



## ML Strategies Advisory Update

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### Supreme Court Will Not Hear Stem Cell Funding Petition

- The on again, off again nature of federal funding for human embryonic stem cell (hESC) research has created a great deal of uncertainty for academic scientists, major research medical centers, venture capital investors, biotechnology companies, and state legislatures and economic development officials.
- There is a great deal of concern that this uncertainty is holding back the field, driving innovation and intellectual capital overseas, and creating an unlevelled playing field in which only a patchwork of states have been able to create favorable R&D environments for stem cell research.
- While some significant opposition to human embryonic stem cell research will likely continue, the recent refusal by the U.S. Supreme Court to hear the *Sherley v. Sebelius* petition may very well signal some stability for this important research across the entire US.
- And with the legality of its funding policy now affirmed, NIH may move to amend and update its Stem Cell Guidelines, published in 2009, to reflect recent scientific and technological advances in the field.

#### Background

On January 6<sup>th</sup>, the U.S. Supreme Court denied the petition for certiorari in *Sherley v. Sebelius*, a case challenging the Obama Administration's policy of permitting federal funding for stem cell research. This denial, without comment by the Court, will allow the National Institutes of Health (NIH) to continue federally funded medical research using hESC. By denying the petition, the Supreme Court chose not to review the earlier ruling of a lower court, in this case the District of Columbia Circuit, which had ruled that funding such research is not banned by

federal law (known as the Dickey-Wicker Amendment) that prohibits federal funding of “research in which a human embryo or embryos are destroyed[.]”

The lawsuit dates back to 2009, when two researchers, James Sherley, a biological engineer at Boston Biomedical Research Institute, and Theresa Deisher, of Washington-based AVM Biotechnology, sued to block funding that President Obama allocated for stem cell research through an Executive Order, saying they were put at a severe disadvantage for funding because they worked with adult stem cells, which does not involve destroying embryos. The Executive Order authorized NIH to grant funds to create new hESC lines for research and expanded stem cell guidelines in effect under President George W. Bush which had previously restricted federal funding of hESC research to a limited number of existing cell lines.

The plaintiffs argued that the expanded stem cell guidance violated a prohibition against using federal funds either to create a new human embryo or to do research in which an embryo is destroyed, discarded, or injured. Congress has enacted this prohibition every year since 1996 through an annual appropriation bill rider known as the Dickey-Wicker Amendment. On August 23, 2010, Chief Judge Royce Lamberth of the U.S. District Court had granted a preliminary injunction halting federal funding of hESC research. However, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit overturned that decision last year.

The Obama Administration has successfully made the case that the ban does not apply to already-existing cell lines because it involves no new destruction of embryos. The Supreme Court’s decision to deny the review of *Sherley v. Sebelius* means that the NIH will be able to continue to operate under its current guidelines, with at least 75 stem cell lines qualifying for federal funding. Thus far, NIH has invested more than \$500 million in hESC and proponents of further federal funding argue that the ruling will not only remove the uncertainty associated with hESC research but will allow greater flexibility for labs to work collaboratively in promoting research that could treat a range of debilitating conditions. Some also believe that the Obama Administration may take this opportunity to update the NIH Guidelines, to reflect technological and scientific advances that have taken place in the past few years.

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