

IN FOCUS

Embryonic Stem Cell Research: A Decade of Debate from Bush to Obama

Varnee Murugan

Yale School of Public Health, New Haven, Connecticut

PRESIDENT GEORGE W. BUSH: STEM CELL POLICY FROM AUGUST 9, 2001 TO MARCH 8, 2009

On August 9, 2001, U.S. President George W. Bush introduced a ban on federal funding for research on newly created human embryonic stem (ES†) cell lines. The policy was intended as a compromise and specified that research on lines created prior to that date would still be eligible for funding. Seventy-one lines from 14 laboratories [1] across the globe met Bush's eligibility criteria, and scientists who wished to investigate these lines could still receive grants through the National Institutes of Health (NIH). In practice, however, only 21 lines proved to be of any use to investigators [2].

CONSEQUENCES OF THE BUSH POLICY

A slew of negative ramifications followed for ES cell researchers. Now facing restrictions on the type of research con-

ducted using federal funds, some scientists were forced to create a dichotomous research environment based on federal vs. private funding of staff, equipment, and lab space [3]. Collaboration and the sharing of knowledge between scientists also was hindered [4,5], and American researchers who previously spearheaded ES cell initiatives were no longer able to offer much of a contribution, stifling relationships with their international counterparts [6].

Further aggravating the situation was the fact that the 21 existing lines were not genetically or ethnically diverse, meaning specific disease processes (such as Parkinson's) could no longer be studied in ES cells. Similarly, any information gleaned from the existing lines was limited to certain ethnicities, leaving uncertainty with regard to cellular processes in minority groups. In terms of therapeutic application, all 21 lines were of decidedly poor utility as they were cultured under inferior conditions by today's standards [7].

During this time, however, there were several advances in the realm of stem cell

To whom all correspondence should be addressed: Varnee Murugan, Yale School of Public Health, 60 College St., New Haven, CT 06520; E-mail: varnee.murugan@yale.edu.

†Abbreviations: ES, embryonic stem; NIH, National Institutes of Health; iPS, induced pluripotent stem; ACD, Advisory Committee to the Director.

research. The discovery of induced pluripotent stem (iPS) cells, whereby adult somatic cells are induced to display properties consistent with ES cells, were first generated in mice by researchers in Japan [8]. Following the discovery, the White House noted that by “supporting alternative approaches, President Bush is encouraging scientific advancement within ethical boundaries” [9]. Subsequent U.S. progress in iPS cell research may have well enjoyed unique encouragement under Bush’s policies.

PRESIDENT BARACK OBAMA: STEM CELL POLICY CHANGES STARTING MARCH 9, 2009

On March 9, 2009, President Barack Obama signed an Executive order revoking the previous orders initiated under his predecessor and giving the NIH 120 days to review the appropriate guidelines and issue new criteria for stem cell research. The new policy allows federally funded researchers to experiment on hundreds of viable ES cell lines restricted under Bush. The reception in the scientific community was largely positive and echoed around the world, with claims of “absolute excitement, enthusiasm, real hope for the future” from some proponents [5]. Clearly, the issue was a popular one, with one Washington Post-ABC News poll showing that almost 60 percent of Americans supported loosening restrictions on federal funding for ES cell research [10]. Obama was able to score major political points with the public and the media, but challenges and obstacles still remain for scientists.

Obama’s revocation of Bush’s policy does not reverse the Dickey-Wicker amendment, a law passed by Congress in 1996 that prohibits federally funded investigators from creating or causing harm to embryos. Dickey-Wicker is a congressional issue, and Obama has stated he intends it to remain that way [11]. So although ES cell resources have largely broadened for researchers, they are still unable to create their own lines using tax dollars — potentially problematic for those who wish to study stem cells with genetically specific or rare characteristics.

NIH GUIDELINES: EFFECTIVE JULY 7, 2009

Scientists were concerned following the April 17 release of the NIH draft regulations that imposed stringent new ethical criteria involving the informed consent of donors. The point of contention was that existing lines created under previous ethical guidelines would not meet the technical specifications of the new criteria — rendering them ineligible for federal funding [12]. Such a scenario would have resulted in fewer ES cell line options than under the Bush administration. However, after receiving approximately 49,000 comments on the draft, the NIH released their finalized guidelines on July 6, also summarizing and addressing the major draft concerns. The final guidelines specified that the new ethical criteria only would be applied to lines derived on or after July 7, 2009, and research on pre-existing lines that do not comply with the new regulations would “undergo review by a Working Group of the Advisory Committee to the Director (ACD)” [13] to determine funding eligibility. The NIH also announced the creation of a registry to document all ES cell lines approved for eligibility.

As in the draft, the final regulations only allow funding for research involving unused embryos from fertility clinics, excluding those embryos created specifically for research purposes or derived from other sources.

CONCLUSION

Stem cell research is a hotly debated issue on Capitol Hill and likely will remain so in the coming years. However, federalism and the presence of wealthy donors have allowed several states and major academic institutions to bypass the NIH entirely and function independently [14]. Nevertheless, as Obama made clear on March 9, “(m)edical miracles do not happen simply by accident. They result from painstaking and costly research . . . and from a government willing to support that work” [15].

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