AMERICAN ACADEMY OF NEUROLOGY

Special Article

Position statement regarding the use of embryonic and adult human stem cells in biomedical research

American Academy of Neurology and American Neurological Association

Preamble. The American Academy of Neurology (AAN) and the American Neurological Association (ANA), organizations representing over 18,000 neurologists and neuroscience professionals, support government funding of basic, clinical, and translational research that will ultimately benefit patients with neurologic diseases. The AAN and ANA believe that the use of human pluripotent stem cells (also known as human embryonic stem cells) in biomedical research may have enormous potential to benefit people affected by neurologic disease throughout the world. In particular, the research involving such cells could improve the lives of many Americans suffering from neurologic diseases, examples of which are ALS (Lou Gehrig disease), Alzheimer disease, epilepsy, Huntington disease, multiple sclerosis, Parkinson disease, spinal cord injury, and stroke.

While the potential of embryonic stem cell research to result in breakthrough therapies is real, it is important to recognize that the translation of research into therapy will take many years, and it is also possible that such therapies may not ever be realized. Similarly, while the use of adult stem cells for research is recognized as an alternative to the use of embryonic stem cells, the potential for translating adult stem-cell research into therapy is far more uncertain. Nonetheless, the only way to know whether either embryonic or adult stem cell research can result in new therapies is to pursue such research under rigorous scrutiny. To quote the preliminary conclusions of the President's Council on Bioethics January 2004 report, Monitoring Stem Cell Research, "This research is expensive and technically challenging, and requires scientists willing to take a long perspective in order to discover, through painstaking research, which combinations of techniques could turn out to be successful. Strong financial support, public and private, will be indispensable to achieving success."[1]

All research, including stem cell research, must meet the standards of scientific and ethical oversight by external peer review. The AAN and ANA promote the highest standards for oversight, which many consider to be that attached to federally funded research. In 2000, the NIH issued *Guidelines for Research Involving Human Pluripotent Stem Cells*, enabling scientists to conduct federally-funded embryonic stem cell research (ESCR) within the constraints of federal oversight and standards.[2] Those guidelines were altered by Presidential order on August 9, 2001, limiting ESCR to stem cell lines that had already been derived at that time.[3] Practical experience since August 2001 demonstrates the scientific restraints that these limits have placed on ESCR in the United States. In fact, as of September 1, 2003, there were only 12 human embryonic stem cell lines that federally supported researchers could purchase.[4] While private stem-cell researchers in the United States are free to study the other embryonic stem-cell lines, keeping pace with researchers in other countries, they are not subject to federal scientific and ethical scrutiny. Thus, a potential adverse consequence of federal restrictions on funding of ESCR is that the NIH standards for ethical and scientific oversight cannot be enforced on research the federal government does not fund.

Additional material related to this article can be found on the *Neurology* Web site. Go to www.neurology.org and scroll down the Table of Contents for the May 24 issue to find the title link for this article.

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The American Academy of Neurology Board of Directors approved the position statement (which was the result of collaborative work among several AAN committees) during its business meeting the weekend of October 16, 2004. The American Neurological Association approved the statement in October 2004.
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Some believe that the process of stem cell research involving somatic cell nuclear transfer (i.e., cloning) cannot be limited to populations of cells to be used for therapeutic purposes, but rather, will lead to reproduction, meaning the cloning or reproduction of a human being. While this outcome is far removed from current scientific knowledge and technical capabilities—it is known that there are serious health problems in animals cloned with these techniques, and all major scientific and professional associations support a ban on reproductive cloning—it remains imperative that research in this field is conducted under the highest scientific standards and ethical safeguards, similar to those applied to ESCR. (A report on the subject of somatic cell nuclear transfer is available in the online appendix at www.neurology.org.)

The AAN and the ANA recognize and respect the concerns of many of their members and the public regarding important ethical principles and values that pertain to research using human embryonic stem cells. On the one hand is respect for human life and concern about the moral status of the blastocyst (which is simultaneously the earliest form of a human embryo and the source of embryonic stem cells for research) and the fact that the process of obtaining stem cells results in the destruction of the blastocyst. On the other hand is a strong moral obligation of physicians and scientists to pursue research that may result in beneficial treatments for diseases that affect many persons. In consideration of taking a specific position on the use of human embryonic stem cells for research, the AAN and the ANA recognize that strongly held and disparate views exist, and it is thus unlikely they can satisfy the concerns of all their members or the public.

The AAN and ANA conclude that the potential benefits of research involving human embryonic stem cells are sufficient to continue such research, that it should be conducted with strict oversight, and that the ethical safeguards developed by the NIH respect both the moral status of the embryo and public sensitivity to this issue, while ensuring that progress in critical medical research continues.

AAN and ANA's position. The AAN and ANA have adopted the following principles relating to the use of embryonic human pluripotent stem cells:

1) We support federal and state use of the 2000 NIH Guidelines as the ethical and scientific standard for research involving human pluripotent stem cells, with certain exceptions made to address advances in somatic cell nuclear transfer (addressed in part 4 of the online appendix). These guidelines respect both the moral status of the embryo and public sensitivity to this issue, while ensuring that progress in critical medical research will continue. The guidelines also deal appropriately with informing and obtaining consent of potential donors of material, with prohibitions on improper inducements to such donors, and with the protection of donor privacy.
2) We support expansion of federal and state funding for human pluripotent stem-cell research projects to include all embryonic stem-cell lines developed under appropriate ethical and scientific guidelines, not just those permitted by the 2001 presidential order. Time is valuable: although private companies are currently conducting research on pluripotent stem cells, these firms are limited in number and their research is not subject to NIH oversight, which limits scientific and ethical scrutiny and the pace of discovery. Changing federal funding policy is critical to permit the full capacity of the biomedical research workforce in the United States to discover and develop the full potential of human pluripotent stem cells under appropriate scientific and ethical guidance.
3) We support continuing research on both embryonic and adult stem-cell lines. Prevailing scientific opinion is that it is far too early to know if adult stem cells have the same potential as do embryonic stem cells. For diseases that prove not to be treatable with adult stem cells, impeding human pluripotent stem cell research risks unnecessary delay for patients who may die or endure needless suffering while the effectiveness of adult stem cells is evaluated.
4) We support somatic cell nuclear transfer for purposes of creating stem cells to be used in biomedical research and treatment (therapeutic cloning), and oppose somatic cell nuclear transfer for purposes of producing a human child (reproductive cloning).
5) The AAN and ANA acknowledge differing ethical opinions on the status of embryos that cannot be resolved to the satisfaction of all through medical science alone. Consequently, the AAN and ANA recommend that ESCR and SCNT research proceed under federal oversight, ensuring that the highest quality and most promising research is conducted with utmost regard for ethical standards.
6) Because scientific knowledge regarding stem cell research is evolving, the AAN and ANA will periodically review this position and revise it as indicated.

References

1. The President's Council on Bioethics. Monitoring stem cell research. Available at: http://bioethics.gov/reports/stemcell/index.html.
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3. Fact sheet: embryonic stem cell research. Available at: http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html.
4. Stem cell information. Available at: http://stemcells.nih.gov/info/faqs.asp#registry.

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