>> Sent: Tuesday, August 03, 1999 2:38 PM

>> To: NBAC Members E-list

>> Subject: RE: stem cell report

>>

>>

>> As I see it we use Dena's informal and "straight ahead" remarks to

>> respond to Meilander's important concern (this concern, I

suspect

>> reflects accurately some elements of public opinion that
>> regards us as a tool being used to promote certain interests).

Her

>> words make clear that we have no intention of playing footsie

and

>> obfuscating the ethical connections between use and derivation

of

>> stem cells. Even though the first sentence of the paragraph in
>> question (p. 22, lines 6- 24) states what our intentions are,
>> perhaps it would be wise to follow Dena's remarks with some

kind of

>> succinct agreement with her.

>> Trish

>>

>>

>>

>> > Date sent: Tue, 3 Aug 1999 13:06:27 -0400

>> > Send reply to: nbac-members@lists.Princeton.EDU

>> > From: "Meslin, Eric (OD)" <MeslinE@od.nih.gov>

>> > To: NBAC Members E-list

<nbac-members@lists.Princeton.EDU>

>> > Subject: RE: stem cell report

>> > Originally to: "nbac-members@lists.Princeton.EDU"

>> > <nbac-members@lists.Princeton.EDU>

>>

>> > Trish, could you say why you disagree with Tom regarding the

Davis

>> comments (so

>> > others will have a chance to understand what is at issue

here).

>> >

>> > Eric M. Meslin, Ph.D

>> > Executive Director

>> > National Bioethics Advisory Commission

>> > 6100 Executive Blvd. Suite 5B01

>> > Rockville, Maryland 20892-7508

>> > Tel: (301) 402-4242

>> > Fax: (301) 480-6900

>> > Email: MeslinE@OD.NIH.GOV

>> > <http://www.bioethics.gov>

>> >

>> > -----Original Message-----

>> > From: TRISH@NH1.NH.PDX.EDU [SMTP:TRISH@NH1.NH.PDX.EDU]

>> > Sent: Tuesday, August 03, 1999 2:02 PM

>> > To: NBAC Members E-list

>> > Subject: Re: stem cell report

>> >

>> > Kathi, Eric, and staff, what I have seen of the report

really

>> > looks good. My few 'me too' remarks are: I agree with

Larry and

>> > Alex's opinions, and also believe that Jim and Tom's

suggestions are

>> > useful and apt. However, I strongly disagree with Tom
about
deleting

>> > Dena's remarks on p. 22 lines 19-24.

>> > Trish

>> >

>> > > Date sent: Tue, 3 Aug 1999 06:56:35 -0700 (PDT)

>> > > Send reply to: nbac-members@lists.Princeton.EDU

>> > > From: Alex Capron <acapron@law.usc.edu>

>> > > To: NBAC Members E-list

>> <nbac-members@lists.Princeton.EDU>

>> > > Subject: Re: stem cell report

>> > > Originally to: NBAC Members E-list

>> <nbac-members@lists.Princeton.EDU>

>> >

>> > > i am just briefly back on e-mail and wanted belatedly to

state

>that

>> > > i largely agree with larry's point about our rising

above the

>> politics

>> > of

>> > > the situation to state what we think is right...and i

also

agree

>> that

>> > we

>> > > soend too much time on the agonized "balancing," though

not

so

>much

>> > that i

>> > > disagree with our doing so

>> > >

>> > > i also hope that by stating the argument well for the

position we

>> > support

>> > > we will actually help others to rise above the present

political

>> > situation

>> > > and i wish well to those who arte talking with leaders

in

congress

>> > about

>> > > this

>> > >

>> > > i also think we must be careful to limit our

recommendations

to

>STEM

>> > CELL

>> > > research and not make generalized statements about the

embryo

>> research
>> > > ban, which we have not studied carefully and which would
provide
>> > > ammunition to those who will oppose our specific
recommendations
>> > >
>> > > alex
>> > >
>> > >
>> > >

>> > Patricia Backlar
>> > Research Associate Professor of Bioethics
>> > Department of Philosophy
>> > Portland State University
>> > POB 751
>> > Portland OR 97207-0751
>> > telephone: 503/725-3499
>> > fax: 503/725-3693 or 503/725-4882
>> > email: backlarp@pdx.edu
>> > or
>> > trish@nh1.nh.pdx.edu
>> >
>> >
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>> Patricia Backlar
>> Research Associate Professor of Bioethics
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>email: backlarp@pdx.edu

> or
> trish@nhl.nh.pdx.edu
>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 6-AUG-1999 16:11:47.00

SUBJECT: RE: Comments on Chap 5

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Thanks Bernie.

p.s. you made the deadline

Eric

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Bernard Lo, M.D. [SMTP:bernie@itsa.ucsf.edu]
Sent: Friday, August 06, 1999 4:10 PM
To: NBAC Members E-list
Subject: Comments on Chap 5

Eric, this may miss the deadline, but our e-mail has been on the blink today.

Generally, I think this reads well. I have a number of suggestions:

Page 3, line 18. Substitute people for elements.

Page 5. Lines 14-23. We talk about diversity of opinion and our intense deliberations at several places in this chapter. It would be best to say it

just once. I would suggest reworking this paragraph as follows: First two sentences as is. Then insert material from page 6, lines 2-5. "Some people are eager to see this area of research go forward as rapidly as possible, while others oppose such research if it is built on any activity connected to abortion

of the destruction of human embryos." Then insert a revision of the (current) last sentence. "The Commission listened closely to testimony from members of the public holding a wide range of position. Our deliberations have been informed by testimony from S" Then return to what is currently the 3rd sentence.

Page 6, lines 1-14. Much of this material can be condensed. I would omit lines 1-2, move material from lines 3-5 as above. Then insert material from lines 6-10 directly after line 29 of page 5. The material on lines 10-14 doesn't really fit the flow of the argument; also I'm not sure we want to encourage a patchwork of policies in different states.

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Scott-Jones, Diane " <dscott@nsf.gov> ("Scott-Jones, Diane " <dscott@nsf.gov> [UNKNOWN])

CREATION DATE/TIME: 8-AUG-1999 20:11:36.00

SUBJECT: A few comments

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Hi everyone,

I apologize for missing the deadline.

I am sending my comments on Ch. 1. Reading the email from other Comissioners, I see that many of my comments have been made by others so I will not take the time to type comments from the other chapters.

Ch. 1

Ch 1 goes rather abruptly into the subject, beginning with very technical information. . The first full paragraph on p. 2 engages the reader in the importance of the ethical as well as scientific issues in embryonic stem cell research. With only minor changes, this paragraph could be moved to the beginning of this chapter and the detailed definitions could come later.

p. 6, line 21. Instead of "existing legal environment", use "existing laws".

p. 7, line 19. Instead of "to clearly define", use "to define clearly".

p. 7, lines 24 - p. 8, line 6. The quote from the Canadian Royal Commission seems unnecessary. We credit that commission with elucidating the confusion surrounding the term embryo, when the definitions they used are standard. It seems appropriate to cite the Canadian Commission here, not because of their definitions, but because we, like the Canadian Commission, decided to use the term embryo as it is used in the general public.

p. 8, line 16 - 17. "we decided to use precise names for each"
instead of "we decided that it should give precise names to each..."

p. 8, line 19. Blastocyst is misspelled.

p. 8, line 20. This is the first use of "conceptus". Define it or use a phrase such as "developing organism".

p. 8, lines 25 - p. 9, line 7. It seems odd to define "totipotency" and pluripotency" on p. 1 of our Introduction and then to explain to the reader

on p. 8-9 that we will not enter into the debate about the meaning of these terms. If we can minimize our use of these terms after p. 9, we should also be able to omit them on p. 1. In addition, the sentences in this section on p. 8-9 are awkwardly written.

p. 9, line 19. Insert comma after treatment.

p. 10 lines 5-9. As written, this sentence too closely links ethical issues to the source of funding. Instead of "....report primarily addresses the ethical issues associated with the use of federal funds for....", substitute
"...report primarily addresses the use of federal funds for..."

p. 10, footnote 1. The statement that we as a Commission concur with the 14-day limit is important enough to be incorporated in the text.

Diane
Diane Scott-Jones, Ph.D.
Program Director, Child Learning and Development
Division of Social, Behavioral, and Economic Research
4201 Wilson Blvd., Room 995
National Science Foundation, Arlington, VA 22230
Phone: 703-306-1732 Fax: 703-306-0485
<http://www.nsf.gov/sbe/sber>
Professor of Psychology, Temple University
Philadelphia PA 19122 215 204-1559

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 21:51:04.00

SUBJECT: Re: more reading-chapter 3

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Please see my reply to Tom's query. No, I don't agree with point two, but can live with point three, although I disagree with keeping it in the report. If point two is kept in, I will not dissent, for the simple reason that I don't want to highlight it any further. Why is it so important to leave it in, when it isn't even related to the discussion of chapter 3?

larry

-----Original Message-----

From: Meslin, Eric (OD) <MeslinE@od.nih.gov>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Monday, August 09, 1999 8:54 AM

Subject: RE: more reading-chapter 3

>Thanks to Alex for these comment since Chapter 3 was very much the product of

>his labors, and certain changes were made to the text (after he was done with

>it), to make it read more closely to what followed in chapters 4 and 5.

Some of

>the changes pointed out by Larry, and accepted by Alex seem straightforward.

>Others, however, require more discussed. Before making these changes, it would

>appear though that Larry needs to indicate whether he accepts Alex's explanation

>for Larry's second and third points. If Larry doesn't agree, he may wish to

>indicate this in a separate statement. If he, does, then the text can stand

as

>is.

>

>Comments from commissioners would be helpful here.

>

>

>Eric

>

>Eric M. Meslin, Ph.D

>Executive Director

>National Bioethics Advisory Commission

>6100 Executive Blvd. Suite 5B01
>Rockville, Maryland 20892-7508
>Tel: (301) 402-4242
>Fax: (301) 480-6900
>Email: MeslinE@OD.NIH.GOV
><http://www.bioethics.gov>

> -----Original Message-----

> From: Alex Capron [SMTP:acapron@law.usc.edu]
> Sent: Monday, August 09, 1999 2:02 PM
> To: NBAC Members E-list
> Subject: Re: more reading-chapter 3

> I'VE JUST RETURNED FROM VACATION AND HAVE TIME JUST FOR A COUPLE OF
> COMMENTS (CAPS TO MAKE IT EASIER TO READ, NOT FOR EMPHASIS)

> alex

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- >

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Alex Capron <acapron@law.usc.edu> (Alex Capron <acapron@law.usc.edu> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 14:02:54.00

SUBJECT: Re: more reading-chapter 3

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

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CREATION DATE/TIME: 9-AUG-1999 09:01:30.00

SUBJECT: Responding to Larry on Points to Consider

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Commissioners--

Last week Larry suggested that the Points to Consider document (Appendix D) make clear that it is for use by those involved in federally funded research. I indicated that the preamble could be modified to make this clear. Below you'll find some suggested language (it is underlined for you to see, it would not be underlined in the final text itself.

Please let us know whether this does the trick.

Eric

The following Points to Consider are presented not to prejudge the question whether research involving the derivation and or use of human embryonic stem (ES) cells or embryonic germ (EG) cells should be conducted using federal funds. Rather, this document describes some of the ethical, scientific, and legal issues that could be considered when designing and/or reviewing studies that involve access to and use of human stem cells. These Points to Consider are only relevant for designing and evaluating studies where the role of the individual(s) who provide gametes, cadaveric fetal tissue or embryos is limited to providing these materials for research intended to develop generalizable new knowledge. This document follows from the recommendations found in this report, and therefore is intended for use by those who design, conduct, and review research involving human ES and EG cells involving federal funds. Private researchers and sponsors also may find it to be of use. These Points to Consider

do not apply to situations in which an individual would be the recipient of a stem cell-based therapy, nor do they apply to studies involving human/animal hybrids.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
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Tel: (301) 402-4242
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Email: MeslinE@OD.NIH.GOV
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Thanks to Larry for his quick reply to Alex's quick reply. If folks can comment before the close of business, it will enable us to resolve chapter 3 difficulties and send it along to the editor--where it will reside with chapters 1 and 2 (and within the next hour, chapter 4).

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-----Original Message-----

From: Larry Miike [SMTP:lhmiike@aloha.com]
Sent: Monday, August 09, 1999 2:46 PM
To: NBAC Members E-list
Subject: Re: more reading-chapter 3

Thanks for the quick reply, alex. While I can accept most of your revisions/comments, I still am left uncomfortable by the discussion that, by funding use, we really are also funding derivation. I still believe it is

unnecessarily inflammatory. I'd like to hear from the other commissioners on this interchange between us.
larry

-----Original Message-----

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To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Monday, August 09, 1999 8:02 AM
Subject: Re: more reading-chapter 3

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>University of Southern California (213) 740-2548 (secretary)

>Los Angeles, CA 90089-0071 (213) 740-0149 (Pac. Ctr. fax)

>

>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 21:28:14.00

SUBJECT: Re: Responding to Larry on Points to Consider

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

okay.

larry

-----Original Message-----

From: Meslin, Eric (OD) <MeslinE@od.nih.gov>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Monday, August 09, 1999 8:50 AM

Subject: RE: Responding to Larry on Points to Consider

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>Eric M. Meslin, Ph.D
>Executive Director
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>6100 Executive Blvd. Suite 5B01
>Rockville, Maryland 20892-7508
>Tel: (301) 402-4242
>Fax: (301) 480-6900
>Email: MeslinE@OD.NIH.GOV
><http://www.bioethics.gov>

>
> -----Original Message-----
> From: Larry Miike [SMTP:lhmiike@aloha.com]
> Sent: Monday, August 09, 1999 2:37 PM
> To: NBAC Members E-list
> Subject: Re: Responding to Larry on Points to Consider
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> -----Original Message-----
> From: Meslin, Eric (OD) <MeslinE@od.nih.gov>
> To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>
> Date: Monday, August 09, 1999 3:02 AM
> Subject: Responding to Larry on Points to Consider

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 14:37:15.00

SUBJECT: Re: Responding to Larry on Points to Consider

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

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From: Meslin, Eric (OD) <MeslinE@od.nih.gov>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Monday, August 09, 1999 3:02 AM

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CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 14:50:56.00

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TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

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From: Meslin, Eric (OD) <MeslinE@od.nih.gov>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Monday, August 09, 1999 3:02 AM

Subject: Responding to Larry on Points to Consider

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 9-AUG-1999 14:53:13.00

SUBJECT: RE: more reading-chapter 3

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Thanks to Alex for these comment since Chapter 3 was very much the product of his labors, and certain changes were made to the text (after he was done with it), to make it read more closely to what followed in chapters 4 and 5. Some of the changes pointed out by Larry, and accepted by Alex seem straightforward. Others, however, require more discussed. Before making these changes, it would appear though that Larry needs to indicate whether he accepts Alex's explanation for Larry's second and third points. If Larry doesn't agree, he may wish to indicate this in a separate statement. If he, does, then the text can stand as is.

Comments from commissioners would be helpful here.

Eric

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-----Original Message-----

From: Alex Capron [SMTP:acapron@law.usc.edu]
Sent: Monday, August 09, 1999 2:02 PM
To: NBAC Members E-list
Subject: Re: more reading-chapter 3

I'VE JUST RETURNED FROM VACATION AND HAVE TIME JUST FOR A COUPLE OF

COMMENTS (CAPS TO MAKE IT EASIER TO READ, NOT FOR EMPHASIS)

alex

On Fri, 6 Aug 1999, Larry Miike wrote:

- > The chapter is quite clear. However, I have several concerns, which
 - > should be easily addressed.
- > First, under the section on Cells and Tissues from Human Embryos,
 - > paragraph 6 begins: "Having concluded that NIH may fund internal and
 - > external research that utilizes but does not destroy embryos in order
 - > to create human ES cells..." I don't believe that is what is
 - > intended. The way the sentence currently reads, NIH can utilize
 - > embryos in order to create human ES cells, as long as the embryos are
 - > not destroyed. First, that is currently not possible. Second, what
 - > is actually meant is that NIH's interpretation is that it can fund
 - > research that utilizes human ES cells but not the derivation of ES
 - > cells because derivation is research on the embryo (and would also
 - > destroy the embryo (and not be of any therapeutic benefit to the
 - > embryo).

I AGREE. AS ORIGINALLY WRITTEN, SENTENCE SAID "HAVING CONCLUDED THAT NIH MAY FUND INTERNAL AND EXTERNAL RESEARCH THAT UTILIZES BUT DOES NOT CREATE HUMAN EMBRYONIC STEM CELLS,..." I WOULD SUGGEST RETURNING TO THAT WORDING.

ALSO, AT THE END OF LINE 9 ON P. 19, "LESS" SHOULD BE "LEST".

- > Second, in the second paragraph of the Conclusions, I strongly
 - > object to the statement that "funding provided for research using ES
 - > cells would of course flow directly to researchers deriving the
 - > cells...indirectly in the form of funds to purchase the ES cells..."
 - > This is unnecessarily inflammatory. Nor would I expect that
 - > researchers will propose research projects in which they haven't any
 - > current access to ES cells and therefore propose a budget that
 - > includes the purchase price (neither would I expect reviewers to give
 - > high marks to these types of proposals). So I expressly ask that this
 - > language be deleted.

I DISAGREE, LARRY. EVERY RESEARCH BUDGET INCLUDES FUNDS FOR MATERIALS.

VERY TYPICALLY, CELL LINES FOR RESEARCH WOULD BE PRODUCED IN THE LAB THAT

WAS FUNDED BY THE GRANT (BUT AS TO ES CELL LINES, THAT IS NOT POSSIBLE

UNDER THE CURRENT REGS, SO....) IN SOME CASES, A LAB WILL SHARE CELLS

WITH ANOTHER LAB (OFTEN ON A RECIPROCAL BASIS...BUT THAT TOO WOULD BE

BEYOND THE BOUNDS OF WHAT THE FEDERALLY FUNDED LAB COULD DO). IF GERON

LICENSES A LAB TO MAKE STEM CELL LINES, DO YOU SUPPOSE THE LAB WILL GIVE

THE CELLS AWAY? PURCHASE OF CELL LINES, LIKE OTHER SUPPLIES, WILL NOT BE

A PART OF A BUDGET THAT WOULD UPSET STUDY SECTIONS.

> Third, I am also disturbed by the tone of the following paragraph,

> which takes NIH to task because of a maybe future distinction between

> funding research with ES cells from any source, or from only sources

> which we have blessed.

LARRY, I HAVE IT ON GOOD AUTHORITY THAT THE PANEL WHICH WROTE THE GUIDELINES, RESPONDING TO THE WISHES OF NIH, HAS TRIED TO MAKE A DISTINCTION BETWEEN EMBRYO SOURCES (I.E., "RESEARCH EMBRYOS" AND "POST-

FERTILITY TREATMENT EMBRYOS"). THE WORDING AT LINES 12-13 OF P. 20, PUTS

IT HYPOTHETICALLY "EVEN IF NIH FUNDS ONLY 'USE' RESEARCH, IT COULD STILL

TRY..." IN ORDER TO ALLOW FOR THE FACT THAT THE NIH GUIDELINES HAVE NOT

YET BEEN FINALIZED. BUT THE NOTION THAT NIH WILL TRY TO "REGULATE" THE

EMBRYOS FROM WHICH STEM CELL LINES ARE MADE-- EVEN AS NBAC ALSO THINKS A

DISTINCTION SHOULD BE MADE RE: "CERTIFIED" CELL LINES -- IS NOT SOME

MISLEADING HYPOTHETICAL.

> The Conclusions section departs in tone and commentary from what has

> gone before. It should just reiterate the principal points of the

> chapter, instead of suddenly taking on a lecturing tone.

THIS IS A "CONCLUSIONS" SECTION, SO IT IS BOUND TO BE A LITTLE MORE POINTED THAN THE DESCRIPTIVE MATERIAL THAT COMES EARLIER. I AGREE IT OUGHT NOT TO SOUND TOO TENDENTIOUS, HOWEVER, AND HOPE THAT THE EDITORIAL PROCESS CAN SOFTEN THE TONE WITHOUT CHANGING THE SUBSTANCE.

ONE POINT THAT I THINK SHOULD BE REINSERTED IS THE ISSUE THAT FACES POLICYMAKERS IF THE CONGRESSIONAL PROTESTORS' VIEW OF THE DHHS/NIH READING OF THE STATUTE IS TAKEN SERIOUSLY. I WOULD PROPOSE ADDING THE FOLLOWING LANGUAGE AS A NEW PARAGRAPH AT LINE 25 ON P. 19, WHICH WOULD INCORPORATE WHAT IS NOW THE FIRST SENTENCE OF THE NEXT PARAGRAPH; THE PARAGRAPH WOULD BE MODIFIED TO BEGIN WITH AN EDITED VERSION OF THE SENTENCE BEGINNING ON LINE 28: "FIRST, A LIMITED EXCEPTION IN THE EMBRYO RESEARCH BAN WOULD AVOID..." THE NEW PARAGRAPH WOULD READ ALONG THESE LINES:

The questions raised by this disagreement go beyond interpreting the language and intent of the DHHS appropriations rider. First, is the justification for research using stems cells compelling enough to justify making an exception to the ban on federal funding for embryo research? Second, can an exception be crafted in a way that continues to give appropriate weight to the values that lay behind the ban in the first place? And third, is the justification for using stem cells strong enough to permit funding of the process of deriving these cells from IVF embryos remaining after fertility treatments? A full answer to these questions requires evaluating the scientific and medical aspects of human embryonic stem cell research described in the previous chapter in light of the ethical considerations discussed in the next chapter. That task is taken up in the balance of this report. It is worthwhile noting here that adopting a limited exception to the funding ban in order to allow federal support for research that involves deriving as well as using human ES cells would confer several advantages beyond its effect on scientists working in this field.

FINALLY, ON LINE 25 OF P. 20, THE "EITHER" SHOULD BE DROPPED.

> I also note that there is no discussion of embryos created
expressly
> for research NOT using sent techniques -- i.e., in IVF clinics.
> Everywhere else in the other chapters, we discuss this potential
> source. Shouldn't it be acknowledged in this chapter also, even
if
> the discussion may be redundant with the discussion on deriving
ES
> cells from excess embryos? Finally, there are the usual extra or
> missing words, misspellings (e.g., "statue" for "statute"), etc.,
which
> I will leave to the editor.

LARRY, I AGREE WITH YOUR POINT ABOUT THE APPARENT ABSENCE OF TEXT
ON
"RESEARCH EMBRYOS," BUT BELIEVE THAT THE DISCUSSION IS REALLY
THERE, BUT
HIDDEN. THE PROBLEM LARGELY RESULTS FROM THE CHANGE OF THE TITLE
FOR THE
WHOLE SECTION ON IVF EMBRYOS ON P. 10. I HAD WRITTEN THAT AS "The
Law
Relating to IVF Embryos as Sources of Stem Cells" BUT IN THIS
VERSION
THE
MODIFIER "Remaining After Infertility Treatments" WAS ADDED. THIS
SHOULD
BE CHANGED BACK, BECAUSE THE TEXTUAL DISCUSSION SHOWS THAT WITH THE
EXCEPTION OF SOME STATE STATUTES, THERE IS NO DIFFERENCE...AND THE
MAIN
DISCUSSION OF FEDERAL LAW MAKES CLEAR THAT THE APPROPRIATIONS RIDER
APPLIES TO BOTH.

Thanks for the comments, Larry, and I hope these responses are
helpful
and
that the suggestions will be incorporated in the revised draft.

Alex

Alexander Morgan Capron
acapron@law.usc.edu

University Professor of Law and Medicine (213) 740-2557 (voice)
Co-Director, Pacific Center for (213)
740-5502 (fax)
Health Policy and Ethics (213) 740-2541 (Pacific Ctr.)
University of Southern California (213) 740-2548
(secretary)
Los Angeles, CA 90089-0071 (213) 740-0149 (Pac. Ctr.)

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME:10-AUG-1999 08:57:02.00

SUBJECT: RE: Responding to Larry on Points to Consider

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Eric,

The language looks clear to me.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Meslin, Eric
(OD)
Sent: Monday, August 09, 1999 9:02 AM
To: NBAC Members E-list
Subject: Responding to Larry on Points to Consider

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME:10-AUG-1999 09:34:29.00

SUBJECT: RE: more reading-chapter 3

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Point two needs to go for the reasons Larry outlines.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Larry Miike
Sent: Monday, August 09, 1999 9:50 PM
To: NBAC Members E-list
Subject: Re: more reading-chapter 3

Please see my reply to Tom's query. No, I don't agree with point two, but can live with point three, although I disagree with keeping it in the report. If point two is kept in, I will not dissent, for the simple reason that I don't want to highlight it any further. Why is it so important to leave it in, when it isn't even related to the discussion of chapter 3?

larry

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>Fax: (301) 480-6900

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>
> -----Original Message-----

> From: Alex Capron [SMTP:acapron@law.usc.edu]

> Sent: Monday, August 09, 1999 2:02 PM

> To: NBAC Members E-list

> Subject: Re: more reading-chapter 3

>
> I'VE JUST RETURNED FROM VACATION AND HAVE TIME JUST FOR A COUPLE OF
> COMMENTS (CAPS TO MAKE IT EASIER TO READ, NOT FOR EMPHASIS)

> alex

> On Fri, 6 Aug 1999, Larry Miike wrote:

>
> > The chapter is quite clear. However, I have several concerns, which
> > should be easily addressed.

>
> > First, under the section on Cells and Tissues from Huma Embryos,
> > paragraph 6 begins: "Having concluded that NIH may fund internal and
> > external research that utilizes but does not destroy embryos in order
> > to create human ES cells..." I don't believe that is what is
> > intended. The way the sentence currently reads, NIH can utilize
> > embryos in order to create human ES cells, as long as the embryos are
> > not destroyed. First, that is currently not possible. Second, what
> > is actually meant is that NIH's interpretation is that it can fund
> > research that utilizes human ES cells but not the derivation of ES
> > cells because derivation is research on the embryo (and would also
> > destroy the embryo (and not be of any therapeutic benefit to the
> > embryo).

>
> I AGREE. AS ORIGINALLY WRITTEN, SENTENCE SAID "HAVING CONCLUDED THAT NIH
> MAY FUND INTERNAL AND EXTERNAL RESEARCH THAT UTILIZES BUT DOES NOT
> CREATE
> HUMAN EMBRYONIC STEM CELLS,..." I WOULD SUGGEST RETURNING TO THAT
> WORDING.

>
> ALSO, AT THE END OF LINE 9 ON P. 19, "LESS" SHOULD BE "LEST".

>

> > Second, in the second paragraph of the Conclusions, I strongly

> > object to the statement that "funding provided for research using ES

> > cells would of course flow directly to researchers deriving the

> > cells...indirectly in the form of funds to purchase the ES cells..."

> > This is unnecessarily inflammatory. Nor would I expect that

> > researchers will propose research projects in which they haven't any

> > current access to ES cells and therefore propose a budget that

> > includes the purchase price (neither would I expect reviewers to give

> > high marks to these types of proposals). So I expressly ask that this

> > language be deleted.

>

> I DISAGREE, LARRY. EVERY RESEARCH BUDGET INCLUDES FUNDS FOR MATERIALS.

> VERY TYPICALLY, CELL LINES FOR RESEARCH WOULD BE PRODUCED IN THE LAB

> THAT

> WAS FUNDED BY THE GRANT (BUT AS TO ES CELL LINES, THAT IS NOT POSSIBLE

> UNDER THE CURRENT REGS, SO....) IN SOME CASES, A LAB WILL SHARE CELLS

> WITH ANOTHER LAB (OFTEN ON A RECIPROCAL BASIS...BUT THAT TOO WOULD BE

> BEYOND THE BOUNDS OF WHAT THE FEDERALLY FUNDED LAB COULD DO). IF GERON

> LICENSES A LAB TO MAKE STEM CELL LINES, DO YOU SUPPOSE THE LAB WILL GIVE

> THE CELLS AWAY? PURCHASE OF CELL LINES, LIKE OTHER SUPPLIES, WILL NOT

> BE

> A PART OF A BUDGET THAT WOULD UPSET STUDY SECTIONS.

>

> > Third, I am also disturbed by the tone of the following paragraph,

> > which takes NIH to task because of a maybe future distinction between

> > funding research with ES cells from any source, or from only sources

> > which we have blessed.

>

> LARRY, I HAVE IT ON GOOD AUTHORITY THAT THE PANEL WHICH WROTE THE

> GUIDELINES, RESPONDING TO THE WISHES OF NIH, HAS TRIED TO MAKE A

> DISTINCTION BETWEEN EMBRYO SOURCES (I.E., "RESEARCH EMBRYOS" AND "POST-

> FERTILITY TREATMENT EMBRYOS"). THE WORDING AT LINES 12-13 OF P. 20,

> PUTS

> IT HYPOTHETICALLY "EVEN IF NIH FUNDS ONLY 'USE' RESEARCH, IT COULD STILL

> TRY..." IN ORDER TO ALLOW FOR THE FACT THAT THE NIH GUIDELINES HAVE NOT

> YET BEEN FINALIZED. BUT THE NOTION THAT NIH WILL TRY TO "REGULATE" THE

> EMBRYOS FROM WHICH STEM CELL LINES ARE MADE-- EVEN AS NBAC ALSO THINKS A

> DISTINCTION SHOULD BE MADE RE: "CERTIFIED" CELL LINES -- IS NOT SOME

> MISLEADING HYPOTHETICAL.

>

>

> > The Conclusions section departs in tone and commentary from what has

> > gone before. It should just reiterate the principal points of the

> > chapter, instead of suddenly taking on a lecturing tone.

>

> THIS IS A "CONCLUSIONS" SECTION, SO IT IS BOUND TO BE A LITTLE MORE

> POINTED THAN THE DESCRIPTIVE MATERIAL THAT COMES EARLIER. I AGREE IT

> OUGHT NOT TO SOUND TOO TENDENTIOUS, HOWEVER, AND HOPE THAT THE EDITORIAL

> PROCESS CAN SOFTEN THE TONE WITHOUT CHANGING THE SUBSTANCE.

>

> ONE POINT THAT I THINK SHOULD BE REINSERTED IS THE ISSUE THAT FACES

> POLICYMAKERS IF THE CONGRESSIONAL PROTESTORS' VIEW OF THE DHHS/NIH

> READING

> OF THE STATUTE IS TAKEN SERIOUSLY. I WOULD PROPOSE ADDING THE FOLLOWING
> LANGUAGE AS A NEW PARAGRAPH AT LINE 25 ON P. 19, WHICH WOULD INCORPORATE
> WHAT IS NOW THE FIRST SENTENCE OF THE NEXT PARAGRAPH; THE PARAGRAPH
> WOULD
> BE MODIFIED TO BEGIN WITH AN EDITED VERSION OF THE SENTENCE BEGINNING ON
> LINE 28: "FIRST, A LIMITED EXCEPTION IN THE EMBRYO RESEARCH BAN WOULD
> AVOID..." THE NEW PARAGRAPH WOULD READ ALONG THESE LINES:

>
> The questions raised by this disagreement go beyond interpreting
> the language and intent of the DHHS appropriations rider. First, is the
> justification for research using stems cells compelling enough to
> justify
> making an exception to the ban on federal funding for embryo research?
> Second, can an exception be crafted in a way that continues to give
> appropriate weight to the values that lay behind the ban in the first
> place? And third, is the justification for using stem cells strong
> enough
> to permit funding of the process of deriving these cells from IVF
> embryos
> remaining after fertility treatments? A full answer to these questions
> requires evaluating the scientific and medical aspects of human
> embryonic
> stem cell research described in the previous chapter in light of the
> ethical considerations discussed in the next chapter. That task is
> taken
> up in the balance of this report. It is worthwhile noting here that
> adopting a limited exception to the funding ban in order to allow
> federal
> support for research that involves deriving as well as using human ES
> cells would confer several advantages beyond its effect on scientists
> working in this field.

>
>
> FINALLY, ON LINE 25 OF P. 20, THE "EITHER" SHOULD BE DROPPED.

>
>> I also note that there is no discussion of embryos created expressly
>> for research NOT using scnt techniques -- i.e., in IVF clinics.
>> Everywhere else in the other chapters, we discuss this potential
>> source. Shouldn't it be acknowledged in this chapter also, even if
>> the discussion may be redundant with the discussion on deriving ES
>> cells from excess embryos? Finally, there are the usual extra or
>> missing words, misspellings (e.g., "statue" for "statute"), etc., which
>> I will leave to the editor.

>
> LARRY, I AGREE WITH YOUR POINT ABOUT THE APPARENT ABSENCE OF TEXT ON
> "RESEARCH EMBRYOS," BUT BELIEVE THAT THE DISCUSSION IS REALLY THERE, BUT
> HIDDEN. THE PROBLEM LARGELY RESULTS FROM THE CHANGE OF THE TITLE FOR THE
> WHOLE SECTION ON IVF EMBRYOS ON P. 10. I HAD WRITTEN THAT AS "The Law
> Relating to IVF Embryos as Sources of Stem Cells" BUT IN THIS VERSION
> THE
> MODIFIER "Remaining After Infertility Treatments" WAS ADDED. THIS
> SHOULD
> BE CHANGED BACK, BECAUSE THE TEXTUAL DISCUSSION SHOWS THAT WITH THE
> EXCEPTION OF SOME STATE STATUTES, THERE IS NO DIFFERENCE...AND THE MAIN

> DISCUSSION OF FEDERAL LAW MAKES CLEAR THAT THE APPROPRIATIONS RIDER
> APPLIES TO BOTH.

>

> Thanks for the comments, Larry, and I hope these responses are helpful

>and

> that the suggestions will be incorporated in the revised draft.

>

> Alex

>

>

>

Alexander Morgan Capron acapron@law.usc.edu

>

> University Professor of Law and Medicine (213) 740-2557 (voice)

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>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME:11-AUG-1999 16:07:51.00

SUBJECT: Chapter 5

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Dear colleagues,

In the hope that these comments may still be useful, I offer the following suggestions on the draft of Chapter 5:

First of all, my heartfelt thanks to Jim for his extraordinarily thorough and thoughtful comments on this chapter. I found myself agreeing with him at virtually every point. I do hope that those responsible for polishing the draft of this chapter will implement all of Jim's suggested changes, especially those he listed under "Major Suggestions for Revision." Would that we all had editors as tenacious and smart!

Now, my suggestions:

p.2:19-20 Delete the sentence "Thus, ES and EG cells are still primarily a matter of intense research interest." Its meaning is somewhat ambiguous and it is in any event redundant.

p.2:29 Insert "human" so that the line reads "be carried out with human ES and EG cells..." The paragraph talks about different species (which may also provide ES and EG cells).

p.4:29 Edit to read "...pluralistic democracy such as ours in the United States." The current language, "...such as that which exists in the..." strikes me as distancing us--the members of NBAC. Rather than describing pluralistic democracy in such cool and distant terms, let us acknowledge that it is our pluralistic democracy.

p.5:15 Replace "which" with "that"

p.7:8 I approve of Jim's revision of this sentence, but urge that we delete the phrase "to some extent." The sentence would now read "Our recommendations reflect respect for diverse views in society..." Otherwise we leave ourselves open to a reading that indicates that to the remaining extent, we do NOT respect diverse views.

P.7:25-26 This sentence the phrase "...the potential to produce direct and

indirect health benefits for individuals..." What is an indirect health benefit? I propose deleting "direct and indirect"

p.10:27 Jim is quite right--we should delete the part of this sentence that begins with "...and the consequences of using it..." (I thought I made that suggestion in the comments I handed back in Cambridge.) I think we should delete the entire sentence. It is redundant with the previous sentence, and it conflates forgoing benefits with causing harm--an error many philosophers will gleefully point out.

p.12:5-6 This sentence must be modified. It now reads "...the intentional withholding of federal funds for research that may lead to promising treatments must be considered unjust or unfair." We withhold funds for lots of "promising treatments"--sometimes because other treatments are even more promising, but, more to the point here, sometimes because doing that research in that way would violate other moral duties.

p.13:17 The differences alluded to here may well be significant, but we agree that they are not decisive. Substitute "decisive" for "significant."

p.14:3-4 This is not a good sentence. It ends with "...the mistaken notion that the two areas of research are so distinct that participating in one need not mean participating in the other." This manner of phrasing it is either flatly wrong (a scientist very well could do research that uses stem cells without also doing research that derives stem cells) or else begs the question (of whether using stem cells makes the scientist complicit in deriving them). The following paragraph (lines 8-21) is where we defend whatever proposition we are offering here. We give three reasons, all of them stressing the scientific importance of being able to derive, not just use, stem cells. Neither separately nor jointly do our reasons support the proposition as stated in the preceding paragraph (even if its meaning were rendered more clear.) I suggest that we revise lines 3-4 to read "...the mistaken notion that derivation and use can be neatly separated without affecting the growth of scientific knowledge." Following this, the sentence on lines 5-6 should end with "...stem cell research." to avoid redundancy.

p.14:13 Replace "elemental" with "fundamental."

p.13:27 Delete "and ethical" The arguments we've offered are better described by the remaining adjective "practical."

p.21:19 Delete "there be"

p.26:15 I know I am entering dangerous territory--the actual text of Recommendation 8. But my question is about logic and grammar. As currently written, it calls for the new Panel "to ensure than all federally funded research involving the derivation and use of human ES or EG cells is conducted in conformance with the ethical principles and recommendations

contained in this report." My concern is with the conjunction "and" in "derivation and use." One could read that to refer only to research that involved BOTH derivation AND use. I don't believe that was our intention, nor do the points a through g that follow suggest as much. Should the recommendation read "derivation OR use"? If I have either our intentions or the logic of this wrong, I apologize.

p.27:19 Insert "also" after "but" as the common construction following "not only."

p.27:29 Insert "of" so that the sentence reads "...participation of the private sector..."

p.29:10 Something is wrong with this sentence. Perhaps deleting the words "important the" would solve the problem.

p.29:16 Replace the indefinite pronoun "they" with "IRBs."

p. 29:21 What do we mean by "particular sensitivities"? It is a vague and awkward construction.

p.30:13 A small disagreement with Jim: The line should probably read "...may better be understood as consent to donate...than as providing informed consent..." The comparison of two alternatives calls for the use of better rather than best.

p.31:6 The sentence should probably read "...oversight and review are still necessary, but do not require..."

p.31:7-10 To avoid an awkward repetition, combine the two sentences to read "In our judgment, these protocols...system in place at federal research agencies for the submission, review, and approval of research proposals."

p.31:19 I think we meant to write "institute" (as at NIH) rather than "institution."

p.36:7-8 Revise to read "Two arguments have been offered..." The current text "...are evident" connotes approval or persuasiveness of the arguments. The substituted language is neutrally descriptive.

p.36:25 Delete "ongoing" as it was used just 3 lines above.

p.37:20 Delete "And" It adds nothing to the meaning of the sentence and avoids beginning a sentence with a conjunction.

That's it!

Tom

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "r. alta charo" <racharo@facstaff.wisc.edu> ("r. alta charo" <racharo@facstaff.wisc.edu> [UNKNOWN])

CREATION DATE/TIME: 18-AUG-1999 14:26:48.00

SUBJECT: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ: UNKNOWN

TEXT:

my email had a major loss of data last week and i lost all the most recent drafts of the stem cell report chapters. altho i cannot participate, i do like to follow the discussions and be able to refer back to the text. if anyone has a moment, could you forward the latest drafts you have to me by email? word perfect is best but all word processing program versions are manageable.

many thanks in advance.

r. alta charo, j.d.
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- att1.htm===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

<html><div>my email had a major loss of data last week and i lost all the most recent drafts of the stem cell report chapters. altho i cannot participate, i do like to follow the discussions and be able to refer back to the text. if anyone has a moment, could you forward the latest drafts you have to me by email? word perfect is best but all word processing program versions are manageable. </div>

many thanks in advance.

<i>-</i>-----

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</html>

===== END ATTACHMENT I =====

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME:20-AUG-1999 13:24:44.00

SUBJECT: FW: fetal cell use

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Commissioners:

Attached please find a project memo from Elisa Eiseman. In order to satisfy ourselves about the accuracy of one of the statements made in the stem cell report about the extent of federal funding already used to support fetal tissue research, Elisa was asked to conduct a small search and report her findings. The attached memo provides the necessary background for the claim in chapter 4 that "It is worth noting that a broad variety of research materials and reagents derived from fetal tissue are widely used in current federally funded research".

Eric

p.s., we will fax to those who can't open the WORD document.

Eric M. Meslin, Ph.D
Executive Director
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-e <<fetal_cell_use.doc>> <<ATT125835.txt>>

- fetal_cell_use.doc - ATT125835.txt===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D80]ARMS225300234.236 to ASCII,
The following is a HEX DUMP:

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

===== ATTACHMENT 2 =====

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

TEXT:

Elisa Eiseman, Ph.D.
RAND Science and Technology Policy Institute
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===== END ATTACHMENT 2 =====

P R O J E C T M E M O R A N D U M

R

Quick Response:

Use of Human Fetal Tissue in Federally Funded Research

Elisa Eiseman

PM-968-NBAC

August 1999

Prepared for the National Bioethics Advisory Commission

Science and Technology Policy Institute

RAND's project memoranda are informal communications between RAND projects and their sponsors. They are intended to be timely and useful. Project memoranda have not been formally reviewed or edited. They should not be cited, quoted, reproduced, or retransmitted without RAND's permission.

PREFACE

This Project Memorandum was prepared in response to a request from the National Bioethics Advisory Commission for timely information on technical issues regarding the use of human fetal tissue in federally funded research. It is not a project deliverable. This document and ones like it are designed to meet specific needs of clients for information on science and technology issues on a short-term basis.

Originally created by Congress in 1991 as the Critical Technologies Institute and renamed in 1998, the Science and Technology Policy Institute is a federally funded research and development center sponsored by the National Science Foundation and managed by RAND. The Institute's mission is to help improve public policy by conducting objective, independent research and analysis on policy issues that involve science and technology. To this end, the Institute

- Supports the Office of Science and Technology Policy and other Executive Branch agencies, offices, and councils
- Helps science and technology decisionmakers understand the likely consequences of their decisions and choose among alternative policies
- Helps improve understanding in both the public and private sectors of the ways in which science and technology can better serve national objectives.

Science and Technology Policy Institute research focuses on problems of science and technology policy that involve multiple agencies. In carrying out its mission the Institute consults broadly with representatives from private industry, institutions of higher education, and other nonprofit institutions.

Inquiries regarding S&TPI or this document may be directed to:

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INTRODUCTION

As part of its report "Ethical Issues in Human Stem Cell Research," the National Bioethics Advisory Commission (NBAC) had questions about whether the federal government is currently funding research that uses human embryonic and fetal tissue. These questions included:

- Is the federal government currently funding research that uses human embryonic tissue, or material and reagents derived from this tissue? If so, what research is being funded?
- Is the federal government currently funding research that uses human fetal tissue, or material and reagents derived from this tissue? If so, what research is being funded?
- What are the sources of the human embryonic and fetal tissue that are being used in federally funded research?

This Project Memorandum attempts to answer these questions, and provides background information for NBAC's report.

DEFINITIONS

Since NBAC has adopted a scheme in its draft report for defining certain terms, such as "zygote," "embryo," and "fetus", that scheme has been adopted here. To be accurate when referring to the details of the stages of human development, the following definitions are used: 1) for the first week of development, from fertilization until implantation into the uterus, the organism is a **zygote**; 2) after implantation, from the beginning of the second week through the end of the eighth week of development, the organism is an **embryo**; and 3) from the ninth week of development until the time of birth, the organism is a **fetus**. Therefore, commonly used terms, such as "embryo research," "embryo donation," and "embryo transfer," are inaccurate, since these procedures all occur with zygotes, not embryos. In addition, fertility specialists refer to the products of *in vitro fertilization* (IVF) as embryos, even though for the first week of development they are actually zygotes. Since these terms are commonly used by fertility clinics and the public, and NBAC uses these terms in this way, products of IVF will be called embryos in this memo.

NBAC also defined the terms "fetal tissue" and "embryonic tissue. Fetal tissue is defined as tissue obtained from an organism between the ninth week of development and the time of birth. Fetal tissue comes from cadaveric fetal tissue that is obtained after either spontaneous or elective abortions. Embryonic tissue is defined as tissue obtained from an organism between the second and eighth weeks of development. In addition to spontaneous and elective abortions, embryonic tissue can also be obtained from embryos created by IVF. Therefore for embryonic tissue, it is important to differentiate between tissue obtained from embryos created by IVF and tissue obtained from abortuses.

METHODS

The following sources were consulted to determine the types of research involving human embryonic and fetal tissue that the federal government is currently funding:

- The American Type Culture Collection (ATCC) website (<http://www.atcc.org>) was queried for cell lines derived from human embryos or fetuses. The cell lines identified were then used as search terms in MEDLINE searches.
- A MEDLINE search of the literature using PUBMED was performed to identify papers about research using human embryonic or fetal tissue. These MEDLINE searches identified publications that had authors affiliated with several agencies of the federal government, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), and the Department of Veterans Affairs. These agencies and departments were selected only to provide examples of those agencies that might be supporting or conducting this research, not to provide a comprehensive assessment thereof.
- RAND's RaDiUS (Research and Development in the United States) database was used to identify federally funded research with human embryonic or fetal tissue. RaDiUS is a comprehensive, real-time accounting of federal research and development (R&D) activities and spending. RaDiUS allows users to see the total R&D investment by all federal agencies, to compare the level of R&D investment in specific areas of science and technology across all federal agencies, or to examine the details of research investments within a specific agency. RaDiUS was searched using proximity and wildcard searches for combinations of seven different search terms: human, embryo(s), fetus, in vitro fertilization, IVF, assisted reproductive technology(ies) and fertility. Proximity searches allow the user to search the database using two or more terms that are within a certain number of words from each other. For example, one could search for the terms "**human**" and "**embryo**" within two words of each other, and would find abstracts that contain the term "**human embryo**," as well as abstracts that contain the phrase "**the embryo of the human species**." Wildcard searches allow the user to search the database for several forms of a word, such as plurals, suffixes and prefixes. For example, using the wildcard character "%" one could search for abstracts containing the words "embryo," "embryos," "embryonic," etc. by searching with "embryo%."

FINDINGS

Currently, the federal government funds research that uses cultured cell lines derived from abortuses, as well as DNA, cells and tissues taken from abortuses. For example, the human embryonic kidney 293 cells, originally derived by researchers at McMaster University in Hamilton, Ontario, Canada (Graham et al., 1977), have been used by researchers at several institutes at the NIH for basic research including:

- 1) gene therapy research at the National Institutes of Neurological Disorders and Stroke (NINDS) (Mochizuki et al., 1998);

- 2) research on insulin-like growth factor-I at the National Cancer Institute (NCI) (Dey et al., 1998) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (Okubo et al., 1998);
- 3) signal transduction research at the National Institute of Dental Research (NIDR) (Lin et al., 1997); and
- 4) research on follicle-stimulating hormone at the National Institute of Child Health and Human Development (NICHD) (Flack et al., 1994).

Cell lines derived from human embryonic or fetal tissue, such as the human embryonic kidney 293 cells, are commonly used by researchers in federally funded research. Many of these cell lines are commercially available from ATCC. A search of the ATCC's catalog for human embryonic cell lines revealed at least 32 cell lines derived from human embryos. However, in ATCC's catalog "embryonic" cell lines include cells derived from embryos ranging from 5 weeks through the first trimester. Since the developing organism is only an embryo through the eighth week of development, some of these "embryonic" cell lines may actually be derived from cadaveric fetal tissue. The ATCC catalog also lists at least 28 cell lines derived from human fetuses. Several of these embryonic and fetal cell lines maintained by ATCC were originally developed and characterized by the Naval Biosciences Laboratory (NBL) in Oakland, California, and then transferred to ATCC in 1982.

Researchers at NIDR have used tissues from human embryos and fetuses to study skeletal development (Hoang et al., 1996; Chang et al., 1994). In these studies, cadaveric embryos and fetuses ranging from 6-13 weeks gestation were fixed, embedded in paraffin, serially cut into 5-7 μ m sections, and mounted on microscope slides. The tissue from the human embryos and fetuses was obtained from legally sanctioned procedures performed at the University of Zagreb Medical School in Zagreb, Croatia (Hoang et al., 1996). The procedure for obtaining autopsy materials was approved by the Internal Review Board of the Ethical Committee at the University of Zagreb School of Medicine and the Office of Human Subjects Research of the NIH (Hoang et al., 1996).

In addition to researchers in the intramural program at the NIH, there are a multitude of researchers at academic institutions that are funded by NIH's extramural program that perform research using human embryonic and fetal tissue. For example, researchers at the University of Iowa are studying the effects of maternal diabetes in human fetal lung development using cultured human fetal lung (Grant Number: R01HL50050). In addition, a group of researchers in the Department of Surgery at the University of California in San Francisco are using fetal skin to study wound healing in fetuses that occurs without scarring (Grant Number: R01GM55814; Stelnicki et al., 1998).

Furthermore, researchers funded by the NIH are not the only federally funded researchers using human embryonic and fetal tissue in research. Researchers at the EPA and the Department of Veterans Affairs are also conducting research with these tissues. For example, the Reproductive Toxicology Division and the Developmental Toxicology Division at the EPA have used human embryonic palates to study the effects of teratogenic chemicals in development of cleft palate (Abbott et al., 1999; Abbott et al., 1998; Abbott et al., 1994; Abbott

and Buckalew 1992). Human embryonic palate explants from embryos of 6-7 weeks gestation are grown in organ culture, and used a model of palate development.

Researchers at the Neurophysiology and Spinal Cord Pharmacology Laboratories at the Veterans Affairs Medical Center in Miami, Florida, have studied neural transmitters in cultured embryonic human dorsal root ganglion neurons (Valeyev et al., 1999). The neurons were obtained with written informed consent and human subjects committee approval in accordance with published guidelines from 5-8 week old cadaveric human embryos through a collaborative agreement with the Central Laboratory for Human Embryology (see below) (Valeyev et al., 1999). In addition, researchers from the Medical Service at the Veterans Administration Medical Center in Palo Alto, California, have studied gene expression in Wilm's tumor, the most common abdominal tumor in children, and compared it to the expression of genes in normal human fetal tissue (Vu and Hoffman 1996). Normal fetal tissue from 6-12 weeks gestation abortuses was obtained from the Central Laboratory for Human Embryology (Vu and Hoffman 1996).

In addition to funding research that uses human embryonic and fetal tissue, the federal government funds tissue banks that collect, study, describe and distribute tissues from abortuses. In 1997, the NICHD awarded ATCC a grant for a feasibility study to explore the utility of various tissues from human abortuses for transplantation and related research (Grant Number: R01HD32179). The Central Laboratory of Human Embryology has been funded by the NIH for 30 years (Grant Number: 5R24HD00836-35). The Central Laboratory of Human Embryology collects, characterizes stages, identifies, processes and distributes human embryonic and fetal tissues within minutes of delivery. Annually, it collects and analyzes 3500 embryos and fetuses. The Central Laboratory of Human Embryology is also participating in a project directed by the Puget Sound Blood Center of Seattle to determine the availability and suitability of embryonic tissue for transplantation research and therapy. Two other institutions, the Northwest Tissue Center and the Fred Hutchinson Cancer Research Center, are participating in this project, and together with the Central Laboratory of Human Embryology have formed the Northwest Fetal Tissue Program.

In contrast, there is no evidence of federally funded research that used embryonic tissue derived from IVF embryos identified in searches of MEDLINE or RaDiUS. While the searches of these databases were broad, they were not designed to be comprehensive, so it was not possible to identify all federally funded research projects that use human embryonic tissue or materials and reagents derived from this tissue. In addition, even though the majority of materials and reagents from human embryonic tissue is derived from cadaveric embryonic tissue obtained after spontaneous and elective abortions, it is not possible to definitively determine the origins of all cultured cell lines and DNA routinely used in research by federally funded investigators.

CONCLUSIONS

The federal government is currently funding research that uses a broad variety of research materials and reagents derived from human embryonic and fetal tissue. The human

embryonic and fetal tissue used in this research comes from cadaveric tissue that is obtained after either spontaneous or elective abortions. There is no evidence revealed through the search conducted for this “Quick Response” that the federal government is funding research that uses cells or tissue derived from embryos remaining after IVF procedures or, more relevantly, cells or tissues derived from embryos created solely for research purposes. But as noted above, lack of evidence of such funding is not equivalent to evidence of lack of funding.

REFERENCES

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME:20-AUG-1999 14:22:36.00

SUBJECT: RE: fetal cell use

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

We'll make that change. Elisa is part of this email list so she'll know of the complement you paid the memo writer.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Larry Miike [SMTP:lhmiike@aloha.com]
Sent: Friday, August 20, 1999 2:10 PM
To: NBAC Members E-list
Subject: Re: fetal cell use

Excellent piece. Good that consent and human subject protection safeguards are mentioned when possible; and obviously, that tissues are from cadaveric tissue and not (to the extent it could be researched) from embryos created for research. Small typo in last paragraph before "Conclusions": "thought" should be "though".

larry

-----Original Message-----

From: Meslin, Eric (OD) <MeslinE@od.nih.gov>
To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>
Date: Friday, August 20, 1999 7:25 AM
Subject: FW: fetal cell use

>Commissioners:

>

>Attached please find a project memo from Elisa Eiseman. In order
to
satisfy
stem
cell
fetal
tissue
>research, Elisa was asked to conduct a small search and report her
findings.
>The attached memo provides the necessary background for the claim
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chapter 4
>that "It is worth noting that a broad variety of research
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>derived from fetal tissue are widely used in current federally
funded
research".
>
>Eric
>
>p.s., we will fax to those who can't open the WORD document.
>
>Eric M. Meslin, Ph.D
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>National Bioethics Advisory Commission
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>Rockville, Maryland 20892-7508
>Tel: (301) 402-4242
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>Email: MeslinE@OD.NIH.GOV
><http://www.bioethics.gov>
>
>-e <<fetal_cell_use.doc>> <<ATT125835.txt>>
>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME:20-AUG-1999 17:25:57.00

SUBJECT: AAAS draft recommendations and stem cell update

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

As Alex mentioned earlier this week, AAAS is holding a public meeting next week to discuss their proposed "Findings and Recommendations on Stem Cell Research and Applications". We are faxing their draft report to each of you.

The current timetable for NBAC'S report is that it will be delivered to the White House on or about August 30/31 (i.e., no sooner than 30th, but possibly a couple of days later). As I've mentioned before, it is Harold's intention to circulate to commissioners the full report (having been substantially reviewed by our editor) later next week. Commissioners will be asked to read through it one more time. It is likely that there will still be extremely minor edits that need attending to, and our editor will do this prior to submission to the WH. As with past reports, commissioners will be given a short period of time (1-2 days) to read the report and if there remain any points of disagreement, commissioners should reflect these in a written statement.

We hope to have a more definitive schedule for circulation to you and distribution to the WH early next week.

Eric

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME:20-AUG-1999 14:10:41.00

SUBJECT: Re: fetal cell use

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Excellent piece. Good that consent and human subject protection safeguards are mentioned when possible; and obviously, that tissues are from cadaveric tissue and not (to the extent it could be researched) from embryos created for research. Small typo in last paragraph before "Conclusions": "thought" should be "though".

larry

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To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Date: Friday, August 20, 1999 7:25 AM

Subject: FW: fetal cell use

>Commissioners:

>

>Attached please find a project memo from Elisa Eiseman. In order to satisfy

>ourselves about the accuracy of one of the statements made in the stem cell

>report about the extent of federal funding already used to support fetal tissue

>research, Elisa was asked to conduct a small search and report her findings.

>The attached memo provides the necessary background for the claim in chapter 4

>that "It is worth noting that a broad variety of research materials and reagents

>derived from fetal tissue are widely used in current federally funded research".

>

>Eric

>

>p.s., we will fax to those who can't open the WORD document.

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RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Kathi E. Hanna" <khanna@chesapeake.net> ("Kathi E. Hanna" <khanna@chesapeake.net> [UNKNOWN])

CREATION DATE/TIME:27-AUG-1999 16:01:10.00

SUBJECT: UPDATE ON STEM CELL REPORT

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Dear Commissioners et al.

We are in the final stages of the first edit of the stem cell report. We hope to send the entire report to you Tuesday for a final review. Please try to restrict your comments to substantive concerns. The editor and a proofreader will make another pass at the document. We will need your comments within a 48-hour period of receipt of the report. At that point final commissioner comments will be incorporated and a draft will be delivered to the White House.

At the same time the report goes to the White House, our designer Tamara Lee will lay out the report and Sara Davidson (our editor) and a proofreader will complete the final edits.

If you have any questions or concerns about this schedule, please let me know as soon as possible.

Thanks,

Kathi

P.S. HBM is at the printer. We hope to see it soon!
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Kathi

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME:30-AUG-1999 14:08:00.00

SUBJECT: RE: UPDATE ON STEM CELL REPORT

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Dear Kathi,

I will be at the ACOG headquarters in DC on Wednesday. If the report cannot be delivered to The Hastings Center before end of day Tuesday, probably better to get it to me at ACOG on Wednesday.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Kathi E. Hanna
Sent: Friday, August 27, 1999 3:59 PM
To: NBAC Members E-list
Subject: UPDATE ON STEM CELL REPORT

Dear Commissioners et al.

We are in the final stages of the first edit of the stem cell report. We hope to send the entire report to you Tuesday for a final review. Please try to restrict your comments to substantive concerns. The editor and a proofreader will make another pass at the document. We will need your comments within a 48-hour period of receipt of the report. At that point final commissioner comments will be incorporated and a draft will be delivered to the White House.

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Thanks,

Kathi

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

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class=330271218-30081999>Tom</DIV>
<BLOCKQUOTE style="MARGIN-RIGHT: 0px">
<DIV align=left class=OutlookMessageHeader dir=ltr><FONT face=Tahoma
size=2>-----Original Message-----
From:
owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Kathi E.
Hanna
Sent: Friday, August 27, 1999 3:59 PM
To: NBAC
Members E-list
Subject: UPDATE ON STEM CELL
REPORT

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<DIV>If you have any questions or concerns about this

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<DIV>Thanks,</DIV>

<DIV> </DIV>

<DIV>Kathi</DIV>

<DIV> </DIV>

<DIV>P.S. HBM is at the printer. We hope to see it soon!</DIV></BLOCKQUOTE></BODY></HTML>

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "James F. Childress" <jfc7c@virginia.edu> ("James F. Childress" <jfc7c@virginia.edu> [UNKNOWN])

CREATION DATE/TIME: 2-SEP-1999 18:04:12.00

SUBJECT: Stem Cell Report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

To: Commissioners
From: Jim Childress
Subj: Some comments on stem cell report.

In general, the report looks fine, but I've only been able to examine some sections closely, with particular attention to Chapter 4. I'll try to go over more of the report tonight. It is clear, however, that some editorial problems remain, and they need to be corrected in order to avoid the collective embarrassment of a report with poor grammar, etc.

First, I agree with Larry that it would be better to end Chapter three where he suggests -- p. 19, at line 17. If the points that appear in what follows in the summary are not adequately addressed elsewhere, then they should be transposed to other places. For instance, they would fit very well, it seems to me, as one set of reasons for federal funding of research, including derivation, which we present in Chapter 4, pp. 26-30.

Let me just take one page to illustrate the editorial problems I mentioned in the first paragraph-- page 18 of Chapter 3, which was already in excellent shape because of Alex's fine writing. Line 6: shouldn't "treats fetuses like other cadavers are treated" be "treats fetuses as other cadavers are treated...."? Lines 11-12: Change "appear" to "appears" -- the subject of the verb is "principal set." On lines 15-16, there is another problem of subject/verb agreement: Change the "is" to "are." It should read "statutory modification and regulatory clarification ARE desirable." Line 31 (continuing onto the next page) -- something is missing about the context. I don't know what's been dropped, but one possible way to handle this would be the following: "NIH has indicated that once it has developed special guidelines, it will fund suitable...."

Chapter 4.

Given the other editorial problems I spotted elsewhere, I was pleasantly surprised that, as far as I could determine, Chapter 4 is in fairly good shape.

P. 2, line 10. Delete "latter". Not needed and confusing.

P. 3, lines 2-7. This paragraph breaks the flow here. It brings back into

this section a position that was already articulated toward the beginning of the previous paragraph. The best way to handle it is to put it in the next section following the heading ASSOCIATION WITH ABORTION. Here it could be revised and incorporate the next paragraph. It would then read: "Opponents of the research use of fetal materials obtained from elective abortions dispute the claim that it is possible to separate the moral issues surrounding the abortion from those involving in obtaining and using fetal material. They argue that those who obtain and use fetal material from elective abortion inevitably become associated, in ethically unacceptable ways, with the abortions that are the source of the material. They identify two major types of unacceptable association or cooperation with abortion: 1) causal responsibility for abortions, and 2) symbolic association with abortions."

P. 5, line 16. insert "direct" before "causal responsibility"

P. 6, lines 18-22, remove outside quotation marks from this quotation.

P. 7, line 11. Change "have been raised" to "have arisen"

P. 9, lines 28-30. This sentence doesn't work well. One possibility is to delete "a distinction in". Another possibility is to revise it this way: "However, whether this similarity is decisive depends hinges on one's perception of the moral status of embryos."

P. 10, line 6. Perhaps change "require" to "claim"

P. 10, lines 10-11. "...the embryos is a mere cluster of cells that has no more moral status than any other human cells." In this case, the editor is referring to "cells" rather than "cluster" -- see the rest of the sentence -- and thus "has" should be changed to "have". "has" could be retained if the end of the sentence were changed to "no more moral status than any other collection of human cells."

P. 10, line 32. Delete "interpreting" This is a terrible addition and is unnecessary.

P. 14, lines 5-6. Change "to be" to "as" -- we "regard" something "as"

P. 16, line 12. Please check the original to see if "offer" should be "offers" -- the subject of this verb is "new research"

P. 17, line 21. "additonal" is misplaced. Revise the first part of this sentence: "Sixth, it is important to develop and widely disseminate additional professional standards of practice...."

P. 18, line 18. Change dash to comma -- otherwise the sentence makes no sense whatsoever.

Line 19. I though we had, following Tom M's suggestion, removed the language of "the lesser of two evils".

P. 21, line 27. Change "Experts and other interested parties" to "Various parties"

Who are "experts" on this topic? It would be possible to change "experts" to "ethicists", but I think "various parties" works better.

P. 22, lines 17-18. The sentence beginning "It is important...." breaks the flow and is unnecessary. Delete.

P. 22, lines 25-26. Change "treating the embryo as a mere thing to be used without regard to its origins" to "treating the embryo as a mere thing"

CHAPTER 5.

Pp. 18-20. Despite earlier suggestions, including some I made, this section remains a bit messy, partly because some material precedes while most material follows the recommendation. The first sentence in this section on p. 18 reads "Existing rules prohibit the practice of designated donation, the provision of monetary inducements too women undergoing abortion, and the pruchase or sale of fetal tissue." This sentence is virtually identical to the first sentence that follows the recommendation.

The whole section needs to be integrated better -- I doubt that, unfortunately, there is still time to do so, but if there is I'd be glad to try my hand at it, building on earlier suggestions.

Comments re Appendix on religious perspectives.

Eric and Kathi, please fax a copy of page 2 -- it was missing from my materials. I'm faxing a copy of the pages on which a few additional changes need to be made in this summary.

First, along the way the language of ES and EG cell research was introduced into this summary -- as I recall it did not appear in the original. Even though its introduction was ok, it is not used consistently. Often when both are encompassed in the discussion (because both the cadaveric fetus and the left-over embryo are being discussed), the language of ES cell research is used. In those cases we should simply say stem cell research or, occasionally, insert EG. I have tried to catch and correct those instances.

I have marked several other minor errors or places where modest changes would be appropriate, and I'll fax those pages to the NBAC office.

James F. Childress
Kyle Professor of Religious Studies &
Professor of Medical Education
University of Virginia
Cocke Hall
Charlottesville, VA 22903
Tel. (804) 924-3741
Fax (804) 924-1467

e-mail: jfc7c@virginia.edu

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Larry Miike <lhmiike@aloha.com> (Larry Miike <lhmiike@aloha.com> [UNKNOWN])

CREATION DATE/TIME: 2-SEP-1999 15:43:54.00

SUBJECT: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

I have reviewed the current draft, and am okay with it except for, again, the summary of chapter 3.

My concerns are twofold, one editorial, one substantive.

First, substantively, I believe the summary should end on page 19, at line 17, in the second paragraph: i.e. it should end with two sentences:
"...Answers to these questions will require evaluation of the scientific and medical aspects of human ES cell research described in the previous chapter in light of the ethical considerations discussed in the next chapter. That task is taken up in the balance of this report."
The rest is commentary, and commentary which "disses" the NIH decision. Why are we doing so here? The analysis of the scientific aspects in chapter 2 (pp. 19-20), the ethical aspects in chapter 4 (pp. 18-20), and the Conclusions and Recommendations in chapter 5 (pp. 11-13) all address the issue in a much better way than the rest of the summary in chapter 3.

Second, chapter 3's "summary" is quite out of line with the summaries in chapter 2, 4, and 5. Those other three chapters have summaries which are only a paragraph long, while chapter 3's, even if shortened to the point I am recommending, still goes on for five paragraphs. So it could appear that the commission had an "axe to grind" with the NIH and the DHHS's counsel's decision.

Larry

- att1.htm===== ATTACHMENT 1 =====

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<DIV> </DIV>
<DIV>Larry</DIV></BODY></HTML>

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 14:51:37.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

I agree with Larry's suggestion that the summary of chapter 3 end at page 19, line 17. The remaining text is more a chiding argument than it is a summary.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Larry Miike
Sent: Thursday, September 02, 1999 3:42 PM
To: NBAC Members E-list
Subject: stem cell report

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My concerns are twofold, one editorial, one substantive.

First, substantively, I believe the summary should end on page 19, at line 17, in the second paragraph: i.e. it should end with two sentences: "...Answers to these questions will require evaluation of the scientific and medical aspects of human ES cell research described in the previous chapter in light of the ethical considerations discussed in the next chapter. That task is taken up in the balance of this report."

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decision.

Larry
- att1.htm===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

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<STYLE></STYLE>
</HEAD>
<BODY bgColor=#ffffff>
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<DIV><SPAN
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<DIV><SPAN
class=630285418-03091999>Tom</DIV>
<BLOCKQUOTE style="MARGIN-RIGHT: 0px">
<DIV align=left class=OutlookMessageHeader dir=ltr><FONT face=Tahoma
size=2>-----Original Message-----
From:
owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Larry
Miike
Sent: Thursday, September 02, 1999 3:42 PM
To: NBAC

Members E-list
Subject: stem cell report

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<DIV> </DIV>

<DIV>Larry</DIV></BLOCKQUOTE></BODY></HTML>

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Thomas Murray <murrayt@thehastingscenter.org> (Thomas Murray <murrayt@thehastingscenter.org> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 14:59:35.00

SUBJECT: RE: Stem Cell Report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Thanks to Jim for picking up the many useful points he makes in this message.

I am particularly grateful to him for noting the failure to correct our mistaken portrayal of Father Demopolous's views as "the lesser of two evils"

claim. I thought that I had explained pretty thoroughly why that was an inaccurate description of his position, and I refer the editors back to my earlier messages. I am also curious to know what other substantial recommended changes were not made.

Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU

[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of James F. Childress

Sent: Thursday, September 02, 1999 5:54 PM

To: NBAC Members E-list

Subject: Stem Cell Report

To: Commissioners

From: Jim Childress

Subj: Some comments on stem cell report.

In general, the report looks fine, but I've only been able to examine some sections closely, with particular attention to Chapter 4. I'll try to go over more of the report tonight. It is clear, however, that some editorial problems remain, and they need to be corrected in order to avoid the collective embarrassment of a report with poor grammar, etc.

First, I agree with Larry that it would be better to end Chapter three where he suggests -- p. 19, at line 17. If the points that appear in what follows in the summary are not adequately addressed elsewhere, then they should be transposed to other places. For instance, they would fit very well, it seems to me, as one set of reasons for federal funding of research, including derivation, which we present in Chapter 4, pp. 26-30.

Let me just take one page to illustrate the editorial problems I mentioned in the first paragraph-- page 18 of Chapter 3, which was already in excellent shape because of Alex's fine writing. Line 6: shouldn't "treats fetuses like other cadavers are treated" be "treats fetuses as other cadavers are treated...."? Lines 11-12: Change "appear" to "appears" -- the subject of the verb is "principal set." On lines 15-16, there is another problem of subject/verb agreement: Change the "is" to "are." It should read "statutory modification and regulatory clarification ARE desirable." Line 31 (continuing onto the next page) -- something is missing about the context. I don't know what's been dropped, but one possible way to handle this would be the following: "NIH has indicated that once it has developed special guidelines, it will fund suitable...."

Chapter 4.

Given the other editorial problems I spotted elsewhere, I was pleasantly surprised that, as far as I could determine, Chapter 4 is in fairly good shape.

P. 2, line 10. Delete "latter". Not needed and confusing.

P. 3, lines 2-7. This paragraph breaks the flow here. It brings back into this section a position that was already articulated toward the beginning of the previous paragraph. The best way to handle it is to put it in the next section following the heading ASSOCIATION WITH ABORTION. Here it could be revised and incorporate the next paragraph. It would then read: "Opponents of the research use of fetal materials obtained from elective abortions dispute the claim that it is possible to separate the moral issues surrounding the abortion from those involving in obtaining and using fetal material. They argue that those who obtain and use fetal material from elective abortion inevitably become associated, in ethically unacceptable ways, with the abortions that are the source of the material. They identify two major types of unacceptable association or cooperation with abortion: 1) causal responsibility for abortions, and 2) symbolic association with abortions."

P. 5, line 16. insert "direct" before "causal responsibility"

P. 6, lines 18-22, remove outside quotation marks from this quotation.

P. 7, line 11. Change "have been raised" to "have arisen"

P. 9, lines 28-30. This sentence doesn't work well. One possibility is to delete "a distinction in". Another possibility is to revise it this way: "However, whether this similarity is decisive depends hinges on one's perception of the moral status of embryos."

P. 10, line 6. Perhaps change "require" to "claim"

P. 10, lines 10-11. "...the embryos is a mere cluster of cells that has no more moral status than any other human cells." In this case, the editor is referring to "cells" rather than "cluster" -- see the rest of the sentence -- and thus "has" should be changed to "have". "has" could be retained if the end of the sentence were changed to "no more moral status than any

other collection of human cells."

P. 10, line 32. Delete "interpreting" This is a terrible addition and is unnecessary.

P. 14, lines 5-6. Change "to be" to "as" -- we "regard" something "as"

P. 16, line 12. Please check the original to see if "offer" should be "offers" -- the subject of this verb is "new research"

P. 17, line 21. "additonal" is misplaced. Revise the first part of this sentence: "Sixth, it is important to develop and widely disseminate additional professional standards of practice...."

P. 18, line 18. Change dash to comma -- otherwise the sentence makes no sense whatsoever.

Line 19. I thought we had, following Tom M's suggestion, removed the language of "the lesser of two evils".

P. 21, line 27. Change "Experts and other interested parties" to "Various parties"
Who are "experts" on this topic? It would be possible to change "experts" to "ethicists", but I think "various parties" works better.

P. 22, lines 17-18. The sentence beginning "It is important...." breaks the flow and is unnecessary. Delete.

P. 22, lines 25-26. Change "treating the embryo as a mere thing to be used without regard to its origins" to "treating the embryo as a mere thing"

CHAPTER 5.

Pp. 18-20. Despite earlier suggestions, including some I made, this section remains a bit messy, partly because some material precedes while most material follows the recommendation. The first sentence in this section on p. 18 reads "Existing rules prohibit the practice of designated donation, the provision of monetary inducements too women undergoing abortion, and the pruchase or sale of fetal tissue." This sentence is virtually identical to the first sentence that follows the recommendation.

The whole section needs to be integrated better -- I doubt that, unfortunately, there is still time to do so, but if there is I'd be glad to try my hand at it, building on earlier suggestions.

Comments re Appendix on religious perspectives.

Eric and Kathi, please fax a copy of page 2 -- it was missing from my materials. I'm faxing a copy of the pages on which a few additional changes need to be made in this summary.

First, along the way the language of ES and EG cell research was introduced

into this summary -- as I recall it did not appear in the original. Even though its introduction was ok, it is not used consistently. Often when both are encompassed in the discussion (because both the cadaveric fetus and the left-over embryo are being discussed), the language of ES cell research is used. In those cases we should simply say stem cell research or, occasionally, insert EG. I have tried to catch and correct those instances.

I have marked several other minor errors or places where modest changes would be appropriate, and I'll fax those pages to the NBAC office.

James F. Childress
Kyle Professor of Religious Studies &
Professor of Medical Education
University of Virginia
Cocke Hall
Charlottesville, VA 22903
Tel. (804) 924-3741
Fax (804) 924-1467
e-mail: jfc7c@virginia.edu

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 14:57:59.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Thanks very much Tom. I appreciate your quick response. If there are other items, let us know.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: Thomas Murray [SMTP:murrayt@thehastingscenter.org]
Sent: Friday, September 03, 1999 2:56 PM
To: NBAC Members E-list
Subject: RE: stem cell report

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at
page 19, line 17. The remaining text is more a chiding argument than it
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Tom

-----Original Message-----

From: owner-nbac-members@lists.Princeton.EDU
[mailto:owner-nbac-members@lists.Princeton.EDU]On Behalf Of Larry Miike
Sent: Thursday, September 02, 1999 3:42 PM
To: NBAC Members E-list
Subject: stem cell report

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Larry

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 14:35:19.00

SUBJECT: Comments on Stem Cell?

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Commissioners--

Several of you have already offered you suggested edits on the stem cell report.
I wanted to emphasize that we must have your comments as soon as possible.
While
yesterday was our requested deadline, anything you have must be in our hands
today. Harold has arranged to deliver the report to the White House on Tuesday.
Staff will spend the weekend (not all of it, hopefully) working with Harold to
review and incorporate those that are non-controversial. If, in Harold's judgment, some of the suggestions are more than stylistic, he or I will contact
you to discuss.

I realize we gave you a tight deadline, but hope you are able to let us know
whether we should be expecting something from you today or not.

Thanks very much.

Eric

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Kathi E. Hanna" <khanna@chesapeake.net> ("Kathi E. Hanna" <khanna@chesapeake.net> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 16:52:20.00

SUBJECT: Re: Stem Cell Report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

Eric:

>From the big picture to the apostrophe, thanks for your comments.

Kathi

----- Original Message -----

From: ecassell <ecassell@email.msn.com>

To: NBAC Members E-list <nbac-members@lists.Princeton.EDU>

Sent: Friday, September 03, 1999 3:58 PM

Subject: Stem Cell Report

> I have not had time to read the entire report in depth. However, as I
> review it as a whole, and particularly Chapter 4 and 5, I am pleased to
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> opinions, yet it makes a good case not only for the recommendations, but
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> A agree with Jim Childress that thorough proofreading is very important.
> The writers, editors, and other work-through-the weekend heroes do not
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> another point by point commentary, however, please remove the apostrophe
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> Eric Cassell
>
>
>
>

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 16:08:05.00

SUBJECT: RE: Stem Cell Report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Thanks very much Eric C.

Eric M.

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
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-----Original Message-----

From: ecassell [SMTP:ecassell@email.msn.com]
Sent: Friday, September 03, 1999 3:58 PM
To: NBAC Members E-list
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Eric Cassell

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: ecassell <ecassell@email.msn.com> (ecassell <ecassell@email.msn.com> [UNKNOWN])

CREATION DATE/TIME: 3-SEP-1999 16:05:01.00

SUBJECT: Stem Cell Report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

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Eric Cassell

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Arturo Brito <abrito@peds.med.miami.edu> (Arturo Brito <abrito@peds.med.miami.edu> [UNKNOWN])

CREATION DATE/TIME: 4-SEP-1999 12:59:50.00

SUBJECT: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:

- att1.htm===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

<html>

Fellow commissioners,

It appears that some of you have expressed concerns that I have not made recent comments about some my earlier anxieties. While I appreciate your thoughtfulness, I feel that many of the issues causing my "sleeplessness" have been adequately dealt with in our revisions of this document. A recent article in the American Medical News very well delineates my struggles with this topic and my satisfaction with (what will be) our end product. In spite of the impressions given at the meetings, I do not feel that my opinions are extreme enough to warrant a separate statement. It would only detract from the body of the paper and would potentially have a negative impact on future research in this area. The deliberative process helped me a great deal to work through some of my concerns. The turning point for me was the meeting at Riggs Hall with the theologians. The disagreement among and within religious leaders made it quite clear to me that we must compromise on this issue as we have. As a Pediatrician, I always put myself in the place of the caretaker and wonder if I would do things differently if it were<i> my

</i>child. Well, I have thought carefully about this: If a loved one of mine were to need a potentially life-saving product that was derived from ES or EG cells that had come from a spare IVF embryo or cadaveric fetal tissue, would I question it? Absolutely not. As long as we maintain respect for the human embryo and have adequate public oversight, I am in agreement with our current conclusions and recommendations.

Specific recommendations:

1) I agree with Bette regarding the use of the phrase,"form of human life." A suggestion for Chapter 1, p. 3 Lines 24-26:

' We believe that most Americans agree that human embryos deserve respect. But, we also recognize that disagreement exists both about the form that such respect should take and about what level of protection is owed at different stages of embryonic development.'

2) The sentence in Chapter 4, p. 1, lines 12-14:

Do we not need to qualify the statement "culture human ES and EG cells" with "completely" (ie., "culture completely human ES and EG cells.")? Hybrid cells contain human material.

3) I agree with earlier comments made by Larry about the summary in Chapter 3.

4) Chapter 5, p. 2., lines 19- 28: I think that it would be prudent to use the word 'alternative' somewhere in this paragraph. While it is implied that we have given careful consideration to the future use of alternative, we need to be blunt.

5) Chapter 2:

p.3, line 15: Define AS cells to be consistent with definitions of ES and EC cells earlier in the same paragraph;

p.3, line 17: delete 'exciting', it takes away from the objectivity;

p. 4, line 1: consistent with Bette's concerns (see rec. #1), I would change the phrase " are destined for death" to, "lack this capability."

Thanks,

Arturo

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

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 5-SEP-1999 12:30:45.00

SUBJECT: RE: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
Thanks Jim....

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

-----Original Message-----

From: James F. Childress [SMTP:jfc7c@virginia.edu]
Sent: Sunday, September 05, 1999 12:20 PM
To: NBAC Members E-list
Subject: Re: stem cell report

Colleagues,

We're all grateful to the "Labor Day" group -- Eric, Kathi, Harold (I'm sure), and any others who may be involved, for bringing this task to its end.

Also thanks very much to Arturo for his personal reflections -- his concerns have been important to us during this whole process, and I'm pleased with his response.

And many thanks to Alex, as usual, for his most helpful proposals. I strongly agree with Alex's suggestion re Dworkin -- I think it strengthens a section about which several of us have had some reservations. He also has a great proposal to avoid the ticklish problem that might be created

by

p. 25, lines 17-23.

Let me propose a way to deal Alex's concerns about p. 20, lines 22-26.

As

I understand it, the sentence refers to the possible charge of inconsistency between affirming the legal analysis offered by HHS and offering a different moral analysis. Hence, I'd propose the following, starting on line 22:

"However, because our [changing "this" to "our"] report focuses on the ethical issues involved in human ES and EG cell research, we find that there is no inconsistency between accepting this legal analysis and, at the same time, concluding that [continue with the rest of this sentence].

[Then change the next sentence to the active voice] We examine the ethical arguments for and against funding both derivation and use after we consider another possible source of stem cells -- embryos that are created solely for research."

Finally, regarding the matter Tom and I had discussed in email re Chap. 4.

19, lines 15-16. We might change it to read: "Some commentators hold that it would be ethically justifiable, though regrettable, to use existing cell lines that were derived through unethical embryo destruction. A version...[then into Demopolos's statements]"

Also on p. 16, lines 25-26. We might consider either of the following to

improve the flow: "Yet in response...." OR "...Demopolos further stated:"

James F. Childress
Kyle Professor of Religious Studies &
Professor of Medical Education

University of Virginia
Cocke Hall
Charlottesville, VA 22903
Tel. (804) 924-3741
Fax (804) 924-1467
e-mail: jfc7c@virginia.edu

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "James F. Childress" <jfc7c@virginia.edu> ("James F. Childress" <jfc7c@virginia.edu> [UNKNOWN])

CREATION DATE/TIME: 5-SEP-1999 12:24:34.00

SUBJECT: Re: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
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We're all grateful to the "Labor Day" group -- Eric, Kathi, Harold (I'm sure), and any others who may be involved, for bringing this task to its end.

Also thanks very much to Arturo for his personal reflections -- his concerns have been important to us during this whole process, and I'm pleased with his response.

And many thanks to Alex, as usual, for his most helpful proposals. I strongly agree with Alex's suggestion re Dworkin -- I think it strengthens a section about which several of us have had some reservations. He also has a great proposal to avoid the ticklish problem that might be created by p. 25, lines 17-23.

Let me propose a way to deal Alex's concerns about p. 20, lines 22-26. As I understand it, the sentence refers to the possible charge of inconsistency between affirming the legal analysis offered by HHS and offering a different moral analysis. Hence, I'd propose the following, starting on line 22:

"However, because our [changing "this" to "our"] report focuses on the ethical issues involved in human ES and EG cell research, we find that there is no inconsistency between accepting this legal analysis and, at the same time, concluding that [continue with the rest of this sentence]. [Then change the next sentence to the active voice] We examine the ethical arguments for and against funding both derivation and use after we consider another possible source of stem cells -- embryos that are created solely for research."

Finally, regarding the matter Tom and I had discussed in email re Chap. 4. 19, lines 15-16. We might change it to read: "Some commentators hold that it would be ethically justifiable, though regrettable, to use existing cell lines that were derived through unethical embryo destruction. A version...[then into Demopolis's statements]"

Also on p. 16, lines 25-26. We might consider either of the following to improve the flow: "Yet in response...." OR "...Demopolis further

stated:"

James F. Childress
Kyle Professor of Religious Studies &
Professor of Medical Education
University of Virginia
Cocke Hall
Charlottesville, VA 22903
Tel. (804) 924-3741
Fax (804) 924-1467
e-mail: jfc7c@virginia.edu

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Meslin, Eric (OD)" <MeslinE@od.nih.gov> ("Meslin, Eric (OD)" <MeslinE@od.nih.gov> [UNKNOWN])

CREATION DATE/TIME: 5-SEP-1999 12:28:36.00

SUBJECT: A MEMO FROM HAROLD

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
<<xCommissioners_.doc>>

Commissioners, et al:

Harold has asked me to send this note on his behalf. I'm also including it in the body of the email below in the event that the attachment can't be opened.

Eric

Eric M. Meslin, Ph.D
Executive Director
National Bioethics Advisory Commission
6100 Executive Blvd. Suite 5B01
Rockville, Maryland 20892-7508
Tel: (301) 402-4242
Fax: (301) 480-6900
Email: MeslinE@OD.NIH.GOV
<http://www.bioethics.gov>

Commissioners:

I want to thank many of you for providing such a careful review of the stem cell draft that was sent out last week. I have discussed each of the proposed changes with Eric and Kathi. The vast majority of suggested changes were excellent and will be made. There are, however, a few items on which there was disagreement that involved not simply stylistic concerns but substantive ones. I want to let you know what I have decided.

1. The phrase "a form of human life" which appears in Chapters, I,

4 and 5.

Both Bette and Arturo indicated concern about this phrase. I understand this concern, but in my view, the phrase does not undermine the commission's arguments. Moreover, since it has been in the draft for some time, I would like it to remain.

2. The applicability of the human subjects federal regulations to ES and EG research. Alex has requested that pg 13 lines, 7-15 in Chapter 3 be deleted since he believes that the regulations do apply. I, on the other hand, would like to retain this text. It indicates, relying on correspondence from OPRR, that there is some question as to whether the Common Rule and/or Subpart B, apply to the research we discuss in this report. Moreover, the additional legal analysis by Ellen Flannery highlights what I believe to be the uncertainty within this area of regulation. I do not think that the report and any of its recommendations are undermined by acknowledging that there is no definitive view on this.

3. The text at the end of Chapter 3. (Page 19, line 18 to the end of the chapter on pg 20). Larry, Alex, Tom and Jim have offered views on this. I would like to strike the text. In addition I do not think, as Alex have suggested, that it should be inserted in Chapter 4. I recognize that Alex and perhaps others may still feel this language is important. If so, it might be best for this view to appear in a personal statement.

The report will be delivered to the White House on Tuesday, and it is possible that we will release it on our website later this week or early next week. Once we have heard from the White House about next steps, I or Eric will let you know.

Again, let me thank you for your dedicated and thoughtful attention to this material.

-- Harold

- xCommissioners_.doc===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

Unable to convert ARMS_EXT:[ATTACH.D99]ARMS20806294O.236 to ASCII,

The following is a HEX DUMP:

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

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-- Harold

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Alex Capron <acapron@law.usc.edu> (Alex Capron <acapron@law.usc.edu> [UNKNOWN])

CREATION DATE/TIME: 6-SEP-1999 20:19:11.00

SUBJECT: Re: stem cell report

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Among the things in Jim's message was:

Let me propose a way to deal Alex's concerns about p. 20, lines 22-26. As I understand it, the sentence refers to the possible charge of inconsistency between affirming the legal analysis offered by HHS and offering a different moral analysis. Hence, I'd propose the following, starting on line 22:

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This at least makes the meaning clear and I think I can live with it.

Thanks, Jim for that as well as for the many other helpful editorial suggestions. And thanks to for those who labored over the weekend. And glad to know that there will be further proofreading, Kathi.

Alex

* Alexander M. Capron acapron@law.usc.edu *
* Henry W. Bruce Professor of Law (213) 740-2557 (voice) *
* University Professor of Law and Medicine (213) 740-5502 (fax) *
* University of Southern California (213) 740-0149 (fax) *
* Los Angeles, CA 90089-0071 *

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Alex Capron <acapron@law.usc.edu> (Alex Capron <acapron@law.usc.edu> [UNKNOWN])

CREATION DATE/TIME: 6-SEP-1999 20:32:31.00

SUBJECT: Re: A MEMO FROM HAROLD

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])

READ:UNKNOWN

TEXT:

Thanks for this information on the finalization of the report. I am not clear when the editorial work that Kathi mentioned will be done if the report is going to the White House tomorrow.

Since Harold has decided to reject the inclusion in the text of chapter four the language that I suggested for transfer from Ch. 3, with the additions/editing that I suggested, I will take him up on his suggestion and request that at the appropriate place in Ch. 4 (I'm sure the pagination has changed--what I have in mind is the end of the paragraph on line 17 of page 29 of Ch. 4) a footnote be dropped (on the same page, as in the HBM report) which would open: "Commissioner Capron notes that as described..." leading into the paragraph I had proposed; this would be followed by the text of what I had proposed would be a footnote {now must be text, because this is already a footnote}, followed by what had been the last paragraph of Ch. 3 (p. 19, ll. 26-31 and p. 20, ll. 1-20).

Thank you.

Alex

On Sun, 5 Sep 1999, Meslin, Eric (OD) wrote:

> <<xCommissioners_.doc>>

>

> Commissioners, et al:

>

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>

> Eric

>

> Eric M. Meslin, Ph.D

> Executive Director

> National Bioethics Advisory Commission

> 6100 Executive Blvd. Suite 5B01

> Rockville, Maryland 20892-7508

> Tel: (301) 402-4242

> Fax: (301) 480-6900

> Email: MeslinE@OD.NIH.GOV

> <http://www.bioethics.gov>

>

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> *****

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> Commissioners:

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>