

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

December 2, 1994

Statement by the President

The Director of the National Institutes of Health has received a recommendation regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions as well as issues concerning the appropriate allocation of federal funds. I appreciate the work of the committees that have considered this complex issue and I understand that advances in in vitro fertilization research and other areas could derive from such work. However, I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research. In order to ensure that advice on complex bioethical issues that affect our society can continue to be developed, we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

-30-30-30-

DRAFT

POSSIBLE STATEMENTS BY THE PRESIDENT REGARDING FEDERAL FUNDING
OF HUMAN EMBRYO RESEARCH

POTUS

1. Presidential directive to NIH

~~I understand that~~ the Director of the National Institutes of Health has received a report regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions, as well as ~~issues concerning the appropriate~~ ^{stet} allocation of federal funds. I ~~am~~ ^{am} appreciative of the hard work of the committees ~~who~~ ^{which} have considered this complex issue ~~and I understand that advances in in vitro~~ ^{stet} fertilization research and other areas could derive from such work. However, I ~~have~~ ^{believe} ~~concluded and will direct NIH that no federal funds should be spent to support~~ ^{for} the creation of human embryos for research purposes. In order to insure that continued advice on complex bioethical issues that affect our society can continue to be developed, we are planning to ~~move forward with the establishment~~ of a National Bioethics Advisory Commission over the next year.

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NIH
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~~NIH~~
I do not
believe fed funds
shd ~~not~~ ^{be} ~~used~~ ^{used} for these
purposes
I have directed
NIH

POSSIBLE STATEMENTS BY THE PRESIDENT REGARDING FEDERAL FUNDING
OF HUMAN EMBRYO RESEARCH

1. Presidential directive to NIH

~~I understand that~~ ⁽¹⁾ The Director of the National Institutes of Health has received a report regarding federal funding of research on human embryos. ~~The subject raises profound ethical and moral questions, as well as issues concerning the appropriate allocation of federal funds.~~ ^{(2) THIS}

~~I am appreciative of the hard work of the committees who have considered this complex issue, and I understand that advances in in vitro fertilization research and other areas, could derive from such work. However, I have concluded and will direct NIH that no federal funds should be spent to support the creation of human embryos for research purposes. In order to insure that we can~~
^{CONTINUE TO DEVELOP} continued advice on complex bioethical issues ~~that affect our society can continue to be developed,~~ ^{I have today} we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

2. Presidential support for NIH decision

I agree with the National Institutes of Health's decision not to support federal funding for the creation of human embryos for research purposes.

⁽³⁾ I have directed today that the ~~NIH~~ NIH should not spend any federal dollars to support the creation of human embryos for research purposes. **[I believe it's wrong.]**

⁽⁴⁾ I appreciate

Marcy Greenwood
OSTP

The Director of the National Institute of Health has received a report regarding federal funding of research on human embryos. This subject raises profound ethical and moral questions. I have directed today that the NIH should not spend any federal dollars to support the creation of human embryos for research purposes. I believe it's wrong. I appreciate the hard work of the committees who have considered this issues. To insure that we can continue to receive advice on complex bioethical issues affecting our society, we plan to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

THE WHITE HOUSE

WASHINGTON

November 21, 1994

MEMORANDUM FOR LEON PANETTA

THROUGH: HAROLD ICKES

FROM: JOEL KLEIN
JACK GIBBONS

CC: BILL GALSTON
GEORGE STEPHANOPOULOS

SUBJECT: Federal Funding for Human Embryo Research

The National Institutes of Health is currently considering whether to engage in federal funding for embryo research. The issue has attracted considerable public attention. The decision is likely to be controversial.

BACKGROUND

1. The research at issue involves the preimplantation human embryo, which exists from the time of fertilization until approximately 14 days later. This research is important to advances in fertility treatments, contraception, and treatment of certain cancers and genetic illnesses. Research may involve byproduct embryos (extra embryos created by *in vitro* fertilization for reproductive purposes) or created embryos (embryos created solely for research purposes).

2. Reagan/Bush Administrations -- The Reagan and Bush Administrations refused to fund *in vitro* fertilization research (which encompasses embryo research).

3. Clinton Administration -- In June 1993, Congress, with bipartisan support, nullified regulatory barriers to *in vitro* fertilization research. NIH Director Harold Varmus responded by convening an ad hoc advisory panel to make recommendations regarding federal funding of embryo research. The panel is made up of highly respected scientists, academics, and ethicists. On September 29, 1994, after holding six public hearings throughout the year, the advisory panel recommended (1) that certain categories of embryo research be permitted, (2) that certain categories of embryo research warrant further consideration, and (3) that certain categories of embryo research not be permitted. The advisory panel emphasized that embryo research could lead to dramatic progress in research on various diseases and fertility

problems. The report recommends strict conditions for research and deems acceptable some research on both byproduct embryos and created embryos.

On December 1, 1994, the NIH Director's standing Advisory Committee will make a public recommendation to the NIH Director about whether to accept the ad hoc panel's recommendations. Sometime thereafter, NIH Director Varmus will decide whether to develop guidelines needed for projects accepted for funding. The Advisory Committee is likely to support the panel's recommendations. NIH Director Varmus and Secretary Shalala have indicated they support the panel's findings.

4. Analogous Research -- Although there has been no federal funding of embryo research, such research is proceeding in the private sector, at private clinics and universities.

According to NIH, 10 States ban some type of embryo research, and 22 States ban payment for embryos. (The NIH outside advisory panel recommends prohibiting payment for embryos in federally funded research, except reimbursement for expenses incurred in the donation process). In addition, the law on embryo research in 11 other Western democracies varies: "One country (Norway) prohibits all research with embryos, six (Australia, Austria, Denmark, France, Germany, and Switzerland) allow very limited research, and four (Canada, Spain, Sweden, and the United Kingdom) permit a range of research on embryos." NIH Backgrounder, pp. 6-7.

Additionally, health and science constituencies find fetal tissue research to be analogous to human embryo research. The Reagan/Bush Administrations banned fetal tissue research. In January, 1993, the President directed Secretary Shalala to lift that ban.

5. Public Reaction (to Date) to Ad Hoc Panel's Report -- Congress. Approximately thirty House members, led by Representative Dornan and including Representative Gingrich, have written to NIH vigorously opposing and promising to use all means to block any federal funding for embryo research.

Media. Newspaper editorial positions representing a range of views have appeared. The Chicago Sun-Times opposed all federal funding. The Washington Post opposed federal funding for research on created embryos. The Nashville Tennessean supported the advisory panel's findings and recommendations. (The Washington Post is not expected to write another editorial until after it meets with NIH Director Varmus).

THE CURRENT ISSUE

If the NIH Director's Advisory Committee recommends accepting the ad hoc panel's report, which is likely, NIH Director Varmus intends to wait until after the holidays to announce his decision. Assuming he accepts the ad hoc panel's report, an extended public process of developing and approving research guidelines would precede any actual research funding. Nevertheless, press and congressional inquiries about the Administration's intentions will likely begin on or about December 1.

Options for White House reaction include:

- (1) Support the NIH process and defer all other comment.
NIH will likely proceed with development of research guidelines.
 - **Advantages:** Defers to the judgment of an impressive panel. Does not foreclose benefits from embryo research. Keeps politics somewhat removed from science. Allows potential bipartisan support to emerge as it has on similar issues in the past. Could be viewed as family values issue because will enable infertile couples to reproduce and can lead to major advances in cancer and disease research.
 - **Disadvantages:** It is likely there will be controversial congressional hearings, and ultimately, we may lose the issue if Congress passes a statute to ban funding this research. As the reactions to the panel report suggest, there may be strong public criticism of NIH's decision on moral and ethical grounds.
- (2) Instruct the NIH Director to go forward with development of guidelines for federal funding of research on byproduct embryos, but ban consideration of federal funding of research on created embryos.
 - **Advantages:** Does not foreclose the possibility of federal funding of research on byproduct embryos, which promises significant research benefits in numerous areas, but removes a controversial issue from the discussion. Congressional hearings could potentially educate the public on this issue.
 - **Disadvantages:** Benefits from federally funded research on created embryos would be lost, which especially affects research in the area of infertility and contraception and new advances for leukemia treatment and organ transplantation research (which infertile couples, women's health and other health advocates

might oppose). Draws focus to the White House and heightens politicization of the issue. In addition, the issue of federal funds for research on byproduct embryos may remain controversial (with opponents objecting that embryos are kept alive for a longer period solely for research purposes). Contentious congressional hearings may occur, the public could ultimately be confused by the issue, and Congress might still overrule our position and ban all research.

(3) Instruct the NIH Director not to fund any human embryo research.

- **Advantages:** Avoids a possible congressional defeat, as well as controversial congressional hearings. Decision could be shaped as either a concern for an issue the NIH has recognized to raise moral/ethical concerns, or as a budgetary prioritization.
- **Disadvantages:** The benefits from federal funding of embryo research would be lost. These include potential benefits from research into cancer, birth defects, and other diseases as well as fertility and contraception. The scientific community and women's health community will react negatively. And the Administration might be accused of flip-flopping on the course set by the decision on fetal tissue transplantation research and caving in to pressure from pro-life groups and the religious right.

Draft 3

November 21, 1994

MEMORANDUM FOR LEON PANETTA

THROUGH: HAROLD ICKES

FROM: JOEL KLEIN
JACK GIBBONS

CC: BILL GALSTON
GEORGE STEPHANOPOULOS

SUBJECT: Federal Funding for Human Embryo Research

The National Institutes of Health is currently considering whether to engage in federal funding for embryo research. The issue has attracted considerable public attention. The decision is likely to be controversial.

BACKGROUND

1. The research at issue involves the preimplantation human embryo, which exists from the time of fertilization until approximately 14 days later. This research is important to advances in fertility treatments, contraception, and treatment of certain cancers and genetic illnesses. Research may involve byproduct embryos (extra embryos created by *in vitro* fertilization for reproductive purposes) or created embryos (embryos created solely for research purposes).

2. Reagan/Bush Administrations -- The Reagan and Bush Administrations refused to fund *in vitro* fertilization research (which encompasses embryo research).

3. Clinton Administration -- In June 1993, Congress, with bipartisan support, nullified regulatory barriers to *in vitro* fertilization research. NIH Director Harold Varmus responded by convening an ad hoc advisory panel to make recommendations regarding federal funding of embryo research. The panel is made up of highly respected scientists, academics, and ethicists. On September 29, 1994, after holding six public hearings throughout the year, the advisory panel recommended (1) that certain categories of embryo research be permitted, (2) that certain categories of embryo research warrant further consideration, and (3) that

certain categories of embryo research not be permitted. The advisory panel emphasized that embryo research could lead to dramatic progress in research on various diseases and fertility problems. The report recommends strict conditions for research and deems acceptable some research on both byproduct embryos and created embryos.

On December 1, 1994, the NIH Director's standing Advisory Committee, will make a public recommendation to the NIH Director about whether to accept the ad hoc panel's recommendations. Sometime thereafter, NIH Director Varmus will decide whether to develop guidelines needed for projects accepted for funding. The Advisory Committee is likely to support the panel's recommendations. NIH Director Varmus and Secretary Shalala have indicated they support the panel's findings.

4. Analogous Research -- Although there has been no federal funding of embryo research, such research is proceeding in the private sector, at private clinics and universities.

According to NIH, 10 States ban some type of embryo research, and 22 States ban payment for embryos. (The NIH outside advisory panel recommends prohibiting payment for embryos in federally funded research, except reimbursement for expenses incurred in the donation process). In addition, the law on embryo research in 11 other Western democracies varies: "One country (Norway) prohibits all research with embryos, six (Australia, Austria, Denmark, France, Germany, and Switzerland) allow very limited research, and four (Canada, Spain, Sweden, and the United Kingdom) permit a range of research on embryos." NIH Backgrounder, pp. 6-7.

Additionally, health and science constituencies find fetal tissue research to be analogous to human embryo research. The Reagan/Bush Administrations banned fetal tissue research. In January, 1993, the President directed Secretary Shalala to lift that ban.

5. Public Reaction (to Date) to Ad Hoc Panel's Report --

Congress. Approximately thirty House member, led by Representative Dornan and including Representative Gingrich, have written to NIH vigorously opposing and promising to use all means to block any federal funding for embryo research.

Media. Newspaper editorial positions representing a range of views have appeared. The Chicago Sun-Times opposed all federal funding. The Washington Post opposed federal funding for research on created embryos. The Nashville Tennessean supported the advisory panel's findings and recommendations. (The Washington Post editorial board has agreed to meet with NIH Director Varmus after his Advisory Committee meeting and will not write another editorial before then.)

THE CURRENT ISSUE

nevertheless

If the NIH Director's Advisory Committee recommends acceptable of the ad hoc panel's report, which is likely, NIH Director Varmus intends to wait until after the holidays to announce his decision. Assuming he accepts the ad hoc panel's report, an extended public process of developing and approving research guidelines would precede any actual research funding. ~~However~~, press and congressional inquiries about the Administration's intentions will likely begin on or about December 1. Options for White House reaction include:

- (1) Support the NIH process and defer all other comment. NIH will likely proceed with development of research guidelines.
 - **Advantages:** Defers to the judgment of ~~a diverse~~ ^{an impressive} panel. Does not foreclose benefits from embryo research. Keeps politics somewhat removed from science. Allows potential bipartisan support to emerge as it has on this issue in the past. Could be viewed as family values issue because will enable infertile couples to reproduce and can lead to major advances in cancer and disease research.
 - **Disadvantages:** It is likely there will be controversial congressional hearings, and ultimately, we may lose the issue if Congress passes a statute to ban funding this research. *Public criticism.*
- (2) Instruct the NIH Director to go forward with development of guidelines for federal funding of research on byproduct embryos, but ban consideration of federal funding of research on created embryos.
 - **Advantages:** Does not foreclose the possibility of federal funding of research on byproduct embryos, which promises significant research benefits in numerous areas, but removes the most controversial issue from the discussion. Congressional hearings could potentially educate the public on this issue.
 - **Disadvantages:** Benefits from federally funded research on created embryos would be lost, which especially affects research in the area of infertility and contraception (which infertile couples, women's health and other health advocates might oppose). Draws focus to the White House and heightens politicization of the issue. In addition, the issue of federal funds for research on byproduct embryos may remain controversial (with opponents objecting that embryos are kept alive for a longer period solely for research purposes). Contentious congressional hearings may occur, the public could ultimately be confused by the issue, and Congress might still overrule our position and ban all research.

(3) Instruct the NIH Director not to fund any human embryo research.

- **Advantages:** Avoids a possible congressional defeat, as well as controversial congressional hearings. Decision could be shaped as either a concern for an issue the NIH has recognized to raise moral/ethical concerns, or as a budgetary prioritization.
- **Disadvantages:** The benefits from federal funding of embryo research would be lost. These include potential benefits from research into cancer, birth defects, and other diseases as well as fertility and contraception. The scientific community and women's health community may react negatively. And the Administration might be accused of flip-flopping on the course set by the decision on fetal tissue transplantation research and caving into pressure from pro-life groups and the religious right.

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WHY SO FAR DOWN
↓

November 21, 1994

↓ WHY SOMEWHERE
SPACES?

MEMORANDUM FOR LEON PANETTA

THROUGH: HAROLD ICKES

FROM: JOEL KLEIN
JACK GIBBONS

CC: BILL GALSTON
GEORGE STEPHANOPOULOS

SUBJECT: Federal Funding for Human Embryo Research

The National Institutes of Health is currently considering whether to engage in federal funding for embryo research. The issue has attracted considerable public attention. The decision is likely to be controversial.

BACKGROUND

1. The research at issue involves the preimplantation human embryo, which exists from the time of fertilization until approximately 14 days later. The research is ~~fundamentally~~ important to advances in fertility treatments, contraception, and treatment of certain cancers and genetic illnesses. Research may involve byproduct embryos (embryos created by in vitro fertilization clinics for implantation) or created embryos (embryos created solely for research purposes).

2. Reagan/Bush Administrations -- The Reagan and Bush Administrations refused to fund in vitro fertilization research (which encompasses embryo research), ~~or fetal tissue transplantation research.~~

3. Clinton Administration -- ~~In January 1993 President Clinton directed Secretary Shalala to lift the moratorium on fetal tissue transplantation research.~~ In June 1993, Congress eliminated the legislative barriers to in vitro fertilization research. Both actions received bipartisan support. ~~GEORGE~~

↓ The
nullified a regulation which had been an obstacle to

NIH Director Harold Varmus responded by convening an ad hoc advisory panel to make recommendations regarding federal funding of embryo research. The panel is made up of highly respected scientists, academics, and ethicists. On September 29, 1994, after holding six public hearings throughout the year, the advisory panel recommended (1) that certain categories of embryo research be permitted, (2) that certain categories of embryo research warrant further consideration, and (3) that certain categories of embryo research not be permitted. The advisory panel emphasized that embryo research could lead to dramatic progress in research on various diseases and fertility problems. ~~(See #1, above?)~~ The report recommends strict conditions for research and deems some research on both byproduct embryos and created embryos acceptable.

On December 1, 1994, the NIH Director's standing Advisory Committee, will make a public recommendation to the NIH Director about whether to accept the ad hoc panel's recommendations. Sometime thereafter, NIH Director Varmus will decide whether to proceed with development of research guidelines that must precede funding. The Advisory Committee is likely to support the panel's recommendations. NIH Director Varmus and Secretary Shalala have indicated they support the panel's findings.

4. Private Sector -- Although there has been no federal funding of embryo research, such research is proceeding ~~unregulated~~ in the private sector, at private clinics and universities.

According to NIH, 10 States ban some type of embryo research, and 22 States ban payment for embryos. (The NIH outside advisory panel recommends prohibiting payment for embryos in federally funded research, except reimbursement for expenses incurred in the donation process). In addition, the law on embryo research in 11 other Western democracies varies: "One country (Norway) prohibits all research with embryos, six (Australia, Austria, Denmark, France, Germany, and Switzerland) allow very limited research, and four (Canada, Spain, Sweden, and the United Kingdom) permit a range of research on embryos." NIH Background, pp. 6-7.

A group of roughly thirty Congressmen

5. Public Reaction (to Date) to Ad Hoc Panel's Report -- Congress. ~~Members of the new House leadership~~, led by Representative Dornan and including Representative Gingrich, have written to NIH vigorously opposing and promising to use all means to block any federal funding for embryo research.

Media. Newspaper editorial positions representing a range of views have appeared. ~~The Chicago Sun-Times~~ opposed all federal funding. ~~[use quote if unconcerned about memo length]~~. The Washington Post opposed federal funding for research on created embryos. ~~[use quote, with same caveat]~~. The Nashville Tennessean

supported the advisory panel's findings and recommendations ~~[quote/caveat]~~. (The Washington Post editorial board has agreed to meet with NIH Director Varmus after his Advisory Committee meeting and will not write another editorial before then),

THE CURRENT ISSUE

The possibility of federal funding for embryo research is controversial. Criticism falls into two principal categories -- those who object to any federal funding of embryo research and those who object to federal funding of embryo research with respect to created embryos.

With regard to the first category, a group of roughly thirty Congressmen, led by Representative Dornan and including Newt Gingrich, have twice written to NIH vigorously opposing any federal funding of embryo research. Some press commentary has also opposed any federal funding of embryo research. (For example, the Chicago Sun-Times observed (10/10/94, "Not to defy the collective wisdom of a panel of more ethicists and scientists than you can count on your fingers, but they were simply wrong when they endorsed federally funded research on human embryos outside the womb.")

With regard to the second category, some observers have argued that the federal government should draw the line at funding the creation of embryos for research purposes. (For example, the Washington Post emphasized (10/2/94), "The creation of human embryos specifically for research that will destroy them is unconscionable. The government has no business funding it.")

Still other commentators support the advisory panel's recommendations on both points. (For example, the Nashville Tennessean concluded (10/8/94), "In all, the recommendations provide a sound and sensitive approach to a difficult issue. . . . Some detractors have vowed to get Congress to intervene. Former Presidents Reagan and Bush rejected embryo research on little more than noisy protests by anti-abortionists. . . . This isn't about destroying life, but about saving and savoring it. No one who claims to care about human life should object.")

If the NIH Director's Advisory Committee recommends acceptable of the ad hoc panel's report, NIH Director Varmus intends to wait until after the holidays to announce his decision. If he accepts the ad hoc panel's report, an extended public process of developing and approving research guidelines would have to precede any actual research funding. However, press and congressional inquiries about the Administration's intentions will likely begin on or about December 1. Options for White House reaction include:

- (1) Support the NIH process and defer all other comment.
NIH will likely proceed with development of research guidelines.

- **Advantages:** Defers to the judgment of ~~adverse~~ ^{an ~~adverse~~ ~~panel~~ ^{esteemed}} panel. Does not ^{foreclose} ~~foreclose~~ benefits from embryo research. ~~Sustains the President's commitment to "keep politics out of science" that was initiated with the decision on fetal tissue research.~~ Allows potential bipartisan support to emerge -- Senators Dole, Specter, Simpson, and Domenici, for instance, have been supporters of this type of research in the past. Sets the stage for capturing an important family values issue for the Administration since many infertile couples and families with cancer or genetic diseases view it in that manner.

- **Disadvantages:** It is likely there will be controversial congressional hearings, and ultimately, we may lose the issue if Congress passes a statute to ban funding this research.

- (2) Instruct the NIH Director to go forward with development of guidelines for federal funding of research on byproduct embryos, but ban consideration of federal funding of research on created embryos.

- **Advantages:** Does not foreclose the possibility of federal funding of research on byproduct embryos, which promises significant research benefits in numerous areas, but removes the most divisive issue from the controversy.

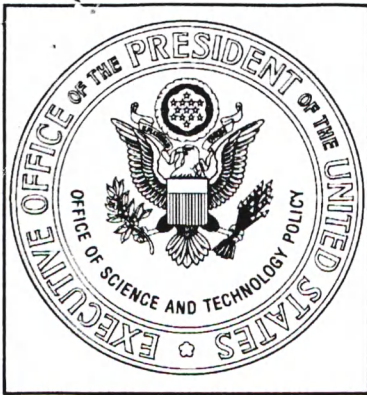
- **Disadvantages:** Benefits from federally funded research on created embryos would be lost, which especially affects research in the area of infertility and contraception (which infertile couples, women's health and other health advocates might oppose). Makes the President a lightning rod on this issue rather than leaving responsibility with Secretary Shalala and NIH Director Varmus. [Threatens existing bipartisan support by raising the political stakes into the White House.] In addition, the issue of federal funds for research on byproduct embryos may remain controversial. Contentious congressional hearings may occur and Congress might still overrule our position and ban all research. On the other hand, hearings would provide an opportunity educate.

(Among other points,
opponents may object that
byproduct embryos are kept alive
for a longer period solely for research purposes.)

(3) Instruct the NIH Director not to fund any human embryo research.

- **Advantages:** Avoids a possible congressional defeat.
- **Disadvantages:** The benefits from federal funding of embryo research would be lost. These include potential benefits from research into cancer, birth defects, and other diseases as well as fertility and contraception. The scientific community and women's health community may react negatively. ~~And the Administration might be accused of flip-flopping on the course set by the decision on fetal tissue transplantation research caving into pressure from pro-life groups and the religious right.~~

Depending on how the decision is framed,
it could be based on respect for what
NIH itself has recognized as ~~an~~ a matter
that "raises profound moral and
ethical concerns."



Date: 11/18/94
To: Cliff Sloan
From: Holly Gwin *HGwin*
Subject: Edits to the Klein/Gibbons memo

OSTP's markup of the draft memo is attached. If you would like help interpreting handwriting, please contact M.R.C. Greenwood. It is somewhat of a walk between markup and inserts, so if you would like it retyped, please contact Chris Clary. Both can be reached at 6-6138.

*Jennifer,
These were the changes from
OSTP. Will make changes
then let's discuss.*

Cliff Sloan/jc

*11/21
9:00am*

CC: JAG, MRC

DRAFT

November 18, 1994

MEMORANDUM FOR LEON PANETTA

THROUGH: HAROLD ICKES

FROM: JOEL KLEIN
JACK GIBBONS

CC: BILL GALSTON
GEORGE STEPHANOPOULOS

SUBJECT: Federal Funding for ^{Human} Embryo Research

The National Institutes of Health is currently considering whether to engage in federal funding for embryo research. The issue has attracted considerable public attention, and is likely to be controversial. ^{The discussion}

BACKGROUND - ~~see attachment for insert/mods~~

^{part 1}
2. Reagan/Bush Administrations -- ~~The Reagan and Bush Administrations imposed a de facto moratorium on federal funding for embryo research. A regulation required that HHS convene an "Ethics Advisory Board" before any embryo research could take place, and no such Board was ever convened during the Reagan and Bush Administrations. see attachment for substitute text~~

3. Clinton Administration -- ~~In June 1993, as part of the "NIH Revitalization Act," Congress nullified the Ethics Advisory Board regulation. see attachment for substitute text~~

NIH Director Harold Varmus responded by convening an ^{ad hoc} outside advisory panel to make recommendations regarding federal funding of embryo ~~experimentation~~ ^{research}. The panel is made up of highly respected scientists, academics, and ethicists. On September 29, 1994, after holding six public hearings throughout the year, the advisory panel recommended (1) that certain categories of embryo research be permitted, (2) that certain categories of embryo research warrant further consideration, and (3) that certain categories of embryo research not be permitted. The advisory panel emphasized that embryo research could lead to dramatic progress in research on various diseases and fertility problems. In broad terms, ~~research on embryos may be done on either byproduct embryos (extra embryos created in the course of the in vitro fertilization process) or created embryos (embryos created solely for research purposes).~~ Although the report ~~requires~~ ^{recommends} strict conditions for research on ~~created embryos~~, it ultimately ~~and~~ ^{acceptably} permits research on both byproduct embryos and created embryos.

^{standing}
On December 1, 1994, the NIH Director's Advisory Committee, will make a public recommendation to the NIH Director ~~on this about whether~~ ^{to go up the subject} and, sometime thereafter, NIH Director Varmus will decide ~~on federal standards for embryo research.~~ The Advisory

~~whether to proceed with research~~ ^{development of} guidelines that must precede funding for embryo research

Committee is likely to support the panel's recommendations, ~~as is~~
NIH Director Varmus ~~and Secretary Shalala have indicated by support~~
~~the panel's findings.~~

3. Private Sector -- Although there has been no federal funding of embryo research, such research is proceeding in the private sector, at private clinics and universities. ^{Convergent}

According to NIH, 10 States ban some type of embryo research, and 22 States ban payment for embryos. (The NIH outside advisory panel recommends prohibiting payment for embryos in federally funded research, except reimbursement for expenses incurred in the donation process). In addition, the law on embryo research in 11 other Western democracies varies: "One country (Norway) prohibits all research with embryos, six (Australia, Austria, Denmark, France, Germany, and Switzerland) allow very limited research, and four (Canada, Spain, Sweden, and the United Kingdom) permit a range of research on embryos." NIH Backgrounder, pp. 6-7.

Insert New #4
→ (see attachment)
THE CURRENT ISSUE

see attachment for new introduction
~~The possibility of federal funding for embryo research is controversial. Criticism falls into two principal categories -- those who object to any federal funding of embryo research and those who object to federal funding of embryo research with respect to created embryos.~~

With regard to the first category, a group of roughly thirty Congressmen, led by Representative Dornan and including Representative Gingrich, have twice written to NIH vigorously opposing proposals for federal funding of embryo research. Some press commentary has also opposed any federal funding of embryo research. (For example, the Chicago Sun-Times observed (10/10/94), "Not to defy the collective wisdom of a panel of more ethicists and scientists than you can count on your fingers, but they were simply wrong when they endorsed federally funded research on human embryos outside the womb").

With regard to the second category, some observers have argued that the federal government should draw the line at funding the creation of embryos for research purposes. (For example, a Washington Post editorial emphasized (10/2/94), "The creation of human embryos specifically for research that will destroy them is unconscionable. The government has no business funding it.")

Still other commentators support the advisory panel's recommendations across the board. (For example, the Nashville Tennessean concluded (10/8/94), "In all, the recommendations provide a sound and sensitive approach to a difficult issue. . . . Some detractors have vowed to get Congress to intervene. Former Presidents Reagan and Bush rejected embryo research on little more than noisy protests by anti-abortionists. . . . This

isn't about destroying life, but about saving and savoring it. No one who claims to care about human life should object.")

CURRENT OPTIONS

In light of the impending advisory committee recommendation on December 1, decisions need to be made about the White House's position.

~~The possible options are:~~

^{Support the} ~~(1) Defer to NIH about all decisions on this matter.~~ ^{process and defer all other comment} This NIH option will likely result in federal funding of research on ~~both created and byproducts of embryos~~ ^{proceed with development of research}

• **Advantages:** Defers to ^{the} scientific judgment ^{of a diverse panel} and allows ~~does not~~ ^{guideline} ~~for~~ full research benefits from embryo research. ^{As part from attachment}

• **Disadvantages:** It is likely there will be controversial congressional hearings, and ultimately, we may lose the issue if Congress passes a statute to ban funding this research.

~~(2) Postpone a decision about White House involvement until after the Advisory Committee makes its recommendation on December 1.~~

• **Advantages:** Permits the NIH process to proceed and preserves White House options.

• **Disadvantages:** The Advisory Committee's likely public agreement with the outside advisory panel probably will add to the public controversy about this research. Since the Committee will announce its decision on December 1, another White House decision would have to be made shortly.

2. ^{Instruct the NIH Director to go forward with development of guidelines for}

~~(3) Permit federal funding of research on byproduct embryos, but ban federal funding of research on created embryos.~~

• **Advantages:** ^{Does not foreclose the possibility of} Permits federal funding of research to go forward on byproduct embryos, ^{with significant research} benefits in numerous areas, but removes the most ~~controversial and~~ divisive issue from the controversy.

• **Disadvantages:** Research benefits from federally funded research on created embryos would be lost, ^{especially effects} in the area of fertility and contraception (which infertile couples, women's health and other health advocates might oppose). ^(B) In addition, the issue of federal funds for research on byproduct embryos may remain controversial. ~~(Among other points, opponents may object that byproduct embryos are kept alive for a longer period solely for research purposes).~~ Contentious

used (B)
1 firm
attachment

see
note

keep

NO

On the other hand, hearings would provide an opportunity to educate.

congressional hearings may occur and Congress might still overrule our position and ban all research.

3 Instruct the NIH Director not to fund ^{any} human
(4) ~~Ban all federal funding of embryo research.~~

- **Advantages:** Avoids a ~~divisive issue~~ ^{keep} and a possible congressional defeat. ~~Depending on how the decision is framed, it could be based on respect for what NIH itself has recognized as a matter that "raises profound moral and ethical concerns."~~
- **Disadvantages:** The research ^{benefits} from federal funding of embryo research would be lost. These include potential benefits from research into cancer, birth defects and other diseases as well as fertility and contraception. The scientific community and women's health community may react negatively. And the Administration might be accused of caving into pressure from pro-life groups and the religious right.

Flip-flopping on the course
set by the decision on ~~the~~
fetal tissue transplantation
research

Could be
shaped as either
concern for issue that
raises moral/ethical
concerns, or as
budgetary prioritization
and nothing more.

Additions/Modifications to Background Section

Insert new #1

OK 1. The research at issue involves the preimplantation human embryo, which exists from the time of fertilization until approximately 14 days later. The research is fundamentally important to advances in infertility treatments, contraception, and treatment of certain cancers and genetic illnesses. Research may involve byproduct embryos (embryos created by in vitro fertilization clinics for implantation) or created embryos (embryos created solely for research purposes).

Number remaining major paragraphs in section sequentially, beginning with 2

Modify #2

OK 2. Reagan/Bush Administrations -- The Reagan and Bush Administrations refused to fund in vitro fertilization research (which encompasses embryo research) or fetal tissue transplantation research.

Modify #3

3. Clinton Administration -- In January 1993 President Clinton directed Secretary Shalala to lift the moratorium on fetal tissue transplantation research. In June 1993, Congress eliminated the legislative barriers to in vitro fertilization research. Both actions received bipartisan support.

→ can't say this w/o saying who it was.
2d and 3rd minor paragraphs remain, as marked

Insert new #4

4. Public Reaction (to Date) to Ad Hoc Panel's Report -- *Congress*. Members of the new House leadership, led by Representative Dornan and including Representative Gingrich, have written to NIH vigorously opposing and promising to use all means to block any federal funding for embryo research.

OK } *Media*. Newspaper editorial positions representing a range of views have appeared. The Chicago Sun-Times opposed all federal funding [use quote if unconcerned about memo length]. The Washington Post opposed federal funding for research on created embryos [use quote, with same caveat]. The Nashville Tennessean supported the advisory panel's findings and recommendations [quote/caveat]. The Washington Post editorial board has agreed to meet with NIH Director Varmus after his Advisory Committee meeting and will not write another editorial before then.

Modifications to The Current Issue Section

current text should be moved to Background Section (as described above) or eliminated *ok*

Modifications/Additions to the Current Options Section

eliminate heading; text (as modified) should appear under The Current Issue heading *(NO)*

new introduction *keep heading*

needs to give White House
If the NIH Director's Advisory Committee recommends acceptance of the ad hoc panel's report, NIH Director Varmus intends to wait until after the holidays to announce his decision. If he accepts the ad hoc panel's report, an extended public process of developing and approving research guidelines would have to precede any actual research funding. However, press and congressional inquiries about the Administration's intentions will likely begin on or about December 1. Options for White House reaction include:

use existing text, as marked, and make following insertions

- A Sustains the President's commitment to "keep politics out of science" that was initiated with the decision on fetal tissue research. Allows potential bipartisan support to emerge -- Senators Dole, Specter, Simpson, and Domenici, for instance, have been supporters of this type of research in the past. Sets the stage for capturing an important family values issue for the Administration since many infertile couples and families with cancer or genetic diseases view it in that manner.
- B Makes the President a lightning rod on this issue rather than leaving responsibility with Secretary Shalala and NIH Director Varmus. Threatens existing bipartisan support by raising the political stakes into the White House.

Draws focus to the White House & heightens politicization of the issue.