NIH panel gives green light to embryo research

WASHINGTON, D.C.—During the first four years of clinical tests involving human gene therapy, the technology has steadily gained acceptance. Yet more recent efforts at the National Institutes of Health (NIH, Bethesda, MD) to seek acceptance for proposals involving preclinical research on human embryos seem far less assured of success, as federal support of such research has been banned for a full 15 years. Although an ad hoc Human Embryo Research Panel (HERP) recently recommended an advisory process for embryo research similar to the one being followed for gene therapy—which is overseen by the National Institutes of Health Recombinant DNA Advisory Committee (NIHRAC)—the question remains whether HERP's recommendations for open review and stringent guidelines will adequately address critics' concerns about embryo ethics.

In proposing guidelines for research on embryos, HERP's 19 researchers, ethicists, and other experts restricted their attention to research on preimplantation embryos, or multicell clusters that are less than 14 days old and that are without defined nervous system. HERP considered a range of subject areas that were "much broader than therapies related to infertility, all of which have a significant promise of human benefit."

At its recent meeting, HERP unveiled a report that it had completed by convening a half dozen times, conferring often between meetings by electronic means, and considering several dozen presentations by nonpanel members, as well as 30,000 written comments, according to HERP's chair, Steven Muller, president emeritus of Johns Hopkins University (Baltimore, MD). The process involved "soul searching—agonizing is not too strong a word," says Muller. "This report represents our best collective thinking."

"The report's basic finding is that it is acceptable public policy to use public funds for embryo research under stringent guidelines," says HERP cochair, Patricia King of the Georgetown University Law Center (Washington, D.C.). Three key principles undergirding the report are that embryo research could bring significant benefits; that preimplantation embryos "warrant serious moral consideration, though not the same consideration as infants and children;" and that federal funding "will bring about consistent, public review" of embryo research.

Indeed, HERP recommends a review process for embryo research that parallels the NIHRAC's oversight of gene therapy. "I agree with HERP's proposal for an extra level of review, with regularly scheduled meetings open to the public," says bioethicist LeRoy Walters of Georgetown University (Washington, D.C.), who is the chair of the NIHRAC but who was not a member of HERP.

Currently, limited research on embryos is being done in the private sector, with most of it under the auspices of *in vitro* fertilization clinics. At least in some cases, however, such clinics are becoming increasingly involved in diagnostic technologies and other biotechnologies, including bone-marrow-transplant procedures. Yet the Biotechnology Industry Organization (Washington, D.C.), for its part, claims that embryo research—perhaps because it is so controversial—is not really a discipline of biotechnology.

According to the HERP report, other areas, besides human fertility, in which embryo research could bring benefits include:

- early human development and the origin of certain birth defects;
- the preimplantation diagnosis of genetic abnormalities that cause inherited diseases;
- how oocytes mature and how eggs are affected by environmental agents;
- the development of cell lines for generating differentiated cells for transplantation and tissue repair.

Even if Harold Varmus, NIH's director, agrees with HERP's recommendations, other questions remain. Several dozen members of Congress, led by Representative Robert Dornan (R-CA), indicate that they oppose federal funding for embryo research. With the backing of the antiabortion movement, moreover, these congressmen could make it difficult to implement HERP's recommendations or to proceed with any of the embryo-research proposals that have been put forward.

—Jeffrey L. Fox

Yet NIH efforts to gain acceptance of proposals for preclinical research on human embryos are precarious, as federal support of such research has been banned for 15 years.

COMMENTARY ON THE ENVIRONMENT — RUSS HOYLE

The unraveling of the Clinton promise

To its everlasting credit, the Clinton administration has pursued an ambitious policy of consensus building on environmental issues from the start. Its aim was to find the middle ground between sustainable protection of the environment that would satisfy environmentalists and economic development that would quiet the regulatory fears of industry. As one observer of the Washington political scene put it, without sarcasm, "There was no shortage of ideas" about how to make such a consensus approach work. This was especially true in two areas of immediate concern to the biotechnology industry: The potential of innovative bioreme-diation technologies for the multibillion-dollar toxic pollution clean-up industry and the promise of naturally occurring and even genetically engineered biological products to replace chemical pesticides.

As little as a year ago, there seemed to be an historic rapprochement between the environmental movement and industry about the directions in which federal policy had to move in order to develop a sensible and economically efficient policy for cleaning up toxic waste dumps and phasing out poisonous chemical pesticides. But that, it seems, was then and—for the Clinton administration, at least—today is another day. "It's common sense—that's the way they wanted to move,"