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Stem cells—why wait?

As *Nature Medicine* went to press, the public comment period on the draft of National Institutes of Health (NIH) guidelines for the ethical and legal use of human pluripotent stem cells in research was due to close. After receiving thousands of letters, the NIH decided to extend the time for comment by three weeks to 22 February. Scientists cannot receive NIH funding for research involving human pluripotent stem cells until the official guidelines are published in the Federal Register and the oversight process is in place. Stem cell research has the potential to yield great advances in our understanding of embryogenesis and lead to new therapeutics for a wide variety of diseases as papers in this issue show (pages 271 and 278). Although we applaud the NIH's desire to provide careful oversight and direction in this controversial area of research, we caution that this research holds too much promise to face further delay. Therefore, the guidelines should be released as quickly as possible and should be flexible enough to accommodate changes in federal law while allowing scientists to continue research that has already advanced quite quickly with only private funding. Otherwise, federally funded scientists will fall further behind those working in the private sector, whose stem cell investigations are not subject to federal regulations or ethical requirements.

The first draft of the guidelines was released 2 December 1999 in response to reports published a year earlier describing the isolation and culture of human pluripotent stem cells. The NIH decided that research involving these cell lines required more stringent oversight than the traditional peer review process. The draft guidelines rightfully limit the source of stem cell lines to those cells "derived from early human embryos that were created for the purpose of infertility treatment and were in excess of clinical need," and also call for the creation of an oversight committee called the Human Pluripotent Stem Cell Review Group (HPSCRG), which will ensure compliance with these guidelines. However, the NIH does not plan to release the final version of the guidelines until next summer.

The research permitted by the official guidelines may depend on the final outcome of a bill recently introduced to the US Congress by Sen. Arlen Specter (R-PA) and Sen. Tom Harkin (D-IA). S. 2015, or the "Stem Cell Research Act of 2000," calls for allowing federally funded scientists to derive their own human pluripotent stem cells from human embryos. Specter and Harkin should be applauded for trying to eliminate the current 'two-faced' system, which allows the use of human pluripotent cells in NIH-funded research as long as private sources derive the cells. Indeed, as long as government-funded scientists are dependent on private sources to supply them with cells (see page 237), they will always be one step behind privately funded researchers, who have immediate and unlimited access to the cells. The national bioethic advisory commission has also pointed out that basic researchers interested in the earliest stages of embryonic development are likely to make fundamental discoveries through isolating embryonic stem cells in their own laboratories. However, if the NIH does delay release of the guidelines until after Congress decides on the bill, stem cell researchers could be in for a long wait. S. 2015 is likely to face a rough road in Congress, battling congressmen like Rep. Jay Dickey (R-AR), who has equated stem cell research to the experiments in Nazi Germany and the Tuskegee syphilis experiments.

Another troubling aspect of the guidelines is that they state that NIH funding cannot be used to generate stem cell lines using somatic cell nuclear transfer. This procedure, which allows scientists to develop stem cell lines capable of differentiating into tissues such as skin, muscle, neurons or blood cells, eliminates the need for human embryonic cells. The approach has been actively developed by privately funded researchers, and Geron Corporation, one of the leading companies in the pursuit of 'therapeutic cloning', already holds a British patent on nuclear transfer methods. Allowing federally funded scientists to create and study these hybrid cells would help them avoid the political debate over the use of human embryonic tissue. Additionally, the guidelines should include a statement that research involving pluripotent cell lines created before the guidelines were published should be eligible for NIH support. Stem cell researchers have already experienced long delays and should not be required to spend months recreating new cell lines, provided the cells were derived in a manner approved by the HPSCRG.

We support the creation of the guidelines and agree that research involving human pluripotent stem cells does warrant more careful review than other types of NIH-funded research. Nonetheless, the guidelines are not of any use until they are actually published in the Federal Register, and they should be written such that when they go into effect, they allow stem cell researchers to gain funding and begin their research immediately. They should also allow scientists to derive their own cell lines and generate new lines by somatic nuclear transfer, in the event that Congress decides to lift the restrictions on creation of embryonic stem cell lines by federally funded scientists. Although Congress and the public must their have their say in the use of public funds for scientific research, to the millions of suffers of debilitating diseases such as diabetes and Parkinson disease, delays in release of the guidelines only mean a longer wait for new therapies.