

US National Institute of Health announces new guidelines for embryo stem cell research

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On August 23, the National Institute of Health (NIH) published guidelines for the public funding of embryo stem cell research in the United States, an about-face of its previous position. Previously embryo stem cell research was funded exclusively by private sources. The NIH announcement lifts a ban which had been in place on such research since 1996. President Bill Clinton welcomed the announcement as offering “potentially staggering benefits”.

The new guidelines have a contradictory nature as they represent a desire by the US government not to lose out in the race by the US biotech industry to effectively exploit the emerging scientific breakthroughs and at the same time an attempt to appease religious and anti-abortion groups which have vociferously denounced embryo stem cell research as abortions.

The new guidelines have been largely welcomed by the scientific community and patient rights groups, but some scientists have expressed concern at the blatant concessions to the religious lobby. Gregory Stock, the director of the program on Medicine, Technology, and Society at the University of California at Los Angeles, said, “this is a political document. It's a very troubling trend when you allow special-interest groups to make minute decisions about lab procedures that have little to do with the larger ethical and moral issues involved.”

The new guidelines limit the researchers to use only cells obtained from frozen embryos that would be discarded anyway, such as remaining embryos from in-vitro fertilisation. The actual harvesting of stem cells can only be carried out by privately funded scientists and publicly funded scientists are still prohibited from obtaining stem cells directly from embryos. Any research has to be first approved by the Human Pluripotent Stem Cell Review Group (HPSCRG). It is

expected that any approved research is not likely to get under way until the end of 2001.

The Clinton administration is walking a tightrope. The whole history of the funding of stem cell research represents the White House's attempt to serve the needs of investment brokers and at the same time try to avoid alienating the Christian Right and the Catholic Church. In 1994, the Human Embryo Research Panel, a body convened by the NIH, concluded that embryonic stem cell research should be publicly funded, as long as embryos were not originally created for research purposes. Clinton rejected the recommendation and banned the use of taxpayer funding for research with human embryos, regardless of the source of the embryos. The ban was strengthened in 1995 and 1998.

In January 1999, the Department of Health and Human Services (HHS) announced that the federal government could fund research on embryonic stem cells harvested from embryos which are destroyed through research. The HHS used a legal loophole arguing “that human embryonic stem cells are not a human embryo within the statutory definition” because “the cells do not have the capacity to develop into a human being even if transferred to the uterus, thus their destruction in the course of research would not constitute the destruction of an embryo.” In other words, the destruction of such cells could not be considered an abortion as they would not further develop if placed into a womb. This legal manoeuvre only served to enrage the various religious groups, which flooded the NIH public inquiry early this year with objections to the new proposals.

The timing of the publication of the guidelines is very revealing as it was previously thought that any announcement would be delayed until after the presidential elections so as not to embarrass

Democratic candidate Vice President Al Gore by raising such a contentious issue. The NIH had produced draft guidelines in December 1999, but suddenly moved to announce the new arrangements, coinciding with recent moves to approve embryonic stem cell research in the United Kingdom and Europe.

The UK proposal is far less restrictive and more far-reaching in its scope than the US guidelines. Recommendations for embryonic stem cell research were put forward by the Chief Medical Officer in England, Professor Liam Donaldson on August 16. British scientists will be given the right to clone human cells. This involves taking a human egg and inserting a nucleus from another cell. The resulting cell then acts as a normally fertilised egg and develops into an embryo. Scientists can obtain stem cells from the cloned embryos. The Blair government has announced its acceptance of the guidelines and legislation facilitating them will be presented to the British parliament before the end of the year. Holland and France are expected to announce their guidelines permitting the use of embryonic stem cells in the next few months.

Even though the first embryonic stem cells were discovered in 1998, a number of biotechnology companies have already emerged to exploit the potentially lucrative discoveries. The NIH announcement was greeted positively by Wall Street, with a number of biotech companies based on stem cell research making considerable gains. The stocks of Aastrom Biosciences Inc. of Ann Arbor, Michigan rose by 71 percent and StemCells Inc. of Sunnyvale, California by 37 percent.

The new guidelines will enable a flow of discoveries from publicly funded research facilities, which private industry will be able to exploit for its own profit. Such a strategy was used in the mapping the human genome. The publicly funded Human Genome Project (HGP) produced data which was made available on the Internet within 24 hours, enabling private companies such as Celera Genomics to use the public data to confirm their own work and so map the whole genome in a much shorter time than if they had to rely on their own research.

The flow of discoveries has fueled a massive influx of investment funds into biotechnology companies. In the first half of this year \$22.1 billion went into the

biotechnology industry, well above the \$12 billion invested in 1999. In March, Celera Genomics issued stock worth \$1 billion in a secondary stock offering and in June, Celera announced its purchase of Geron Corporation, a company based on stem cell research, for an undisclosed price.

Opposition has not abated with the current announcement. The Vatican has condemned the decision as “gravely immoral”. Representative Jay Dickey, an Arkansas Republican who sponsored the 1996 ban, said that the new guidelines represented a “boldfaced violation of the law” and that “the [Clinton] administration didn't have to bring this up right in the middle of the election. Their concern is not so much with science as it is with promoting the Clinton-Gore pro-abortion agenda.”

A spokesperson for Republican presidential candidate George W. Bush, Ray Sullivan, stated, “Governor Bush opposes federal funding for stem cell research when it involves destroying a living, human embryo.” Democratic vice presidential candidate Joseph Lieberman has said that he and Gore support the new NIH guidelines.

The half-hearted nature of the new NIH guidelines highlights the conflict between the profit motives of the biotech corporations, which want to milk the discoveries for all they are worth, and the political agenda of the right-wing religious forces, which want to stifle scientific discovery altogether. Both influences ultimately have a destructive effect on the full development of this research.



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