Stem Cell Researchers Face an Unsettled Legal Environment

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Long before South Korean scientists announced last month that they had become the first to produce human embryos and stem cells through cloning, stem cell research challenged science to accommodate politics and ethics like no other issue facing us today.1 Researchers believe that undifferentiated stem cells, which are found in early human embryos, might be manipulated to treat a range of currently incurable debilitating diseases. However, with existing technologies, they can be retrieved only from embryos that are destroyed, that is, embryos that are discarded after in vitro fertilization procedures. Many abortion opponents perceive this as a threat to incipient human life. Government interventions over the past three years have created an uncertain and changing legal landscape.

THE PROMISE AND PERILS OF STEM CELLS

Scientists have been excited about stem cells since the discovery in 1998 that as the precursors to almost every kind of specialized cell in the body, they have the potential to be transformed into any of them. In a laboratory, stem cells might be coaxed into becoming “spare parts” for cells that no longer function properly. This capability holds particular promise for damaged cells that normally do not regenerate, such as those in the brain and spinal cord. Among the many possible applications of stem cells, researchers see the chance to create “substitute” brain cells to treat Alzheimer’s disease and Parkinson’s disease and to create pancreatic cells to treat type 1 (insulin-dependent) diabetes.

Although stem cells are present throughout the human life cycle, even in adulthood, researchers so far have succeeded in fully manipulating only those stem cells present in the first few weeks of embryonic development. Fortunately, after stem cells are extracted, they can reproduce indefinitely to form immortal lines of identical copies, each with the same ability to become any “specialized” cell type. Only one embryo is needed to create each line.

Scientists anticipate the further prospect of “cloning” customized stem cells from the genetic material of individual patients. Technically named somatic cell nuclear transfer (SCNT), and popularly referred to as “therapeutic cloning,” this process involves transplanting the nucleus of an adult cell into an unfertilized egg. As the new hybrid cell develops, it produces its own stem cells that match the donor’s tissue type.

The use of cloned stem cells eliminates the risk that replacement tissue will be rejected by the patient’s immune system. Therapeutic cloning is distinct from “reproductive cloning,” a technique that is still untested in humans and that is intended to create an actual offspring from the cloned cell.

Despite this promise of a therapeutic revolution, controversy looms. Although stem cell lines can continue indefinitely after they are created, the first step requires that an embryo be destroyed. Many abortion opponents, who see human life as beginning with conception, consider the destruction of embryos as equivalent to murder. They view the cells created through therapeutic cloning, which contain a full complement of human genetic material, as human beings. For opponents of stem cell technology, it is not morally justifiable to end one life in order to save another.

THE LEGAL STORM

The clash of ethical perspectives has led to ambiguous and conflicting legal responses at both federal and state levels. The first legal response was President Bush’s decision on August 9, 2001, to limit federal funding of embryonic stem cell research to investigations using existing cell lines. This decision prohibited support, which could otherwise flow from the National Institutes of Health (NIH), for research that destroyed additional embryos or that used embryos destroyed after the date of the decision, including those already frozen. Moreover, research with existing lines could be funded only if the lines had been derived with the informed consent of the donors, from excess embryos created solely for reproductive purposes and without any financial inducement to the donors. Because stem cells can be obtained from umbilical cords, placentas, adults, and animals without destroying human embryos, funding for studies using these stem cells was permitted to proceed.

The President’s directive applies only to federal funding and places no limits on stem cell studies supported by private funds or even by public funds from the states. However, NIH, with an annual budget of $2.7 billion, can support research on a scale that no private or other public source can match. NIH also enforces a level of quality and ethical oversight through peer review and monitoring that most other funding agencies cannot replicate. In issuing his order, President Bush pointed to 60 existing stem cell lines for which federal research funding may continue, but many scientists have complained that not all of them are suitable for research and that many more lines are needed.

The presidential directive allows considerable leeway to the states to add legal dictates of their own. Utah and Louisiana have responded by banning all embryonic stem cell research entirely, with or without federal funds. California and New Jersey have gone in the opposite direction, passing laws that specifically permit research to be conducted on existing or new embryonic stem cell lines within the states’ borders. Similar legislation is under consideration in other states, including Massachusetts.
Governor James McGreevey of New Jersey plans to take that state even one step further by allocating $50 million over five years for state funding of stem cell research.

Two proposals pending in Congress have taken opposite positions on therapeutic cloning. One proposal, introduced in the House and Senate, would make all cloning, whether for reproductive or therapeutic purposes, a crime. The other, introduced so far only in the Senate, would ban reproductive cloning but would permit therapeutic cloning research to continue. Several states are considering laws on both sides of the issue as well.

CONCLUSION

The politics of abortion makes debate over stem cell research particularly emotional and intractable. The resulting legal inconsistencies and ambiguities leave scientists, and the public at large, at a significant disadvantage. The growing patchwork of state legislation might block research collaboration among universities and scientific institutes on the basis of geography. The uncertain status of NIH funding leaves gaps in regulatory oversight for the research that does proceed.

It is possible that more favorable legal environments in other nations, such as the United Kingdom and Canada, might encourage important research to move overseas. Whether or not embryonic stem cell research remains legal in the U.S., it will be difficult for science to move forward until the legal framework stabilizes.

REFERENCE
