

New regulations give UK the lead in stem cell work

Britain has taken a further step towards establishing itself as the world leader in embryonic stem (ES) cell research by extending regulations permitting research on ES cells and cells derived by nuclear transfer, and announcing that it intends to create a national stem-cell bank.

A select committee convened 12 months ago by the House of Lords has extended the 1990 Human Fertilization and Embryology Act to cover 3 additional purposes: increasing knowledge about the development of embryos, increasing knowledge about serious disease, and enabling any such knowledge to be applied in developing treatments for serious disease. Thus, experimentation is no longer restricted to research related to fertility. See www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8310.htm.

Two teams have been granted the first research licenses under the new regulations. Researchers at the University of Edinburgh's Center for Genome Research are looking primarily at the methodology for producing stem cells by investigating the processes of multipotential stem-cell self-renewal and differentiation. They aim to find ways of directing stem cells to make nerve, heart and blood cells. "Any stem-cell lines that we derive will be deposited in the national stem-cell bank," Austin Smith, the director of the center, said in a statement. He also emphasized that the research team is only using 'spare' embryos generated for—but not subsequently used in—infertility treatment.

The second group, from Kings College in London, is also looking at the basic mechanisms by which stem cells operate. Neurobiologist Stephen Minger is currently investigating how mouse stem cells can be 'driven' to become β cells, and is interested in exploring similar opportunities using human stem cells. "At present, we are doing this as basic science, in order to understand the fundamental mechanisms at work," says Minger. He describes the creation of the bank as a "really positive" development, and adds: "If we can generate good cell lines, then it is going to be an incredibly useful scientific source."

The stem-cell bank, which is expected to hold both adult and embryonic cell lines, is to be set up by the Medical Research Council (MRC), at the request of the Department of Health. It follows

discussions between both bodies and the Human Fertilization and Embryology Authority (HFEA), the statutory body that regulates and licenses human embryo research in the UK. The HFEA must be satisfied that there are no existing ES cell lines in the bank suitable for proposed research before granting any new license to establish human cell lines.

A key goal of the bank will be to ensure that the ES cell lines to which scientists are provided access are of guaranteed purity and provenance. "One hears of many cell lines currently on offer that are difficult to work with and of poor quality," says one researcher. "Researchers in the field need to know what they are getting." It is not clear at present who will have access to the cells in the bank and whether this will be re-

stricted to UK-based scientists only.

The government is also keen to ensure that the cell lines in the bank come from sources that operate under ethically approved standards—for example, that the appropriate informed consent has been given by the couples from whom the embryos originate. To ensure that both the scientific and ethical criteria are met, the MRC is to set up an advisory committee, chaired by Geneva Richardson, professor of public law at Queen Mary College in London. Part of this committee's responsibilities will be to generate what the research council describes as "route maps" designed to help scientists to identify which licenses and accreditations they will need if that want to carry out stem-cell research.

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Systems biology—the new R&D buzzword?

The strategy of analyzing all levels of biological information and constructing complex pathways of how entire organisms work seems to be the new discipline on the R&D block. Indeed, US pharmaceutical giant Eli Lilly will demonstrate their faith in this concept, known as systems biology, this spring when it opens the doors of a new center for drug discovery in Singapore. Lilly is investing US \$140 million over the next five years in the Lilly Center for Systems Biology (CSB).

Although the idea of studying biology at the entire system level rather than one gene or one protein at a time is not new, systems biology has only become feasible with the advent of high-throughput genomic tools and technologies to analyze and process enormous amounts of data. But while many acknowledge the potential for this integrative approach to drug discovery, so far only a handful of labs and small biotechnology companies have embraced it. Lilly is the first major company to enter the systems arena.

The traditional approach to identifying targets for therapy is to compare expression of various genes or proteins in disease tissue and then develop a drug to regulate one of those genes. The thinking behind systems biology is that looking at information on only one level gives an incomplete picture. Instead, gathering information at all levels and examining complex interactions among molecules will help hone in on the right

targets more precisely. "Systems biology allows you to understand how a very dynamic system works so that you can find ways to target disease better than just blocking a pathway," says Howard Schulman, vice president of research at California-based SurroMed.

The term 'systems biology' comes from the field of engineering and describes a theoretical framework for controlling complicated systems, for example, how to fly a plane. "We are not nearly as mature a field as is the engineering analog," says Adam Arkin, a Howard Hughes investigator and assistant professor in Chemistry and Bioengineering at the University of California at Berkeley. Arkin's lab, which includes engineers, mathematicians, biologists, chemists, physicists and information technology specialists, is elucidating problems on a systems biology level such as how a neutrophil reaches bacteria.

In 1999, Leroy Hood founded the Institute for Systems Biology in Seattle. He left his post as chair of the department of molecular biotechnology at the University of Washington to set up the new institute, which takes a multi-disciplinary approach to studying complex systems such as the immune system. Since then, a handful of academic centers and small biotechnology companies have followed the lead. Beyond Genomics, established in February 2000 in Massachusetts, is the first self-declared systems biology company. "We are