Stem Cells:
A Pluripotent Challenge

Recent advances in human stem cell research have generated enormous enthusiasm on the part of researchers and optimistic predictions of revolutionary advances in biomedicine. These same advances have also sparked considerable ethical debate.

The main ethical challenges associated with stem cell research have to do with the source of those cells. Although some advances have been made in the use of adult stem cells, the consensus seems to be that the most promising categories of stem cells are embryonic stem (ES) cells (derived from the five- to seven-day-old embryos known as blastocysts) and embryonic germ (EG) cells, derived from immature aborted fetuses.

In fact, there are four main sources of (non-adult) stem cells, and each presents its own challenging ethical issues. The first such source (of ES cells) is the surplus embryos that are a by-product of the activities of in vitro fertilisation (IVF) labs. One ethical concern here has to do with the status of the embryo itself. The degree of respect that ought to be granted to a human embryo is highly controversial. Some hold that the embryo - genetically human and a potential person - deserves our full respect and protection. Others hold that while the embryo may be genetically human, it has (particularly at early stages) none of the characteristics of persons. It is not conscious; it is not self-aware. It is a cluster of cells with no independent ethical status. Still others hold an in-between view, arguing that while the early embryo clearly is not a person (and so clearly does not warrant the ethical status of a human adult or child) it is a part of the human life-cycle, part of the human story, and so ought (like a human corpse) to be treated with a degree of respect. This seems a reasonable compromise. Yet just how much respect embryos deserve, and what sorts of research (if any) might be consistent with that respect, remains controversial.

Secondly, it is clear that 'spare' embryos from IVF clinics may only be used for research if the embryo donors give their informed consent. But the issue of consenting to have a donated embryo used in stem cell research raises special questions. Are donors (or can they be) adequately informed about, for example, the possibility of using stem cells derived from the donated fetus to create immortal cell lines, the possibility of commercialisation of scientific discoveries that might result from their donation, and the implications that donating genetic material might have for donor privacy?

The second potential source of ES cells results from uniting donated eggs and sperm to create embryos in the lab. The same issue of the ethical status of embryos arises here as arise with embryos from IVF clinics. But in addition, custom-made embryos raise questions about the ethics of using human embryos solely and explicitly as a means to some end. Excess embryos from IVF clinics, if not used in research, are otherwise destined for destruction. Many see using them for research (out of which some good may come) as a relatively dignified and respectful alternative. But this rationale does not apply to custom-made embryos. They are created solely as laboratory materials; they are used, in a sense that many find incompatible with the concept of human dignity.

> How much respect do embryos deserve?

A third potential source of ES cells is embryos created through SCNT, or somatic cell nuclear transfer. SCNT is the process through which the genetic material from a body cell is transplanted into an egg cell; this allows the creation of an embryo without fertilising the egg with a sperm. Embryos created through SCNT would pose, to start with, the same concerns as embryos in the first two categories. But in addition there is the worry that SCNT is a cloning technique. Work using SCNT to clone stem cell lines would, incidentally, improve our understanding of the techniques that would be required to attempt human reproductive cloning. And since human reproductive cloning is considered by most people to be beyond the pale, the use (and inevitable improvement) of a technique such as SCNT is bound to cause concern.

The final source to consider is the source of EG cells, namely aborted fetuses. Use of tissue (including EG cells) from aborted fetuses raises questions of consent similar to those raised by donated embryos. Do patients really understand what it means to donate fetal tissue “to science?” But most problematic is the fact that use of EG cells enmeshes stem cell research in the ongoing, emotionally charged debate over abortion. To many, condoning the harvesting of EG cells for research is equivalent to endorsing the abortion that made those cells available. For some, that is unproblematic. For others, it is an impassable barrier.

Thus while stem cell research holds considerable therapeutic promise, the possible gains must be weighed against the ethical worries. Whether the worries outweigh the anticipated benefits, or vice versa, depends on one's views on a number of controversial issues. Controversies such as these are endemic to biotechnology. This is likely so for two reasons. First, biotechnology involves manipulating the building blocks of life itself: stem cells, GMOs, transgenics, xenotransplantation, cloning. Heady stuff, by anyone's accounting. Secondly, biotechnology is a field subject to incredibly rapid change. Thoughtful analyses of ethical problems related to

a line of research can be rendered irrelevant by the publication of new scientific findings. For example, the status of 'spare' embryos from IVF is only a relevant concern until IVF techniques advance to the stage at which no spares need to be generated. Then the focus of the ethical debate will necessarily shift. In biotechnology, barely have philosophers and other humanists digested a particular bit of science and begun to formulate an approach to understanding the relevant ethical and social issues when a new paper in Science or Nature makes last year's (or last month's!) science obsolete.

How should biotech companies and researchers conduct themselves in such a context? Responsible researchers and corporations know that the opinions of one's community matter. But when public opinion is divided, shifting, and often ill-informed, what is the well-intentioned biotechnologist to do?

In situations in which there is uncertainty or disagreement over substance, sometimes we must settle for agreeing on process. Let us look at two examples from other domains. First, think of the process of criminal justice. While we cannot always be certain of innocence or guilt in particular cases, we are fairly confident that trial of an accused (considered "innocent until proven guilty") by a jury of their peers is, while not foolproof, a tolerably good method of balancing the search for truth with the need to protect individual rights. Next, think of the process of financial audits. While no one can provide investors with complete certainty as to the financial status and prospects of a firm in which they are considering investing, we are fairly confident that a diligent analysis of corporate books by an independent external auditor provides a sound process for arriving at the best advice reasonably possible. Sometimes good process suffices, when the best particular solution is unknown.

So what I suggest for biotech firms is a kind of 'ethics due diligence.' Doing due diligence means exercising a reasonable degree of care in any given situation. In the field of biotechnology, nothing short of inaction can guarantee that we won't make decisions that end up seeming, in retrospect, to have been mistakes. But steps can be taken that will minimise the chance of mistakes, and that will go some distance toward ensuring that mistakes that are made are not, at least, the result of anything like negligence.

1. Learn about ethics. Learn about what values are at play in your community. Learn about the language spoken in academic and regulatory ethics.

2. Foster critical discussion. Hiding from public scrutiny will only delay, and perhaps exacerbate, the problem. Be open and responsive.

3. Avoid falling to the lowest common denominator. Search out (or create), and adhere to, guidelines that fit the definition of corporate 'best practice' or clinical 'standard of care.'

Ethics, as a discipline, is about careful consideration of issues that matter to human well-being and to human freedom. The debate over stem cell research sits squarely within this domain. In practical terms, ethics requires arriving at courses of action that seem reasonable - if not always ideal - to one's neighbours. Ethical progress on the matter of stem cells will require dialogue. In some cases, disagreements between biotech companies and the larger community will be resolved by educating the public in such a way as to render corporate activities reasonable, if not always ideal, in the public's eye. In other cases, disagreements will be resolved by the public educating corporations about which things are important to them, and why. Either way, the route to accountability, and to sound ethical judgement, begins with dialogue.

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