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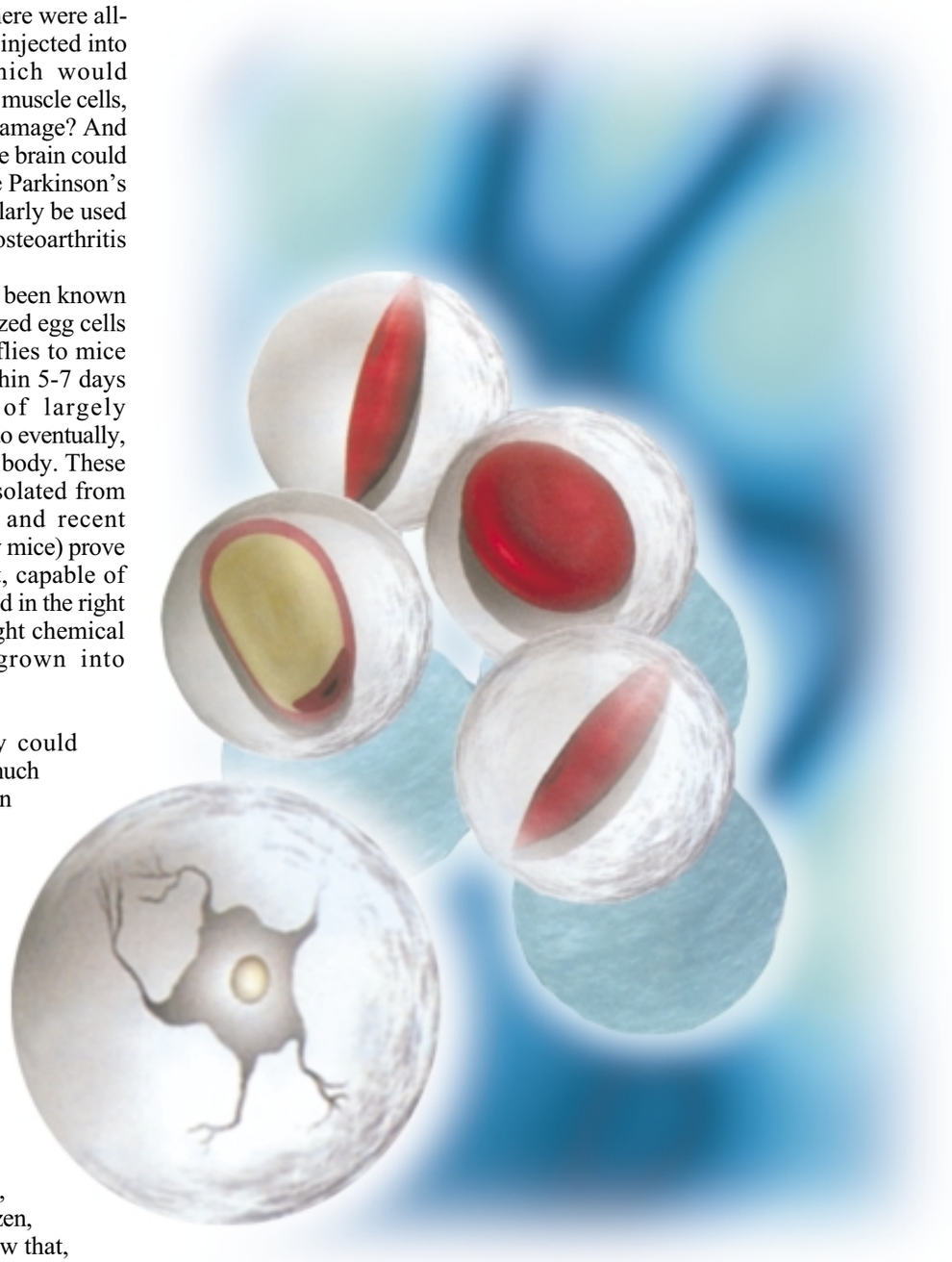
Academy Panel Advises Israeli Stem Cell Research

Wouldn't it be wonderful if there were all-purpose cells that could be injected into damaged hearts and which would automatically turn into heart muscle cells, find their right place and repair the damage? And what if the same cells, injected into the brain could become functioning neurons and cure Parkinson's disease? And what if they could similarly be used to treat diabetes, multiple sclerosis, osteoarthritis and Alzheimer's disease?

Too good to be true? Such cells have been known to exist for over a century. The fertilized egg cells of all higher organisms, from fruit flies to mice to man, divide again and again. Within 5-7 days they form a sac (blastocyst) of largely undifferentiated cells, which can and do eventually, as a whole, become every cell of the body. These embryonic stem cells can now be isolated from the inner part of the blastocyst, and recent laboratory tests using animals (usually mice) prove that they are indeed fully totipotent, capable of becoming any desired cell when placed in the right environment and subjected to the right chemical commands. They can also be grown into therapeutic tissue implants.



Such a lifesaving new technology could revolutionize medicine and alleviate much human suffering, but, as with organ transplantation before it, complicated ethical issues abound. Although once isolated human stem cells can be multiplied and maintained in culture, like many other cells, how can the initial "starter" cells be ethically obtained? Since *in vitro* fertilization (IVF) therapy requires producing many "embryos," many of which are not suitable or used for implantation, they would seem a natural choice, particularly since they are now routinely discarded, before or after a five-year, literally frozen, waiting period. Still, how do we know that, if the demand for life-giving stem cells increases, "excess" embryos will not be deliberately created or that the parental donors will not be pressured or induced to donate excess embryos against their deeper will?

There is also disagreement about when an embryo becomes a being with its own rights: fully at conception (the Catholic view, which also prohibits IVF), progressively from 40 days (one Jewish view) or 120 days (one Moslem view) until birth, or at most from 14 days on (one modern "bioethical" view). The latter view argues that the blastomere mass cannot yet represent a potential personality, since, if divided at that early stage, it would grow into two separate twins with separate personalities. Even so, most religious traditions do not allow the wanton "wastage" of any human germ cells (eggs and sperm). What, therefore, constitutes justifiable use? Surely a specific patient awaiting a lifesaving tissue transplant might qualify, but what about general research whose results may yield human health benefits only years hence…or never?

Although useful stem cells could also be isolated from more mature 5-9 week-old (35-63 day-old) aborted fetuses, they would not be quite as flexible. A fetus is also far more human-looking than the ball-shaped blastocyst, and abortion itself is an ethical "hot" and divisive issue. Elective abortions are widely permitted in many countries, and the aborted fetuses are often discarded or used for research, but anything which might increase their frequency is ethically contentious. Although a few types of stem cells are found in adults, their cellular repertoire, replication ability and chances for therapeutic success are currently believed to be much lower. Still, certain human bone marrow cells can be coaxed into new careers as blood, liver and cardiac muscle cells; and certain brain cells can be coaxed into becoming heart, lung or liver cells. Adult cells are believed more likely to infect already severely ill patients with dangerous pathogens, although embryonic stem cells cultures may have their own disadvantages (little is known about their long-term proliferation, stability and transformation potential). So, like it or not, the ethical benefits (e.g., saving human lives) and concerns of embryonic stem cells have to be faced head on.

Not surprisingly, countries differ over this balance. Germany, Switzerland, Italy and Hungary forbid fertilizing ova unless they will be implanted. Australia, Canada, Sweden and Finland allow research using "extra" IVF embryos, subject to the 14-day rule and donor consent. The U.K. is considering even allowing the deliberate creation of early-stage embryos specifically for research and therapeutic purposes. The U.S. Government does not forbid such research (although nine states do), but it will not pay for research involving the extraction of such cells. Privately-funded scientists have to extract them and give or sell them to their government-funded colleagues (this was recently limited to several already-created cell lines). Several private companies in the U.S., Australia and Singapore already sell a few embryonic stem cell lines, but the variety and long-term stability of their cultures would seem insufficient for optimal progress.

What about Israel? Existing Extra-Corporeal Fertilization Regulations (1987) forbid the deliberate formation of embryos only for research, but do not forbid the use of "excess" early-stage IVF embryos for such purposes. A 1999 Genetic Intervention Act places a 5-year ban on cloning human embryos or genetically modifying the human-germ line to create full-term humans, but also does not address the stem cell issue. The Israel Ministry of Health has, however, established a "Helsinki" Committee for Genetics to assure that proposed stem-cell research is consistent with "human dignity." The Israel Academy of Sciences and Humanities' Bioethics Advisory Committee has recommended a carefully balanced set of national guidelines for this purpose. The 10-person Committee, which included a judge, a lawyer, a bioethicist and two philosophers, as well as senior life scientists, published its carefully documented report in Hebrew and English in August 2001.

The Academy's guidelines allow the donation of "excess" early-stage IVF embryos for research, subject to the free consent of the donors, and without negative consequences for those who refuse. The IVF and research teams must be separate, and the embryos cannot be bought or sold, to avoid encouraging excess production (a safeguard also found in many organ transplantation regulations). A 12-day limit on blastocyst growth before extracting the stem cells prevents the possibility of cloning. Confidentiality and medical seriousness of purpose are also required.

Although more controversial, the guidelines also allow transferring the nuclei from adult ("patient") somatic cells into fertilized egg cells whose nuclei have been removed, even though no reproductive purpose is served. This new embryo can then be grown to the blastocyst (ball-shaped) stage and then the embryonic stem cells can be harvested. The possibility of creating therapeutically urgent tissues which will not be rejected by the patient as foreign – since their nucleus is his or her own – makes such research a high human priority. It may even prove possible to use existing stem cells rather than fertilized eggs as the starting material. Research on cells from aborted fetuses – subject to existing fetal tissue guidelines – adults and cadavers should also continue to be explored as ethical alternatives, although their practicality is currently unclear.

Once the embryonic stem cells have been collected from the blastomere mass and can no longer, even potentially, grow towards personhood, they can be treated as any other human cells under existing human tissue culture regulations. The demands of social justice and public benefit must also be reconciled with the likely commercialization of new materials, therapies and knowledge. In all, the Committee has been widely praised in the international press for crossing this ethical minefield with due regard for both human needs and human dignity.