

Congress of the United States
House of Representatives
Washington, D.C. 20515

March 2, 2004

The President
The White House
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear Mr. President:

We are writing with new information about human embryonic stem cell research and recent changes to the President's Advisory Council on Bioethics. This new information conflicts with repeated Administration pronouncements. It now appears that the Administration may have misinformed the public and interfered with science on an issue of great public health significance.

In August 2001, you assured the American people that your policy banning federal funding for studies on newly derived lines of embryonic stem cells would allow research on "more than sixty" existing cell lines worldwide. As recently as last fall, the just-departed head of the Domestic Policy Council in the White House wrote that 78 cell lines were eligible for federal funding. While only a fraction of these cell lines have been made available to scientists so far, the Administration has indicated that many more are in development. These assurances were integral to the claim that your policy would not impede the development of "breakthrough therapies and cures."

We have learned, however, that the senior scientist overseeing stem cell research at the National Institutes of Health has concluded that the "best case scenario" today is that only 23 cell lines will ever be available for federal funding under current policy. This information from NIH, which has not been publicly released, calls into doubt the adequacy of your policy on stem cell research.

We have also learned that your Administration may have misled the public about why the Administration removed cell biologist Dr. Elizabeth Blackburn and ethicist Dr. William May from the President's Advisory Council on Bioethics last Friday. According to your spokeswoman, the dismissal of these distinguished experts was related to their "expertise and experience." We have learned, however, that Dr. Blackburn was dismissed soon after she objected that a major Council report was misleading with regard to stem cell research.

Millions of Americans suffer from diseases that may be treated as a result of embryonic stem cell research. The Administration should release all information about the number of viable stem cell lines available to researchers and should turn to the nonpartisan and impartial National Academy of Sciences for expert advice.

The Stem Cell Lines

On August 9, 2001, in a nationally televised address, you announced a ban on the use of federal funds for new lines of embryonic stem cells.¹ At the time, you assured the American people that research progress would not suffer. You claimed that there were “more than 60 genetically diverse” cell lines already in existence around the world that met your criteria for federal funding. You stated that “research on these 60 cell lines has great promise that could lead to breakthrough therapies and cures.”²

Soon after your statement, it became clear that only a small fraction of the “more than 60” stem cell lines were fully characterized and accessible to researchers. Your advisers counseled patience. Secretary of Health and Human Services Tommy Thompson testified in September 2001 before the Senate:

We believe that the five lines that are currently existing will be able to get us a long way down the road doing the basic research. But there are many more. We feel right now roughly there are 25, 24, 25 fully cell lines established, and there are 64 in the various phases, from the proliferation, to the characterization, to the cell line established. And out of those remaining ones, we think there will be a lot more that will be established that will be able to use the vials at the end or the cells are frozen and be able to send out to researchers around the world.³

As recently as October 30, 2003, Jay Lefkowitz, who had just left his position as head of the Domestic Policy Council in the White House, claimed that 78 cell lines qualified for federal funds. He wrote that “there is every reason to believe that more and more will make their way to scientists once they are properly readied.”⁴

We now have learned that such statements misinformed the public. Last week, we obtained an assessment of available stem cell lines from the office of Dr. James Battey, the director of the stem cell task force at the National Institutes of Health. Dr. Battey has determined

¹The President, *Remarks by the President on Stem Cell Research* (Aug. 9, 2001).

²*Id.*

³Secretary of Health and Human Services Secretary Tommy G. Thompson, *Testimony before the Senate Committee on Health, Education, Labor and Pensions* (Sept. 5, 2001).

⁴Jay Lefkowitz, *The Facts on Stem Cells*, Washington Post (Oct. 30, 2003).

that the “best case scenario” today is that just 23 of these cell lines will ever be available to the research community.⁵ Eight of these 23 lines are not yet ready for distribution.

Of 55 additional existing cell lines, Dr. Battey has found that seven are duplicates and 17 have failed to replicate.⁶ Thirty-one lines are the property of institutions outside the United States that do not have NIH funding. Of these 31 lines, Dr. Battey wrote:

We have no indication that any of these institutions will ever seek NIH support to develop their lines, or will make any effort to distribute their lines to the research community. Since we provide no funding for these derivations, the suppliers have no reason to disclose their plans for these derivations to the NIH. The status of these derivations is unclear, although it does not seem likely that any of these derivations will be freely available for widespread distribution at any time in the foreseeable future.⁷

Dr. Battey’s findings have significant ramifications. Scientists working with human embryonic stem cells with federal funds may be unable to replicate experiments and develop therapies using a range of genetically diverse cell lines. Soon after you announced your policy in 2001, former NIH Director Dr. Harold Varmus and molecular biologist Dr. Douglas Melton wrote:

What happens if workable cell lines are few and encumbered by restrictive conditions? Scientists in other countries and in the private sector, working unfettered by strict rules, are likely to produce new and better cell lines; but, unless the rules change, investigators dependent on federal dollars will again be excluded from the most promising opportunities.⁸

This prediction appears to be coming true.

The Administration has not released Dr. Battey’s assessment to the public.

⁵Dr. James Battey, *Update on the Status of the 78 Eligible Entries on the NIH Human Embryonic Stem Cell Registry as of February 23, 2004* (Feb. 23, 2004).

⁶*Id.*

⁷*Id.*

⁸Dr. Harold Varmus and Dr. Douglas Melton, *The Stem Cell Compromise*, Wall Street Journal (Aug. 14, 2001).

The President's Council on Bioethics

We have also learned that the recent dismissal of a distinguished scientist from the President's Council on Bioethics occurred soon after she objected that a major Council report was misleading with regard to stem cell research.

Over two years ago, you created the President's Council to monitor research and make recommendations related to new technologies. At the time, you said that this council would "consist of leading scientists, doctors, ethicists, lawyers, theologians and others" and "give our nation a forum to continue to discuss and evaluate these important issues."⁹

Last Friday, you dismissed two Council members, cell biologist Dr. Elizabeth Blackburn and ethicist Dr. William May. Both Dr. Blackburn and Dr. May had expressed reservations about your stem cell policy. Refusing to acknowledge any ideological motive, your spokeswoman said, "We've decided to go ahead and appoint other individuals with different expertise and experience."¹⁰

One of the dismissed experts, Dr. Blackburn, is a cell biologist and member of the National Academy of Sciences and the Institute of Medicine from the University of California at San Francisco. We now understand that she was fired soon after she informed the Council chair, Dr. Leon Kass, of problems with *Monitoring Stem Cell Research*, a January Council report.

The report provides a generally sunny assessment of the promise of research using "adult" stem cells, which some consider an alternative to research using embryonic stem cells, for a variety of diseases.¹¹ Dr. Blackburn, a past president of American Society for Cell Biology and one of three scientists on the Council, found the report to be misleading. She expressed the view that the report could benefit from additional discussion of the technical barriers to research on "adult" stem cells.

The concerns of Dr. Blackburn, a respected cell biologist, should have been addressed in the drafting of the Council's report. Instead, she was removed from the Council.

Conclusion

We understand that many social conservatives who represent part of your "political base" are opposed to stem cell research. But their opposition should not obscure the fact that your

⁹The President, *supra* note 1.

¹⁰*Bush Ejects Two from Bioethics Council*, Washington Post (Feb. 28, 2004).

¹¹President's Council on Bioethics, *Monitoring Stem Cell Research* (Jan. 2004).

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policy is inhibiting research. Nor does political ideology justify turning an independent advisory committee into an echo chamber.

We urge you to turn to the nonpartisan and impartial National Academy of Sciences for advice and guidance and then rethink your stem cell policy.

Sincerely,



Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



Louise M. Slaughter
Member of Congress