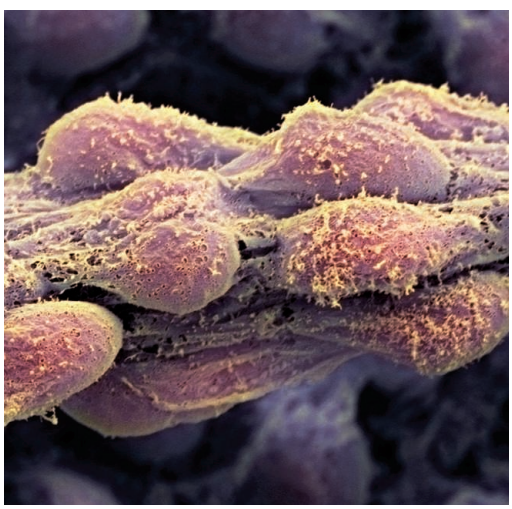
EDITORIAL

Emerging stem cell ethics

It has been 20 years since the first derivation of human embryonic stem cells. That milestone marked the start of a scientific and public fascination with stem cells, not just for their biological properties but also for their potentially transformative medical uses. The next two decades of stem cell research animated an array of bioethical debates, from the destruction of embryos to derive stem cells to the creation of human-animal hybrids. Ethical tensions related to stem cell clinical translation and regulatory policy are now center stage and a topic of global discussion this week at the International Society for Stem Cell Research (ISSCR) annual meeting in Melbourne, Australia. Care must be taken to ensure that entry of stem cell–based products into the medical marketplace does not come at too high a human or monetary price.



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Despite great strides in understanding stem cell biology, very few stem cell–based therapeutics are as yet used in standard clinical practice. Some countries have responded to patient demand and the imperatives of economic competition by promulgating policies to hasten market entry of stem cell–based treatments. Japan, for example, created a conditional approvals scheme for regenerative medicine products and has already put one stem cell treatment on the market based on preliminary evidence of efficacy. Italy provisionally approved a stem cell product under an existing European Union early access program. And last year, the United States introduced an expedited review program to smooth the path for investigational stem cell–based applications, at least 16 of which have been granted already. However, early and perhaps premature access to experimental interventions has uncertain consequences for patients and health systems.

A staggering amount of public money has been spent on stem cell research globally. Those seeking to develop stem cell products may now not only leverage that valuable body of resulting scientific knowledge but also find that their costs for clinical testing are markedly reduced by deregulation. How should this influence affordability and access? The state and the taxpaying public's interests should arguably be reflected in the pricing of stem cell products that were developed through publicly funded research and the regulatory subsidies. Detailed programs for recouping taxpayers' investments in stem cell research and development must be established.

Rushing new commercial stem cell products into the market also entails considerations inherent to the ethics of using pharmaceuticals and medical devices. For example, once a product is approved for a given indication, it becomes possible for physicians to prescribe it for "off-label use." We have already witnessed the untoward effects of the elevated expectations that stem cells can serve as a kind of cellular panacea, a misconception that underlies the direct-to-consumer marketing of unproven uses of stem cells. Once off-label use of approved products becomes an option, there may be a new flood of untested therapeutic claims with which to contend. The ISSCR and the United States Federation of State Medical Boards have both recently issued guidelines on clinical translation and use, but adoption and enforcement remain key issues.

The new frontiers of stem cell–based medicine also raise questions about the use of fast-tracked products. In countries where healthcare is not considered a public good, who should pay for post-market efficacy testing? Patients already bear a substantial burden of risk when they volunteer for experimental interventions. Frameworks that ask them to pay to participate in medical research warrant much closer scrutiny than has been seen thus far.

Striking the proper balance between streamlining review processes and ensuring that there is sufficient evidence before bringing products into clinical use is a perennial predicament for patients, payers, scientists, clinicians, and regulators. For stem cell treatments, attaining this balance will require frank and open discussion between all stakeholders, including the patients it seeks to benefit and the taxpayers who make it possible.

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