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— Quality Life Through Research —

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President

Richard B. Marchase, Ph.D.
Vice President for Research
Professor of Cell Biology
University of Alabama at Birmingham
AB 720E - 1530 3rd Ave S.
Birmingham, AL 35294-0107
Telephone (205) 934-1294
Fax (205) 975-2533
marchase@uab.edu

9650 Rockville Pike
Bethesda, MD 20814-3998
Telephone (301) 634-7090
Fax (301) 634-7049
http://www.faseb.org

May 26, 2009

Raynard Kington, M.D., Ph.D.
Acting Director, National Institutes of Health

Dear Dr. Kington:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the National Institutes of Health (NIH) draft guidelines on human embryonic stem cell (hESC) research. FASEB represents 22 scientific societies, comprising nearly 90,000 biomedical researchers, and we commend NIH for its expediency in releasing draft guidelines in advance of the due date set by the Executive Order on hESC research. This is an exciting and still relatively young area of science, and FASEB is pleased that NIH, as the world's premiere sponsor of biomedical research, will have an expanded capacity to fund stem cell studies. Generally, FASEB supports the NIH draft guidelines and notes their congruence with existing voluntary guidelines, such as those produced by the National Academies and the International Society for Stem Cell Research, which FASEB has provided input on and endorsed in the past. However, we did wish to provide NIH with some additional feedback on the draft guidelines.

Eligibility of currently eligible hESC lines: The human subjects protection and informed consent criteria in the draft guidelines are extensive and appropriate. FASEB has long supported the idea that hESC research should be conducted under a sound, ethical framework. However, concerns have been raised in the scientific community that the retrospective application of the guidelines would render ineligible some existing hESC lines including, perhaps, those eligible for funding under the Bush administration restrictions. Since the intent of Executive Order 13505 was clearly to expand the number of lines eligible for federal funding, new restrictions would run counter to that intent. In addition, the Bush administration eligible lines and others that have been derived and studied through private funding have been well characterized and serve as the foundation for our understanding of hESC science. Backtracking to recreate this data with new lines or having to continue to maintain separate lab facilities for eligible and ineligible lines would also seem to violate the spirit of the Executive Order. FASEB urges NIH to examine this issue carefully and to consider some mechanism that would allow waivers for existing lines, even if on a case-by-case basis.

Scope of the guidelines: FASEB recognizes NIH's rationale for limiting funding eligibility only to those hESC lines derived from surplus fertility clinic embryos. It may be true that the American public would not currently support federal funding for hESC derived from deliberately created embryos, through technologies such as somatic cell nuclear transfer (SCNT). Given the enormous potential to create disease-specific or genetically defined hESC lines with SCNT, FASEB believes this technology should be supported by federal research funds. Unfortunately, the lack of a federal prohibition on human reproductive cloning using SCNT, which FASEB strongly supports, makes federal sponsorship of SCNT problematic. However, public opinion and policy, like science, evolves and shifts over time. Therefore, FASEB urges NIH to regularly revisit and update the guidelines, possibly including hESC lines produced by new and existing technologies, to ensure they remain in line with the current state of science, law, and society.

Thank you again for considering FASEB's input on this important topic. If there is any other way in which we may be of assistance, please do not hesitate to contact me.

Sincerely,

Richard B. Marchase

Richard B. Marchase, Ph.D.
FASEB President