

LETTERS TO NIH DIRECTORS

On July 10, 2006, Senator Specter and Senator Harkin wrote to Dr. Zerhouni and 18 other NIH institute directors asking that they answer questions in preparation for the upcoming stem cell debate. They asked that the responses “be submitted directly to us without editing, revision, or comment by the Department of Health and Human Services as required by” the fiscal year 2006 appropriations bill. The questions and a summary of their answers are listed below:

QUESTION 1. Do you believe that embryonic stem cell research holds promise for treating, curing and improving our understanding of diseases? If so, please describe some of the most promising potential applications of this research. Would access to additional and newer stem cell lines hasten progress towards these basic and clinical applications?

Dr. Zerhouni (Director, NIH)

- “Yes, embryonic stem cell research holds great promise for treating, curing, and improving our understanding of disease, as well as revealing important basic mechanisms involved in cell differentiation and development.”
- “...from a purely scientific standpoint, it is clear that more cell lines would be helpful in ensuring expeditious progress in this important field of science.”

Dr. Fauci (Director, Allergy Institute)

- “The National Institute of Allergy and Infectious Diseases (NIAID) believes that research on embryonic stem cells could potentially increase scientific understanding of the biology of human diseases and also lead to improvements in the treatment of many human diseases.”
- **“NIAID believes that embryonic stem cell research could be advanced by the availability of additional cell lines. Individual stem cell lines have unique properties. Thus, we may be limiting our ability to achieve the full range of potential therapeutic applications of embryonic stem cells by restricting research to the relatively small number of lines currently available.”**

Dr. Battey (Director Deafness Institute)

- The National Institute on Deafness and Other Communications Disorders believes embryonic stem cell research holds promise for increased understanding of an possible treatments for diseases and conditions especially within the research mission areas of the Institute.”
- **“The more cell lines available for study, the more likely a cell line will be maximally useful for a given research, and potentially clinical, application....the scientific community would be best served by having a greater number of human embryonic stem cell lines available for study.”**

Dr. Nabel (Director, Heart, Lung and Blood Institute)

- “Embryonic stem cell research has vast potential for addressing critical health needs in a number of areas relevant to the mission of the National Heart, Lung and Blood Institute.”
- **“...we recognize that the limitations of existing cell lines are hindering scientific progress among a community that is very eager to move forward in this promising area. We support the creation and dissemination of newer stem cell lines in the expectation that it will advance this field and hasten progress in basic and clinical research.”**

- "...additional and newer stem cell lines would enable the research enterprise to overcome...major limitations ...spontaneous mutations that can arise after any cell line is maintained long-term...the human embryonic stem cell lines in the NIH Registry were derived using animal cell feeder layers... and the limited genetic diversity of the current NIH Registry lines."

Dr. Tabak (Director, Dental Institute)

- "The currently available stem cell lines have provided the first step in our understanding of their basic biology. However, due to limitations ...**newer and improved stem cell lines could unleash the full potential of stem cells for clinical utility.**"
- "**...unless conditions are determined to better maintain them, the current lines will become exhausted. This instability also leads one to think that the ways in which the currently available human embryonic stem cell lines were derived may not have been optimal.**"

Dr. Volkow (Director, National Institute of Drug Abuse)

- "Yes, embryonic stem cells are promising research tools that can be used to identify and investigate a variety of therapeutic approaches."
- "**Access to a wider array of embryonic stem cell lines would definitely increase scientific opportunity and the chances of breakthrough discoveries, as well as their eventual application in the form of novel therapies for many diseases... the translation of any discovery into clinical research and practice can be expected to be severely hindered by the fact that the cells now available for research are likely to be rejected by a patient's immune system.**"

Dr. Collins (Director of the Human Genome Institute)

- "Stem cell research has tremendous potential for therapeutic advances in diseases affecting many Americans."
- "Access to newer and more varied stem cell lines would benefit researchers not only because modern cultural techniques have increased the utility of stem cell lines, but also because newer lines would provide greater genetic and cellular diversity."

Dr. Neiderhuber (Director, Cancer Institute)

- "Embryonic stem cells are important research tools that may provide important knowledge about key processes in cancer metastasis, new blood vessel development, and the regulation of cell replication and programmed death."

Dr. Rodgers (Acting Director, Diabetes and Digestive Disease Institute)

- "Access to additional and newer stem cell lines is likely to hasten progress towards basic and clinical applications."

Dr. Landis (Director, Neurology Institute)

- "For neurological disorders, embryonic stem cells present considerable promise as an agent of therapy, in the development of therapeutics, and for advancing our understanding of disease."
- "**Access to newer lines, however, would hasten progress, particularly as therapies move toward human testing.**"

Jeremy Berg (Director General Medical Sciences Institute (NIGMS))

- “The National Institute of General Medical Sciences firmly believes that embryonic stem cell research holds enormous promise for treating, curing and improving our understanding of many diseases.”
- “Access to additional and newer cell lines could be beneficial to this basic research endeavor in several ways. ... a limited number of embryos may restrict the ability to compare fundamental processes that differ as a function of genetic variability.”

Dr. Alexander (Director, Child Health Institute – NICHD)

- “The NICHD believes that human embryonic stem cell research holds exceptional promise for treating, curing and improving our understanding of diseases.”
- “Access to more and newer stem cell lines would benefit basic and clinical research applications...it is necessary to be able to derive new embryonic stem cell lines (ESC) from embryos of high quality in order to know whether those embryonic stem cell lines would possess any capabilities or behave differently than the ESC from the discarded embryos.”

Dr. Sieving (Director, Eye Institute)

- “Yes, it is my professional opinion that human embryonic stem cell research holds considerable promise for treating, curing, and improving our understanding of ocular diseases.... better access could hasten progress by increasing the number of investigators willing to work in this area.”

Dr. Schwartz (Director, Environmental Health Institute)

- “I believe that human stem cell research represents one of the most exciting opportunities in biomedical research. Embryonic stem cell research holds great promise for improving our understanding of disease etiology, prevention, and therapy.”

Dr. Hodes (Director, Aging Institute)

- “Embryonic stem cell research holds promise for helping us find more effective ways to prevent or treat a number of age-related conditions in which cell loss plays a critical role...Alzheimer’s and Parkinson’s diseases, and the damage and cell death related to heart diseases and diabetes.”

Dr. Li (Director, Alcohol Abuse Institute)

- “As with other stem cell types, embryonic stem cells may hold great promise for the treatment of certain diseases.”
- “It is possible that the ability of researches to access newer human embryonic stem cell lines might serve to enhance our goal to understand cellular processes that govern regeneration which has the long-term potential to clinically translate our research findings.”

Dr. Alving (Acting Director, Center for Research Resources)

- “Embryonic stem cell research holds promise for treating, curing, and improving our understanding of diseases...From a scientific standpoint, access to additional and new stem cell lines has the potential to advance the field of medical research...newer lines can be derived in the absence of animal products...genetic background of the current lines is very limited.”

QUESTION 2. Have researchers reported difficulties in obtaining any of the 21 lines currently available to NIH-funded researchers? If so, please provide examples. In practice, how many of the 21 lines are in common use by NIH-funded researchers?

Dr. Zerhouni (Director, NIH)

- “...all of the human embryonic stem cell (hESC) lines listed on the NIH Human Embryonic Stem Cell Registry are privately owned and many are from foreign sources. The private owners are under no obligation to make their hESC lines widely available for research in other laboratories. Many scientists expressed concern that access to these cell lines was a major obstacle hindering hESC research eligible for Federal funding.”

Dr. Nabel (Director, Heart, Lung and Blood Institute)

- “...only four cell lines were in common use...we believe that the availability of additional cell lines would be of great service to NHLBI-funded researchers.”

Dr. Landis (Director, Neurology Institute)

- “The NIH unit that is systematically characterizing the approved lines and making that information available now has 18 of the 21 lines, and the others are on order.”

Jeremy Berg (Director General Medical Sciences Institute (NIGMS))

- “Although NIGMS grantees have purchased 13 of the 21 approved human embryonic stem cell lines, only 6 lines are in common use.”

Dr. Hodes (Director, Aging Institute)

- “...one National Institute on Aging intramural investigator involved with human embryonic stem cell researching using approved cell lines identified genetic abnormalities and contaminations from mouse feeder cells in the embryonic stem cells that made them unusable for his research. In part because of his inability to continue his research with approved cell lines, he has left the Institute.”

Dr. Volkow (Director, National Institute of Drug Abuse (NIDA))

- “...obtaining these lines has been procedurally complex and expensive. Despite general interest and enthusiasm in the scientific community for embryonic stem cell research, the limited number of available lines has, the NIDA’s case, translated into a general lack of research proposals.”