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# Cloning, legislation and human welfare

For one week last month, human cloning and stem cell research were again topics of heated discussion, reviving a debate that had subsided after the terrorist attacks on the United States. The recent hoopla was caused by the announcement by Advanced Cell Technology (ACT), a small biotechnology company in Massachusetts, that it had produced cloned human embryos for the purpose of deriving stem cells. Whereas it was not the first time that scientists have reported cultivating human embryos, it was a first for US researchers and the first report to be published in a scientific journal.

The facts pale in comparison to the reaction they elicited. ACT published the results of experiments using somatic nuclear transfer to produce human embryos. The team fused nuclei from adult cumulus cells—the ovarian cells that surround eggs after ovulation—with human eggs stripped of their nuclei. Three of eight reconstituted eggs divided to the four- or six-cell stage—nowhere near the stage required for the isolation of stem cells. (The researchers also tried the technique using nuclei from adult skin cells, but they did not divide.)

Many in the scientific community said that the experiments were a failure and criticized the publication, which was picked up by every major news outlet, as being premature. John Gearhart, stem cell research pioneer, resigned from the editorial board of *The Journal of Regenerative Medicine*, in which the study was published, saying that the paper lacked important data and controls and should not have passed editorial review.

The firestorm over ACT's announcement subsided, but the episode brought to light the downside of keeping publicly funded scientists from being actively involved in certain areas of research.

In the US, researchers funded by taxpayers through the National Institutes of Health (NIH) can work on a limited number of human embryonic stem (ES) cells established prior to 9 August, 2001. Only privately funded researchers can use human ES cells established since the 9 August deadline, generate new human ES cells, and derive ES cells from cloned human embryos—with minimal oversight. In fact, in the US there is no federal law to stop privately funded researchers from taking cloned embryos and implanting them into a woman's uterus.

The two-tier US approach is unique. Other countries with strong research agendas, such as the United Kingdom, have made a clear decision about the limits of embryo research, regardless of how it is funded, and instituted a system of oversight for all relevant studies.

Whereas the US approach gives industry more freedom, it carries significant risks. After ACT's announcement and hyped reports by the media, senators threatened to ban all human cloning research. A ban would stop a potentially promising field in its infancy, and once in place, would be difficult to undo.

One problem with research carried out in the private sector is that commercial interests inevitably influence it. Many criticized ACT for overselling the work, and leading scientists, including former NIH director Harold Varmus, said that the company's motive was to attract investors. A company cannot be faulted for paying attention to its investors, but in early stages of technology development, it is risky and irresponsible to build hope on the promise of imminent therapy. Another problem is that research carried out in commercial labs is not as accessible and amenable to being judged and criticized by other scientists. The absence of transparency and scrutiny not only hinders scientific advance but also can make the public, and lawmakers, nervous.

But perhaps the greatest risk of not including federally funded researchers as full partners in human ES research is that there is a great deal of basic research that needs to be done to determine the potential of ES cells—the kind of research in which the private sector is not usually prepared to invest. The cessation of all funding of research on human embryos and anything related to *in vitro* fertilization, as advised by The NIH Ethics Committee in the 1970s, had no impact on research carried out in the commercial sector. This has led to a marked emphasis on marketing clinical advances to infertile couples—understanding the biology of, say, germ cells, fertilization and the early embryo has taken a back seat to short-term commercial considerations. Government funding is essential to embryonic stem cell research, and in this respect, allowing NIH funded scientists to work on existing stem lines is a welcome first step in the right direction.

Scientists and scientific societies have made a strong case to let research using human ES cells proceed in all sectors in the US. A report issued last year by the National Academies of Science, which went almost unnoticed (it was published on 11 September), recommended the creation of a national advisory body of leading scientists, ethicists, and other stakeholders. The advisory body would monitor proposals for federal funding of human ES cell work and ensure that such studies are justified on scientific grounds and that they meet federal ethical guidelines. President Bush announced that he was creating an advisory council on ES cell research on 10 August, but it seems that his selection of Leon R. Cass (Univ. Chicago), a vocal opponent of cloning for any purpose, did little to convince scientists and research advocates that the council would fairly consider the views of those who support ES cell research. The extent to which scientists and ethicists of all views are represented will determine the extent to which the council's advice is taken seriously by a broad sector of scientists and others. Certainly, having an advisory council is an idea worth pursuing, as a similar system has worked well in the past.

In the 1970s, recombinant DNA techniques had raised concerns about safety, and many scientists called for a moratorium on such research. The Recombinant DNA Advisory Committee was established to set guidelines for federally funded scientists working with recombinant DNA. The power of that committee gave an incentive to industry to follow the guidelines voluntarily—and so in the end, Congress did not deem it necessary to legislate.

Keeping taxpayers' money out of controversial research areas while allowing research to continue in the private sector may make political sense, but it is a shortsighted approach. Only with the full involvement of publicly funded scientists can government ensure that the potential of human ES cell research is reached.