MEMO

TO: NBAC

FROM: Eric M. Meslin, Ph.D. and Kathi E. Hanna, M.S., Ph.D.

SUBJECT: Research Involving Human Stem Cells: Status of Work and Suggestions for Discussion

DATE: February 24, 1999

A brief summary of the Commission's discussions appears below. Later in this memo, we provide a summary of work in progress in support of the report and describe other briefing materials appearing in the briefing book.

Summary of February Discussion

At the last meeting, the Commission began deliberations on research involving human stem cells. Using the approach proposed by Dr. Miike and others at the January meeting, NBAC worked its way, in a preliminary manner, through the four categories of sources from which human stem cells might be derived. These include: 1) fetal tissue; 2) spare embryos remaining after infertility treatment; 3) embryos created for research purposes via somatic cell nuclear transfer; and 4) embryos created for research purposes using donated gametes and IVF.

New technologies have demonstrated that there may be more than one way to make an embryo or embryonic-like cell line. Somatic cell nuclear transfer, cell fusion, and human/non-human hybrids have expanded the diversity of reproductive technologies beyond *in vitro* fertilization (i.e., *ex utero* fertilization of egg and sperm). It will be important to consider whether the technique used to make the embryo (which subsequently could be the source of embryonic stem cells) offers any distinctions of scientific, ethical, or legal importance.

The February discussion was aimed at determining whether NBAC would find it acceptable for federal funds to be used for 1) the use of stem cells derived from each source, and 2) the derivation of stem cells from each source. What follows is our understanding of what Commissioner's views were; this is based on our review of the transcripts and the audio tapes. It may be that our descriptions do not correspond with what Commissioners believed they had been concluding; if so, any of these items can be revisited.

Fetal Tissue

There was general agreement that federal funding for both the derivation and use of stem cells from this source should continue to be acceptable for federal funding. Commissioners discussed whether the timing and means of abortion (e.g., spontaneous or induced) affect the scientific desirability and ethical acceptability of the tissue. There was general agreement that as long as the research use of the tissue does not affect the timing or means of abortion, fetal tissue from either spontaneous or induced abortion should be ethically acceptable for research use. It was unclear whether the scientific desirability of this source differs from others. The applicability of existing fetal tissue transplantation regulations was questioned. It was decided that NBAC staff should find out whether the existing laws and regulations would need to be altered for transplantation therapies using human stem cells.

Spare Embryos Remaining After Infertility Treatment

There was general agreement that federal funding should be available for both the derivation and use of stem cells derived from this source, given appropriate oversight and protections. Discussion centered on when choices regarding donation should be offered and how payment for gametes affects legal and ethical considerations. The point was raised that it might be difficult to prevent clinics from producing more embryos than needed for clinical purposes, thus posing some complexity in sorting this category out as different from that of category 4, i.e., embryos created for research purposes using donated gametes and IVF.

Embryos Produced Expressly for Research (via SCNT or IVF)

Many Commissioners were of the view that, at this time, it will not be necessary for the federal government to fund the derivation of stem cells from embryos produced for research purposes because: 1) there should be a sufficient supply of material from other sources; 2) more scientific work should be conducted on fetal tissue and spare embryos before proceeding with this source; and 3) it is a sensitive public policy issue. However, the possible benefits of research using embryos produced through somatic cell nuclear transfer (SCNT) (e.g. autologous transplants) make this source of stem cells worth further review. A suggestion was made that NIH convene a panel to track SCNT research and review any evidence that might justify using stem cells derived from embryos produced by this method. More ethically problematic is the production of embryos for research purposes using IVF. These concerns must be carefully addressed in the NBAC report.

Several Commissioners, however, felt that it is ethically acceptable for the federal government to support research *using* stem cells derived from embryos produced for research purposes. There was no consensus about

whether one approach is more acceptable than the other (i.e., SCNT vs. IVF) but Dr. Miike and Prof. Capron suggested that stem cells might be "labeled" according to their source so that researchers and institutions are aware of their origin. Others felt that making such a distinction gives a false impression that there is some scientific reason for doing so, when that reason is neither known nor proven. Such a labeling plan would be done for public policy, not scientific, reasons.

Ongoing Staff and Commissioned Work

To provide the Commission with sufficient background material and advice, we have contracted with several individuals, some of whom will be writing commissioned papers; others will be providing on-going consultation and review of documents that are being developed. All of these individuals are in close contact with NBAC staff and are provided with relevant transcripts and NBAC information as it becomes available. In this way, we hope to receive documents that closely track NBAC's deliberations and meet its needs. These individuals are in addition to our usual staff complement.

Lori Knowles, LL.B. B.C.L. MA LL.M., the Hastings Center, is preparing a paper on international law and regulation on this set of issues. She will present her preliminary findings at the March meeting. An outline of her draft is included in this briefing book.

John Fletcher, Ph.D., Professor (emeritus) of Biomedical Ethics at the University of Virginia (UVA) School of Medicine, is preparing a paper on "An Incremental Approach to NBAC Deliberation on Human Pluripotential Stem Cells Research." Dr. Fletcher's draft outline is included in this briefing book.

Erik Parens, Ph.D., the Hastings Center, is preparing a paper on certain aspects of the moral status argument, including the relevance of the distinction between embryos that are discarded vs. those that are produced for research purposes; and whether the intention of the persons making the embryos for research purposes has relevance.

LeRoy Walters, Ph.D., Director, Kennedy Institute of Ethics, Georgetown University, has agreed to consult with the NBAC staff on the ethical issues associated with human stem cell research. Dr. Walters has been helping to develop the staff draft "Points to Consider" which is included in this briefing book.

Elisa Eiseman, Ph.D., RAND Science and Technology Policy Institute, is drafting text describing the science of stem cell research, to be available at the meeting.

Andrew Siegel, Ph.D., J.D., NBAC staff, has prepared a "Summary of Some Ethical Issues in Human Stem Cell Research", included in this briefing book.

J. Kyle Kinner, J.D., M.P.A., Presidential Management Intern, NBAC staff, has prepared a summary of the history, regulations, and statutes concerning use of fetal tissue in research and therapy, included in the briefing book.

Jeffrey P. Kahn, Ph.D., MPH, Director, Center for Bioethics, University of Minnesota, has agreed to consult with the NBAC staff on the policy framework that the report adopts.

Anna C. Mastroianni, JD, MPH. Lecturer, University of Washington, has agreed to consult with the NBAC staff on the policy framework that the report adopts. Both Dr. Kahn and Prof. Mastroianni have extensive experience in bioethics and public policy, having been associate directors for the Advisory Committee on Human Radiation Experiments.

Other Materials

You have received a number of items over the past month from us. Several additional materials are included in the briefing book that are relevant:

- A letter we have sent to Harriet Rabb, General Counsel/DHHS, requesting clarification on an issue arising in her opinion of January 15, 1999
- Copies of the letters from members of Congress to Secretary Shalala
- Copy of letter sent from medical and scientific groups to all members of Congress
- A recent article by Lori Andrews which appeared in the Chronicle of Higher Education
- Responses we have received from our letter to professional societies asking for their views on stem cell research

Next Steps

Commissioners have already reviewed the initial staff outline of the report. Given that there are now several pieces being brought together—the commissioned papers and the additional material provided in this briefing book—we believe it is possible to produce a first draft of the report for review at the NBAC meeting in April. In order to do this, we think that it would be most useful for the commissioners to take the following next steps at this meeting:

1. Review the summary of commissioner discussion from the February meeting and confirm its accuracy. Allow time to revisit any items to permit commissioners who were unable to attend the Princeton meeting to express their views.

2. Discuss the presentation by Dr. Fletcher and decide whether it provides an approach the Commission wishes to adopt. In particular, discuss the two recommendations Dr. Fletcher would have NBAC adopt.

3. Identify any initial recommendations that can enjoy initial consensus at this point. Such recommendations can either take the form of:

    a) permissibility of federal funding by source of stem cell
    b) permissibility of federal funding by type of research

4. Identify areas of fact (science or law) which require further staff investigation.

5. Identify areas of policy or ethics requiring clarification.